

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3 - A-05

Subject: Direct-to-Consumer Diagnostic Imaging Tests

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Referred to: Reference Committee on Amendments to Constitution and Bylaws
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1 Resolution 508 (I-01), “Inappropriate Medical Screening Tests” and Resolution 509 (A-02),
2 “Commercialized Medical Screening” raised concerns regarding the emergence into the market
3 place of “commercial medical screening,” wherein tests are advertised directly to consumers. Thus,
4 patients without referral from a physician can pay to be tested for a broad range of conditions.
5 Together, these resolutions called for a close examination of the use of such tests, their
6 effectiveness, and their marketing.

7
8 At the 2003 Annual Meeting, the Council on Scientific Affairs (CSA) presented its report on
9 scientific aspects of three specific diagnostic imaging tests.** The CSA Report was built upon the
10 premise that preventive services should be supported by evidence that demonstrates improved
11 health outcomes or quality of life, as well as cost-effectiveness. It briefly discussed issues of
12 sensitivity, specificity, and predictive value regarding screening tests, and emphasized that to be
13 considered effective, screening tests should be capable of detecting a high proportion of disease in
14 preclinical phase, among other criteria. Overall, the report concluded that evidence was currently
15 lacking to support these three specific tests without referral by a physician. Finally, in its
16 recommendations, the CSA noted “That considering the summary information in this report, the
17 Council on Ethical and Judicial Affairs [should] further consider the ethical ramifications of
18 commercialized medical screening.”

19
20 The proliferation of direct-to-consumer diagnostic imaging tests, including full-body scans, raises
21 not only scientific and policy questions regarding effectiveness and overall costs but also ethical
22 questions regarding the limited clinical encounter that takes place between patient and physician.
23 This report, therefore, focuses on the role of the physician involved in delivering direct-to-
24 consumer diagnostic imaging tests and also considers issues related to their commercialization.
25 This report does not address other diagnostic tests that may be available to patients without
26 referrals, such as pregnancy tests, HIV tests, genetic screening, and other laboratory tests, nor
27 scientifically validated screening imaging services such as mammography.

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** Electron beam computed tomography (CT) for determining coronary artery calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer screening.

1 MEDICAL ENCOUNTERS TO PROVIDE PREVENTIVE SERVICES

2
3 All encounters between patients and physicians need not stem from symptoms of a possible
4 medical illness or be related to therapeutic interventions. Indeed, there has been considerable
5 emphasis on preventive care, as physicians can play an important role in assisting patients to
6 maintain good health. However, there also has been substantial debate in recent years regarding
7 various preventive services and their clinical validity, particularly in relation to expanding use of
8 imaging technology. In the face of uncertainty, large-scale studies have been undertaken to better
9 assess the benefits and harms of various interventions. When findings from such research have
10 failed to support common practices, there has been much confusion among the public. As much as
11 possible, medical practice should be based on evidence; similarly, preventive services should be
12 rigorously evaluated before they are widely adopted.¹

13
14 *Screening tests and informed consent*

15
16 Whenever offering tests, whether for diagnostic workup or for screening purposes, physicians
17 generally must obtain informed consent. Moreover, the ethical and legal principles of a patient's
18 right to self-determination and physicians' concurrent obligation to respect patients' autonomy
19 generally require that physicians and patients engage in a shared decision-making process. This
20 entails physicians sharing with patients information that addresses the nature of the test, the reasons
21 for it, and the benefits that may result (i.e. diagnostic information). In addition, any physical risks
22 inherent in an imaging test,² as well as other risks such as ambiguous results that necessitate further
23 testing, and alternatives to the test (with their respective advantages and disadvantages) must be
24 communicated. By presenting such information in addition to their own recommendations,
25 physicians generally seek the patient's understanding and authorization to proceed. This exchange
26 of information is intended to help patients make choices that are aligned with their own values and
27 preferences. When the goal of mutual understanding and agreement has been reached, the ethical
28 and legal requirements for informed consent have been fulfilled.

29
30- When tests are performed in asymptomatic patients, it is imperative that physicians explain their
31 nature and possible results. Overall, physicians must be able to explain to patients that some tests
32 are more or less accurate and that results may not be definitive but may merely reveal increased
33 probabilities that a certain condition may develop. When presenting risks of testing, physicians
34 must discuss the possibility of false negatives: if this is not mentioned, the patient may leave with a
35 (false) sense of well-being and later ignore symptoms of ill health. The possibility of false
36 positives – a frequent outcome of CT screening³ – may lead to additional tests, costs, and anxiety.
37 Even true negative results must be explained carefully, since a patient may otherwise have the
38 impression that unhealthy behavior can be continued – for example, continuing smoking because a
39 lung scan was negative. On a more positive note, there may be some psychological benefit if a test
40 accurately detects no disease. Yet, physicians must not capitalize on patients' fears and should not
41 offer testing when, in their judgments, the risks outweigh the potential benefit (e.g. given the
42 patient's age and medical history, the low probability of a positive finding is outweighed by the
43 risks of the procedure). Overall, physicians must communicate in terms that patients can
44 understand the unique aspects of diagnostic and screening tests including their specificity,
45 sensitivity, and predictive value.⁴

46
47- Although the benefits of positive findings may appear straightforward, detection of a condition
48 may have no effect on morbidity or mortality. Therefore, before testing, physicians also should
49 discuss the implications of positive findings, including the likelihood of successful treatment.

1- *Limitations of direct-to-consumer diagnostic imaging services*

2

3 In the context of certain imaging tests, it has been argued that patients should be permitted to
4 access and pay for such tests without a referral because the risk of physical harm caused by the test
5 is minimal. This is a departure from the practice of tests being ordered within an existing patient-
6 physician relationship, in which either the physician ordering the test or the one performing it is
7 available to discuss the test and its results, and to offer treatment options or other follow-up advice
8 as may be necessary. Such discussion and follow-up are necessary even though there may be few
9 or no options for treatment.

10

11 A study of self-referred full-body CT imaging found that follow-up often is lacking. A large
12 proportion of centers offering such tests simply mail results to the patient; a smaller proportion of
13 centers provided results during a consultation between a physician and the patient; and only one
14 center mailed results to the patient's primary care physician after a consultation.⁵

15

16 OFFERING NEW TECHNOLOGIES

17

18 *Assessment of new technologies*

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20 The profession has certain responsibilities in the development of new medical knowledge,
21 including helping to determine the safety, efficacy, and appropriateness of new treatments or
22 products. Some have argued that new technologies should be tested in a controlled setting before
23 broad clinical adoption. Moreover, "foregoing this step may jeopardize future research, place the
24 patient at risk of unexpected health consequences due to invasive follow-up, and lead to
25 unwarranted health care expenditures well beyond the out-of-pocket expense initially incurred."

26

27 The American College of Radiology (ACR), in a statement on CT screening examinations, has
28 concluded that more research is necessary to evaluate whether lung scanning, coronary artery
29 calcium scoring, and virtual colonoscopy are clinically valid or reduce the rate of mortality. The
30 ACR has concluded that there is not sufficient evidence to justify recommending total-body CT
31 screening to patients with no symptoms or family history suggesting disease.⁶

32

33 According to Opinion E-2.19, "Unnecessary Services," physicians should not provide medical
34 services that they know are unnecessary. Medical services should always be based on scientific
35 evidence, sound medical judgment, relevant professional guidelines, and due concern for economic
36 prudence, as well as patient preferences.

37

38 *Considerations of cost*

39

40 At a societal level, one of the most vexing concerns about new high-technology imaging tests is the
41 question of costs. Although at this time direct-to-consumer tests are not reimbursed by health plans
42 and therefore are available only to patients who are able to pay for them out-of-pocket, follow-up
43 tests generally are covered by health plans. From this perspective, some commentators have
44 criticized the practice of some hospitals to offer such screening programs as a means of generating
45 income through the follow-up testing that is required to validate a positive test.⁷

46

47 These commentators also have pointed out that many patients who are asymptomatic but desire
48 high technology imaging tests, rather than self-referring and paying out-of-pocket, are seeking a
49 referral with a false diagnosis by their physicians. The impact of pressure to "game the system"

1 has been analyzed elsewhere,⁸ and the practice has been condemned by CEJA: Opinion E-9.132,
2 “Health Care Fraud and Abuse,” states that “Physicians should make no intentional
3 misrepresentations... to secure non-covered health benefits for their patients.”
4

5 *Commercial motivations*
6

7 The Council previously has noted that ownership interests in health care facilities can lead to
8 conflicts of interest, whereby physicians’ clinical judgment may be unduly influenced by the
9 prospect of financial gains from referrals.⁹ When a physician holds financial interests in a
10 diagnostic imaging facility, every test carried out increases revenues, and every test not done
11 represents a financial loss. In such circumstances, physicians should be guided by the warning not
12 to provide, prescribe, or seek compensation for medical services that are unnecessary.¹⁰
13
14 Commercial pressures are likely to be amplified when physicians who offer diagnostic imaging
15 tests advertise their services directly to the public. Direct-to-consumer advertising can create false
16 expectations and can compromise patient care rather than enhance it, especially when it does not
17 appropriately convey to patients the risks involved in using a product or undergoing a treatment.¹¹
18 Direct-to-consumer advertising regarding diagnostic imaging tests is likely to create the same kind
19 of expectations unless it is truthful, easily comprehensible, and is not intended to mislead or
20 deceive patients.
21

22 Physicians who offer direct-to-consumer diagnostic imaging services must be mindful that patients
23 trust physicians’ medical expertise and rely on their advice to identify appropriate or necessary
24 care. Patients’ desires and ability to pay are not sufficient by themselves to justify the provision of
25 care when risks are present; balancing of benefits and harms is necessary. Physicians can preserve
26 the professional ethos of medicine only by placing patients’ medical interests above their own
27 financial interests.
28

29 **CONCLUSION**
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31 There are many concerns regarding the medical appropriateness of patient-requested diagnostic
32 imaging tests. Ideally, these services should be supported by evidence demonstrating improved
33 health outcomes or quality of life, as well as cost-effectiveness.¹² At this time, scientific data is
34 insufficient to support broad access to these tests; more needs to be known about their predictive
35 value, sensitivity, and specificity. While consumers may believe that these tests can bring
36 psychological and emotional benefits, this also remains to be studied. Necessary data can only be
37 gathered through carefully developed research protocols. Diagnostic imaging services that are
38 performed without referral and outside of research protocols run counter to the medical
39 profession’s intent to develop and use new technologies in a manner that is evidence-based and
40 economically responsible.
41

42 **RECOMMENDATIONS**
43

44 The Council recommends that the following be adopted and the remainder of the report be filed:
45

46 Diagnostic imaging services that have not been scientifically validated for screening purposes
47 are being offered without prior referral by a personal physician. Examples include total body
48 scanning, electron beam computed tomography (CT) for determining coronary artery
49 calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer
50 screening. Physicians and relevant specialty societies should advocate for the conduct of

1 appropriate trials aimed at determining the predictive power of the tests, and their sensitivity
2 and specificity for target abnormalities. When adequate data regarding a screening diagnostic
3 imaging service become available, the profession has a responsibility to develop suitable
4 guidelines, as has been done for mammography.
5

6 The following ethical guidelines apply to physicians providing screening imaging services that
7 have not been scientifically validated, without referral from another physician:
8

- 9 (1) Performance of a diagnostic imaging test at the request of an individual is justifiable only
10 if, in the judgment of the physician, the potential benefits of the service outweigh the
11 risks.
12
- 13 (2) Once a physician agrees to perform the test, a patient-physician relationship is
14 established with all the obligations such a relationship entails. (See Opinion 10.01,
15 “Fundamental Elements of the Patient-Physician Relationship” and Opinion 10.015,
16 “The Patient-Physician Relationship”).
17

18 In the absence of a referring physician who orders the test, the testing physician assumes
19 responsibility for relevant clinical evaluation, as well as pre-test and post-test counseling
20 concerning the test, its results, and indicated follow-up. Post-test counseling may also be
21 accomplished through referral to an appropriate physician who accepts the referral.
22

23 In obtaining the patient’s informed consent (see Opinion 8.08, “Informed Consent”), the
24 testing physician should discuss, in a manner the patient can understand, the usual
25 elements of informed consent as well as (1) the inaccuracies inherent in the proposed
26 test, (2) the possibility of inconclusive results, (3) false positives or false negatives, and
27 (4) circumstances which may require further assessment and additional costs.
28

- 29 (3) Physicians who hold financial interests in imaging facilities must not place those
30 interests above the welfare of their patients, as stated in Opinions 8.03, “Conflicts of
31 Interest: Guidelines” and 8.032, “Conflicts of Interest: Health Facility Ownership by a
32 Physician.” Moreover, physicians who advertise diagnostic imaging services should
33 ensure that advertisements are truthful and not misleading or deceptive. (New
34 HOD/CEJA Policy)

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Fiscal Note: Staff cost estimated at less than \$500.00 to implement.

REFERENCES

- ¹ See U.S. Food and Drug Administration. Center for Devices and Radiological Health. Whole Body Scanning: Using Computed Tomography (CT) at www.fda.gov/cdrh/ct/index.html (last visited April 6, 2004).
- ² Brenner DJ, Elliston CD. Estimated radiation risks potentially associated with full-body CT screening. *Radiology*. 2004; 232:735-738.
- ³ Hillman BJ. CT screening: Who benefits and who pays? *Radiology*. 2003;228:26-28.
- ⁴ See U.S. Food and Drug Administration. Center for Devices and Radiological Health. Whole-Body CT Screening – Should I or Shouldn't I Get One at www.fda.gov/cdrh/ct/screening.html (last visited April 6, 2004).
- ⁵ Iles J, Fan E, Koenig BA, Raffin TA, Kann D, Atlas SW. Self-referred whole body CT imaging: Current implications for health care consumers. *Radiology*. 2003;228:346-351 find reference of study
- ⁶ American College of Radiology statement on CT screening exams. Available at www.acr.org/departments/pub_rel/press_releases/total-bodyCT.htm. Accessed March 27, 2003.
- ⁷ Lee TH, Brennan TA. Direct-to-consumer marketing of high-technology screening tests. *NEJM*. 2002;346:529-531.
- ⁸ Wynia MK, Cummins DS, VanGeest JB, Wilson IB. Should physician manipulate reimbursement rules to benefit patients? *JAMA*. 2000; 284:1382-3.
- ⁹ CEJA Opinion 8.032
- ¹⁰ CEJA Opinion 2.19
- ¹¹ CEJA Opinion 5.015
- ¹² CSA Report 10-A-03 and Policy H-425.997, Preventive Services, AMA Policy Database