



Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology

EDITORIAL

Direct-to-consumer advertising for oral cancer screening devices

The marketing of goods and services to the general public is critical for any commercial enterprise. Consumers will never purchase a product they haven't heard about. Although this concept makes inherent sense for most products or services, the expansion of marketing to consumers in the realm of health care continues to be a controversial subject. Direct-to-consumer advertising of pharmaceutical products (DTCA) can take the form of television, radio, magazine, internet, and billboard ads. With the exception of the United States and New Zealand, all other countries have prohibited DTCA since the 1940s. In 1997, following intense lobbying from industry, the United States Food and Drug Administration (FDA) altered their rules to make DTCA acceptable. In the subsequent decade, DTCA has become a billion-dollar business. In 2005, over \$4 billion was spent on this form of advertising, a 330% since 1997.¹

How beneficial is DTCA for patients and health care providers? Advocates argue that DTCA enhances patient education and empowers them to understand their disease as well as the potential treatment options. They also argue that DTCA will promote better communication between clinicians and their patients. Although in principle this makes sense, there are considerable data that do not support these arguments. For example, the ability of health care providers to make treatment decisions based on sound scientific/therapeutic principles may be hampered if patients begin to demand some type of treatment by name.^{2,3} Furthermore, there is concern that DTCA erodes the doctor-patient relationship to nothing more than a consumer-provider relationship.^{4,5} Data also suggest that DTCA may cause physicians to write prescriptions for a particular product that a patient does not necessarily require or that might not be as efficacious as some alternative product.⁶ A recent survey regarding the perceived effect of DTCA on the practice of orthopedic surgeons provided some worrisome information. The authors reported that 74% of the surgeons felt that DTCA had a negative

effect on their ability to provide patient care as well as on their doctor-patient relationships. Perhaps even more concerning, the study found that 77% of patients obtained inaccurate information regarding a particular treatment as a direct result of DTCA.⁷

Why are patients receiving inaccurate or misleading information? The FDA is responsible for reviewing the labeling of products. As such, it is charged with ensuring that the claims made regarding a product are accurate and that the statements of efficacy and risks and benefits are "fair and balanced." Despite these regulations, the unfortunate reality is that these regulations are often ignored. Several studies have demonstrated a lack of "fair balance" in advertisements regarding risks, benefits, and efficacy.^{8,9} In fact, approximately 84% of the FDA regulatory letters concerning DTCA were generated as a result of companies either minimizing the risks or making unsubstantiated claims about their product.¹

In truth, DTCA are carefully disguised "educational" advertisements designed to increase the profits of the company in question. A 2003 Kaiser Foundation study found that drug companies realize an increase in revenue of \$4.20 for every \$1 they spend on advertising.¹⁰ For better or worse, we live in a capitalist society and industry's primary purpose is to sell products that allow them to maximize their net revenue. We should certainly acknowledge the tremendous benefits that new drugs and devices developed by industry have brought to our society. However, it is disingenuous to suggest that billions of dollars are spent every year on DTCA for the main purpose of educating and empowering patients.

With this background, the question at hand is whether companies making oral cancer screening devices have crossed the line with their current DTCA practices. Specifically, are the advertisements fair and balanced, and do they provide sufficient information for the public to fully understand their potential utility, indications, efficacy, and benefits? For example, one

company has stated that their screening aid is now the “standard of care.” Yet another company’s recent DTCA stated that their technology can “prevent/stop oral cancer.” They further argue that their technology has “saved thousands of lives.” Each of these statements would be readily welcome by all involved in the diagnosis and treatment of oral cancer if they were accurate. Unfortunately, the peer-reviewed scientific literature does not support any of these contentions.

What is particularly worrisome about DTCA and oral cancer screening devices is the mechanism by which these devices were first “cleared” by the FDA in the first place. Because all of these products were cleared under the 510K paradigm (requiring only a demonstration of “substantial equivalence” to an existing approved device), none of these products were required to demonstrate the product’s efficacy as an oral cancer screening device. Perhaps the greatest concern is a recent tactic in which certain DTCAs have encouraged patients to go the company’s website to identify dentists in their area who use their technology. The underlying message of this type of marketing is that if one’s dentist is not using our technology, you should find a “better” dentist who is. This type of DTCA is considerably different from the type of advertising that encourages consumers to “ask your doctor about product X.” Further, this type of advertising has the potential to place an irreparable wedge in doctor-patient relationships, based on incomplete and inaccurate information provided by the company to the consumers.

In conclusion, biased information not supported by scientific evidence contained in DTCA has the potential to harm the doctor-patient relationship, generate unrealistic patient expectations, and potentially result in the use of unproven technologies. The end result of this could have dire and expensive public health consequences. I believe that the FDA should more aggressively enforce regulation of DTCA related to oral cancer screening devices. One could reasonably argue that

there are “bigger fish to fry” within the FDA. However, given that oral cancer is the sixth most common malignancy in the world today and 1 person dies every hour from this devastating disease, I would hope that this regulatory body can appreciate the importance of this disease and make greater efforts to compel industry to modify the content of their DTCA in a fashion that is scientifically accurate.

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