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HEALTH QUALITY AND ETHICS*

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May 3, 2012

Council on Ethical and Judicial Affairs
American Medical Association
515 N. State Street
Chicago, IL 60654
ceja@ama-assn.org

To the Council on Ethical and Judicial Affairs:

We are filing this complaint for violation of medical ethics with the American Medical Association (AMA) on behalf of the Institute for Health Quality and Ethics, a national non-profit organization dedicated to ensuring that our system of healthcare is based on high quality, evidence-based medical practices without regard to gender, race, age, socioeconomic status, or religion.

This complaint is filed against the American College of Radiology (ACR), a professional medical organization which is a member of the American Medical Association and listed on the AMA website as a National Medical Specialty Member of the AMA¹.

The ACR has repeatedly and systematically violated AMA Ethical Guidelines by supporting the practice of withholding material medical information from women who obtain screening mammograms for the early detection of breast cancer, thereby denying millions of women the right to make informed decisions about their own medical care. We estimate that this practice also results in the preventable deaths of 10,000 women each year.

We have filed this complaint only after patient advocates have spent years attempting to work with the ACR to ensure that they comply with basic ethical guidelines. This action is necessary due to the blatant disregard for established ethical behavior on the part of the ACR leadership as evidenced in its policies, its practices, its lobbying efforts, and its actions towards patients.

¹ <http://www.ama-assn.org/ama/pub/about-ama/our-people/the-federation-medicine/national-medical-specialty-society-websites.page> Accessed April 26, 2012

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This issue should be a matter of grave concern not only to the AMA, but to other professional medical organizations that are responsible for conducting and evaluating research, developing practice guidelines, and for integrating new evidence-based medical practices into those guidelines when appropriate. The AMA and its members have expressed growing concern regarding the intrusion of lawmakers and politics into the patient-physician relationship²³. In some instances, this concern may very well be justified, and in those instances, we support constructive public debate and discussion.

However, in this matter, we are addressing the systemic practice of withholding material medical information from mammogram results, a practice which has begun to seriously erode the trust that the public places in its physicians. It has forced patient advocates to fight professional medical organizations like the ACR and the American College of Gynecology (ACOG) in order to ensure that women have access to material medical information that these organizations aggressively lobby to withhold. Even more troubling, however, is the growing suspicion among patients that these organizations are not advocating for this violation of medical ethics due to a misplaced sense of altruism, but due to their reliance on the \$7 Billion annual revenue stream attributed to mammograms.

Because the principle of informed consent is such an integral underpinning of our medical system, the AMA's ethical guidelines extend beyond the responsibilities of physicians to include the responsibilities of patients. *"Patients have the responsibility to communicate openly, to participate in decisions about the diagnostic and treatment recommendations, and to comply with the agreed-upon treatment program⁴"* However, because the patient's right (and responsibility) to make medical decisions according to the principle of informed consent is so central to medical ethics, the willful actions on the part of the ACR consequently violate many ethical guidelines.

"Ethical values and legal principles are usually closely related, but ethical obligations typically exceed legal duties.⁵" (Opinion 1.02 The Relation of Law and Ethics) Our assessment has led us to conclude that these violations, conducted in a deliberate, willful manner, with disregard to well-

² Wah, Robert, *Connecting personally with women's health care issues*, AMA Leader Commentary. <http://www.ama-assn.org/amednews/2012/04/16/edca0416.htm> Accessed April 30, 2012.

³ <http://www.ncbi.nlm.nih.gov/pubmed/22015887/> Accessed April 30, 2012

⁴ Opinion 10.02 - Patient Responsibilities. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1002.page?> Accessed April 27, 2012

⁵ Opinion 1.02 The Relation of Law and Ethics, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion102.page?> Accessed April 27, 2012.

known ethical guidelines and in contravention of long-standing, well-documented evidence, meet the criteria of both ethical and legal transgressions. This document, however, is narrowly focused on the ethical violations of the ACR, specifically related to the withholding of material medical information and the denial of informed consent.

Synopsis of Underlying Medical Issue

Breast tissue density refers to the amount of fatty tissue in the breast vs. the amount of “fibroglandular” tissue. The mammogram, which is simply an x-ray of the breast, is reasonably suited to detect most, but not all, cancers in fatty breasts. Because the fatty tissue appears dark, and cancers appear white, it is relatively easy to detect cancers. However, fibroglandular tissue appears white on an x-ray, which means that it can easily hide a cancer. The more dense fibroglandular tissue, the less effective a mammogram is at distinguishing a cancer from the surrounding tissue. While mammograms may be 98% effective for women with fatty tissue, they are only half as effective for women with dense tissue, predictably missing about half of cancers.

Density occurs along a continuum, and for the purposes of communicating density, the ACR has utilized its BI-RADS™ Density scale without controversy for over two decades. The BI-RADS Density scale categorizes density into one of four quadrants. Tissue with the least density, “predominantly fatty tissue” is categorized as a “1,” and the breast tissue with the highest density is categorized as a “4.”

Studies of density on both mammographic effectiveness and breast cancer risk categorize density as “high” using BI-RADS density 3 and 4 and “not high” for categories 1 and 2. High density has been found to affect overall sensitivity of the mammogram between 75%⁶ and 40%⁷, with even further degradation of sensitivity at higher density levels, although a small cancer can be obscured by even a small amount of fibroglandular tissue.

Breast tissue density is very common; 55% of women age 40 to 50, and 33% of women over the age of 50 have high breast tissue density⁸. The overall percentage of women with high breast

⁶ Carney PA, Miglioretti DL, Yankaskas BC, et al. Individual and combined effects of age, breast density, and hormone replacement therapy on the accuracy of screening. *Ann Int Med*, 2003; 138:168-75.

⁷ Pisano ED, Hendrick HE, Yaffe MJ, et al. Diagnostic accuracy of digital versus film mammography: exploratory analysis of selected population subgroups in DMIST. *Radiology* 2008; 246(2):376-83.

⁸ Stomper PC, D’Souza, DJ, DiNitto PA, Arredondo MA. Analysis of parenchymal density on mammograms in 1353 women 25-79 years old. *AJR Am J Roentgenol*. 1996;167(5):1261-1265.

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tissue density in a general screening population was found to be in excess of 40%. Density has also been well-documented to be one of the highest risk factors associated with breast cancer.

Given the elevated risk associated with high density, as well as **the high percentage of women for whom mammograms are not effective, makes this an important public health issue.** The ACR plays several distinct and important roles within the breast cancer screening industry. First, members of the ACR sit on the FDA advisory board for the governmental organization which implements and enforces the provisions of the Mammogram Quality Standards Act (MQSA) of 1992.

As the (virtually) monopoly accreditor of imaging facilities nationwide, the ACR also earns significant revenue streams ensuring compliance with the MQSA. The ACR uses both public and private funding to conduct research and clinical trials, and as the professional medical organization of radiologists, it develops practice guidelines and drafts the sample patient notification letter mandated under the MQSA. This is a closed system which allows the ACR to exert tremendous influence over the breast screening industry. Because it is one of the most highly funded PACs in medicine, the ACR also spends considerable sums lobbying Congress and state legislators regarding imaging-related and other legislation.

The current patient notification letter drafted by the ACR and provided to women when no cancer is detected states, **“We are pleased to inform you that the results of your recent mammography examination are normal/benign.”⁹ This letter is provided even to women with dense breast tissue, for whom a mammogram is only half as effective.**

Women understand that a screening test will not detect all cancers. However, they do expect that their results are provided with a reasonable degree of certainty. While a mammogram is 98% accurate for those women with fatty tissue, it is only an average of 27% (film) and 59% (digital) effective for women with dense tissue, missing about half of cancers in these women. There are other approved technologies that are readily available and can detect these missed cancers when used as an adjunct to mammography for women who choose to be screened for cancer.

⁹ American College of Radiology, downloaded from http://www.acr.org/accreditation/mammography/mammo_sample_letters.aspx. 10/29/11.

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Providing a “normal” mammogram result to a woman with dense breast tissue without informing her that 1) she has dense breast tissue, that 2) dense tissue significantly reduces mammogram effectiveness, and that 3) there are other screening options available will can raise the level of certainty to above 95%, is providing false and misleading results to these women. It is also a very serious violation of medical ethics.

Because density information is not included in the patient notification letter, approximately 15 million women who have dense breast tissue receive false and misleading information in their mammogram reports. These women are significantly more likely to receive a normal report when a cancer is present (a “false negative” finding) than women with tissue that is predominantly fatty. The Institute for Health Quality and Ethics has estimated that between 40,000 and 50,000 women each year receive false negative mammogram reports, meaning that their cancer remains undetected while it is small and most treatable. The vast majority of these women are women with dense breast tissue. Because of the delay in diagnosis, approximately 10,000 of these women will be dead within 10 years.

Violation of Opinion 8.082: Withholding Information from Patients

“Withholding medical information from patients without their knowledge or consent is ethically unacceptable.”

As referenced in the introduction on breast cancer screening, breast tissue density is material medical information that is routinely withheld from women:

- 40% of women have “dense breast tissue” which is characterized as a 3 or 4 on the BI-RADS Density scale.
- For these women, mammograms only detect an average of 27% of cancers (film mammograms) and 59% of cancers (digital mammograms).
- Despite this low level of certainty, if no cancer is detected, these women typically receive a letter stating that their results are “normal.”

There is no justifiable reason for withholding this information from patients. Patients who have been diagnosed with late stage cancer despite many years of normal mammograms have reported cancers that were missed by mammography for multiple years. In addition to the fact that density reduces mammogram effectiveness, density is also one of the highest known risk factors for breast cancer. As such, breast tissue density level is material medical information that, in and of itself, should be communicated to patients.

The ACR, however, has engaged in the practice of deliberately and systemically withholding this material information from patients. This organization has further compounded their ethical violations by making false claims about the increased risks associated with breast density, and repeatedly asserting in both public and private forums that the linkage between breast density and increased risk for breast cancer is tenuous or controversial.

Violation of Opinion 8.08 – Denial of Informed Consent

Opinion 8.082 states in part that:

“The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician’s obligation is to present the medical facts accurately to the patient...”

“Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.”¹⁰

The AMA provides further context to informed consent on its website, stating:

“Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- ***The patient’s diagnosis, if known;***
- ***The nature and purpose of a proposed treatment or procedure;***
- ***The risks and benefits of a proposed treatment or procedure;***
- ***Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);***

¹⁰ AMA Code of Medical Ethics <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.page>, Accessed April 30, 2012

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- **The risks and benefits of the alternative treatment or procedure; and**
- **The risks and benefits of not receiving or undergoing a treatment or procedure.**

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states.¹¹

The MQSA requires that the imaging center or radiologist provide each patient with a notification letter in terms easily understood by a layperson. The ACR has routinely abdicated this ethical responsibility to patients by withholding material medical information regarding density from patients in the patient notification letter. Because women are not informed of their breast density, they are unaware of its risk implications, and of the implications of density on mammogram effectiveness. Patients are therefore unable to discuss how effective (or ineffective) mammogram screening is for them, and they are further denied the opportunity to make an informed decision regarding whether or not to pursue additional screening.

It has only been in recent years, as more and more patients have been diagnosed with late stage cancer after years of “normal” mammograms, that patient advocates have begun to demand changes in how mammograms results are reported to women, and to demand that all material medical information be included.

Despite years of requests by patient advocates, the ACR refused to adequately inform patients, who have been forced to enact legislation in order to ensure that women had access to material information and could make their own medical decisions regarding breast cancer screening. The most recent justifications that the ACR has utilized for withholding material medical information from patients was presented as written testimony at the FDA hearing on November 4th 2011. The Institute responded to the inaccuracies made in that testimony, and made it available to the public on www.inhqe.com.

¹¹ AMA Website: <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.page> Accessed April 30, 2012.

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A copy of this paper, which provides detail on the specific written statements which constitute ethical violations on the part of the ACR, is included with this complaint to the AMA. The ACR has lobbied extensively to ***prevent the communication*** of this material medical information. In order to defeat legislation, the ACR has hired lobbyists to convince legislators to reject these state efforts on the part of patient advocates, and they have worked with other groups, such as ACOG and CMA in California and ACOG in New York, to defeat the legislation.

The justification for withholding this information and not informing women of alternatives to mammograms is detailed in the attached document. Other statements have included the following:

In 2011 emails to Florida Senator Jeremy Ring via lobbyists:

“There is potential benefit from any test. Why not offer whole body screening?”

“Many radiologists who read breast imaging studies are not breast specialists and would balk at the idea of being responsible for whole breast ultrasounds.”

“If the center can't afford the [whole breast ultrasound] equipment, it takes one technologist about 45 minutes to do the test.”

“Breast density appraisal is subjective.”

“The patient can retrieve it [the radiologist's report which includes density information] herself from the medical records department if she had it done at a center associated with a hospital.”

“There is probably a slight increase in risk of breast cancer in those with dense tissue.”

“Yes, it is easier to miss a cancer in those with dense tissue. A bigger problem is just getting women to have their yearly mammogram.”

“You can't offer a test only because some women might be able to pay out of pocket. We do not know who can pay and who cannot, and it is ill advised and unethical to operate otherwise.”

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The ACR justification for opposing legislation in Florida takes a stance which flouts the AMA ethical guidelines requiring physicians to provide information on medical interventions, ***“regardless of the cost of those treatments or the extent to which the treatment options are covered by health insurance.”***

“The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor...”

Because material medical information regarding 1) the patient’s breast density, which is determined by the mammogram, and 2) dense tissue’s well-documented impact of reducing mammogram effectiveness is withheld, patients are prevented from engaging in a meaningful discussion with their physicians regarding their level of comfort with the reliability of the results and their desire to either seek or refrain from further screening.

With many of its justifications, the ACR purports to be making decisions that will benefit the most women in an efficient way, introducing cost and resource arguments. Not only do these behind-the-scenes allocation of resources amount to illegal and unauthorized healthcare rationing, but the ACR’s assessment of the risks and benefits appear to be quite biased towards ubiquitous mammogram screening, when a more individualized approach to screening for breast cancer may be warranted by the evidence. The Ethical Guidelines address this issue in Opinion 8.082:

“The treating physician must remain a patient advocate and therefore should not make allocation decisions. Patients denied access to resources have the right to be informed of the reasoning behind the decision. The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession.”

The ACR’s public statements on breast cancer screening have also been contradictory even with its own recommendations. In 2010, the ACR and its subsidiary organization the Society for Breast Imaging (SBI) released the following statement on Breast Cancer Screening:

“It has been demonstrated that the sensitivity of mammography is lower in women with dense breasts, and regardless of whether women with dense breasts are at increased risk or not, it has been shown that the use of supplemental ultrasound screening will result in the detection of otherwise occult cancers.¹²”

This followed an early release of the ACRIN 6666 trial in 2008, which made the same claim. The evidence supporting adjuvant screening for women with dense tissue has been available for years, but has been withheld from patients. The best breast imaging centers, such as the Mayo Clinic and Montclair Breast Center, routinely offer mammogram screening, Molecular Breast Imaging, whole breast ultrasound, and MRI as options for patients depending upon their individual needs and preferences. Two independent studies following the enactment of legislation in Connecticut demonstrated that ultrasound doubled invasive cancer detection in women with dense breast tissue and negative mammogram results. While 3.2 cancers were discovered per 1000 women with dense breast tissue, an additional 3.2 invasive cancers were discovered in women with **negative mammograms** using adjuvant ultrasound screening.

In addition to what we believe are the consistently disingenuous and misleading statements made to the public, members of the ACR who serve on the FDA NMQAAB failed to either prevent or correct the written testimony provided at the hearing, which stated in part that:

*“The ACR recognizes that breast density has an impact on mammographic screening. The ACR’s BI-RADS lexicon describes four categories of breast parenchymal density and instructs radiologists to include this density information in the medical report. It is well known that greater breast density results in lower sensitivity for mammography. By including this information in the medical report, the referring health care provider is given a general idea of the likelihood that cancer will be detected or missed based on the parenchymal pattern. **The ACR supports the FDA mandate that information on breast parenchymal density be included in the mammography report.** However, it is less clear how the typical patient would interpret or understand the same information if included in a lay summary.”*

While the ACR claimed to support **“the FDA mandate that information on breast parenchymal density be included in the mammography report,”** there is no FDA mandate that density be

¹² Lee et al., *Statement on Breast Cancer Screening*, *J Am Coll. Radiol*, 2010;7:18-27

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included in the mammogram report. The ACR provides this information to physicians because it is material medical information which directly and significantly impacts the reliability of the results. Four members of the ACR leadership attended the National Mammography Quality Assurance Advisory Committee meetings on November 4, 2011, in their official capacities, and heard testimony by Charles Finder, MD, FDA Associate Director, Division of Mammography Quality and Radiation Programs, stating that ***“At the present time, the MQSA regulations do not require that breast density be reported in either the mammography report sent to the referring physician or the lay summary sent to the patient.”***

It is beyond the time to have a clear and open discussion of how the field of radiology can integrate evidence-based medicine in breast imaging for the benefit of its patients. The clinical evidence to change current practices exists and has been well-established across years of peer-reviewed studies as well as in the ACR’s own recommendations as cited above.

Continuing to withhold information from women for reasons of "anxiety," concerns over third party payor reimbursement, a patient’s ability to pay, a perceived right on the part of the ACR to make broad policy decisions without public discussion, or any other non-clinical considerations, does not do credit to the dedicated members of the ACR who have made the early detection of breast cancer their life's work and passion.

Sincerely,

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