



## DTCA for PTCA — Crossing the Line in Consumer Health Education?

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On November 22, 2007, viewers of the nationally televised Thanksgiving Day football game between the Dallas Cowboys and the New York Jets witnessed the launch of the first direct-to-consumer

advertising (DTCA) campaign for percutaneous transluminal coronary angioplasty (PTCA) with a drug-eluting coronary stent. The airing of “Life Wide Open,” the 60-second commercial for Cypher, the sirolimus-coated stent produced by the Cordis division of Johnson & Johnson, marked the dawn of a new era in medical DTCA, which has for the past decade focused on brand-name pharmaceutical agents.

To many consumers, the stent ad may not have seemed surprising or out of place — no different from television ads touting the virtues of drugs for acute coro-

nary syndromes, arthritis, depression, prostatic enlargement, fibromyalgia, restless legs syndrome, and, of course, erectile dysfunction. But in making the leap from pharmaceuticals to medical devices, the ad campaign raises important questions regarding the net societal benefit of medical advertising directed at the lay public. Even if there is an overall benefit from the unfettered transmission of information in a free society, has industry crossed the line this time? In the ad for Cypher, a device is being promoted to millions of people who are ill-equipped to make judg-

ments about the many clinically relevant but subtle and complex therapeutic issues that even specialists continue to debate.

The statutory authority for current regulation of DTCA by the Food and Drug Administration (FDA) is based on the 1938 Federal Food, Drug, and Cosmetic Act, which outlined the requirements for pharmaceutical products for which companies sought U.S. marketing approval. In 1962, Congress specifically granted the FDA statutory authority to regulate prescription-drug labeling and advertising, including DTCA.<sup>1</sup> In 1969, the agency issued final regulations governing drug advertising, stipulating that advertisements must not be false or misleading, must present a “fair balance” of information about the risks and benefits of using

Potential Adverse Events Associated with the Sirolimus-Coated Cypher Stent Disclosed in Cordis's Television Ad, Web Site, and Patient-Education Brochure.		
Potential Adverse Events Disclosed		
	Associated with Coronary-Stent Placement	Associated with Use of Sirolimus
<b>Television ad</b>	<ul style="list-style-type: none"> <li>“If you can't take antiplatelet medicine or have certain allergies, it's not for you”</li> <li>Formation of a blood clot in the stent</li> <li>Heart attack</li> <li>Repeat procedure</li> </ul>	None
<b>Web site</b>	<ul style="list-style-type: none"> <li>Allergic reaction</li> <li>Irregular heart rhythm</li> <li>Stent thrombosis</li> <li>Death</li> <li>Reactions to antiplatelet or anticoagulant medications or to dyes used during placement</li> <li>Emergency bypass surgery</li> <li>Fever</li> <li>Bleeding at the puncture site</li> <li>Chest pain or angina</li> <li>Stroke</li> </ul>	<ul style="list-style-type: none"> <li>Infection</li> <li>Tumor formation</li> <li>Fatigue</li> <li>Joint pain</li> <li>Diarrhea</li> </ul>
<b>Patient-education brochure</b>	<ul style="list-style-type: none"> <li>Allergic reaction</li> <li>Aneurysm</li> <li>Arrhythmia</li> <li>Cardiac tamponade</li> <li>Death</li> <li>Dissection</li> <li>Drug reactions to antiplatelet or anticoagulant agents, or to contrast mediums</li> <li>Emboli, distal (tissue, air, or thrombotic emboli)</li> <li>Embolization, stent</li> <li>Emergency coronary-artery bypass grafting</li> <li>Failure to deliver the stent to the intended site</li> <li>Fever</li> <li>Fistulization</li> <li>Hemorrhage</li> <li>Hypotension–hypertension</li> <li>Incomplete stent apposition</li> <li>Infection and pain at the intended site</li> <li>Myocardial infarction</li> <li>Myocardial ischemia</li> <li>Occlusion</li> <li>Prolonged angina</li> <li>Pseudoaneurysm</li> <li>Renal failure</li> <li>Restenosis of stented segment (greater than 50% obstruction)</li> <li>Rupture of native coronary artery or bypass graft</li> <li>Stent compression</li> <li>Stent migration</li> <li>Thrombosis (acute, subacute, late)</li> <li>Ventricular fibrillation</li> <li>Vessel perforation</li> <li>Vessel spasm</li> </ul>	<ul style="list-style-type: none"> <li>Abnormal liver function</li> <li>Anemia</li> <li>Arthralgias</li> <li>Diarrhea</li> <li>Hypercholesterolemia</li> <li>Hypersensitivity, including anaphylactic or anaphylactoid reactions</li> <li>Hypertriglyceridemia</li> <li>Hypokalemia</li> <li>Infections</li> <li>Interstitial lung disease</li> <li>Leukopenia</li> <li>Lymphoma and other cancers</li> <li>Thrombocytopenia</li> </ul>

the drug, must contain facts that are “material” to the product’s advertised uses, and must include a “brief summary” mentioning every risk described in the product’s approved labeling.

The agency regulations differentiate between print and broadcast DTCA. In the former, all information about associated risks, including major side effects, contraindications, and precautions contained in the drug’s FDA label, must be explicitly divulged. In the latter, only “major risk information” must be disclosed, but such broadcast ads must direct viewers to other accessible sources containing complete information on associated risks. This distinction reflected a pragmatic recognition of the time limitations (typically 30 to 60 seconds) of broadcast ads.

DTCA does have some benefits for consumers. Two national telephone surveys, conducted by the FDA in 1999 and 2002, found that consumer ads prompted many patients to actively seek out newly available medical treatments for various (usually chronic) conditions and that patients had become increasingly motivated to ask better questions of their health care providers.<sup>1</sup> There are some data to support the observation that DTCA for a brand-name drug sometimes creates a halo effect, prompting or enabling patients to seek medical advice for conditions that might otherwise go untreated. Thus, such advertising could lead to a more open and well-informed dialogue between patients and physicians and could, for example, lead to lifestyle changes beneficial to patients’ health — regardless of whether they begin using drugs

for angina, hypertension, or dyslipidemia.<sup>2</sup>

There are also obvious benefits for industry. Many pharmaceuti-

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cal companies rely on DTCA to stimulate demand and increase sales for high-revenue products. According to one report, DTCA resulted in a positive return on investment for more than 90% of brand-name drugs, 70% of which had returns in excess of \$1.50 for every \$1.00 invested and 35% of which had returns in excess of \$2.50 for every \$1.00 invested. In addition, 10 of the leading 12 brand-name drugs with DTCA campaigns had sales in excess of \$1 billion annually.<sup>3</sup> It is difficult to dismiss the effect of DTCA on profits.

But no matter what the potential merits of DTCA for both health care consumers and industry, it is disturbing that television ads

promoting drugs inevitably fail to fully disclose the benefits and risks that must be included in print advertising, whether in medical journals or lay publications. Although broadcast ads may adhere to the letter of the law in disclosing limited risks and benefits, the restriction of content necessitated by time limitations creates an inevitable inequality between these ads and print ads, which must disclose in detail the entire spectrum of risks and benefits. This lower standard for disclosure is of great concern to physician opponents of DTCA, as well as to congressional oversight committees, which have objected that DTCA plays down the risks of certain medications while promoting their putative benefits.<sup>4</sup>

The 60-second ad promoting the Cypher stent opens with a middle-aged man slumped in a chair, as a text overlay asks, “How big is the world? Ask the tough guy cornered by chest pains.” The ad then shows several middle-aged adults actively engaged in various healthful physical activities, such as swimming, fishing, and jogging. In saying “when your arteries narrow, so does your life” and “it’s time to open it,” the ad implies that in “opening millions of lives” the stent provides more than just symptom relief, even though recent evidence from clinical trials indicates that PTCA is not superior to optimal medical therapy in reducing the risk of death or myocardial infarction.<sup>5</sup> To its credit, the ad does warn that antiplatelet therapy is also needed to prevent the formation of dangerous clots, and it specifically mentions some of the well-recognized complications or

adverse events that can occur after stent implantation (e.g., myocardial infarction and stroke). It makes no explicit mention, however, of death or serious complications such as coronary dissection, rupture, or an absence of reflow that might necessitate emergency coronary bypass surgery. The ad lists a Web address for the product ([www.cypherusa.com](http://www.cypherusa.com)), and the Web site's home page directs consumers to another page for "important patient safety information." Unfortunately, that page fails to adequately address important safety concerns or to direct patients to a source of educational information that provides comprehensive detail on the gamut of complications, risks, and adverse events associated with the stent.

The average layperson may or may not perceive the "Life Wide Open" campaign as misleading. For the FDA, the acid test is the degree to which the ad promotes fair balance with respect to risks and benefits in terms that patients can and need to understand.

Unlike a drug, whose use merely requires an office visit to a physician and a prescription the patient can fill at a pharmacy, a specialized medical device such as a stent can be selected and implanted only by someone with a very sophisticated medical under-

standing that no member of the lay public could realistically expect to gain from a DTCA campaign. It seems almost unimaginable that a patient would challenge an interventional cardiologist's judgment about the use of a particular stent or that a cardiologist would accede to a patient's request for a particular stent on the basis of the information gleaned from a television ad. Indeed, the notion that television viewers, inspired by such an ad, would go to their physicians and request not only a stent but a specific brand and model of stent is frightening, if not utterly absurd. This possibility makes the central questions about the "Life Wide Open" campaign even more pressing. Why does the patient-education brochure for the Cypher stent detail all potential serious complications (see table), whereas the television ad almost exclusively promotes the potential benefits? Does such a DTCA campaign comply with the FDA's existing requirement of "fair balance," or does it fall far short of such stipulations?

We believe that the FDA should perform a critical postrelease review of the "Life Wide Open" campaign to assess whether it meets the basic regulatory requirements for nondeceptive prescription-drug advertising. Until

such an evaluation is conducted, the campaign should be viewed as a "device" of potentially deceptive advertising and as a bold, preliminary experiment in interventional psychology.

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