

Advertising, Patient Decision Making, and Self-referral for Computed Tomographic and Magnetic Resonance Imaging

Judy Illes, PhD; Dylan Kann, BA; Kim Karetsky, BA; Phillip Letourneau, BA; Thomas A. Raffin, MD; Pamela Schraedley-Desmond, PhD; Barbara A. Koenig, PhD; Scott W. Atlas, MD

Background: Self-referred imaging is one of the latest health care services to be marketed directly to consumers. Most aspects of these services are unregulated, and little is known about the messages in advertising used to attract potential consumers. We conducted a detailed analysis of print advertisements and informational brochures for self-referred imaging with respect to themes, content, accuracy, and emotional valence.

Methods: Forty print advertisements from US newspapers around the country and 20 informational brochures were analyzed by 2 independent raters according to 7 major themes: health care technology; emotion, empowerment, and assurance; incentives; limited supporting evidence; popular appeal; statistics; and images. The Fisher exact test was used to identify significant differences in information content.

Results: Both the advertisements and the brochures emphasized health care and technology information and provided assurances of good health and incentives to self-

refer. These materials also encouraged consumers to seek further information from company resources; virtually none referred to noncompany sources of information or to the risks of having a scan. Images of people commonly portrayed European Americans. We found statistical differences between newspaper advertisements and mailed brochures for references to "prevalence of disease" ($P < .001$), "death" ($P < .003$), and "radiation" ($P < .001$). Statements lacking clear scientific evidence were identified in 38% of the advertisements ($n = 15$) and 25% of the brochures ($n = 5$).

Conclusions: Direct-to-consumer marketing of self-referred imaging services, in both print advertisements and informational brochures, fails to provide prospective consumers with comprehensive balanced information vital to informed autonomous decision making. Professional guidelines and oversight for advertising and promotion of these services are needed.

Arch Intern Med. 2004;164:2415-2419

SELF-REFERRAL TO HEALTH CARE products and services has risen steadily since 1988, when direct-to-consumer (DTC) marketing of pharmaceuticals was authorized by the US Federal Trade Commission (FTC).¹ Since the late 1990s, self-referral for whole-body computed tomography (CT) and magnetic resonance imaging (MRI) for early screening for cancer, cardiovascular disease, and other diseases has followed this trend. Despite calls for clinical trials, better regulation of these services, and even closure of several privately held and academically based centers, the resilience of the industry suggests that our society equates innovative medical technology with better care and supports market-based approaches to a range of services that emphasize consumer choice and responsibility.²⁻⁵

Marketing of imaging services, like marketing of prescription pharmaceuticals, is

accomplished through print and broadcast media and generally capitalizes on a range of consumer emotions and potential motivations, from fear about disease to promises of health.⁶⁻¹⁰ However, empowered and informed consumerism is a goal that is unlikely to be achieved from the telegraphic information available in advertisements. In fact, several studies have reported that when commercial interests are

For editorial comment see page 2406

at stake, print advertisements, printed information for providers and consumers, and self-accessible Web-based materials all fail to provide complete and unbiased quality information.¹¹⁻¹⁴ In 1 series of studies,^{11,12} DTC advertising for genetic screening in print and on the Internet was heavily criticized for the complexity and probabilistic nature of the information being adver-

Author Affiliations: Stanford Center for Biomedical Ethics (Drs Illes, Raffin, and Koenig, Messrs Kann and Letourneau, and Ms Karetsky), Program in Human Biology (Mr Kann), and Departments of Radiology (Drs Illes, Schraedley-Desmond, and Atlas), Medicine (Dr Raffin), and Neurology and Neurological Sciences (Dr Koenig), Stanford University, Stanford, Calif.
Financial Disclosure: None.

tised, exaggerated promises, and the lack of scientific evidence for the clinical value of the product.

To investigate the content and valence of marketing messages for self-referral for CT and MRI screening, we examined print advertisements in US national and local newspapers. We compared these data with information in printed informational brochures mailed on request in which, we predicted, more comprehensive information could reasonably be expected. Drawing on the American Medical Association's statement that "the patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice,"¹⁵ we focused on the nature of the information and whether and how patient autonomy and informed choice were emphasized in these materials.

While DTC marketing of products and services has the potential to lead to greater patient access to diagnostic options and treatments and may be empowering for patients and physicians,¹⁶ it has also led to widespread marketing of health care products. In 1997, the US Food and Drug Administration (FDA) established rules for DTC broadcast advertising of pharmaceutical products and diagnostic services, including requirements for additional sources of information and referral to a health care provider.¹⁷ Nonetheless, concerns over the information contained within DTC advertisements remain, especially among those who see a conflict of interest when advertising is also used as a form of consumer education.¹⁸ Several groups have found that the elderly, while cautious in adopting new procedures, are particularly likely to attach great importance to advertisements, guarantees, store reputation, and information provided by salespeople.^{19,20}

Unlike prescription drugs, screening and diagnostic imaging procedures that may be purchased without physician referral have fallen through regulatory cracks. As such, the first point and primary source of information for consumers may well be the advertisements that appear in the morning newspaper or on the radio during commuter hours. Are consumers urged to seek further information from other sources, either from available internal company resources or primary care physicians, about these services? What messages are conveyed about the promise of radiologic screening? What cautions and warnings about risks and limitations are introduced? With recent growth in both the self-referred imaging industry and other commercial medical procedures, further evaluation of these practices is needed.

METHODS

SOURCE MATERIAL

Advertisements for the self-referred imaging industry were collected systematically from November 2001 to February 2003 through page-by-page searches of 2 San Francisco Bay Area newspapers (*San Francisco Chronicle* and *San Jose Mercury News*) and 2 smaller newspapers local to the Palo Alto, Calif, area (the *Palo Alto Daily* and *The Stanford Daily*) to capture advertising for mobile services and through a search of front and health sections of 4 national newspapers (*The New York Times*, *Seattle Post-Intelligencer*, *The Boston Globe*, *The Washington Post*) on microfilm. Several advertisements were also acquired incidentally through

the cooperation of collaborators who retained them for us. For each newspaper print advertisement for which it was available, we recorded the size, the newspaper in which it appeared, the company advertised, and the date of publication. Using information available publicly on pricing of advertisements in the relevant newspapers, we calculated the cost of small and large advertisements.

Informational brochures were requested from all centers from which we had advertisements, as well as from other centers listed in our database from a prior study.² Brochures were requested by telephone. Radio and Web-stream commercials were also retained, as available, for qualitative comparison with the print materials.

THEMATIC CODING

Drawing on previous studies in the literature on advertising for health care products,¹¹⁻¹³ we constructed thematic categories to describe the content in the print materials. Decision rules for rating were set by 3 of us (J.I., D.K., and P.S.D.) and raters trained. After a pilot phase, the themes were refined to increase overall data capture and ensure distinctiveness of categories. The final thematic categories designated for both the printed newspaper advertisements and mailed brochures with which they were compared were as follows:

1. Health care technology: references to technology, diagnosis, detection, and cure of disease;
2. Emotion, empowerment, and assurance (EE&A): statements directed at encouraging consumer action to benefit from early findings or avert catastrophic health consequences in the event of inaction;
3. Incentives: financing, discounts (eg, price reductions and 2-for-1 offers), specials (eg, seasonal promotions);
4. Limited supporting evidence: statements with marginal scientific data supporting them; statements that do not follow from prior claims or standards; statements investigators considered vague or misleading. Assessments were based on FTC guidelines defining deceptive advertising as likely to "mislead a consumer acting reasonably under the circumstances"²¹ and lacking substantiation when there is no reasonable basis for claims made. Furthermore, "an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support"²¹;
5. Popular appeal: references to popularity of screening examinations, spread of use, testimonials, statements about benefit to the public, and mention of celebrities;
6. Statistics: numerical data relating to health care, disease, or the examination advertised;
7. Images: pictures of people, specialized text, scans, equipment, and logos.

Two raters independently analyzed the print advertisements and mailed brochures for the presence of content satisfying the thematic criteria.

CONTENT ANALYSIS

All advertisement and brochure data for which there was concordance between the 2 raters in the content-rich health care technology and EE&A themes were analyzed in further detail.²² This included specific diseases, details about the imaging technology, other resources for consumer information, and risks and benefits. Images were also analyzed separately for ethnicity of people depicted—patients or providers—and for third parties such as spouses, elders, or children.

VALENCE ANALYSIS

Measures of emotional valence²³ were made on the basis of the content analysis with each advertisement coded for invoking

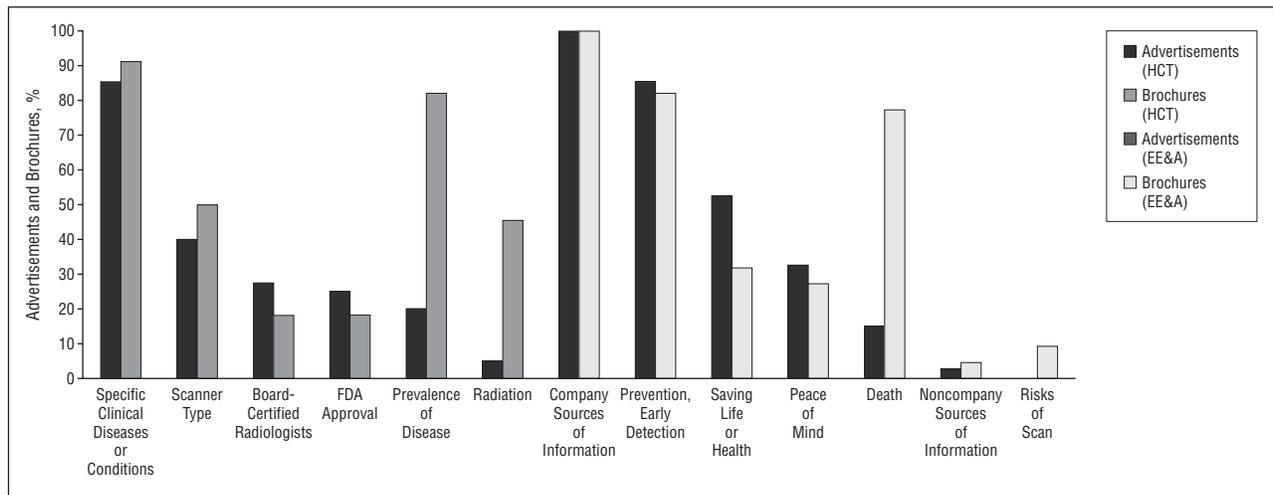


Figure. Advertisement and brochure content analysis for themes of health care technology (HCT) and emotion, empowerment, and assurance (EE&A).

a positive valence (eg, promises of assurance and benefits of the examination), negative valence (eg, threatening advertising through statements, images, or statistics that explicitly challenge consumer chances of good health), or both.

STATISTICAL ANALYSIS

We calculated the percentage of concordance for advertisements and mailed brochures for the thematic categories. This method was used rather than the more traditional κ statistics because several categories had nearly 100% presence or concordance. We used the Fisher exact test to compare content between print advertisements and mailed brochures.

RESULTS

CHARACTERISTICS OF THE SAMPLE

We obtained and analyzed 40 print advertisements from 8 different newspapers. Nine different companies were represented by the advertisements; 2 prominent companies providing services on both the East and West Coasts of the United States accounted for 62% of the ads. Of the advertisements analyzed, 94% were collected from national newspapers. The 3 largest sources of print advertisements were the *San Francisco Chronicle*, *The New York Times*, and *The Washington Post*, representing 73% of the sample (29 of 40). A newspaper source was not available or identifiable for 7 of the collected advertisements.

The range for cost of newspaper print advertising was estimated from the size of the advertisement and the type of newspaper. The smallest 1-time advertisement in the *San Francisco Chronicle* was 2 columns by 3 in at an estimated cost of \$3198. The largest 1-time advertisement in the *San Francisco Chronicle* was 6 columns by 9 in (half page) at an estimated cost of \$28782. In *The New York Times*, the smallest and largest advertisements collected were 2 columns by 7 in (approximated cost, \$13636) and 3 columns by 10 in (approximated cost, \$29220), respectively. The advertisements in the smaller local papers were for mobile scans, of which none were found in the national newspapers.

Mailed brochures were received from 20 of the 29 scanning companies from which they were requested (69%).

Four companies referred the caller to the company's Internet site rather than providing a brochure. The remaining 5 companies did not send the materials promised.

The mailings included cover letters, glossy brochures, testimonials, pricing sheets, and financing information. One mailing included a video that presented a hosted show of personal testimonials, information on heart disease rates, and video clips of CT procedures, hospitals, and ambulances.

THEMATIC ANALYSIS

Rater concordance for thematic analysis of print advertisements was 100% for images; 85% to 95% for health care technology, EE&A, incentives, popular appeal, and statistics; and 70% for supporting evidence. Rater concordance for informational brochure analysis had a similar distribution.

The theme of health care technology was present in 93% of the advertisements ($n = 37$), EE&A in 98% ($n = 39$), incentives in 88% ($n = 35$), and images in 100%. In the brochures, the health care technology theme was present in 100% ($n = 20$), EE&A in 85% ($n = 17$), incentives in 80% ($n = 16$), and images in 100% ($n = 20$) of the advertisements. Statistics were present in 23% of the advertisements ($n = 9$) compared with 80% of brochures ($n = 16$), representing the largest thematic difference between the 2 media. Limited supporting evidence was found in 38% of newspaper advertisements ($n = 15$) from 4 companies and in 25% of the informational brochures ($n = 5$), with an overall concordance of 70%. This result may be a conservative estimate since, individually, unsupported information was identified by 1 rater in a total of 22 (55%) of the advertisements and by the other rater in 16 (40%). Frequency of this same theme in the mailed brochures varied between raters (37%-47%).

CONTENT ANALYSIS

The **Figure** shows the results of the specific content analysis for both newspaper advertisements and the mailings

for the thematic categories of health care technology and EE&A. References to other company sources of information (eg, the Internet), specific diseases, and benefits of the scans were cited most frequently. Using the Fisher exact test, we found statistical differences between newspaper advertisements and mailed brochures for references to “prevalence of disease” ($P < .001$), “death” ($P < .003$), and “radiation” ($P < .001$).

In the analysis of images, we found that all patients depicted in the newspaper advertisements were European Americans. In the brochures, 50% of the patients were European Americans. One newspaper graphic depicted a non-European American as a technologist. Of the advertisements that contained images of patients, 62% ($n = 21$) depicted them with other family members, including parents, spouses, sons, daughters, and grandchildren. In 1 advertisement, a man who presumably did not undergo an examination and did not survive an undetected heart problem is shown as a ghost. His outline walks arm-in-arm with others who appear to be family members.

Valence in the newspaper advertisements was examined specifically. Positive valence content, including messages of happiness and benefits of a scan (eg, “Thank you [company name]. You’ve Given Us Peace of Mind” and “Give the Gift of Health”), was identified in 100% of the advertisement sample. Negative valence, including fear-evoking messages (eg, “30 minutes can save a life—your own,” “You deserve better protection than a mammogram,” and “I had a time bomb in my body . . . You need to know”), was identified in 45% (18/40) of the total advertisements across 7 of the 10 companies. Therefore, 45% ($n = 18$) included messages with both positive and negative valence in a single advertisement.

Of 3 radio advertisements captured, each contained information primarily about disease statistics and financing possibilities. Two Web-based videos focused on personal testimonials attesting to life-saving findings. A third video was nontestimonial and contained a black-and-white walk-through of a graveyard with a narrator commenting on diseases and the necessity of early screening.

COMMENT

We examined print DTC advertisements for self-referred imaging services and compared themes and informational content in these materials with printed informational brochures mailed on request. Overall, we found an emphasis on information about health care technology, assurances of good health, and incentives to self-refer in both groups. Print advertisements and brochures encouraged consumers to seek further information from company resources either by calling a toll-free number or by consulting the company’s Internet site; virtually none referred to secondary sources of information, such as a primary care physician, or mentioned risks of having a scan. Images, primarily of European Americans, appeared both with and without others presumed to be family members and were widely used in both contexts. Many contained messages conveying a false sense of reassurance, and some conveyed fear. These results sug-

gest that DTC marketing of self-referred imaging services through either form of print media does not provide prospective consumers with the information that allows them to be truly autonomous, informed decision makers.

Despite conservative estimates, we also found statements that raters considered scientifically unsupported in a third of the advertisements and a fifth of the brochures. Such specific claims furthermore stretch the definition of proper advertising under FTC²⁴ and FDA¹ guidelines. Unlike the unregulated DTC marketing of CT and MRI services, guidelines for prescription pharmaceuticals require that companies present balanced information, including possible adverse effects, contraindications, and effectiveness. In the context of newspaper advertisements for self-referred screening, for example, information regarding false-positive rates was not found, nor were data on correlations of scan findings with clinically confirmed disease. Only a single mailed brochure addressed clinical follow-up of a severe abnormality. Consumers are not made aware of the possibility or rate of false-positive findings and the procedures needed to follow-up ambiguous test results or of the absence of clinical trial findings that validate the benefit of screening asymptomatic individuals.²⁵

Content validity and phrasing were also troubling in many of the newspaper advertisements. Twenty-five percent of advertisements ($n = 10$) stated that the technology was FDA approved, even though the FDA has explicitly stated otherwise:

Statements by CT imaging facilities that imply FDA “approval,” “clearance,” or “certification” of CT for screening procedures misrepresent the actual situation. FDA has never approved or cleared or certified any CT system specifically for use in screening (ie, of individuals without symptoms), because no manufacturer has ever demonstrated to the FDA that their CT scanner is effective for screening for any disease or condition.²⁶

References to the potential risk of irradiation associated with CT scans were also notably missing from the advertisements. In contrast, we observed that advertisements from these same companies for MRI make explicit reference to the nonradiation modality.

Advertisements coded for negative valence contained statistics about death rates, elicited concerns about the well-being of family members, and highlighted guilt and anxiety associated with inaction. Many critics consider the use of fear unethical in advertising if it contains or generates a sense of threat.²³ By increasing consumer sensitivity, fear appeals can influence behavior by inserting new factors into decision making or changing consumer values.⁸ Several advertisements also conveyed negative evaluations of accepted screening practices, including colonoscopy, mammography, and treadmill and cholesterol tests, compared with the benefit of as yet unevaluated scan-based screening procedures. These strategies may have an adverse impact on patient views about well-substantiated primary care disease screening practices.

Many consumers may see legitimate benefits to undergoing screening procedures beyond those offered by traditional health care plans; these consumers may be able

to pay high out-of-pocket costs ranging from \$400 to \$1200 for these examinations. However, to meet a minimum criterion for informed consumerism, the consumer must be provided with balanced and accurate information. This is especially true as the benefits of screening through imaging continue to be debated in the academic and public sectors.²⁷⁻³⁰

Our present results apply to only a limited sample of written informational materials about the self-referred imaging product and not to Internet sources, consent forms, or verbal communications between providers and consumers either during information gathering or at the time that services are provided. Nonetheless, as others have noted, advertising should provide enough clear information to allow for fair comparison among relevant competing options.^{23,31} Additionally, just as physician consultation is essential in the purchase of prescription drugs, similar physician involvement might provide considerable benefit during procedure selection and follow-up to consumers interested in self-referred imaging services.

Direct-to-consumer marketing of information about new imaging procedures has the potential to enhance consumer choice. Indeed, self-referred diagnostic screening has already expanded to functional brain imaging using single-photon emission CT. This procedure is advertised with an emphasis on school-aged children performing at marginal educational levels and adults concerned about memory loss and has already reached the open marketplace (<http://www.amenclinic.com> and <http://www.brain-spect.com/spectoverview.html>). However, if the information presented to consumers overestimates the value of technologies and does not reasonably disclose risks, then choice is constrained, not enhanced. We conclude that a model of advertising and promotion that favors true autonomy in decision making is needed for self-referred imaging today and for new applications of self-referral to medical interventions in the future. To achieve this goal, guidelines need to be formulated from dialogue among stakeholders in the medical community, professional associations, industry, and patient advocacy. A multidisciplinary proactive approach will receive far greater acceptance in the professional community than legislation created reactively to monitor unregulated medical practices.

As a final note, we learned with interest that on October 31, 2003, the company from which the greatest number of advertisements was analyzed for this study closed its doors. At the time of this writing, legal action by the San Francisco District Attorney and the Medical Board of California is pending against the company for actions related to its breast MRI advertisement campaign.

Accepted for Publication: May 7, 2004.

Correspondence: Judy Illes, PhD, Stanford Center for Biomedical Ethics, 701 Welch Rd, Palo Alto, CA 94304-5748 (illes@stanford.edu).

Funding/Support: This study was supported by The Greenwall Foundation, New York, NY.

Acknowledgment: Many thanks to all who assisted in the collection of advertisements for this study.

REFERENCES

1. Prescription Drug Advertising 21 CFR §202.1.
2. Illes J, Fan E, Koenig BA, Raffin TA, Kann D, Atlas SW. Self-referred whole body imaging: current implications for health care consumers. *Radiology*. 2003; 228:346-351.
3. Feedback Research Services. *Cardiac & Preventive Scanning Markets: Service and System Revenues*. Jacksonville, Ore: Feedback Research Services; 2001.
4. Fuchs V. The growing demand for medical care. *N Engl J Med*. 1968;279:190-195.
5. Koenig BA. The technological imperative in medical practice: the social creation of a routine treatment. In: Lock M, Gordon D, eds. *Biomedicine Examined*. Boston, Mass: Kluwer; 1988:465-496.
6. Wolfe SM. Direct-to-consumer advertising: education or emotion promotion? *N Engl J Med*. 2002;346:524-526.
7. Terzian T. Direct-to-consumer prescription drug advertising. *Am J Law Med Ethics*. 1999;25:149-167.
8. Duke CR, Pickett GM, Carlson L, Groe SJ. A method for evaluating the ethics of fear appeals. *J Public Policy Marketing*. 2001;12:120-129.
9. Arthur D, Wuester P. The ethicality of using fear for social advertising. *Australias Marketing J*. 2003;11:12-27.
10. Everett SE. Lay audience response to prescription drug advertising. *J Advert Res*. 1991;April/May:43-49.
11. Gollust SE, Hull SC, Wilfond BS. Limitations of direct-to-consumer advertising for clinical genetic testing. *JAMA*. 2002;288:1762-1767.
12. Gollust SE, Wilfond BS, Hull SC. Direct-to-consumer sales of genetic services on the internet. *Genet Med*. 2003;5:332-337.
13. Cho MK, Arruda M, Holtzman NA. Educational material about genetic tests: does it provide key information for patients and practitioners? *Am J Med Genet*. 1997; 73:314-320.
14. Risk A, Petersen C. Health information on the internet: quality issues and international initiatives. *JAMA*. 2002;287:2713-2715.
15. American Medical Association. *Current Opinions of the Judicial Council of the AMA*. Chicago, Ill: American Medical Association; 1982:sect 8.07.
16. Rotzoll K, Haefner J. *Advertising in Contemporary Society*. Urbana: University of Illinois Press; 1996.
17. Food and Drug Administration. Guidance for industry: consumer-directed broadcast advertisements. 62 *Federal Register* 43-171 (1991).
18. Mitchell JM, Scott E. New evidence of the prevalence and scope of physician joint ventures. *JAMA*. 1992;268:80-84.
19. Lumpkin JR, Festervand TA. Purchase information source of the elderly. *J Advert Res*. 1987;27:31-43.
20. Strutton DD, Lumpkin JR. Information sources used by elderly health care product adopters. *J Advert Res*. July/August 1992:20-30.
21. Federal Trade Commission. FTC Policy Statement on Deception. 45, Antitrust and Trade Regulatory Report; October 27, 1983. Available at: <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>. Accessed November 5, 2003.
22. Denzin NK, Lincoln YS, eds. *Handbook of Qualitative Research*. Thousand Oaks, Calif: Sage Publications; 1994.
23. Shiv B, Edell JA, Payne JW. Factors affecting the impact of negatively and positively framed ad messages. *J Consum Res*. 1997;24:285-294.
24. Federal Trade Commission Act. Section 12, 15 USC §52.
25. Lee TH, Brennan TA. Direct-to-consumer marketing of high technology screening tests. *N Engl J Med*. 2002;346:529-531.
26. US Food and Drug Administration. Whole body scanning: using computed tomography (CT). Available at: www.fda.gov/cdrh/ct. Accessed November 5, 2003.
27. Brant-Zawadzki M. CT screening: why I do it. *AJR Am J Roentgenol*. 2002;179: 319-326.
28. Modic MT, Obuchowski N. Whole-body CT screening for cancer and coronary disease: does it pass the test? *Cleve Clin J Med*. 2004;71:47-56.
29. Brenner DJ, Elliston CD. Estimated radiation risks potentially associated with full-body CT screening. *Radiology*. 2004;232:735-738.
30. Le Heron JC, Coakley KS. CT screening: whole-body and targeted. *Australas Phys Eng Sci Med*. 2004;27:1-4.
31. Morris LA, Brinberg D, Klimberg R, Rivera C, Millstein LG. Miscomprehension rates for prescription drug advertisements. *Curr Issues Res Advert*. 1986;9: 93-117.