Update on Direct-to-Consumer Marketing in Oncology

By Stacy W. Gray, MD, AM, and Gregory A. Abel, MD, MPH

Dana-Farber Cancer Institute, Boston, MA

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There has been a dramatic rise in direct-to-consumer marketing (DTCM) of cancer-related goods and services in the United States during the past few decades.[1] Such marketing strategies manifest in oncology in several ways, with the latest addition being DTCM of cancer screening tests, a practice described in detail in a recent commentary by Lovett et al in *Journal of Clinical Oncology*.[2] Indeed, just a few years ago, the availability of such testing outside of the traditional medical setting would have been unthinkable, especially because the data regarding the efficacy of most screening tests are difficult to interpret even for highly trained physicians.

The overall trend toward an increasing presence and number of venues for DTCM has been possible because significant technological, cultural, and regulatory paradigm shifts have occurred. First, widespread access to television, computers, the Internet, and mobile technologies have allowed patients to obtain cancer-related information from a broad range of sources both instantaneously and on demand.[3] Second, a significant sociomedical cultural shift has occurred in which patients are encouraged to be more actively engaged "consumers" of medical care.[4] Indeed, numerous studies have found that a majority of patients with cancer actively seek cancer-related information,[5-6] and that such information seeking is associated with patient behaviors including increased engagement in medical decision making and the use of targeted cancer therapies.[5,7-8] Finally, changes in the regulation of pharmaceutical advertising in the 1980s and again in the 1990s allowed direct-to-consumer advertising (DTCA) for prescription drugs, first in print media and then on television. Taken together, these trends have ushered in an age in which DTCM of cancer-related services and products seems ubiquitous. A review of how DTCM currently manifests in oncology seems essential to understanding its potential impact for practicing oncologists and policymakers.

DTCM Sales Models

The DTCM spectrum comprises a number of sales models. On one end is DTCA, which is a promotional effort by a pharmaceutical company or other provider of medical services to present information about medications or medical services to the public in lay media.[9] In this model, patients may express an interest in an advertised product or service, but access can be obtained only through a qualified health care provider. On the other end of the spectrum are direct-to-consumer (DTC) sales models that lie entirely outside of the established health care system, in which companies provide medical goods or services to consumers without using a health care provider as an intermediary. Between these extremes are a variety of models in which providers, employed by for-profit companies, engage with consumers to varying degrees. For example, there are some DTC genetic testing companies that employ staff physicians who are responsible for ordering all genomic tests, even though they may not have contact with consumers. In other models, consumers are directed to clinics that employ health professionals who are affiliated with, and trained by, the DTC company.[10-11] Notably, the independence of these physicians has been called into question, as the so-called training is often provided by the commercial entity itself.[10] For the purposes of this article, we discuss the broad concept of DTCM, which includes all aspects of the process of promoting, selling, and distributing medical products or services and thus covers DTCA, DTC sales of medical services, and the hybrid sales models between the extremes.

Cancer-Related DTCA

As the first entry into the oncology-related DTCM arena, the growth and potential impact of DTCA for cancer-related medications has been debated and researched since the mid 2000s.[1,12-13] For example, Viale et al[13a] surveyed 221 oncology nurse practitioners, finding that 94% reported having experienced at least one advertisement-driven patient request for a medication, with 40% experiencing one to five such requests per week. As to the contents and quality of cancer-related advertisements, a content analysis of DTCA occurring during a 3.5-year period found that approximately equal amounts of text were devoted to benefits and to risks and/or adverse effects, and that all text was exceedingly difficult to read as scored with a standard measure of readability.[14] During the study period, there were 284 advertisements: 49 unique campaigns for 22 different cancer products. Appeals to medication effectiveness were frequent (95%) and often made with clinical trial data (61%).

Are patients with cancer actually exposed to DTCA, and, more importantly, does it affect their treatment? A survey of 348 patients with cancer found that 86.2% reported being aware of cancer-related DTCA, most frequently from television.[15] Of those aware, 17.3% reported talking to their provider about an advertised medication, and approximately 3% ultimately received a prescription for the advertised medication. This low rate of reported treatment changes resulting from oncology-related DTCA is reassuring; on the other hand, 11.2% of those aware reported that cancer-related DTCA made

them "less confident" in their providers' judgment, a potentially devastating development for the patient-provider relationship.

A recent review of the cost-effectiveness of DTCA concluded that it does lead to increased demand for advertised medications, but suggested that the most important issue regarding DTCA is its potential effects on appropriate versus inappropriate prescribing.[16] Although such data are not yet available for cancer medications, one study found that patients who asked their physician about an advertised Cox-2 inhibitor were significantly more likely to be prescribed the medication even when a nonsteroidal anti-inflammatory drug was more appropriate given current guidelines.[17] Another study found that DTCA affected an increase in unnecessary screening tests for human papillomavirus.[18]

DTCM for Cancer Facilities

Whereas advertisements for cancer-related medications are clear examples of DTCM, it is equally important to recognize that many cancer-related facilities—including academic nonprofit centers—advertise their services with the intention of influencing patient demand and provider referral patterns. One study evaluated advertising by medical centers named to the US News and World Report's list of America's best hospitals.[19] The investigators found that 16 of the 17 hospitals reported that the purpose of their advertising was to attract patients, and that, unlike advertising to attract research subjects, advertisements that aimed to attract patients did not require institutional review board approval. In addition, the study found that advertisements for academic medical centers often highlighted cancer services and that ads commonly used emotional marketing appeals, promoted unproven interventions, and failed to quantify positive claims or mention potential harms of their services.[19]

DTCM for Imaging Services

In addition to academic medical centers, many nonacademic facilities engage in DTCM. An important example in this category is the marketing of high-technology radiology tests such as screening whole-body positron emission tomography or computed tomography (CT).[20-23] Although there are no rigorous published data on cancer screening by whole-body CT scan, experts have doubted the utility of such scanning in asymptomatic individuals.[21,24-25] Screening of this nature is likely to be of low sensitivity and specificity, and it exposes patients to the possibility of both false positive and false negative test results. Less controversial are companies that market services such as open magnetic resonance imaging (MRI) to patients who do not tolerate traditional MRI imaging. Interestingly, an analysis of print advertisements and brochures from DTCM imaging facilities found that they often make statements without scientific evidence, include financial incentives for self-referral, and provide little information on the potential risks of scanning.[23] Many experts have outlined the potential societal consequences of DTCM of screening imaging, including the high cost of follow-up evaluations of abnormal scans[20,25-26] and the potential for consumer harm and conflicts of interest if physicians have ownership interests in the imaging facilities.[22,26]

DTCM of Genetic Tests

Another rapidly expanding DTC market is for genomic testing; there are currently more than 30 Web sites that market and sell genomic tests directly to consumers.[27] Although not all Internet-based companies sell cancer-related testing, DTC testing for cancer susceptibility genes (eg, *BRCA1*), single nucleotide polymorphism testing that relates to cancer risk, and pharmacogenomic testing (eg, CYP 2D6 for tamoxifen metabolism) is available. Some argue that DTC genetic testing is valuable because it may increase consumer awareness of and access to genetic services as well as empower consumers to be more active in managing their health.[1,28-30] In contrast, others have raised concerns about the potential lack of counseling available through DTC companies, potential patient misunderstanding of test results, and the privacy and the security of genomic data.[1,28-32]

Unfortunately, few studies to date have addressed the impact of DTC genetic testing on consumer behavior. Some have demonstrated that Web sites contain more claims of benefits than risks,[33] that consumers might misunderstand information on DTC genetic testing Web sites,[33-35] and that risk information provision may influence consumer's attitudes and intentions about DTC genetic testing.[36-37] Other work in this area has found that people who have had DTC genetic testing and who were found to have an elevated risk of developing cancer report higher intentions to engage in cancer screening (eg, mammography and prostate-specific antigen testing).[38]

DTCM of Cancer Screening and Surveillance Tests

In a provocative article recently published by Lovett et al in *Journal of Clinical Oncology*,[2] the authors debate the value of DTCM of cancer-related biomarkers such as carcinoembryonic antigen (CEA) and CA-19-9. The authors report that several tumor markers have become available for sale to patients directly, are supported by suspect advertising claims, and that the "disconcerting nature of online DTC tumor marker promotion for cancer screening requires urgent legal and policy attention." Because the use of cancer-related biomarkers for cancer screening is not recommended or evidenced based, the interpretation of tests (be they "positive" or "negative"), is unclear, even in the hands of experienced oncologists (eg, an elevated CEA in a person without cancer is very difficult to interpret). Although DTC sales of cancer-related biomarkers is shocking, it is only the latest in the range of DTCM we have presented above. Indeed, it is not difficult to foresee DTCM offering such tests to patients who already have cancer, for disease surveillance.

Regulation of DTCM

Although regulations related to print and television advertisements for US Food and Drug Administration (FDA) –approved pharmaceuticals or medical devices are well established and require the provision of fair and balanced information to

consumers,[31] there is still significant debate over the extent to which Internet advertisements or Web sites should be regulated. This issue arises in the setting of both FDA-approved products (which can be promoted and sold for both on-label and off-label indications) and for goods and services that are sold without FDA review. Another major issue related to DTCM is whether there should be more regulation of the development and use of new technologies. For example, the vast majority of genomic tests are not subject to FDA approval; thus, companies do not have to demonstrate a test's validity or effectiveness before putting the test on the market.[31,39-40] The third major question for policymakers is whether there should be enhanced regulation of access to medical technologies. There is a clear precedent for provider-mediated access in the case of prescription pharmaceuticals, and numerous experts and organizations have discouraged direct patient access to screening imaging services, genomic technologies, and cancer screening tests.[2,24,41-43] Although legislation may be necessary to enhance consumer protection in some areas, it is essential that such laws balance consumer protection with the constitutional right to free speech,[31] and any new regulations foster scientific discovery rather than impede technological innovation.[40]

DTCM Research Priorities

Many potential problems with DTCM of cancer-related technologies are driven by a lack of certainty about the impact of marketing, unregulated technology use, and direct access to goods and services. There is a desperate need for high-quality research to address these evidence gaps. Rigorous health services research methods must be used to explore the content of DTCM, patient-related outcomes in the setting of test or treatment use, the economic impact of new technologies marketed directly to patients, and the potential impact of regulation on consumer health and behavior. Research in these areas is vital to the practice of oncology and is an essential step in ensuring optimal cancer care.

Implications for Clinical Practice

DTCM in oncology is widespread and continues to manifest in new ways. Health care providers have a simple choice when faced with patients who are inquiring about or who have used DTC goods and services: they can choose to either engage with these patients or not. In cases where there is robust evidence supporting the use of a DTC cancer-related test or treatment, physicians may want to commend patients' efforts and integrate those data into clinical decision making. In cases where there are data about DTC cancer-related goods or services that demonstrate ineffectiveness or harm, or those for which there are no quality data, providers may opt to see these opportunities as "teachable moments" and engage patients in conversations about the importance of evidenced-based decision making. In doing so, providers may be able to capitalize on a patient's motivation, interest, and enthusiasm with respect to their own health and redirect them to established interventions that could improve outcomes. With the growing use of DTCM in oncology, it is our hope that providers will both engage with their patients/consumers and participate in the public policy debate; indeed, if we do not, we run the risk of potentially enabling them to obtain their cancer care outside of the traditional medical system.

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Corresponding author: Gregory A. Abel, Dana-Farber Cancer Institute, Division of Population Sciences, Medical Oncology, 450 Brookline Ave, Dana 1106, Boston, MA 02115; e-mail: gregory_abel@dfci.harvard.edu.

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