VOLUME 25 · NUMBER 7 · MARCH 1 2007

JOURNAL OF CLINICAL ONCOLOGY

THE ART OF ONCOLOGY:
When the Tumor Is Not the Target

Conflicts of Interest and the Physician-Patient Relationship in the Era of Direct-to-Patient Advertising

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Submitted August 15, 2006; accepted September 11, 2006.

Author's disclosures of potential conflicts of interest are found at the end of this article.

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0732-183X/07/2507-902/$20.00

DOI: 10.1200/JCO.2006.08.7122

CONSIDER SIX CASES

The first patient, who is receiving radiotherapy for the treatment of breast cancer, presents for weekly physician assessment. She asks for a prescription for an agent that promotes RBC production, having seen a magazine advertisement touting its potential for reducing cancer treatment-related fatigue. The patient's hemoglobin level is 14. In a lengthy visit, the physician counsels the patient regarding her fatigue and why it is unlikely to be alleviated by the medication requested.

The second patient is receiving treatment for advanced lung cancer. She has had difficulty sleeping, anorexia, and overwhelming sadness. She asks her physician for a specific antidepressant she saw discussed on a talk show. Unbeknownst to the patient, the episode was orchestrated by the drug's manufacturer. The physician provides the requested prescription as the sole intervention.

The third patient will soon begin chemotherapy and radiation for locally advanced oropharyngeal cancer. The treating physician serves on the speakers' bureau of a company that produces a radioprotectant. Much of the information to which the physician has been exposed about this medication has been provided by industry representatives, and the physician has received payment for his services as a speaker. He provides company-produced pamphlets and what he feels to be impartial counsel to the patient, and the patient elects to have the medication administered.

The fourth patient is a healthy 50-year-old who passes a billboard advertising low-dose spiral computed tomography (CT) scanning to screen for lung cancer. Although she has no family history of cancer and has never smoked, she has had several friends diagnosed with cancer recently and worries that she herself has an occult malignancy. The patient proceeds to purchase a scan out-of-pocket at the advertised imaging center (at which the radiologist profits from the number of scans interpreted), and an abnormality is found. A biopsy is performed (during which a complication occurs) and is negative.

The fifth patient has been diagnosed with a tumor occupying the parasellar region of the brain. He sees an advertisement in a local newspaper for a hospital, touting its possession of a specific radiosurgical treatment unit. The physician he sees at the advertised facility has an ownership interest in the machine and profits from its use. Given the proximity of the tumor to the optic chiasm ($\approx$ 1 mm), there would be a substantially lower risk of visual injury if the patient received multiple small fractionated doses of radiation rather than one large dose, as would ordinarily be administered with this particular radiosurgical unit. The physician decides that the risk of damage to the optic structures is relatively low even with single-fraction radiation, since he would not target part of the tumor that rests beside the chiasm, and so schedules the patient for treatment on his machine without discussing the possibility of treatment elsewhere with a fractionated technique.

The sixth patient, who has recently been diagnosed with prostate cancer, finds a web site promoting MiracleZap, a novel method and sequence of combined brachytherapy and external-beam radiotherapy. The site, which is run by a private medical practice, goes on to say that their practice is the only source for MiracleZap. Physicians in the practice have published excellent results from their single-institution series of patients treated with MiracleZap, and they truly believe they offer the public a unique service. However, the web site does not discuss the potential disadvantages of combining external-beam radiotherapy and prostate brachytherapy, nor does it clarify that combining these approaches is something that many centers are capable of performing, although they may not choose to do so.

INTRODUCTION

These examples demonstrate how advertising increasingly intrudes on the physician-patient relationship in the modern era. Furthermore, they highlight the ways in which increasingly complex relationships between physicians and industry may complicate the traditional ability of physicians to

serve as impartial fiduciary agents to their patients. Existing ethical guidelines[1] and regulations[2] regarding direct-to-consumer (DTC) advertising require further attention and refinement in light of the issues raised by these cases. This article discusses the implications of the rise in DTC marketing of medical therapy and the complications arising when physicians are unable to function as unbiased intermediaries between patients and industry. The article highlights the ethical dilemmas facing patients, physicians, and society, and exposes the inconsistencies in medical arguments, the extraordinary power achieved by industry, and the glaring lack of guidelines for communication in medical practice.

ADVERTISING TO PHYSICIANS AND PATIENTS

Particularly following revisions to US Food and Drug Administration regulations governing DTC advertising in 1997, industry spending on DTC advertising has increased dramatically, reaching approximately $2.5 billion in 2000.[3-7] DTC advertising has had a substantial impact on oncology,[8] with one survey revealing that 94% of oncology nurse practitioners had received medication requests prompted by DTC ads and 40% receive one to five such requests per week.[9]

The primary goal of advertising is to increase utilization, and evidence suggests DTC advertising is effective in doing so.[10-14] One survey of the public found that 30% had initiated conversations with their physicians about a medicine they saw advertised, and, of these, 44% said they actually received a prescription for the drug as the outcome of the conversation.[15] Whether or not advertising yields net benefits, then, depends at least somewhat on whether the product advertised is underutilized, adequately utilized, or overutilized in the absence of advertising.

Proponents of DTC advertising claim that it also provides a public service by fulfilling an educational role.[16,17] Indeed, some evidence suggests that DTC advertising may improve patient education and physician-patient communication,[18,19] especially for patients of low socioeconomic status who may be encouraged to seek care.[20] If advertising informs and empowers patients, it might improve the extent to which health care reflects patients' needs and values.[21] Critics note, however, that DTC advertising may result in misunderstandings, increased costs, and disruption of the physician-patient relationship.[22] Moreover, DTC advertisements[23] (like advertisements to physicians[24]) may skew information to portray products in a positive light.

As in case 1, when the product advertised has clear indications and physicians can easily correct misunderstandings—and have no incentive to do otherwise—advertising seems to have the least potential for harm. Still, even in this least problematic scenario, explaining why a requested medication is inappropriate may increase the length and costs of the encounter or distract from more important discussions. Moreover, advertising may disrupt the trust necessary in the doctor-patient relationship, particularly if the physician does not prescribe the medication requested. The common catch-phrase itself, "Ask your doctor about x," implies that one's doctor may not be trusted to provide necessary information without prompting. Therefore, physicians need to hone their communication skills in order to preserve their rapport with the patient in the face of suspicion and solidify the relationship through an honest exchange.

Case 2 highlights the additional problematic fact that not all promotional activities targeting consumers are designed to be visible. "Stealth" advertising techniques include hiring celebrities to discuss diseases and treatments during the course of interviews, funding medical programming on "The Patient Channel" that plays to a captive audience of inpatients nationwide, and founding what appear to be grassroots advocacy groups for various conditions.[25] This practice is particularly troubling because it disguises both the source and the nature of information offered.

CONFLICTS OF INTEREST

Of more concern are situations in which physicians are too closely allied with a specific treatment to offer objective assessment of its merits, or when physicians face incentives against correcting misinformation, as illustrated by cases 3 through 6.

In case 3, both the physician and the patient are targeted by advertising. Ethicists have long deliberated over the appropriateness of the gift relationship between industry and physicians.[26,27] In recent years, the ways in which companies target physicians have grown more sophisticated and even more subtle. Companies now not only provide samples, gifts, dinners, and junkets, but also consulting fees, honoraria for speaking engagements, ghostwriting services, and financial support for research.[28,29] Speakers bureaus like that described in case 3 are commonplace, and some worry that industry trains more speakers than it needs,[30] using this as yet another means of directly influencing physicians' knowledge and legitimizing larger gifts than might otherwise seem appropriate. Furthermore, as the importance of industry funding of research increases, conflicts of interest become increasingly acute for physician-investigators and academic institutions. These sorts of financial arrangements affect physician behavior, although the bias that results from this entanglement with industry may be unintentional and unconscious, with most physicians steadfastly believing that they themselves cannot be influenced in this way.[31]

To deal with this, Brennan and colleagues[32] propose that academic medical centers ban all gifts, meals, payment for travel to or time at meetings, and payment for participation in online continuing medical education (CME) from industry to physicians. They suggest a number of distancing tactics, such as provision of vouchers rather than samples for low-income patients, exclusion of physicians with financial relationships to industry from formulary committees, elimination of direct funding of CME, prohibition of faculty participation in speakers bureaus, and limitation of grants for general support of research to institutions rather than individual physician-investigators.

Unfortunately, the sorts of conflicts of interest exemplified by cases 4, 5, and 6 cannot be remedied in similar straightforward fashion to those resulting from industry gifts to physicians. Cases 4 and 5 are complicated by the fact that the services advertised involve complex medical equipment with high capital costs. In such a situation, the physician may have an ownership interest in the equipment being advertised and financial interest in its use.[33] The physicians who have invested in a particular radiosurgical unit or CT scanner may well have done so because they believe in its promise. Nevertheless, once they have a financial interest in the use of this equipment, it is difficult to rely exclusively on them as arbiters of its use. Indeed, in many cases, an advertisement for a certain machine is, in effect, an advertisement for

the physician(s) owning the only such machine in an area. Case 6 takes this problem one step further by actually promoting physician services themselves, rather than products such as medications, devices, or equipment. Some may disagree with including web sites (which the patient must actively discover) in the category of advertising. However, given their general promotional nature, their inclusion seems appropriate here, given the context of this discussion.

Cases 4, 5, and 6 typify classes of advertising that appear to require greater scrutiny and regulation than the more commonly considered case of marketing of prescription drugs. Indeed, it may be prudent for regulatory bodies to limit the extent to which equipment manufacturers and physicians may target patients with DTC advertisements in these sorts of cases. However, in these cases, advertising seems to be exacerbating an underlying problem, which cannot be solved by restricting advertising alone.

INFORMED CONSENT AND DISCLOSURE OF CONFLICTS

The balance of power between physicians and patients in recent years has shifted considerably.[34-37] As technological advances, such as the internet, have become widely available to disperse information, the medical profession no longer possesses exclusive access to its once privileged realm of knowledge. Moreover, as Ranade notes, "social and political deference... [i]s fast disappearing as a result of growing affluence, exposure to health information in the media and higher educational standards."[38] The rise of DTC advertising itself is part of this complex landscape.[16]

Nevertheless, enough informational asymmetry remains that patients must continue to rely on physicians as fiduciary agents (learned intermediaries in legal parlance)[39,40] to help them interpret the inherently biased information being showered on them by industry. As a result, there should be greater emphasis on disclosure and consent in routine physician-patient encounters. The conflicts of interest that complicate the interactions between physicians and patients are hardly new, but they take on heightened importance in the context of the modern doctor-patient relationship, as brought into sharp relief by increased DTC advertising. Measures to correct the informational asymmetry—not only with regard to the medical issues themselves, but also with regard to the incentives and interests of the physicians helping to interpret these issues—are essential in the current day.

The explicit disclosure of potential conflicts of interest is commonplace in academic medicine; it is, for example, required by academic journals. Similarly, physicians are required to obtain informed consent before performing invasive diagnostic or therapeutic procedures on patients, whether for research purposes or not. Yet, while physicians are highly attuned to issues of disclosure and consent in the settings of academic research and invasive procedures, few extend these useful constructs to more routine encounters with patients.

Encounters in which the physician prescribes medications or orders noninvasive testing (or, for that matter, counsels the patient to change health behaviors or recommends expectant management) are also cases in which patients make health decisions on the basis of professional advice. When provided with comprehensive information about not only what is recommended, but also the provider's own incentives for promoting that option, the patient can more ably exercise his individual autonomy to make a decision that best reflects his own preferences, priorities, and goals.

Of course, patients are not always capable of behaving as rational consumers, particularly when their ability to deliberate and explore alternatives is compromised by illness. Health care is unique in the opacity that surrounds costs of various goods and services, as well as providers' incentives. Furthermore, insured patients have little incentive to determine how their providers are reimbursed. While legislators and analysts have devoted greater attention to policies mandating disclosure of providers' financial incentives since the rise of managed care, the focus has generally been on disclosure by managed care plans rather than providers themselves.[41-43] In any case, most patients remain ignorant of the magnitude and even the direction of the financial incentives of their physicians in any given encounter, with many wholly unfamiliar with even basic concepts of capitation and fee-for-service reimbursement.[44]

Perhaps the most important policy intervention, then, is to improve the flow of information to patients, not only about medical issues but also about the incentives and interests of the learned intermediaries on whom they are relying for information and counsel. Some might worry that publicizing this information would do more harm than good, interfering with the trust of the doctor-patient relationship by exposing ways in which providers' incentives may diverge from those of the patients to whom they serve as fiduciaries.[45,46] In my opinion, disclosing this information appropriately may help to strengthen the relationship by raising the conversation between physician and patient to a higher level.

Of course, in the extreme, the disclosure model raises a new series of challenges. Is every physician to change the tone of her medical consultation to provide detailed information about each and every financial implication of the patient's choices? No. But it does behoove physicians to call attention to conflicts of interests that exist.

Of note, conflicts of interest abound even when physicians do not have relationships with industry. For example, in the treatment of localized prostate cancer, it has been shown that urologists are more likely to recommend prostatectomy, whereas radiation oncologists are more likely to believe radiotherapy is equivalent treatment.[47] To some extent, this probably reflects a natural bias about the efficacy of the modality with which the physician is most familiar and experienced. Moreover, physicians may have self-selected into the specialties they believe offer the most therapeutic promise. Still, financial interests may also play some role. Therefore, in some circumstances, it may be necessary to guide the patient to utilize several learned intermediaries, whose own personal interests may conflict—in the example of prostate cancer, a urologist whose financial interests favor prostatectomy, a primary care provider whose financial interests in a capitated system might favor expectant management, and a radiation oncologist whose financial interests would favor radiotherapy. Indeed, it is the inherent financial conflict of interest (arising from the fact that physicians are reimbursed for the services they provide) that makes promotion of physician services like that in case 6 particularly problematic as a class.

As medical ethics shifts away from models of beneficence and emphasizes patient autonomy, it is crucial to ensure patients have the information necessary for informed decision making. While detailed disclosure and the multiple consultations that may be necessary in certain circumstances may increase health care costs, ultimately, they may be the only way to ensure that patient choices are guided appropriately.

The matter at the heart of all of the cases discussed in this article is the increasingly empowered consumer-patient's desperate need for unbiased information. The proliferation of advertisements from parties with financial interest is particularly dangerous when the physician cannot serve in an unbiased intermediary role. As illustrated by the cases herein, these situations are far from uncommon. As a result, physicians owe their patients disclosure of potential conflicts of interest. In addition, physicians should avoid becoming entangled in the potential conflicts of interest created by direct gift relationships with industry and should advocate for restraint in DTC advertising when other conflicts of interest are particularly acute, as in the cases of ads for physician services or equipment with high capital costs in which physicians have an ownership interest. Efforts to improve the quality of information available to patients through advertising and other media must be accompanied by concomitant efforts on the part of the medical profession to improve the ways in which physicians communicate with their patients, not only about the medical issues themselves but also about the conflicts of interest that are an inherent part of every physician-patient relationship.

AUTHOR'S DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author indicated no potential conflicts of interest.

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Acknowledgment

I acknowledge helpful discussions on this subject with members of the Department of Radiation Oncology at the University of Michigan (Ann Arbor, MI), the Edmond J. Safra Center for Ethics at Harvard University (Boston, MA), and the Department of Radiation Oncology at the Massachusetts General Hospital (Boston, MA).