

**MAMMOGRAPHY QUALITY STANDARDS ACT  
(MQSA)**

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**HEARING**  
OF THE  
**COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS**  
**UNITED STATES SENATE**  
ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

EXAMINING THE MAMMOGRAPHY STANDARDS ACT OF 1992, TO AMEND  
THE PUBLIC HEALTH SERVICE ACT TO ESTABLISH THE AUTHORITY  
FOR THE REGULATION OF MAMMOGRAPHY SERVICES AND RADIO-  
LOGICAL EQUIPMENT

APRIL 8, 2003

Printed for the use of the Committee on Health, Education, Labor, and Pensions



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# C O N T E N T S

## STATEMENTS

APRIL 8, 2003

|   | Page |
|---|------|
| Ensign, Hon. John, a U.S. Senator from the State of Nevada .....  | 1    |
| Mikulski, Hon. Barbara A., a U.S. Senator from the State of Maryland .....  | 2    |
| Dershaw, David, M.D., Vice President, Society For Breast Imaging, Reston,<br>VA; Diana Rowden, Affiliate Service Manager, Susan G. Komen Breast<br>Cancer Foundation, Dallas, TX; and Leonard Berlin, M.D., Chairman, De-<br>partment of Radiology, Rush North Shore Medical Center, Skokie, IL ..... | 6    |

## ADDITIONAL MATERIAL

|  |    |
|--|----|
| Statements, articles, publications, letters, etc.: |    |
| D. David Dershaw, M.D. ....                        | 23 |
| Diana Rowden .....                                 | 24 |
| Leonard Berlin, M.D. ....                          | 31 |



## **MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)**

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**TUESDAY, APRIL 8, 2003**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Senator Ensign presiding. Present: Senators Ensign and Mikulski.

### OPENING STATEMENT OF SENATOR ENSIGN

Senator ENSIGN. I call the hearing to order and I would like to welcome our witnesses to the table. We will make some brief opening statements, first by myself and then by my esteemed colleague, Senator Mikulski, and we will then proceed with the hearing and the very, very important topic that we are dealing with this morning, the Mammography Quality Standards Act.

Breast cancer is the second leading cause of cancer deaths among women. An estimated 211,300 new cases of invasive breast cancer are expected to occur among the women in the United States in 2003. In my home State of Nevada alone, 1,400 new cases of breast cancer will be diagnosed in women and an estimated 300 women in Nevada will die.

Breast cancer is something that the more it affects you personally, I think the more passionate that you become about early detection, early diagnosis, and hopefully some day, a complete eradication of this disease. A personal experience that my wife and I had was a very close friend of ours was diagnosed, actually 5 years before that. We watched her go through chemotherapy and a mastectomy and even to the point of a bone marrow transplant at the City of Hope. She ended up suffering through all of that but was an incredible women, an incredible strength of character, and was an inspiration to a lot of people even to this day. Sadly, she ended up dying in my wife's arms just about 10 years ago.

That is kind of our personal entre into this dreaded disease. We have become passionate since then. We cofounded the Breast Cancer Coalition of Nevada. We helped secure the funds to get a mobile mammography unit for the underserved women of Nevada. So I come to this issue with a lot of passion and also with a little bit of a medical background as a veterinarian, so I understand some of these issues. However, I also understand that medicine is an art and a science and because of that, unfortunately it is very inexact in its interpretation.

I remember in veterinary school when we started learning radiology. That was when the radiologists said okay, now you must put on your "imagnoscope", as they put it, because it is such an inexact science. The better trained you are, the better you get at radiology, but it is never a perfect science. As the machines improve, radiology improves. As more training goes into the people who are reading, as well as those taking the pictures, obviously diagnoses improve, and that is really what this is about today. It is about getting better diagnostic standards so that in the future we reduce the number of false positives and we reduce the number of false negatives.

That really is the bottom line of this hearing today, along with the serious problem we have with medical liability abuses in the system. I do not want to turn the whole hearing into a debate on the medical liability issue but it certainly is an issue that we are facing in this country. Also, because we are dealing with an issue of access to care because more and more physicians are leaving their practices around the country, we do not want to do something up here that has the unintended consequence of creating more lawsuits. That leads to fewer and fewer people who are able and willing to go into the practice or who leave early the practice of medicine, leaving patients with less and less access to care.

It is a delicate balancing act and I appreciate all the work that Senator Mikulski has put into this over the years. She certainly comes at it from a legislative perspective with a lot more experience than I have and I appreciate hearing from her, as well as our witnesses today.

So after I yield to you, Senator Mikulski, for any opening statement you wish to make, I then look forward to our witnesses.

#### OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you very much, Mr. Chairman. I want to thank you for chairing this hearing today on mammography quality standards. Both in our private conversations on the floor and in your opening statement I would like to thank you for your compassionate and common sense approach to how to reauthorize mammography quality standards where we get the best mammograms for the women and make sure that we have the best trained people and the most accurate equipment to be able to do that. I think if we follow those two guidelines of compassion and common sense, we will arrive at a position where I know you and I both want to be, which is in a very sensible center to be able to move the legislation forward.

Your own comments about the involvement of both you and your wife really show that first of all, cancer is not only a woman's issue; it is really a family issue, and then it becomes a community issue. When a woman gets breast cancer, it affects her in a most horrific, challenging kind of way, but it has an incredible impact on her family. It affects her husband as they struggle through what is the best treatment, the impact that it will have on their lives, and the impact that it will have on their children. If you are going to lose your mom, that is a pretty big loss.

I would also like to salute you and your wife for what you have been doing in Nevada. It is very much appreciated.

Today's hearing is about saving lives and that is what the mammography quality standards do. Accurate mammograms detect breast cancer early so that women can get the right treatment at the earliest time and therefore be survivors.

Today we are looking at the reauthorization of mammography quality standards. It is my belief that number one, we must keep the standards that we have already arrived at in mammogram quality standards because it is so vast improved over where we were 10 years ago. Then we look at how we can improve the skills of those who do the mammograms. So I look forward to working with all of our colleagues in the committee.

Eleven years ago I was the lead authorizer of mammogram quality standards so that they would be safe and accurate. Before we had MQSA there was an uneven and often conflicting patchwork for standards of mammography in this country. There were no national standards for personnel or equipment. Image quality of mammograms and patient exposure to radiation varied widely. There were those who were actually even giving mammograms using the old chest x-ray equipment. They looked at it with the same technology and the same skill set as if you were testing for TB. The quality of the equipment was poor and even very well intentioned physicians and technologists had not quite come into this.

I remember my very first mammogram. The equipment was really klutzy, overwhelming and overpowering. I felt like some massive airbag had gone off on my body and it was only because I knew the importance of it that I stayed the course until the technology changed.

Well, the technology has changed and it has so improved. It is a tribute to the genius of America's private sector that we now have great equipment, that we have now radiologic technologists that are trained just in mammography, radiology technicians and then, of course, the physicians who set about reading it.

Right now we have personnel who interpret the mammograms, the equipment, and even operating procedures, and by creating those national standards through FDA, Congress helped make mammograms a more reliable tool for detecting breast cancer.

Now, however, we are facing new challenges. A study by the University of Washington School of Medicine found that a woman has a 50 percent chance of getting a false positive reading for her mammogram over 10 years. I am concerned that in some instances, those who read mammograms miss the breast cancer about 15 percent of the time.

A year-long investigation by the New York Times paints a very disturbing picture and found that while Federal standards had improved the quality of breast x-ray films, some radiologists were still missing an alarming number of breast cancers because they lacked the experience or training they needed. Misreading mammograms means one of two things. Either a woman who has it is told she does not and a life-saving treatment is delayed, or again false positives.

We have been listening to the American Medical Association, the Accreditation Council for Continuing Medical Education and others. We want to hear from the witnesses today because what we

want to do is see how we can address the flashing yellow lights and figure out what is the best way to improve the quality standards from the last 10 years.

I know that radiologists reading mammograms face many challenges—low reimbursement for mammography, difficulty in reading them, and even with their technology now, high medical malpractice rates. Also radiologists are uniquely regulated by MQSA in a way that they are not for any other procedures or processes they do.

So I want to find that right balance to improve the skill of physicians, to make sure the equipment is the best available, and to make sure that we do save the women's lives. This is why we want to hear today from survivors with their observations and insights, of course speaking for the wonderful Komen Foundation, as well as physicians themselves. Again, to get the best ideas so we can come up with the best legislation and have no unintended consequences, either the impact on women's lives or driving very dedicated people from the profession.

[The prepared statement of Senator Mikulski follows:]

#### PREPARED STATEMENT OF SENATOR MIKULSKI

Mr. Chairman, thank you for holding this hearing today on the Mammography Quality Standards Act (MQSA). I also want to thank Chairman Gregg for scheduling this hearing at my request. Today's hearing is about saving lives—that's what MQSA does. Accurate mammograms detect breast cancer early, so women can get treatment and be survivors.

We're here today looking at the reauthorization of MQSA. We must keep the standards we have under MQSA, and we must improve the skills of doctors who read mammograms. I want to work with Senators Gregg, Kennedy, Snowe and other members of this committee to get MQSA reauthorized and strengthened this year.

I authored MQSA over ten years ago to improve the quality of mammograms so that they are safe and accurate. Before MQSA became law, there was an uneven and conflicting patchwork of standards for mammography in this country. There were no national quality standards for personnel or equipment. Image quality of mammograms and patient exposure to radiation levels varied widely. The quality of mammography equipment was poor. Physicians and technologists were poorly trained. Inspections were lacking.

MQSA set federal safety and quality assurance standards for mammography facilities for: personnel, including doctors who interpret mammograms; equipment; and operating procedures. By creating national standards, Congress helped make mammograms a more reliable tool for detecting breast cancer. In 1998, Congress improved MQSA by giving information on test results directly to the women being tested, so no woman falls through the cracks because she never learns about a suspicious finding on her mammogram. Now it is time to renew MQSA and strengthen it further.

A study by the University of Washington School of Medicine found that a woman has a 50% chance of getting a "false positive" reading from her mammogram over 10 years. I'm gravely concerned about reports that doctors miss about 15% of breast cancers on mammograms. A year-long investigation by the New York Times



paints a very disturbing picture. It found that while federal standards had improved the quality of breast x-ray films, some radiologists were missing an alarming number of breast cancers because they lacked the experience or training they needed.

Misreading mammograms means one of two things: either a woman who has breast cancer is told she doesn't and life-saving treatment is delayed. I have also heard heartbreaking stories from women who were told they have breast cancer, only to find out later—after expensive and sometimes painful tests—that they do not. I want to acknowledge that the vast majority of doctors do a great job. They make sure women get accurate readings of mammograms. I understand that mammograms are among the most difficult x-ray images to read.

I have been listening to professional groups such as the American College of Radiology, the American Medical Association, and the Accreditation Council for Continuing Medical Education. I have also been listening to patient groups like: the Komen Foundation, the American Cancer Society, and the National Alliance of Breast Cancer Organizations.

Radiologists already meet continuing education requirements under MQSA. Some recommend that a skills assessment be included in this requirement. This skills assessment would give radiologists feedback on their mammogram reading skills. It would show them where they may need additional training. I look forward to hearing from the witnesses their ideas about the best ways to design a skills assessment and other thoughts they have about improving the skills of radiologists reading mammograms.

I know that radiologists reading mammograms face many challenges: low reimbursement for mammography; the difficulty of reading mammograms; high medical malpractice rates; and unique regulation by MQSA. I want to find the right balance to improve the skills of physicians reading mammograms to make sure women's lives are saved through the accurate reading of quality mammograms, but not take steps that drive radiologists away from mammography. Women need well-trained physicians to read these mammograms.

My bottom line is quality mammography to save women's lives. I look forward to the testimony of our witnesses to help the Committee to strengthen and reauthorize MQSA this year.

Senator ENSIGN. I would like to welcome the witnesses to the table. First we have Dr. David Dershaw, who is the director of the Breast Imaging Section in the Department of Radiology at Sloan-Kettering Memorial Cancer Center in New York and a professor of radiology at Cornell University School of Medicine. He is the incoming president of the Society of Breast Imaging. He has chaired the New York State Breast Cancer Detection Education Advisory Council from 1991 to 2000. He is the director of the American College of Radiology and Armed Forces Institute of Pathology training program for residents in mammography, has written over 100 peer-reviewed journal articles, authored half a dozen books, and contributed over 60 chapters and videotapes on breast imaging.

Dr. Dershaw is a recognized authority on breast imaging, frequently lecturing around the United States and internationally on topics related to breast disease.

Diana Rowden was diagnosed with breast cancer in 1991 at the age of 38. Because of her first mammogram, doctors were able to correctly diagnose her condition and operate accordingly. Thankfully, the procedure was a success and now Ms. Rowden only requires follow-up visits by her medical oncologist.

Ms. Rowden began volunteering with the Susan G. Komen Breast Cancer Foundation in Dallas, TX as one of the first volunteer counselors on the foundation's national toll-free help line. She later served on the Komen Foundation's executive committee, first as vice chair of education, then as vice chair of grants. She was named chair-elect for 1996 and then chair of the national board in 1997-1998.

Ms. Rowden then returned to volunteering on the help line and continued to represent the foundation in a number of national and local breast cancer committees and boards. In November 2002 Ms. Rowden joined the Komen Foundation staff as affiliate services manager.

Dr. Leonard Berlin is a professor of radiology at Rush Medical College and also still maintains a teaching position at the University of Illinois College of Medicine. He has written more than 200 scientific articles, as well as a book entitled "Malpractice Issues in Radiology." Dr. Berlin has also given more than 150 lectures on various medical subjects throughout the Nation. He is board-certified by the American Board of Radiology and was elected as a fellow in the American College of Radiology in 1979. He was awarded the gold medal for distinguished service to radiology by the American Radiology Society in 2002. In 1997-1998 he served as president of the Chicago Radiological Society.

Welcome, all of you, and if you could now deliver your testimony, we would appreciate it. We will start with Dr. Dershaw and work down the table. Dr. Dershaw?

**STATEMENTS OF DAVID DERSHAW, M.D., VICE PRESIDENT, SOCIETY FOR BREAST IMAGING, RESTON, VA; DIANA ROWDEN, AFFILIATE SERVICE MANAGER, SUSAN G. KOMEN BREAST CANCER FOUNDATION, DALLAS, TX; AND LEONARD BERLIN, M.D., CHAIRMAN, DEPARTMENT OF RADIOLOGY, RUSH NORTH SHORE MEDICAL CENTER, SKOKIE, IL**

Dr. DERSHAW. Thank you, Mr. Chairman. Good morning. I appreciate your invitation and Senator Mikulski's invitation to testify regarding reauthorization of the Mammography Quality Standards Act of 1992. I am testifying on behalf of the Society of Breast Imaging and I am also a member of the American College of Radiology.

The Mammography Quality Standards Act has played a significant role in improving the quality of mammography. This program needs to be reauthorized so that women can continue to benefit from high quality mammography.

Currently MQSA requires the physicians interpreting mammograms participate in 15 hours of continuing medical education every 3 years. The American College of Radiology has designed and tested over the past decade the mammography interpretive skills assessment, the purpose of which is to provide the radiologist with an assessment of his or her skills and to identify areas in which improvement is warranted. This is not a pass/fail test or one that

is intended to certify or judge participants. The emphasis is on self-help.

While self-assessment testing may be of value, it should be recognized that there are no data to indicate that such tests provide feedback that currently determines competence. There is also no science to indicate that such tests will result in improvement in the quality of medical care. Nonetheless, by providing the physician with seven or eight hours of CME, depending on the version of the test that is utilized, physicians would be strongly encouraged to use this mammography self-assessment test for both continuing education, as well as self-assessment.

This might be a useful method for determining skills in addition to the data that are presently derived from the end results assessment required under MQSA regulation. The tabulation of these practice and results data is a strong indicator of how a radiologist is interpreting mammograms in comparison to others in his or her group. These data would be more valuable if screening and diagnostic examinations were tabulated separately, and I would encourage the committee to recommend to the FDA that such separation of data be included in regulations of MQSA.

The developing crisis in the availability of mammography service is the greatest threat to quality mammography at the present time. The best and brightest radiologists in training are discouraged from entering breast imaging. The low level of reimbursement, the time and effort needed to comply with government regulation and the burden of medical malpractice all contribute to this situation.

The committee should carefully consider the possible perceived advantage of mandated self-evaluation against the detrimental impact of increased regulation of mammography facilities and radiologists interpreting mammograms. Steps that might further discourage radiologists to incorporate mammography into their careers may accelerate the developing crisis in the availability of mammography services.

Radiologists interpreting mammograms are already in short supply due to poor reimbursement rates and high litigation. It is my belief that providing plaintiff lawyers with another potential avenue for litigation will lead many more radiologists to turn away from mammography, exacerbating the already critical access problem many women face in receiving timely mammography services. If the results of self-assessment activities were to be subjected to discoverability in litigation cases against physicians, the Society of Breast Imaging would strongly oppose the incorporation of such testing into MQSA regulation.

The committee should also recognize that the greatest threat to the delivery of quality mammography services in the United States is the impending shortage of radiologists, technologists and imaging facilities to provide this service. Inadequate reimbursement persists with payments for service often less than the cost of performing and interpreting mammograms.

The most tenuous financial reimbursement is for hospital-based services. As this is the site where most women on Medicare and Medicaid receive their health care, the availability of mammography to these women is the most threatened by inadequate reimbursement. Hospitals are also the sites where most of the training

of physicians and technologists occur. Poor reimbursement, particularly when compared to reimbursement levels for other areas of radiology services, has left those deciding what area of radiology to specialize in with an impression of mammography as a big money loser. Along with high malpractice exposure and considerable time and effort required to meet Federal and often local regulation, this negative impression works to discourage those in training from selecting mammography as an area of specialization.

One of the most discouraging aspects of mammography practice today is the excessive legal liability associated with it. Since one of every 10 breast cancers approximately cannot be detected on a mammogram, the radiologist reading these studies is potentially faced with a failure-to-diagnose suit for 10 percent of the cancers that are screened by his or her facility. This leaves the physician with the feeling that litigation is almost inevitable if a career path in breast imaging is chosen. In this atmosphere it is not a surprise that there has been a progressive decline in radiologists entering this field.

Additionally, I would like to note that as authorized under the original legislation and recommended by the National Mammography Assurance Advisory Committee, regulation of mammography services should be expanded to include stereotactic breast biopsy and equipment used in needle localization procedures.

Also, the current requirement for continuing medical education credits beyond those required for initial training does not improve quality of practice or contribute to improved patient safety. The requirement is often difficult to meet, it is perceived as a real burden by radiologists in the field and the committee should recommend that it be discontinued.

I greatly appreciate the opportunity to testify and, of course, will be happy to answer any questions.

Senator ENSIGN. Thank you.

[The prepared statement of Dr. Dershaw may be found in additional material.]

Senator ENSIGN. Ms. Rowden?

Ms. ROWDEN. Mr. Chairman Ensign, Senator Mikulski, thank you for the opportunity to testify on the reauthorization of the Mammography Quality Standards Act.

My name is Diana Rowden and I am a breast cancer survivor. I consider myself blessed because mammography led to the early detection of my breast cancer. This has allowed me to have the option of less extensive therapy, as well as enjoy a wonderful life these past 12 years.

I am honored to be able to thank you in person for enacting the MQSA. The Susan G. Komen Breast Cancer Foundation and its many constituents across the Nation are grateful for your dedicated leadership and support for improving the quality of breast health and breast cancer care in the United States.

I have been a patient-advocate for these past 10 years and now in my current capacity on staff with the Komen Foundation I have the joy and pleasure of working with many volunteers around the country who work in our affiliate network. These affiliates and the volunteers within them raise tens of millions of dollars every year

to support programs within their communities, as well as supporting our national research program.

The Komen Foundation invests millions of dollars annually in cutting edge breast cancer research. This we do for the future, but we are also very aware of the urgent need for those who are facing breast cancer today. The statistics are all too familiar, as Senator Ensign pointed out.

Early detection, we know, saves lives and mammography screening, while imperfect, remains the best tool available today to help detect breast cancer at its earliest, most treatable stages, and I truly believe that this is part of the reason why I am here alive today to testify.

More than 10 years ago Senator Mikulski and other senators recognized that the effectiveness of mammography hinges on the quality of equipment, as well as the accuracy of the interpreting physicians. We are grateful for these standards and the uniformity set by MQSA.

The death rate from cancer in the U.S. has been decreasing about 2 percent annually during the past decade, suggesting that public awareness, early detection and improved therapies are having an impact on the disease, but we do have a long way to go still.

MQSA has led to the improvement of image quality and other aspects of mammography. There is less certainty, however, about the act's impact on the quality of image interpretation. When it comes to quality assurance in interpreting mammograms, patients would benefit from strengthening MQSA. Studies demonstrate wide variation in the interpretation of the same mammogram by different radiologists. This variation is troublesome.

Poor quality interpretation leads to the false negatives, as have been mentioned, which produce delayed and more costly treatment. Poor quality interpretation also leads to false positives, also very troubling because this leads to unnecessary biopsies, increased anxiety for women, not to mention increased health care costs.

Physicians can and should do more to sharpen their interpretation skills. Radiologists who perform only the minimum number of exams required will encounter relatively few breast cancers in their careers. Numerous studies now show a strong correlation between the accuracy of mammography interpretation and reader volume. In order to develop the necessary expertise, radiologists must be exposed to a larger number of mammograms.

The traditional form for CME is lecture courses. Although beneficial, our constituents tell us that such courses are largely ineffective for improving interpretation skills. CME requirements should direct radiologists toward hands-on, skill-based courses, rather than lecture series alone. Self-assessment as a component of CME would provide radiologists with more opportunities to look at breast cancers and help them better understand suspect images.

Given these potentially life-saving benefits, the Komen Foundation urges Congress to require skills assessment as a component of CME. We support the proposal to mandate that one-third of CME be dedicated to skills assessment study.

The Komen Foundation recognizes that these issues cannot be looked at in a vacuum. It is also essential that insurers, including Medicare, provide adequate reimbursement to providers of mam-

mography services to ensure the quality of care and quality of life. We do not want either compromised.

Reports of growing disinterest among physicians and technicians in the field of mammography abound. We do hear that radiologists are being deterred from choosing mammography as a specialty because of the numerous disincentives to enter the field—fear of liability, high cost of malpractice insurance, inadequate reimbursement, workload and high stress levels. Reports cite facility closings and suggest that many are the result of reimbursement rates that do not cover the cost of providing mammography.

The Komen Foundation is very concerned about the reported decline in these services and its potential impact on access to care. Further study is needed to verify the reported correlation between inadequate reimbursement and facility closings and to determine whether this has resulted in a decline in available services, as we suspect. We strongly suggest that language calling for such study be included in any proposal for authorization.

The Komen Foundation also strongly supports a two-year reauthorization time frame. A two-year cycle would allow for the implementation of a system yet provide the flexibility necessary to evaluate concerns in a timely manner.

I appreciate the real improvements in mammography and the progress in breast cancer treatment over the years. We have made significant strides and are on the edge of a real breakthrough that could save thousands of lives. But until researchers find a cure for breast cancer or better yet, a way to prevent the disease, we must not lose sight of the importance of mammography screening for detecting breast cancer early. Reauthorizing MQSA with new provisions that result in better image interpretation will help ensure the delivery of high quality breast cancer care in the United States.

The Komen Foundation will continue in our commitment to fund ground-breaking research for future generations but rest assured we also remain committed to ensuring that everyone facing a diagnosis of breast cancer today have access to the best care currently available.

Thank you for the opportunity to present this testimony.

Senator ENSIGN. Thank you.

[The prepared statement of Ms. Rowden may be found in additional material.]

Senator ENSIGN. Dr. Berlin?

Dr. BERLIN. Mr. Chairman, Senator Mikulski, my name is Leonard Berlin. I am a practicing radiologist, a member of the American College of Radiology, and the chair of a radiology department in suburban Chicago, as well as a professor of radiology at a medical school.

I am honored to have been asked to testify regarding the reauthorization of MQSA. At the outset let me say that I categorically endorse reauthorizing MQSA for I believe that the act has been of great benefit to the medical community at large, particularly radiologists, as well as the public.

I understand that the committee also favors reauthorizing the act but at the same time, I am aware that concern has arisen that MQSA as currently constructed does not address certain professional aspects of mammography, such as the accuracy with which

radiologists render mammographic interpretations. Because of such concerns, there may be a 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 receive competent, relatively uniform radiological evaluation.

Should Congress decide to mandate radiologist participation in a self-assessment program, 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 be a controversial issue is whether the results of such a mandated self-assessment process should be made 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, namely 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 have shown a rampant increase in lawsuits associated with mammography such that mammography has now become the most common reason that malpractice lawsuits are filed against radiologists.

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 and going through a simple mathematical calculation and thus all radiologists should arrive at the same interpretation. Alas, such as not the case. Shadows on mammograms are far more often varying shades of gray, normal 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 percent, as estimated by some researchers, are not visualized on mammograms.

Because the public perceives or rather misperceives that mammography is 100 percent accurate, women frequently resort to malpractice litigation if breast cancer is diagnosed subsequent to having had a mammogram that was 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 medical testimony that a delay had no ill effect, juries are nevertheless all too ready and willing to award compensation to the patient. Although the average indemnification of breast cancer approaches \$500,000, awards of 3 or 5 or even 10 or 12 million dollars are not that unusual.

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. The end result is that more and more radiologists are refusing to perform mammography and fewer and fewer young radi-

ologists are opting even to begin practicing mammography. In turn, mammography facilities are closing.

To illustrate the effect the medical malpractice quagmire is having on radiologists who interpret mammograms and to put it all on a more personal level, let me quote just briefly from several unsolicited letters that I recently received from radiologists around the Nation who perform mammography. "I am a private practicing radiologist in a western suburb of Milwaukee, WI. I 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 diagnosis. Because of the current atmosphere of litigation, if I were given the choice to stop manning our women's center I would seriously consider it." The letter is enclosed in the written material with his signature.

Here is another letter. "My junior partners and I are running scared. 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 8 months prior to discovery of the cancer, but the truth is irrelevant. The patient developed liver and brain metastases during the discovery process and the insurance company settled for \$800,000. Our malpractice premium rose to \$50,000 per man and the junior partner is now leaving Florida to go to New Mexico. Even perfect professional performance provides no protection in Florida."

One more letter from Houston, TX. "It is unfortunately occurred to me of late that in a short time we will not have to worry about mammography anymore because breast imaging simply will be something done only in a handful of centers. The current statistics are grim. As of now, well over 600 facilities have closed their doors and the current rate of closings does not appear to be declining. Just this morning one of the fellows that I trained in mammography 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 mammography center in Carmel, CA and he said they simply shut down all breast imaging for reasons related to malpractice."

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 is made public or discoverable. The malpractice litigation will be exacerbated and as a result, many more radiologists will simply refuse to undergo self-assessment or participate in performance improvement activities. Therefore I ask that if self-assessment is made mandatory as part of MQSA reauthorization, the results remain privileged.

Let me summarize. Radiologists are in short supply. Breast imagers are in even shorter supply. The combination of low reimbursement with a high probability of being sued for a misdiagnosis is clearly not the best tool for recruiting young radiologists to participate in mammography. Seven hundred mammography facilities have closed nationwide over the last 2 years and 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 nondiscoverable.

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

[The prepared statement of Dr. Berlin may be found in additional material.]

Senator ENSIGN. I want to thank all of you for your testimony. I do not know how many of our other colleagues will be here this morning, so we can keep this kind of free-flowing.

Senator MIKULSKI. Sure.

Senator ENSIGN. We can just have a real good discussion this morning and even back and forth between the witnesses to try to get some healthy dialogue.

I want to start with Ms. Rowden. The point has been brought up about self-assessment. No studies have shown, according to the testimony of Dr. Dershaw, as far as objective studies go, that it actually improves quality, but the gut feeling is that it may improve the reading and may not be a bad thing to do. But as Dr. Berlin has testified, that could be an open door to more liability in the future and we all know the problems that are occurring across the country and certainly in my State.

Do you have a position, or does the Komen Foundation have a position, on whether that should be nondiscoverable in a jury trial?

Ms. ROWDEN. We would not want something like the CME skills assessment to be punitive for the doctors who are making an effort to learn and be up to date with their skills and their training. In no way would we want that to come back on them when they are trying to improve their knowledge and do the best job that they can.

Senator ENSIGN. Thank you.

Dr. Berlin, I am obviously very involved on the whole medical liability issue on a different level and I do not want to turn this hearing into that, but I think it is important that we focus on that issue for a moment. Sometimes the worst laws that we make around here are the laws of unintended consequences. More regulation can lead to more litigation. The unintended consequence can lead to then fewer doctors and the worst unintended consequence can lead to the unavailability of mammography for lots of women.

I know I mentioned in my opening statement what we call the mammovan, the portable mammography unit that drives around our State. For months and months at a time we cannot use it because we cannot find the technicians to perform the procedures because they are not available. And they are paying actually a very, very good rate, competitive rates, and they just cannot find people to perform these procedures. So, I have had personal experience dealing with that particular issue as far as the lack of availability.

Can you focus maybe your answer on the medical liability issue as far as MQSA is concerned to the potential of what could happen in the future? Also, are there any statistics on how much more it

costs in your practice, your medical liability coverage, if you perform mammograms versus not performing mammograms?

Dr. BERLIN. Yes, Senator. First of all, on the shortage of radiologists and technologists, indeed there is an acute shortage around the Nation, not only of the physicians, the radiologists, but of all radiology technologists, and mammography is certainly no exception. The shortage occurred fairly abruptly over the last 2 years or so and will probably continue for the next five or six or 7 years.

And I am sorry; the rest of your question?

Senator ENSIGN. The difference in rates.

Dr. BERLIN. Yes, the difference in rates. I will tell you anecdotally, and there have been several articles written, as well, that various malpractice insurance companies have come to radiology groups in various states and it is not a matter of cost but it is a matter of saying to these groups we will insure you only if you stop doing mammography. One big mammography center, as a matter of fact, in Las Vegas was confronted with this and I know the radiologist who runs that personally, but this has happened elsewhere, too.

Now as you know, because of the increase in malpractice around the Nation, and we will not get into the issue about whether the insurance companies are at fault or not at fault but the fact of the matter is no matter who is at fault, many insurance companies are pulling out of the market and this leaves less insurers available and this is one of the reasons for the crisis around the Nation, is that radiologists, as all physicians, are having difficulty in finding an insurance carrier.

So if there are only one or two or three insurance carriers in a given State that will insure physicians and radiologists and if they tell the radiologists we will only insure you if you give up mammography, then the radiologist has no choice but to do so.

As far as the difference in premium, I do not have any specific evidence on that. I will certainly check with the college and if we do, we will certainly submit that in a written report, sir.

Senator ENSIGN. I appreciate that. Also, as Ms. Rowden testified, the more you read mammograms, the better you become. I do not know that insurance companies have gotten to this yet but with OB-GYNs, the more babies that you deliver, the better you become at it. However, they have limited most OB-GYNs because of medical liability costs. The more that you deliver, the more chances there are that you are going to have a problem, just because of sheer numbers.

Well, the more mammographies you read, the more chances you are going to have of missing something, so it is a double-edged sword, I guess is the point that I am making. So we want people to read more but are the insurance companies addressing that yet? Maybe they have not caught onto that yet.

Dr. BERLIN. Yes, I think you are right on both counts. It is a delicate balance. Actually there have been research studies published pointing out that probably about 2,000 mammograms a year is when a radiologist hits peak performance—this is a general statement in one particular article—and fewer than that or considerably fewer or considerably more than that, the accuracy apparently decreases slightly.

I think you are correct. I do not think the insurance companies have caught up with that yet. There is no question whether we are delivering babies or we are reading mammograms, the more patients or babies we deliver or the more mammograms we read, the greater our chance of incurring a malpractice lawsuit. There is no question about that.

Senator ENSIGN. I will turn it over to you for a little bit and we will go back and forth, okay?

Senator MIKULSKI. Thank you, Senator.

Ms. Rowden, I want to ask you a question. I was a little bit confused about page 6 of your testimony and medical outcomes. I want to be sure that I understand the Komen Foundation recommendations. You say "One way to better understand outcomes would be to require consistent collection and utilization of data." Then you go through this list that you see on page 6—the number and types of all mammograms, the number of screenings.

Is this by individual or is this by group? I kind of got lost there.

Ms. ROWDEN. You mean by individual practitioner or—

Senator MIKULSKI. No, I am asking you. On page 6 you say "One way to understand about outcomes would be to require consistent collection and utilization of data," and then you have a list of the data to be collected. From whom do you want the data to be collected?

Ms. ROWDEN. Well, from mammography centers or centers providing mammography services.

Senator MIKULSKI. So this would be a center, not an individual.

Ms. ROWDEN. Correct.

Senator MIKULSKI. Why do you want this?

Ms. ROWDEN. Well, one is a way to measure whether or not the mammography is a benefit in terms of screening. I mean it is a way to look at some research issues in terms of benefits of screening, as well as look at the ratio of screening to number of actual biopsies that are performed to get a better picture and handle on the effectiveness of this tool.

Senator MIKULSKI. But this then is the regulation of the center, rather than of the physician; is this correct?

Ms. ROWDEN. To look at it in aggregate, yes.

Senator MIKULSKI. OK, I could see that.

Let me then go to the mammogram quality standards. Mr. Chairman, I think we have a couple of issues, one of which is the equipment itself. Even though we have excellent work done by FDA, the Institute of Medicine has a study that says there is potentially more promising technology out there. Mammography is not a fool-proof, 100 percent tool. It still has limited but necessary utility. We need to look at what are the barriers, and this also goes to some of your issues around regulation, to new technologies being able to come on to be less intrusive, less klutzy, and also more accurate. So that is one for us, to really make sure we have a legislative and regulatory framework for new thinking to come on medical diagnostic breast cancer testing.

The second issue is the shortage of people, both in radiology and the x-ray or radiology technologists. Mr. Chairman, I fear that we are going into radiology technicians the same kind of crisis we went into with nurses and I would really respectfully suggest that

the committee hold a hearing with the radiology technologist community to identify the reasons for the shortage and if we would look at it along the same lines that we looked at the Nurse Reinvestment Act, again to make sure that we have the opportunity for there to be the technicians.

Then we get to the issue of reimbursement, which is spartan and skimpy. This goes to then Dr. Berlin and Dr. Dershaw. When we talk about the skimpy reimbursement, is that both from private insurance or is that the Medicare insurance or is that both? Dr. Dershaw, would you comment on that?

Dr. DERSHAW. It is both.

Senator MIKULSKI. Because again we are looking to barriers to doing mammograms.

Dr. DERSHAW. It is pervasive. Not only does it often not cover the cost of performing the mammogram or marginally cover the cost of performing the mammogram but in addition to that, I think it is appropriate to look at it in terms of what the reimbursement level is for mammography compared to the reimbursement for other tasks that radiologists perform.

Senator MIKULSKI. Could you give us an example of that?

Dr. DERSHAW. Well, let me tell you that I had a meeting with my chairman this week, last week, and we were going over dollars billed per manpower hours. Mammography had the lowest in the department and the highest billers in the mammography section were those who also read CTs. We are notorious for being loss leaders or marginally profitable.

Senator MIKULSKI. What is the reimbursement rate?

Dr. DERSHAW. The reimbursement for a screening mammogram is \$81.81. The cost, the tabulated national cost of doing a mammogram, screening mammogram in an office is \$86 and in a hospital it is \$122. So we are paying for women to have mammograms.

Senator MIKULSKI. In other words, there is a subsidy to do it. I will come back to the reimbursement issue. I think this is a real issue and I think we have to look at where government reimburses and it goes to two issues, one of which is in the Medicare area and to really look at our responsibility to the physician community because I think what you are talking about here is an average cost—

Dr. DERSHAW. Yes.

Senator MIKULSKI. It sounds enormously reasonable, to buy the equipment, the professional training, the salaries, etc. I would imagine the reason that they are higher in hospitals is because of the very nature of often they are academic centers or world class, such as the one that you come from. But is that not where most poor women go?

Dr. DERSHAW. Yes, Medicare and Medicaid services are largely provided through hospitals, as well as training largely being done through hospitals, as well as training not only being provided through hospitals but the experience that is conveyed to the trainee during the training experience is at the hospital. So the entire milieu that exists there is conveyed to people making career choices.

Senator MIKULSKI. Mr. Chairman, I was the author, along with Senator Olympia Snowe and other colleagues, on essentially a screening program and detection and treatment for women in that

gray area—the non-Medicaid women, the women who do not have health insurance—often the retail clerks, the Norma Rays, etc.

So I think we need to look at reimbursement but then let us go to regulation. So the barriers are one, you need to have enough people; we need to look at that. Better equipment, and I think you would agree.

Dr. DERSHAW. Yes.

Senator MIKULSKI. And the private sector would agree because the medical device community really says—and even the Institute of Medicine says there are deterrents for them to pursue research on how to have better equipment.

Now let us go to the doctors. We have heard now that we want to improve skill assessment and I would really like your advice on how we can improve the skill assessment aspects of the legislation without it being a deterrent.

Dr. DERSHAW. I think there are a variety of avenues that you can go down. First, I think with the outcome data that has been commented on several times already, the outcome data does not mean very much the way it is accumulated now where we are mixing women coming in for screening mammograms with women coming in with symptoms of breast cancer. Those two populations have to be separated and the data looked at separately.

So I think in the end results we should be separating diagnosis from screening to give more meaning to the data and have that be a more meaningful self-assessment evaluation than what it is presently.

I think certainly a self-assessment endeavor, such as that designed by the College of Radiology, may have a positive impact. Now we do not know for sure whether it does or whether it does not, but in fact, it may have a positive impact.

I think, though, the use of that has to be tempered with the imposition of further requirements on people who are performing breast imaging. Perhaps either radiologists could be encouraged by the CME credits that are offered to them or perhaps the system that presently is used, presently is mandated by FDA could be completely reviewed so that we could look at which mandates remain appropriate 10 years after the system was put into effect, which ones could be set by the wayside, and which ones could be added.

So there would be a sense at least among radiologists who are involved in breast imaging that it is not a constant superimposition of one regulation on top of another but it is, in fact, a reassessment of appropriate regulation.

The breast imaging community is very proud of, has been very aggressive about and certainly encourages endeavors that make the quality of mammographic interpretation better. I would remind you that before MQSA was instituted there was a voluntary program which made this possible and it was unique to breast imaging. So we are in favor of doing efforts that would improve our quality.

Senator MIKULSKI. What do you think of a mandated requirement requiring skill assessment as part of CME and then there becomes the issue of its availability for either public scrutiny or as data in a malpractice suit? What do you think about mandating essentially what has been developed by the American College of Radiology?

Dr. DERSHAW. I think that further mandates on the practice of breast imaging potentially have a negative effect. I think that a mandated utilization of a self-assessment examination would not be met with a hew and cry in the breast imaging community but it would be met with a sigh saying there is another regulation that we need to comply with.

So I think that it would be greeted more enthusiastically, I think rather enthusiastically, if it were optional with considerable CME credit attached to it. We would all be willing to participate in it, I think, under those circumstances.

Senator MIKULSKI. In other words, one of the things would be to add more CME credit to it.

Dr. DERSHAW. Or make that mandate part of a review of all of the mandates and regulations that are now associated with MQSA to determine which ones remain valuable and which ones could be discontinued. That would be met, I think, with the greatest enthusiasm.

Senator MIKULSKI. Well, that would then go to a GAO or the IOM study.

Dr. DERSHAW. Yes.

Senator MIKULSKI. I want to come back to that because that goes to the length of time of reauthorization. But—

Senator ENSIGN. Can I follow that up?

Senator MIKULSKI. Just one second. This is the last and then I will be happy to turn it over.

In the Komen Foundation testimony, Ms. Rowden, you say an example of a sensible step in the right direction is the Centers for Medicaid and Medicaid Services, CMS. In a recent announcement, they are going to award CME credit to physicians who participate in newly designed quality improvement courses provided by the Medicare Quality Improvement Organization.

I would like you to look, Dr. Dershaw or Dr. Berlin, at the Rowden testimony where government essentially says okay, if you are going to do this, it is like a good guy bonus. In other words, you volunteer to do this and actually be more rigorous, which hopefully you will benefit from as a clinician. We just presume if you came into this field to save lives, help people, you want to be good at what you do. That is your own personal motivation. So we would like to combine your own professional desires with this framework, make it more insistent, though, than just voluntary.

But I would be really willing to look at what I will call good guy or good gal bonuses, if you will, that if you participate, there is some other way of acknowledging that this is rigorous and more demanding than looking at other diagnostic avenues for radiology. I mean this is a lot different than orthopedics, that still has—you know, you can miss that hairline.

Dr. DERSHAW. Certainly.

Senator MIKULSKI. In other words, nobody is perfect but if you are not always perfect all the time, we do not want you to be nailed. Do you see where I am heading?

Dr. DERSHAW. Yes.

Senator MIKULSKI. Mr. Chairman, you wanted to follow up but I think that is a very good way of saying it.

Senator ENSIGN. I wanted to follow up and either one of the doctors can respond to this. I was intrigued by your testimony or your response about reviewing all the regulations. One of my fears always is that regulations will stifle new procedures and new innovations because if something is put in regulation, oftentimes people are less likely to do anything new because, once again getting back to the malpractice issue, that is not the standard of practice. It may be a poor analogy to use there but it is along those lines.

In finalizing this reauthorization, do you have suggestions of any regulations to take off? And in adding new regulations, what is the potential for hurting innovation or for hurting new technologies coming on in the future? Are there any?

Dr. DERSHAW. Well, I think we should in an organized fashion, probably through the Institute of Medicine, look at the regulatory package that is presently out there and examine that. I will tell you that much of it is considered burdensome. The inspector, the on-site examination, I have had to close mammography, various mammography services for 11 days so far this year in order to have inspections. That is expensive and that is burdensome.

The paperwork that is involved when the inspector comes for my technologist is about this high and for me is about this high. I had 1 year an inspector come and say to me, "How many mammograms did each of your people read?" I told the inspector, who then asked for documentation of it. We had to print out every mammogram that was done in the past year. We do over 20,000 mammograms a year. We had to print out every mammogram that was done in the last year and who did it. Now that is one problem that we have that would be easily corrected.

Now another problem that we have which has just begun is the accumulation of end results data, unless we have approval, IRB approval, violates the HIPAA regulations of patient privacy, our attorneys have told us at the hospital. So we have had to go to our IRB, which has taken me an extra day or two of paperwork to fill out so that I can comply with the Federal law of HIPAA and comply with MQSA. It is increasing time and effort.

There is another regulation under MQSA by the FDA that requires that certain words be used in every mammogram report to State the end results. That means that in every reading station I have where mammograms are done, we have a little poster that has what the exact words are that you have to use.

Now it does not make an awful lot of difference to me but when I have residents and fellows in training coming through and I tell them that the Federal Government requires that they use this word and if they do not use this word we are in violation and can be fined, and in New York we can be put on the front page of some newspaper that follows the results of these investigations, it puts a whole different spin on what some of these regulations mean, what the impact is, and how they are perceived by people in training as they are coming through the programs.

Now why would somebody want to read mammograms, where they are told what the report has to say, when they can read a CT and they can use whatever words they want?

Senator MIKULSKI. But maybe they want that language for consistency in data gathering.

Dr. DERSHAW. But what difference does it make if you say negative or normal? If you say one you are in compliance; if you say another, you are in violation.

Senator MIKULSKI. And that is why I want the IOM study.

Dr. DERSHAW. Right.

Senator MIKULSKI. Mr. Chairman, when we did an initial draft of this legislation before close of session last year and I was the chair, I wanted two studies done and I think you would like them. First of all, what I wanted was limited time, a limited reauthorization and that we would do two studies—one, a GAO study reporting in a year on accessibility, the role of the states for accreditation and certification, etc, but the IOM study, the Institute of Medicine, would be on how physicians could interpret mammograms better, could be better trained, what additional requirements should there be, and essentially a whole review that you are talking about, which is steps that should be taken to improve the quality. There would be the professional Institute of Medicine to reach out to the appropriate stakeholders, if you will, the physicians, the academic centers training them, the women who are going to be affected by their reading, and say let us take a step back that we cannot do in a congressional hearing.

I mean no matter how diligent we want to be, we need, in addition to the excellent academies and Komen, a true scrub of where we are and what is really now even dated because of technological innovation, all the way through to what we are doing. This is why even now I would hope that we would do these two studies and we would think of the reauthorization as an interim and not be too heavy-handed in it or too lax, but to find that balance. Then in 2 years—this study is due in 18 months—have a chance for everybody to look at it, come back and then do it again without pushing docs out or pushing women away because they think mammograms do not mean anything.

Remember we have had a lot of press that said mammograms do not mean anything and we held a hearing on that. The biostatisticians said we wonder about their utility, and yet all the clinicians, like yourself, said it is still the best thing we have going and we ought to do it.

You see where I am heading? And I do not know if the chairman would agree.

Senator ENSIGN. This sounds like a direction. I am happy that actually just the two of us are here today and we can have a little more informal discussion. A common sense approach is to eliminate the bad and put in the good.

Dr. DERSHAW. Exactly.

Senator ENSIGN. Dr. Berlin?

Dr. BERLIN. Senators, may I go back to one thing that Senator Mikulski brought up a couple of minutes ago about missing the hairline fracture on a leg? There is a basic difference. If a patient comes to a radiologist for a leg x-ray after an injury and we miss a hairline fracture, in a day or two that patient is going to come back because that patient is going to have symptoms and we will have the opportunity to find our mistake and correct it soon so that there is no damage.



Unfortunately with a mammogram, with a screening mammogram where we have an asymptomatic patient, the woman comes in once a year and if for whatever reason we miss that breast cancer, probably no one will ever know about it until a year later. So there is that difference, so therefore the sensitivity, the scrutiny, if you will, probably lies a little greater with the people reading mammograms.

Now I do not think any of us here, certainly not the college or we radiologists, are soliciting a mandatory self-assessment. I do not think we are soliciting it. On the other hand, my looking at it fairly, I think, and objectively, I think Congress does have to take a look at it for the simple reason that if we assume, and I suspect it is true, 95, 98, 99 percent of radiologists already are doing optional self-assessment, whether they are doing it from the American College of Radiology or alternative means in their hospitals, and so forth; I am convinced most radiologists are doing it; however, we all know that maybe 1 or 2 percent of radiologists are not. If something is optional, the substandard radiologist is not going to opt to undergo self-assessment. He or she will only do it if it is mandatory.

So, as I say, not that I am soliciting mandatory, but it is something, I think, for Congress to keep in mind.

Senator MIKULSKI. But your recommendation, if I might, Mr. Chairman, Dr. Berlin and others, and I believe it is also the Komen Foundation through Mrs. Rowden; she says we do not want mammocops because we are not here to fingerprint. We are here to pinpoint improvement.

So your recommendation would be as we look at the next period of reauthorization to use the carrot approach to encourage it and even if we mandate it, that we put carrots into it through either bonuses for continuing ed and so on, so that we encourage it. We do not use a stick and we really ask the Institute of Medicine and so on to take a look, knowing that we are going to come back again and see where we are.

Is that the direction you are recommending? And I would wonder what other carrots you might recommend. Also, Ms. Rowden, you, too.

Dr. BERLIN. I personally think—let me tell you a little about how it works. The Joint Commission, the Joint Commission of Accreditation of Health Care Organizations comes in every 2 years and inspects hospitals. One of the regulations that they have in there, one of the requirements, is that performance improvement be done, specifically in radiology. We are talking about radiology.

Now they come in, their inspectors come in and they say, "Show us your performance improvement. Show us that you are doing it." Now they are not there to micromanage. They are not there to microdetail who is doing what, which doctor is reading this, which doctor is reading that. They want to know that we are doing it and that we are doing something about it and we are monitoring ourselves.

So I think it all falls back to that if Congress does decide to mandate some kind of self-assessment, it is what form that self-assessment will take and if it is not too much of a burden on us, I think the radiologic community will buy into it.

Senator ENSIGN. Just to kind of summarize, I think it has been a great discussion this morning. As we go forward I think that we are all after the same goals, and that is to improve the quality of mammography taking, reading, interpretation—obviously for early diagnosis. I think that lowering the cost as much as possible through the elimination of some regulation is a good idea. This interim reauthorization is a direction that we could be looking in to be able to understand what we have to do for a permanent or at least a longer term reauthorization beyond that point.

Our goals need to be that it does not raise the cost through medical liability insurance rates, and that we are encouraging more people to go into it because we are simplifying things and maybe bringing down the cost. We do not control the reimbursement rates on this committee—that is over on the Finance Committee—but certainly it would be something we could make a point of when we bring the legislation to the floor. We can certainly make a point of that, as one of the big deterrents to people continuing to do mammography or even wanting to become readers of mammograms.

I think that it has been a productive hearing today. Both Senator Mikulski and I have other commitments we have to get to but we appreciate all of you being here today. It has been a great start for us working together. I think you can see that both of us are committed to working to come up with some answers. There is no reason for this thing to be partisan. I think everybody can get together on this and come up with something which we can go forward on with all the stakeholders being satisfied.

Senator MIKULSKI. I, too, would like to thank the witnesses. There is a great deal of thought in it, first to the clinicians and practitioners who bring insights and recommendations and also to Ms. Rowden representing the Komen Foundation. I think that this has been outstanding.

I think one, we have a long-range hearing, which is the shortage in personnel, and that even goes to physicians, also, as well as the technologists because I do see this as a looming crisis, particularly in the allied health fields. We see it with a shortage in pharmacists, etc. You know, people are majoring in mass communication and yet we face mass health challenges from public health to clinical practice. That is one thing.

And here, Mr. Chairman, I would really like us to think about a reauthorization that has a shorter time limit than we might otherwise do and really get the studies. At the same time, not just rubber-stamp or ratify what we have and really think of the carrot approach, looking both to the Komen Foundation and the American Cancer Society, as well as the professional associations and the clinicians about what would be some of the carrots to encourage self-assessment, but it not break new ground as cause for action in malpractice. I think we would all feel pretty comfortable with that. Would you agree?

Dr. DERSHAW. Wonderful.

Dr. BERLIN. Great.

Senator ENSIGN. OK, thank you all very much and you are excused. This hearing is concluded.

[Additional material follows:]

## ADDITIONAL MATERIAL

PREPARED STATEMENT OF D. DAVID DERSHAW, M.D.

Good Morning. My name is David Dershaw. I am Professor of Radiology at Cornell University Medical College and the director of breast imaging at Memorial Sloan-Kettering Cancer Center in New York City. I am also the incoming president of the Society of Breast Imaging, the subspecialty professional organization of radiologists who do mammography, and I am testifying on the Society's behalf.

Thank you, Mr. Chairman, for inviting me to testify regarding the reauthorization of the Mammography Quality Standards Act of 1992. It is my belief that MQSA has played a significant role in improving the quality of mammography. This program needs to be reauthorized so that women can continue to benefit from high quality mammography.

Since enactment of the Mammography Quality Assurance Standards Act (MQSA) in 1992, women in the U.S. have gained confidence in the providers of their mammograms through the knowledge that mammography facilities were being certified in accordance with Federal standards. A continuing decline in breast cancer death rates (almost  $\frac{1}{3}$  reduction for invasive cancers in the 1990's) and increasing utilization of mammography screening services (increased from 27 percent of eligible women in the two years before 1987 to 66 percent in the two years before 1997) are testaments to the success of the collaboration of radiologists, mammography facility operators, and government regulators. This consortium was carefully designed into the law. The improved quality of mammography services has undoubtedly saved many lives and diminished the anxiety of women in the United States about the quality of their screening studies. The continued force of MQSA in maintaining this high level of service is essential. On behalf of the Society of Breast Imaging I again urge the reenactment of this legislation.

### MAMMOGRAPHY INTERPRETIVE SKILLS ASSESSMENT

Currently, MQSA requires that physicians interpreting mammograms participate in 15 hours of Continuing Medical Education (CME) every three years. CME is offered in a variety of ways such as attending meetings and lectures. Although valuable in their content, these meetings are rarely designed for radiologists to assess their skills.

The American College of Radiology has designed and tested over the past decade the Mammography Interpretive Skills Assessment (MISA) test.

In 1999, this was made available as an interactive computer-based CD-ROM. This offers radiologists an opportunity to participate in a mammography self-assessment examination.

The purpose of the MISA is to provide the radiologist with an assessment of his or her skills and to identify areas in which additional study or skills improvement is warranted. This is not a pass/fail test or one that is intended to certify or judge participants. The emphasis is on self-help.

By providing the physician with seven or eight hours of CME, depending on which CD the physician uses, physicians would be encouraged to use the MISA for both continuing education and self-assessment. This might be useful as a method of determining skills in addition to the data are presently derived from the end results assessment required under MQSA regulation.

While self-assessment testing may be of value, it should also be recognized that there are no data to indicate that such tests provide feedback that accurately determines competence. There is also no science to indicate that such tests result in improvement in the quality of medical care.

I am certain that the Committee recognizes that in order to achieve the benefits obtained under MQSA those involved in mammography practice have added time, effort and expense to the delivery of screening and diagnostic mammography services because of the need to comply with MQSA's regulations. Although the mammography community is appreciative of the higher standard set for its care than that generally required in radiology or other areas of medical care, these have also imposed a burden that has discourage some from offering these services. The possible advantage of mandated self-evaluation, an additional regulation that would need to be fulfilled and documented by mammography facilities, should be weighed against the detrimental impact of increased regulation of mammography facilities and radiologists interpreting mammograms. Steps that might further discourage radiologists to incorporate mammography into their careers may accelerate the developing crisis in availability of mammography services.

Radiologists interpreting mammograms are already in short supply due to poor reimbursement rates and high litigation. It is my belief that providing plaintiff law-

yers with another potential avenue for litigation will lead many more radiologists to turn away from mammography, thus exacerbating the already critical access problem many women face in receiving timely mammography services. If results of self-assessment activities were to be subjected to discoverability in litigation cases against physicians, the Society of Breast Imaging would strongly oppose the incorporation of such testing into MQSA regulation.

The Committee should also recognize that the greatest threat to the delivery of quality mammography services in the United States is the impending shortage of radiologists, technologists and imaging facilities to provide this service. Inadequate reimbursement persists with payments for service often less than the cost of performing and interpreting mammography. The most tenuous financial reimbursement is for hospital-based services. As this is the site where most women on Medicare and Medicaid receive their health care, the availability of mammography to these women is the most threatened by inadequate reimbursement.

Hospitals are also the sites where most of the training of physicians and technologists occurs. Poor reimbursement, particularly when compared to reimbursement levels for other radiology services, has left those deciding what area of radiology to specialize in with an impression of mammography as a big money loser. Along with high malpractice exposure and considerable time and effort required to meet Federal (and often local) regulation, this negative impression works to discourage those in training from selecting mammography as an area of specialization.

As the Committee considers reenactment of MQSA, I would like to make a few comments about modifications that might be recommended in current regulations.

As authorized under the original legislation and recommended by the National Mammography Assurance Advisory Committee, regulation of mammography services should be expanded to include stereotactic breast biopsy and equipment used in needle localization procedures.

Furthermore, the current requirement for CME in digital mammography beyond the initial training required before using digital mammography on patients does not improve the quality of practice or contribute need training to improve patient safety. This requirement is often difficult to meet and the Committee should recommend that it be discontinued.

Thank you for the opportunity to testify. I would be happy to answer any questions.

#### PREPARED STATEMENT OF DIANA ROWDEN

Chairman Gregg, Senator Mikulski, and distinguished Members of the Committee, thank you for the opportunity to testify on the reauthorization of the Mammography Quality Standards Act (MQSA). My name is Diana Rowden. I am a breast cancer survivor. I consider myself blessed because mammography led to the early detection of my breast cancer, which allowed me to take advantage of less intrusive treatment options and enjoy a higher quality of life during the almost 12 years since my diagnosis. I am honored to be able to thank you in person for enacting the MQSA, which gives women increased confidence about the quality of mammography screening. The Susan G. Komen Foundation Breast Cancer Foundation and its many constituents of breast cancer survivors across the nation appreciate and are grateful for your dedicated leadership and support for improving the quality of breast health and breast cancer care in the United States.

#### **Patient Education, Advocacy and Outreach**

As a result of my experience, in the spring of 1992 I became a patient advocate volunteering for the Komen Foundation. Komen was established in 1982 by Nancy Brinker, to honor the memory of her sister, Suzy Komen, who died of breast cancer at the age of 36. The Komen Foundation has 118 domestic Affiliates, with over 75,000 volunteers across the United States, and 3 international Affiliates.

I was one of the first volunteer counselors on the Foundation's national toll-free Helpline, 1-800-I'M AWARE®, which receives approximately 60,000 inquiries every year from women and their families, seeking critical information about breast health and breast cancer care. I served on the Komen Foundation's executive committee, first as vice-chair of education and then as vice-chair of grants. From 1997-98, I served as the elected Chair of Komen's National Board of Directors. Since then I have continued my volunteer work for Komen, participating as the Foundation's representative on numerous local and national committees and boards, including the Intercultural Cancer Council which, consistent with Komen's mission, advocates the elimination of the unequal burden of cancer on racial and ethnic minorities and the medically underserved. In addition, I was an ad hoc member on the integration panel for the U.S. Army Breast Cancer Research Program. In November 2002, I

joined the Komen staff as the Affiliate Service Manager overseeing Komen's domestic Affiliate network. I also serve as a member of the National Cancer Institute (NCI) Consumer Advocates in Research and Related Activities (CARRA) Program and the National Surgical Adjuvant Breast and Bowel Project (NSABP) Patient Advocacy Committee.

My current work with Komen's vast Affiliate network keeps me in close touch with our many volunteers across the nation—survivors and their loved ones dedicated to the fight against breast cancer. Through programs like the Komen Race for the Cure® and other education and outreach programs, as well as our Komen Champions for the Cure™ public policy grassroots program, the Komen Foundation remains steadfast in our commitment to eradicate breast cancer as a life-threatening disease by advancing research, education, screening, and treatment. The Komen Foundation has become the largest private funding source of breast cancer research in the U.S. Since its inception, the Foundation has raised nearly \$600 million in the fight against breast cancer. In addition, Komen Affiliates provide tens of millions of dollars annually to fund non-duplicative education and outreach programs that address unmet breast health needs in local communities.

#### **Access To Early Detection Save Lives**

However, while the Komen Foundation invests millions of dollars annually in cutting-edge breast cancer research for the future, we recognize the urgency of helping to meet the needs of those who are facing breast cancer today. This year in the U.S. alone, more than 200,000 women and men will be diagnosed with breast cancer, and over 40,000 will die from this devastating disease. Every 3 minutes a woman is diagnosed with breast cancer, and every 13 minutes a woman dies from this disease. All of us here today will be touched by breast cancer in some way during our lifetime.

I believe that early detection of breast cancer saves lives. Mammography screening, while imperfect, remains the best tool available to detect breast cancer at its earliest, most treatable stages. It is the reason I am alive to testify before you today.

More than 10 years ago, Senator Mikulski and other Senators recognized that the effectiveness of mammography hinges on the quality of equipment used and the accuracy of interpreting physicians. You led the effort in 1992 to enact the MQSA and establish national standards of mammography care. Worried about inconsistencies and the often poor quality of mammography, Congress, through MQSA, mandated that the Food and Drug Administration (FDA) oversee the more than 10,000 facilities that perform mammograms across the United States through accreditation and annual inspection programs. Congress reauthorized MQSA again in 1998, adding the helpful requirement that letters be sent to patients to notify them of their mammography results. Komen Affiliates across the country tell us that they are grateful for these minimum standards and uniformity established by MQSA. Many recognize through their own experiences that quality mammography can save lives, and they sincerely appreciate the efforts of the Congress, the FDA, and the medical community to continue to balance the need for both quality and accessibility of mammography services.

As the GAO recognized in its 1997 report, the MQSA has had a positive impact on the quality of mammography services.<sup>1</sup> Citing American College of Radiology (ACR) data, the GAO reported that prior to MQSA implementation, only 37 to 44 percent of mammography units met the ACR's quality standards; subsequent to MQSA implementation, that number increased to 66 percent in 1995, and to 82 percent in 1997.<sup>2</sup>

In addition, the death rate from breast cancer among women in the U.S. has been decreasing by about two percent annually during the past decade, suggesting that public awareness, early detection, and improved therapies are having an impact on the disease. In the early 1980s, only 13 percent of women in the U.S. received mammograms. At that time, the average size of a tumor when first detected was 3 cm. During the late 1990s, with 60 percent of U.S. women obtaining mammography screening, the average size of tumors detected decreased to 2 cm—a significant and meaningful difference. But we still have a long way to go. Mortality rates in some minority populations have not declined at the same rate as it has in other populations, and we must ensure that all Americans, regardless of race or ethnicity, have access to quality breast health and breast cancer care.

#### **Next Steps—Improving the MQSA**

Few disagree that MQSA has led to the improvement of image quality and other technical aspects of mammography services. There is less certainty, however, about the Act's impact on the quality of image interpretation. The FDA's implementing regulations primarily focus on equipment and technical quality assurance issues.

Some argue that sufficient enforcement mechanisms need to be enhanced. When it comes to quality assurance in reading and interpreting films or in collecting data related to these services, patients would benefit from strengthening MQSA in these important areas.

The MQSA reauthorization process presents Congress with an important opportunity to build upon the existing quality standards related to image interpretation. Determining the quality of image interpretation is essential to improving the effectiveness of mammography. Several studies demonstrate wide variation in the interpretation of the same mammogram by different radiologists.<sup>3</sup> The New York Times reported last summer that the “biggest problem of all” in the mammography industry is the skill of physicians interpreting films.<sup>4</sup>

This variation is troublesome. Poor quality interpretation can lead to false negatives, (missed cancers) and delayed treatment, and even result in avoidable deaths. It can also lead to false positives, which may result in needless anxiety, and costly additional testing, such as unnecessary biopsies.

Therefore, during the MQSA reauthorization process, I urge Congress to consider how best to improve current requirements related to radiologist training and medical outcomes data.

### **Strengthening Radiologist Training**

The current FDA regulations set forth minimum standards for certification of physicians, both radiologists and non-radiologists. These rules mandate that interpreting physicians read at least 480 mammograms each year—a relatively low number.<sup>5</sup> In addition, educational requirements demand that interpreting physicians obtain 15 Category I Continuing Medical Education (CME) units specific to mammography every three years to further their professional development.<sup>6</sup> Even though these requirements demonstrate that the FDA understands the importance of reading a minimum number of mammograms and completing CME courses to maintain sharp interpretation skills, many within the survivor community do not believe that these requirements are rigorous enough. In fact, some of the recent medical journal studies and news articles make one pause about the adequacy of these standards.

I am among the thousands of women, as well as many providers, who strongly believe that physicians should do more to strengthen and sharpen their skills in reading mammograms so that the lives of women are not put at increased risk. The average radiologist is not exposed to a high-volume of mammograms. Radiologists who perform only the minimum number of exams required annually will encounter a relatively small number of women with breast cancer. Numerous studies now show a strong correlation between the accuracy of mammography interpretation and reader-volume, specifically as to small breast cancers. In order to develop the expertise necessary to recognize the varied forms of breast cancers and the manner in which they present, radiologists must be exposed to a larger number of mammograms.

The traditional forum for CME is lecture courses. Although beneficial, our constituents tell us that such courses are largely ineffective for improving interpretation skills. The Komen Foundation believes that CME requirements should direct radiologists toward hands-on, skill-based courses, including self-assessment, rather than lecture series alone. Hands-on training would provide radiologists with more opportunities to look at breast cancers and help them better understand suspect images. Further, self-assessment as a component of CME would require radiologists to look at actual cases, evaluate them, and then compare their interpretation with the correct result. Self-assessment would also provide radiologists with real-time feedback about how well they are doing and where improvement is needed. This interactive process can help radiologists determine what types of cancers they may misread and allow them to adjust their techniques to decrease future mistakes. Since interactive tools that provide hands-on training and opportunities for assessing interpretation skills already exist, it is *not* expected that modification of current CME requirements would add significant costs to the current system.

Requiring skills-assessment as part of CME can be expected to sharpen interpretation skills, which translates into fewer missed breast cancers and more lives saved. Given these important and potentially life-saving benefits, the Komen Foundation urges Congress to require skills-assessment as a component of CME. We support the current proposal mandating that one-third of CME be dedicated to skills-assessment study. Any such requirement should not be considered a test of competency but, rather, an opportunity for interpreting physicians to improve and enhance their ability to interpret mammograms.

The Komen Foundation recognizes that these issues cannot be looked at in a vacuum. The MQSA should provide incentives for mammography-related CME courses to assist radiologists with improving their skills. An example of a sensible step in

the right direction is the Centers for Medicare and Medicaid Services' (CMS) recent announcement that it will award CME credit to physicians who participate in newly designed quality improvement courses provided by Medicare's Quality Improvement Organizations (QIOs). This development demonstrates how the government can create incentives for providers to attend courses designed to improve their proficiency in mammography interpretation.

In addressing the CME issue legislatively, Congress should act more deftly than pursuing a "mammo police" approach. While we must ensure meaningful results for women, it is essential to strike the correct balance that we do not create additional barriers to access to quality care by driving radiologists from the field.

#### **Improving Medical Outcomes Data**

In addition to strengthening the training of radiologists, it is critical that any mammography quality assurance program be able to assess its performance. This assessment can and should occur through evaluation of medical outcomes data. Currently, the MQSA regulations include only a general requirement that each facility maintain mammography data and perform a medical outcomes audit.<sup>7</sup> These audits are limited to reviewing data of patients with tests interpreted as "positive" ("suspicious abnormality" or "highly suggestive for malignancy"). The results are meant to provide feedback to the interpreting physician as part of a facility's own internal quality assurance program. The regulations do not require facilities to report this information to population-based cancer registries, other sources maintaining pathology data, or even the FDA. Creating such links would greatly advance the goal of quality assurance, as well as breast cancer research-related activities, because it would then be possible to determine the accuracy of outcomes of patients whose results were initially interpreted as "normal."

Nor is comprehensive information about physician performance available from other sources. Certain data sources, such as the vitally important Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP), as well as state cancer registries may contain some useful information. Nonetheless, comparable clinical data measuring outcome changes simply are not available. Furthermore, while the FDA's regulations establish federal qualification requirements for physicians who interpret mammograms, the agency has not developed or implemented sufficient criteria to measure the accuracy of their performance.<sup>8</sup>

Although there may be many ways to improve quality assurance in performance, it is appropriate to consider reviewing current medical outcomes audits mandated in the MQSA regulations. Under current law, all MQSA certified mammography facilities must collect certain quality-related data. This data should provide facilities with a basis for measuring current performance and comparing relative performance over time. In short, the audits provide the *potential* for improving the quality of interpretation.

An interesting example of this *potential* appeared in the *New York Times* article describing a "revolution" in mammography commenced at Kaiser Permanente Colorado. The Chief of Radiology began reviewing physicians' records, counting cancers found and missed, and charting and publishing internally the outcomes data. Physician accountability led to some house cleaning but ultimately a much higher level of accuracy. The Kaiser group achieved higher quality of interpretation by directing the interpreting physicians to read more mammograms per year and undergoing a form of self-assessment three times a year. Also, yearly, the radiology section sent out lists of "false negatives" so that the physicians could study and learn from the outcomes data. Furthermore, Kaiser began to look at outcomes data for biopsies, as well as mammograms. In sum, by examining medical outcomes data, the Kaiser project discovered weaknesses, took steps to increase efficiency and quality of interpretation, found cancers previously undetected, and created a program that inspired additional confidence.

During the reauthorization process, I encourage the Committee to explore these important quality assurance issues further. The FDA should be asked and may be readily able to provide answers about its quality assurance efforts in the area of physicians' interpretive proficiency and medical outcomes data audits. Certainly more needs to be known about what happens during the audits and whether anything is done with the data beyond what the originating facility does. Some questions, however, may require more thought and study over a longer period of time.

One way to understand more about outcomes, of course, would be to require consistent collection and utilization of outcomes data in any program of quality assurance. Although the following list is not exhaustive, it includes the type of image interpretation data that would be most helpful if collected for each facility:

- The number and types of all mammograms performed per year;

- The number of screening patients recalled for diagnostic studies;
- The number of radiologists interpreting screening mammograms;
- The number of screening mammograms interpreted by each radiologist;
- The percentage of cases reported annually in each of the five reporting categories (e.g., BI-RADS) used by each facility;
- The number biopsies performed;
- Follow-up of all findings in which any further image or other study is recommended; and
- Retrospective review of the mammograms of each patient diagnosed with breast cancer in the population receiving mammograms at a particular facility.

It also would be extremely helpful to efforts to eliminate health disparities if the quality assurance medical outcomes audit provisions were to require collection of information on patient age and ethnicity, and in a manner that would facilitate the correlation of this data to the BI-RADS categories.

Furthermore, the value of such outcomes data would be significantly enhanced if it were linked to national cancer registries. Not only could such linkages help show how well mammography is working, but it also would allow us to determine how particular facilities are performing. In addition, it would make available better data to inform the breast cancer research community and potentially improve significantly the quality of care received by millions of American women and men.

Of course, any link to a national database demands that the confidentiality of the data be protected and any results be released only in the aggregate without individual identifiable health information attached. In addition, any corrections to the system must consider and weigh current and future burdens to mammography facilities and to radiologists, including economic costs, which might impede patient access to quality care.

Given that some of these issues will require serious review, it may be appropriate to include them in any study requested of the GAO or the Institute of Medicine. This approach would be consistent with proposals for MQSA reauthorization introduced during the 107th Congress. Such study, if completed before the reauthorization expires, could provide greater insight into these issues in time for the next round of MQSA reauthorization deliberations.

#### **Inclusion of Interventional Mammography Procedures**

Since the enactment of MQSA and the establishment of minimum quality standards, women throughout the country have gained further confidence in the quality of mammography services. Now, we must also ensure that these minimum standards of quality apply uniformly to interventional modalities (e.g., mammography-guided needle localization and stereotactic breast biopsy). Interventional mammography is performed in follow-up to an abnormal mammogram. Such procedures can improve a patient's quality of life by allowing further examination of the abnormality while avoiding a more invasive surgical procedure. Research and development of cutting-edge technologies for the diagnosis and treatment of breast cancer, including stereotactic breast biopsy and needle localization, have dramatically improved the quality of life for many patients and their families. Patients must be assured that the care they are receiving as a result of these innovative technologies meets minimum quality standards. The Komen Foundation urges Congress to mandate the inclusion of interventional mammography equipment under the umbrella of MQSA oversight.

#### **Additional Concerns of Patients and Providers**

As previously mentioned, to ensure the success of any new quality assurance system, it is critically important to enhance the quality of continued training and outcomes data collection and analysis. Equally important is the need to strike a balance between the interests of both patients and providers.

Patients should not fear that the confidentiality of their personal health information would be breached. Therefore, I urge the Committee to be sensitive to these concerns and develop a quality assurance system that complies with appropriate federal and state confidentiality laws.

In addition, providers should not have to worry about the misuse of quality information. If providers fear that quality assurance information will be used against them, they may very well stop providing mammography services. If this happens, the strides we have made in providing access to mammography for all women will diminish. Therefore, any quality improvement initiative must contain adequate assurances to ease radiologists' concerns in this regard, and any information released publicly should be aggregated by facility and not linked to particular providers.

The Komen Foundation believes that quality of image interpretation is essential to improving mammography services and building confidence in the continued use



of mammography. Yet we also appreciate that requiring new quality standards could impose additional burdens on providers.

It bears repeating that MQSA deliberations always must balance the need to improve image interpretation with the competing need to maintain access to quality mammography services. It would be counterproductive to implement strict quality standards that result in radiologists leaving the field because they fear potential liability and inadequate reimbursement to implement changes necessary to improve quality.

Reports of growing disinterest among physicians and technicians in the field of mammography abound. Komen constituents increasingly report and survey data suggests that radiologists are being deterred from choosing mammography as a specialty because of the numerous disincentives to enter this field, such as fear of liability, high costs of malpractice insurance, inadequate reimbursement rates, workload and high stress levels. In addition, the number of mammography training fellowships for radiologists decreased by approximately one quarter from 1996 to 2001.<sup>9</sup> Many radiologists contend that the reimbursement levels for mammography are too low in relation to the time, effort and interpretive skill it requires, compared to the other imaging procedures.

In addition, numerous anecdotal reports cite facility closings and suggest that many such closings are the result of inadequate mammography reimbursement rates that do not adequately cover the costs of providing mammography services. The Komen Foundation is very concerned about the reported decline in mammography services and its potential impact on access to quality care. This is of further concern in light of the aging baby boomer population, which will vastly increase the number of women who require mammography services. Further study is needed to verify the reported correlation between inadequate mammography reimbursement rates and facility closings and to determine whether this has resulted in a decline in available mammography services.

The Komen Foundation believes that all insurers, including Medicare, must provide adequate reimbursement to providers of mammography services, making sure that reimbursement rates increase to keep pace with costs attendant to added requirements. Without proper levels of reimbursement, the specter of unfunded mandates could accelerate the deterioration of these potentially life-saving services, and result in diminished quality of life and quality of care for breast cancer patients and others facing a diagnosis of breast cancer.

As to what can be done in MQSA, the Komen Foundation urges adoption of the approach proposed in previous reauthorization bills for additional studies of access-related issues, specifically including a review of the reported link between facility closures and inadequate reimbursement rates.

#### **Reauthorization Period**

In view of the difficult questions that must be addressed to ensure Congress strikes the correct balance, the Komen Foundation strongly supports a *two-year* reauthorization timeframe. With the many unanswered questions about the existing quality assurance structure, whatever system Congress adopts will need to be refined in the coming years. A two-year cycle allows for the implementation of a system, yet provides the flexibility necessary to evaluate concerns in a timely manner. Waiting more than two years to evaluate the system may lead to unnecessary access problems if radiologists, feeling overwhelmed by new requirements that are locked in for five years, decide to stop providing mammography services and new physicians choose to avoid entering the field entirely.

As a patient advocate, I appreciate the real improvements in mammography and marvel at the progress in breast cancer treatment over the years. In addition to the technological advancements, technicians and radiologists are better trained and more knowledgeable about breast cancer than ever before. These successes are based in large part on the requirements of MQSA. However, as a society we cannot afford to rest on these accomplishments. We must strive to do better. This includes enhancing MQSA to ensure high quality image interpretation so that women who need mammography services receive the best available care.

Thanks to innovative research, what we now know about breast cancer is at an all time high, and the push for research and development of new technologies and therapies continues. We have made significant strides in the war against breast cancer. Furthermore, we believe we are on the edge of genuine breakthroughs that could save thousands of additional lives. But, until researchers find a cure for breast cancer and, better yet, a way to prevent this disease, we must not lose sight of the importance of mammography screening for detecting breast cancer early. Indeed, we must maintain focus on the men and women of today who rely on current technology to help them face this devastating disease. Reauthorizing MQSA with new

provisions that result in better image interpretation will help ensure the delivery of high quality breast health and breast cancer care in the U.S. Please be assured that while the Komen Foundation will continue in our commitment to fund groundbreaking research for future generations, we will also remain committed to ensuring that all women and men who currently face a diagnosis of breast cancer have access to the best care currently available.

I appreciate the opportunity to present this testimony and thank you very much.

## REFERENCES

<sup>1</sup>General Accounting Office, “Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes,” 1 (October 1997).

<sup>2</sup>*Id.* at 7.

<sup>3</sup>*See, e.g.*, R.E. Bird, T.W. Wallace, B.C. Yankaskas, “Analysis of Cancers Missed at Screening Mammography” 184 *Radiology* 613–17 (1992); C.L. Robertson, “A Private Breast Imaging Practice: Medical Audit of 25,788 Screening and 1,077 Diagnostic Examinations” 187 *Radiology* 75–79 (1993); D.G. Sienko, R.A. Hahn, E.M. Mills, et al., “Mammography Use and Outcomes in a Community” 71 *Cancer* 1801–09 (1993); K. Kerlikowske, D. Grady, J. Barclay, et al., “Variability and Accuracy in Mammographic Interpretation Using the American College of Radiology Breast Imaging Reporting and Data System” 90 *J. Nat’l. Cancer Inst.* 1801–09 (1998).

<sup>4</sup>Michael Moss, “Spotting Breast Cancer: Doctors are Weak Link” *New York Times* (June 27, 2002).

<sup>5</sup>21 C.F.R. § 900.12.

<sup>6</sup>*Id.*

<sup>7</sup>21 C.F.R. § 900.12.

<sup>8</sup>GAO, *supra*, at 2.

<sup>9</sup>*Institute of Medicine Report—Mammography and Beyond, Developing Technologies for the Early Detection of Breast Cancer*

<sup>10</sup>General Accounting Office, “Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes,” 1 (October 1997).

<sup>11</sup>*Id.* at 7.

<sup>12</sup>*See, e.g.*, R.E. Bird, T.W. Wallace, B.C. Yankaskas, “Analysis of Cancers Missed at Screening Mammography” 184 *Radiology* 613–17 (1992); C.L. Robertson, “A Private Breast Imaging Practice: Medical Audit of 25,788 Screening and 1,077 Diagnostic Examinations” 187 *Radiology* 75–79 (1993); D.G. Sienko, R.A. Hahn, E.M. Mills, et al., “Mammography Use and Outcomes in a Community” 71 *Cancer* 1801–09 (1993); K. Kerlikowske, D. Grady, J. Barclay, et al., “Variability and Accuracy in Mammographic Interpretation Using the American College of Radiology Breast Imaging Reporting and Data System” 90 *J. Nat’l. Cancer Inst.* 1801–09 (1998).

<sup>13</sup>Michael Moss, “Spotting Breast Cancer: Doctors are Weak Link” *New York Times* (June 27, 2002).

<sup>14</sup>21 C.F.R. § 900.12.

<sup>15</sup>*Id.*

<sup>16</sup>21 C.F.R. § 900.12.

<sup>17</sup>GAO, *supra*, at 2.

<sup>18</sup>*Institute of Medicine Report—Mammography and Beyond, Developing Technologies for the Early Detection of Breast Cancer*<sup>18</sup>

<sup>18</sup>General Accounting Office, “Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes,” 1 (October 1997).

<sup>18</sup>*Id.* at 7.

<sup>18</sup>*See, e.g.*, R.E. Bird, T.W. Wallace, B.C. Yankaskas, “Analysis of Cancers Missed at Screening Mammography” 184 *Radiology* 613–17 (1992); C.L. Robertson, “A Private Breast Imaging Practice: Medical Audit of 25,788 Screening and 1,077 Diagnostic Examinations” 187 *Radiology* 75–79 (1993); D.G. Sienko, R.A. Hahn, E.M. Mills, et al., “Mammography Use and Outcomes in a Community” 71 *Cancer* 1809–09 (1993); K. Kerlikowske, D. Grady, J. Barclay, et al., “Variability and Accuracy in Mammographic Interpretation Using the American College of Radiology Breast Imaging Reporting and Data Systems” 90 *J. Cancer Inst.* 1801–09 (1998).

<sup>18</sup>21 C.F.R. § 900.12.

<sup>18</sup>*Id.*

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<sup>18</sup>GAO, *supra*, at 2.

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<sup>18</sup>See, e.g., R.E. Bird, T.W. Wallace, B.C. Yankaskas, "Analysis of Cancers Missed at Screening Mammography" 184 *Radiology* 613-17 (1992); C.L. Robertson, "A Private Breast Imaging Practice: Medical Audit of 25,788 Screening and 1,077 Diagnostic Examinations" 187 *Radiology* 75-79 (1993); D.G. Sienko, R.A. Hahn, E.M. Mills, et al., "Mammography Use and Outcomes in a Community" 71 *Cancer* 1809-09 (1993); K. Kerlikowske, D. Grady, J. Barclay, et al., "Variability and Accuracy in Mammographic Interpretation Using the American College of Radiology Breast Imaging Reporting and Data Systems" 90 *J. Cancer Inst.* 1801-09 (1998).

<sup>13</sup>Michael Moss, "Spotting Breast Cancer: Doctors are Weak Link" *New York Times* (June 27, 2002).

<sup>14</sup>21 C.F.R. § 900.12.

<sup>15</sup>*Id.*

<sup>16</sup>21 C.F.R. § 900.12.

<sup>17</sup>GAO, *supra*, at 2.

<sup>18</sup>*Institute of Medicine Report—Mammography and Beyond, Developing Technologies for the Early Detection of Breast Cancer*

PREPARED STATEMENT OF LEONARD BERLIN, M.D.

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 percent 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 percent to 20 percent 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 percent of lung cancers, and 70 percent 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 percent 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:

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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

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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 to 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

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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

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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.

[Whereupon, at 11:13 a.m., the committee was adjourned.]