

The Mammography Quality Standards Act

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Witness:

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Testimony:

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. 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. 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. The New York Times reported last summer that the "biggest problem of all" in the mammography industry is the skill of physicians interpreting films.

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. 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. 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. 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.

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:

- v The number and types of all mammograms performed per year;
- v The number of screening patients recalled for diagnostic studies;
- v The number of radiologists interpreting screening mammograms;
- v The number of screening mammograms interpreted by each radiologist;
- v The percentage of cases reported annually in each of the five reporting categories (e.g.,

BI-RADS) used by each facility;

v The number biopsies performed;

v Follow-up of all findings in which any further image or other study is recommended; and

v 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. 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 ground-breaking 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.

1. General Accounting Office, "Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes," 1 (October 1997).

2. *Id.* at 7.

3. 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).

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

5. 21 C.F.R. § 900.12.

6. *Id.*

7. 21 C.F.R. § 900.12.

8. GAO, *supra*, at 2.

9. Institute of Medicine Report – Mammography and Beyond, Developing Technologies for the Early Detection of Breast Cancer