

Ethics of Direct Advertising to Consumers

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Advertising has many detractors. F. Scott Fitzgerald is quoted as saying, "Advertising is a racket . . . its constructive contribution to humanity is exactly minus zero."¹ Stephen Leacock considered advertising to be "the science of arresting the human intelligence long enough to get money from it."² Many physicians agree with these sentiments, particularly when applied to direct advertising by medical companies. These feelings are reinforced by the observation that the increase in direct-to-consumer advertising (DTCA) correlates directly with the increase in overall drug spending and drug prices. The quantity of advertisements for "lifestyle" drugs such as for erectile dysfunction or hair loss reinforces the tawdry image of medical advertising.

The Role of Autonomy

The morality of direct advertising rests on the primacy of personal autonomy in the lives of every human being. Consider this definition of autonomy.

I wish my life and decisions to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not of other men's acts of will. I wish to be a subject, not an object; to be moved by reasons, which are my own, not by causes which affect me from outside. I wish, above all, to be conscious of myself as a thinking, willing, active being, bearing responsibility for my choices and able to explain them by reference to my own ideas and purposes.³

Certainly those who feel this strongly about their inherent right to make decisions would expect to make their medical decisions as well as other life changing decisions.

It is this universal personal right to make decisions that is the target of direct advertising to the public.

Autonomy is the specific justification for direct-to-consumer advertising (DTCA) of high technology screening tests by physicians. Tests such as computed tomography for coronary artery disease and early cancer of the lung do not have data supporting their usefulness, but they are promoted because the consumer has the right to spend their own funds for "peace of mind."⁴

Marketing as Education

Those engaging in direct marketing justify their efforts as education. There is considerable evidence that people are not receiving the medical care required for optimal disease control. For example, in one study only 24% of people with diabetes had adequate glycemic testing. About three-quarters of the participants had recommended blood pressure control care and treatment for coronary artery disease. The authors concluded that, on the average, Americans receive about one half of the medical care recommended.⁵

This leads to two approaches in direct marketing. The first is strictly informational: these advertisements discuss a disease or screening methods. They do not, however, recommend a particular drug or procedure. Such advertisements are not regulated by the FDA.

The second is direct advertising that promotes a specific drug or device, even if within the context of increasing awareness of a health condition. These are regulated by the FDA and have been allowed since 1997. Physicians have mixed responses to both types of marketing but are more aggressive in denouncing the latter.

The companies may identify the advertising as education, but it can also create a market. Male pattern baldness was not considered a disease until the extensive marketing program for Rogaine. By creating a disease, they created a market.

The evidence against direct marketing as an educational tool is not persuasive. In one study of patients who initiated a request for a drug they had seen advertised, 88% understood the condition for which the drug might be indicated.⁶ In another study, about two-thirds of the physicians thought that direct advertising had educated their patients about available treatments and indicated it allowed for better discussions.⁷ The downside was that in both studies the physicians reported the patients understood benefits better than risks. This is not unlike studies of informed consent for surgery.^{8 9}

One can still ask if advertisements combining information about a disease and a specific drug is trying to serve two masters. The company is ultimately responsible to

its shareholders for profits, not to the public as a provider of credible information.¹⁰

Advertisers may claim patients seek more information, but it seems that patients are swimming, and sometimes drowning, in a sea of health information. DTCA is only one of the sources of this; there are also web sites, blogs, and doctor-based television dramas. Most of these are unregulated and totally interest-driven. In 2005, 60% of North American adults reported receiving medical information from the internet.¹¹ None of these media do a good job of separating the excitement of the newest research from a serious discussion of the risks.

The quantity of information and the emotional charge attached to it is a problem for doctors. There may be a few who feel their authority is being challenged, but for most it is much more pragmatic. It takes a lot of time to explain why the patient's preferred choice is not consistent with the physician's best judgment. In a survey of physicians concerning direct marketing, the use of time was the number one complaint.⁶

Doctors should think twice about being too loud in their opposition to direct advertising since many of them also rely upon and are directly influenced by industry sources of information. In pharmaceuticals, the spending to influence physicians is eight times the spending to directly influence consumers.¹² Listening to discussion among equipment and implant representatives would lead one to believe that they are the primary source of information for many orthopaedic surgeons.

Marketing as Selling Hope

Direct advertising is frequently critiqued for its accuracy or distortion. The power of advertising may reside, not in the accuracy of the presentation, but in its ability to take advantage of the consumer without using overt deception. Emotions are a powerful determinant, both in our capacity to make decisions and the content of the final decision. Emotions do this by framing the deliberation by filtering the information and providing modes of interpreting what is presented.¹³

Of the emotions involved in advertising, hope is one of the most powerful and most frequently used. The young man drinking beer in a bar hopes the brand of beer

makes him attractive to beautiful women. In medical advertising, the drugs offer hope—hope that an acute problem can be eliminated or a chronic condition can be reduced. A drug for irritable bowel syndrome, Zelnorm, is only 5-10% more effective than placebo for women and does not work for men yet more than 2,100,000 prescriptions were written for it in 2005. The reason? A highly visible television campaign with attractive young women pulling up their shirts to show their abdomen with these words written on it: “I feel better.”¹⁴ They sell hope.

Similarly, the advertisements for drugs to treat erectile dysfunction speak directly to hope. The scenes are designed to produce feelings of romantic anticipation and physical sexual fulfillment with the hope the viewer will experience equal success. These do not project information; they sell hope. The data indicates these drugs are better than placebos, but not by much.¹⁵ The hope is the distortion.

Marketing Strategy

Marketing can be thought of in terms of “push and pull,” words to describe how products are moved through the marketing chain. When a company sells its widgets to a wholesaler, who sells to a retailer, who sells to a customer, this is called “push.” That is, the product is pushed through the marketing chain. In medical marketing, “push” is marketing to hospital or doctor who will then pass along the drug or implant to the consumer who accepts the recommendation.

“Pull” is direct advertising to consumers who then “pull” the product through the pipeline. Direct advertising is aimed at “pull.” The product is “pulled” through the marketing chain by the requests of the consumer at the end of the chain. In medicine it is the consumer who comes to the physician with a specific drug in mind and fully expects to receive a prescription for it.

This strategy rests on the assumption that consumers are the buyers in the health care market and that much of health care is a commodity like soap or hair dye. In a milieu of commodities it is necessary to differentiate a product or service from others, and marketing is the process by which this is done. The rise of direct marketing in health care is a manifestation of the belief that medicine is a commodity.

A discussion with a local pharmacist revealed the power of “pull.” They stock numerous drugs solely because the customers want the exact brand, not an equivalent, and certainly not a generic. She showed me 16 linear feet of shelf space, 8 shelves high, stacked with non-prescription drugs and patches that customers demand by brand name. Her professional life is almost free from marketing “push” but dominated by “pull.”

The literature supports the anecdotal experience of the pharmacist. It is well accepted that DCTA is very effective. When patients came to the physician asking for a specific brand name drug, this request, in one study, resulted in a prescription 69% of the time.⁶ Another study reported about 75% of patients received the specific drug requested.¹⁶ In general, the advertising resulted in a positive return on investment for the companies in 90% of the brand name drugs. Of these, 70% had return on investment of 150%, and 35% had a return of 250%.¹⁷

Another marketing strategy is to segment the market. This is frequently done according to race. A combination of drugs is marketed to African-Americans as being specifically for their biological type of heart disease. Skin creams that claim to reduce wrinkles come in specific jars for Caucasians, African-Americans, and Hispanics. Market segmentation can also be on the basis of gender. A total knee is advertised as designed specifically for women. This differentiates this knee from those sold by their competitors.

Orthopaedic Devices

Although there may be some justification for claiming to be educating the public in the case of diabetes and hypertension, it is difficult to apply this idea to devices. Yet, they are also widely advertised. Consider the most prevalent advertisements for joint implants. At the first level we have competing celebrities. One company presents a famous golfer walking the course and hitting long drives because of his new hip. In another, a famous coach gliding painlessly around the basketball court. If you ever wished to participate in sports, these advertisements give you hope. Even unknown people make good advertising copy. One advertisement for total knees shows a happy

person walking the hills of San Francisco because of a new knee.

Endorsements can come from both experts and regular consumers. For experiential products, research suggests that the opinions of regular consumers is valued more highly than those of experts.¹⁸ Celebrities catch the eye of the consumer, but are regarded as “regular folks” and therefore are highly effective means of product sales.

These advertisements, and others, could be considered as informative in that total joint replacement surgery is generally very satisfactory. A consensus report from the NIH suggested that only a small proportion of those who would benefit from a joint implant were actually treated.¹⁹ If a person did not realize that his or her lifestyle could be improved by pain relief and increased function, this is an important message.

These messages, however, are deceptive in that they suggest the implant is the sole determinant of success. They do not mention the competitive drive of the athletes that would motivate rehabilitation. They do not suggest that, if the patient was a couch potato for five years before the surgery, it will take great personal effort to be able to walk the San Francisco hills.

The second problem is the message that the hope of a pain free existence is tied to a particular material or brand. This portion of the message is a distortion since many different models and brands function exceedingly well. Another sales tactic that distorts the general message is the prevalence of advertisements for implants that specify gender or type of incision. All of the advertisements appeal to autonomy since they suggest the person takes the initiative with their doctor concerning the surgery.

Orthopaedists are much more negative about direct-to-consumer advertisements than internists and primary care physicians. In a large randomized study, 32% of physicians thought that DTCA negatively impacted their relationships with their patients.⁷ In contrast, 74% of orthopaedic surgeons thought the relationship was negatively affected. An equal number believed the patients were confused or misinformed and had unrealistic expectations of implant surgery. Eighty-four percent believed patients had unrealistic expectations associated with a specific implant or

incision.²⁰

The presidents of hip-replacement manufactures have no doubt that DTCA is very effective. They expect people in their 70s to “do the research,” and that means gathering information from sources other than surgeons. They expect the patient will come into an orthopaedic surgeon’s office and say, “I want Coach K’s hip,” “I want what Jack Nicholas has.” They are also attempting to persuade patients to choose the type of incision, claiming “we are trying to let people know you don’t have to give up your life.”²¹ To suggest that traditional incisions are the equivalent of “giving up your life” has crossed the line from education to unimaginable hubris.

Consider the problem for the surgeon who routinely uses the implants of another company or who does not believe in the safety of mini-incisions. In a survey of symposium attendees at the 2006 AOA meeting, 88% of surgeons believed that patients would change surgeons before they would change their desired brand of implant.²² Although this was a convenience, not a randomized, sample, the magnitude of the DOCA effect and the brand loyalty is amazing.

One of the ways to include physicians in advertising is to put the company and the physician together in what is known as “co-branding.” Here the “brand” of the physician and the “brand” of the implant are tied together. On the web page for “Coach K’s Hip” are a list of surgeons who use that brand and therefore could assure the patient that “yes, you will get a hip just like Coach K.” The advantage to the surgeon is obvious. A new patient that otherwise might not come to that office is sitting in front of the doctor. There is no need to discuss the equivalency of different brands. The likelihood of the patient having surgery from that surgeon is high. Co-branding is not limited to a single company.

A personal aside. A few years ago I had a total knee arthroplasty performed by one of my former residents. On the second post-operative day an old orthopaedist had seen my name on the operative schedule and came to visit me. His first words were, “What kind of a knee did you get?” He then went on to describe the latest, fanciest, and most expensive implant, which he was certain I must have demanded. I was

dumbstruck. I suddenly realized I had no idea what artificial knee my surgeon had implanted. I trusted his judgment and didn't even think to ask.

In retrospect I am still comfortable with this. The decision to trust his judgment was as much an autonomous choice as any decision about the implant or a specific incision. This trust is not only unavoidable; it is rational to depend on the expertise and trustworthiness of medical professionals. It is helpful to have knowledge-- I am not advocating ignorance-- but it is not necessary to be a self-sufficient source of all wisdom.

Spinal implants do not seem to have reached the realm of television marketing, but many websites are filled with hope. The "X-Stop" site related that 50% of patients had satisfactory results and only 6% needed a laminectomy. It does have considerably more information concerning potential complications than other sites.

Oversight and Control

When direct-to-consumer advertising was approved in 1997, the FDA was assigned to monitor advertising. The regulations are comprehensive and complete. However, advertisements are reviewed superficially after they are released and only carefully after complaints by other companies or health care providers.

There is evidence that the intensity of surveillance and the number of regulatory actions has decreased while the assignment has ballooned. The number of staff has not increased substantially while the amount spent in advertising has tripled. The number of regulatory letters relating to advertising violations dropped from 142 in 1997 to 29 in 2007 and, if this year's trend continues, to 16 for 2008.

Approval by the FDA is required for drug and device distribution to the public. In the best of worlds, this would allow for careful study and evaluation prior to release. However, the work load of the FDA and the high incidence of conflict-of-interest of those on the advisory panels casts doubt on the efficiency of the process.

In February 2008, the Supreme Court ruled that device manufacturers could not be sued in state courts if the FDA had previously had given approval. Because federal law has no provisions for suing device makers, this effectively protects manufacturers

from the courts. This assumes strong regulatory oversight by the FDA that seems to be lacking. DTCA is a secondary issue behind this already inadequate oversight.

How Should Surgeons React?

First, we must realize that some things will not change. Conversations with device manufacturers are unlikely to be productive. They are very happy with the present situation and are likely only to intensify their efforts. The FDA is unable to do anything about more than the most gross distortions in advertising. The specialty societies have little or no power.

Surgeons need to make a virtue out of what is now perceived as a vice. A major complaint by surgeons is that direct advertising requires them to spend additional time with patients. Plan to spend it, and more!! This is the opportunity to become a physician, examine the patient, even if it means touching them. I hear the complaint over and over again that “the doctor didn’t even touch my knee.” Make a diagnosis; maybe the patient doesn’t need the implant. Discuss the alternatives, including your agreement that the brand of implant they requested would work very well but there are reasons why you don’t use it. Over the course of the visit, establish your authority as an expert who is perfectly competent to disagree with the direct advertising.

Some surgeons will resist; spending time talking is not what they enjoy doing. These surgeons will lose patients because of the patient’s preferences for some particular brand of implant. But, these potential losses can be overcome by surgeons who want to do the surgery enough to invest the time beforehand.

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