AMA Code of Medical Ethics

9.6.8 Direct-to-Consumer Diagnostic Imaging Tests

Diagnostic imaging tests are sometimes marketed directly to consumers before they have been scientifically validated. This can help consumers prevent disease and promote health, but may also expose patients to risk without benefit, create conflicts of interests for physicians, and be abused for profits.

Individually, physicians who offer diagnostic imaging services that have not been scientifically validated and for which a patient has not been referred by another physician have an ethical obligation to:

- (a) Perform a requested diagnostic imaging test only when, in the physician's judgment, the possible benefits of the service outweigh its risks.
- (b) Recognizing that in agreeing to perform diagnostic imaging on request, the physician:
 - (i) establishes a patient-physician relationship, with all the ethical and professional obligations such relationship entails;
 - (ii) assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Physicians may choose to refer the patient for post-test counseling to an appropriate physician who accepts the patient.
- (c) Obtain the patient's informed consent. In addition to the usual elements of informed consent, the physician should disclose:
 - (i) that the diagnostic imaging test has not been validated scientifically;
 - (ii) the inaccuracies inherent in the proposed test;
 - (iii) the possibility of inconclusive results;
 - (iv) the likelihood of false positive and false negative results;
 - (v) circumstances that may require further assessments and additional cost.
- (d) Ensure that the patient's interests are primary and place patient welfare above physician interests when the physician has a financial interest in the imaging facility.
- (e) Ensure that any advertisements for the services are truthful and not misleading or deceptive, in keeping with ethics guidance and applicable law.

Collectively, physicians should:

- (f) Advocate for the conduct of appropriate trials aimed at determining the predictive power of diagnostic imaging tests and their sensitivity and specificity for target populations.
- (g) Develop suitable guidelines for specific diagnostic imaging tests when adequate scientific data become available.