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Direct-to-Consumer Advertising of Restricted, Surgically Implanted Medical Devices: What Does the Advertising Arena Look Like, and Whose Regulatory Problem Is It

Bruce Patsner

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**DIRECT-TO-CONSUMER ADVERTISING OF
RESTRICTED, SURGICALLY IMPLANTED MEDICAL
DEVICES: WHAT DOES THE ADVERTISING ARENA
LOOK LIKE, AND WHOSE REGULATORY
PROBLEM IS IT?**

Bruce Patsner[†]

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I. INTRODUCTION

The advertising and promotion of a diverse array of medical products to consumers has been an established part of American culture for decades,¹ particularly so for the advertising and promotion of prescription and over-the-counter drugs. Efforts by federal agencies, such as the U.S. Food and Drug Administration (FDA), to restrict this type of commercial speech invariably have

[†] MD, JD, Professor of Law, Director of Health Law & Policy, Yonsei Law School, Seoul, Korea.

1. See Scott H. Podolsky & Jeremy A. Greene, *A Historical Perspective of Pharmaceutical Promotion and Physician Education*, 300 JAMA 831, 831 (2008).

crashed on the rocks of the *Hudson*,² almost without regard to how uninformative, misleading, or less than completely truthful such advertising to consumers has been.³ Efforts to rein in this practice have invariably been judged by federal courts to not be tailored narrowly enough to outweigh the purported but unproven benefits of such practices,⁴ or to justify chipping away at the constitutional pedestal of protection of commercial speech on which direct-to-consumer advertising (DTCA) of medical products stands.

Although purely false advertising does not enjoy First Amendment protection,⁵ almost anything above this low bar has been difficult to suppress, at least in the arena of food and drugs. In general, court decisions have usually determined that the alleged potential proclaimed benefits of DTCA—education of citizens, improvement of the physician-patient relationship, vigorous defense against efforts to limit freedom of expression⁶—outweigh the alleged risks posed by limiting this type of commercial speech. Of the three claimed benefits society enjoys from DTCA, the potential to educate health consumers (i.e., real people) is by far the most important. Commercial speech enjoys much less protection, in general, than an individual's freedom of speech, and the blizzard of negative press in the past decade about the relationship between academic medicine and the pharmaceutical industry⁷ would seem to make any claimed favorable effect of DTCA on the physician-patient relationship a stretch at best. The same holds true for the relationship between medical device manufacturers and the surgeons or surgical

2. Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

3. *Id.* Although the *Central Hudson* standard for review of commercial speech protection is two-pronged, with the first test being whether the regulated speech is misleading or concerns an illegal activity (and if so, the speech receives no constitutional protection), *Id.* at 563–64, virtually any television advertisement for a prescription drug could be found to be misleading in the manner in which serious drug side effects are presented and in which any discussion of whether, on balance, such serious side effects outweigh the sometimes negligible benefits obtained from taking the drug product. There are some apparent standards for what constitutes a fair and balanced pharmaceutical ad, but the same claim cannot be made for restricted implantable medical devices.

4. *Id.* at 567–72.

5. DANIEL A. FARBER, *THE FIRST AMENDMENT* 154 (3d ed. 2010).

6. *Id.* at 150–52.

7. Podolsky & Greene, *supra* note 1, at 831; *see also* Wayne L. Pines, *A History and Perspective of Direct-to-Consumer Promotion*, 54 *FOOD & DRUG L.J.* 489 (1999).

specialty groups who use their products.⁸

The bottom line is that it is really only the potential to educate consumers about the potential benefits (and risks) of medical devices that justifies efforts to protect such commercial speech from attempts by state and federal agencies to restrict (or even ban) it. For this reason, the information contained in medical device advertisements and the information that should be contained in such ads to really educate a consumer, is one area in which this article will focus. The focus here will also be exclusively on prescription, restricted, surgically implanted medical devices—cardiac pacemakers, artificial knees and hips, coronary artery stents, biliary tract stents, and so forth. The reasons are straightforward. These medical devices are the most likely to have undergone some sort of clinical testing; are among the most expensive (and potentially lucrative) on the market; are the most likely to be advertised to consumers by medical centers and surgeons or surgical groups seeking patient referrals and a marketing advantage; are usually the most dangerous; and, lastly, are those devices in which the morbidity of the device is a function not only of the inherent properties of the device itself but also the skill of the surgeon and the facility in which the device is implanted in the patient. Although technically not permanently implanted in patients, nor restricted in the sense that they reached the market via a premarket approval (PMA), robotic surgical systems such as the da Vinci are complex surgical devices that are temporarily inserted into patients and are prescription devices; that is, they can only be used under the direct supervision of an operating surgeon. These devices will be mentioned as well in this article, as there is literature on the accuracy of DTCA claims for this product.

The importance of the medical device industry, and of the advertising of devices, cannot be overstated. The topic of DTCA of medical devices in general, and restricted, surgically implanted devices in particular, deserves a closer look. There are several good reasons for this.

First, the medical device industry in the United States has grown, and continues to grow, almost exponentially over the last

8. Senate investigators say Medtronic helped write medical journal articles promoting bone graft. Michelle Fay Cortez & Drew Armstrong, *Medtronic Manipulated Bone Product Data, Senate Panel Says*, WASH. POST, Oct. 25, 2012, <http://washpost.bloomberg.com/Story?docId=1376-MCFN7M0UQVI901-3A6GLRR45DE8GQBSDJ5GNEFQ1C>.

two decades and now is at the tip of the spear of the medical technology juggernaut in the United States. Despite this, the enabling statute that effectively defined and regulates the medical device industry—the 1976 Medical Device Amendments to the 1938 Federal Food, Drug, and Cosmetic Act—has remained largely unchanged in the basic manner in which medical devices are classified and the mechanisms by which they may reach United States consumers. Second, the wide diversity of new medical devices and the engineering complexity of medical devices (including restricted, surgically implanted medical devices) is a quantum leap over previous generations. Despite this, some innovative and potentially dangerous medical devices still reach United States markets via the abbreviated 510(k) clearance mechanism. This mechanism requires no independent testing for either safety or effectiveness and allows many new medical devices to reach consumers merely by the sponsor briefly claiming that its new device is substantially equivalent to an already-marketed predicate medical device, which may be many generations afield from the new device and may no longer be either the gold standard or remotely relevant in terms of potential morbidity to the new device. Third, as with prescription drugs there is a substantial amount of off-label use of restricted, surgically implanted medical devices; by virtue of coming under the practice of medicine, this activity remains outside the FDA’s direct regulatory control. And as with off-label use of prescription drugs, this activity for medical devices shows no sign of slowing down. Lastly, as the medical device industry has expanded, DTCA and promotion of certain medical devices has begun to emerge.

II. THE STATUTORY FRAMEWORK FOR MEDICAL DEVICE CLASSIFICATION AND REGULATION OF ADVERTISING

The FDA assumed direct regulatory authority over medical devices as a result of the 1976 Medical Device Amendments⁹ to the 1938 Federal Food, Drug, and Cosmetic Act.¹⁰ Medical devices are classified into one of three classes (I, II, and III) based on safety risk, with class III devices being the most dangerous.¹¹ Medical

9. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

10. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331–397 (2006)).

11. 21 U.S.C. § 360c(a)(1).

devices can either be marketed directly (e.g., a new kind of tongue depressor) without any direct FDA involvement; be cleared for marketing via a 510(k) mechanism, which allows a new medical device to be sold if it is found to be substantially equivalent to an existing medical device already on the market; or approved following submission of a PMA,¹² which unlike the 510(k) clearance actually requires substantial, new clinical trial data on safety and efficacy. There are labeling requirements for both 510(k)- and PMA-approved device marketing, but the requirements for the latter are more stringent.

Another layer in the FDA medical device regulatory mechanism is the concept of the restricted, as well as the prescription, medical device. Most non-class I medical devices are prescription medical devices, which are approved either via 510(k) clearance or PMA and which are defined as devices that the FDA deems safe only if used under the supervision of a licensed medical practitioner.¹³ Prescription medical devices are subject to FDA labeling requirements that, among other things, require labeling that includes adequate information for use associated with the device in order for the device to not be considered misbranded.¹⁴ Because labeling encompasses brochures and promotional materials sent to physicians and consumers, in addition to the medical device label itself,¹⁵ this means that medical device manufacturers are liable for the absence of such information in DTCA of their devices. The statute does not apply to physicians, surgical groups, hospitals, or academic medical centers when they are doing the promotion for the device as part of marketing activities since FDA regulations are intended only for industry, and promotional practices are an aspect of medical practice regulated by individual state medical boards.¹⁶

Restricted medical devices are a subset of prescription medical devices. A restricted device is subject to general prescription medical device labeling requirements but is also subject to

12. *Id.* § 360e.

13. 21 C.F.R. § 801.109 (2011); *see also* 21 U.S.C. § 352(f).

14. 21 U.S.C. § 352(r)(2); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ALTERNATIVE TO CERTAIN PRESCRIPTION DEVICE LABELING REQUIREMENTS (2000), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072748.pdf>.

15. *Kordel v. United States*, 335 U.S. 345, 349 (1948).

16. *Cf.* 21 U.S.C. § 396.

additional requirements on sale, use, distribution, or advertising. These additional restrictions may be imposed by the PMA, which authorizes the sale of the device, or by a separate regulation¹⁷ that recognizes that the device has a particular potential for harm or the device is so complicated to use that special measures are necessary to ensure that it is used properly and safely. These are the only two ways prescription devices are also considered restricted medical devices.

Some, but not all, surgically implanted restricted medical devices have reached consumers via PMAs. Innovative, new, groundbreaking surgically implanted medical devices for which there is no predicate device—an already existing, marketed device to which the new device must be determined to be substantially equivalent—must do so via this route exclusively. In the past, some surgically implanted medical devices have reached the market via the 510(k) clearance mechanism. Since these devices are prescription devices but not restricted devices (because they were not approved via a PMA nor specified as restricted by specific regulation), this creates a problem whenever these devices are advertised and promoted by the manufacturer. The reason for this is straightforward: the FDA has specific authority (by statute) to regulate advertising of restricted medical devices but does not have general statutory authority to regulate all other medical device advertising.¹⁸ This means that some surgically implanted device advertising cannot be regulated by the FDA if the device is not a restricted one. This could be the case for a complex, surgically implanted class III device that reached the market via 510(k) clearance because there was a predicate device on the market to which it was substantially equivalent, even if the two devices are so dissimilar that, under ideal circumstances, *de novo* clinical trials demonstrating efficacy and safety should be required. Although there are supposed to be calls by the FDA for submission of PMAs for such devices to correct this lag,¹⁹ the problem persists.

For those surgically implanted class III medical devices that have reached consumers via PMA and that have been appropriately

17. *Id.* §§ 352(e), 360j(f). Only a handful of medical devices have been specifically designated as restricted by separate regulation. One example is ASRs, specific reagents used for complex testing in certain laboratories. Another example is hearing aids. Restricted medical devices almost always are designated as such in the PMA.

18. *Id.* § 352(q)–(r).

19. *See id.* § 360e(a)(1), (i).

classified as restricted, the FDA has the statutory authority to regulate the advertising and promotion of such devices to consumers. In general, the advertising of such devices cannot be “false or misleading in any particular.”²⁰ For this reason, the general guidelines for medical devices mirror, though not exactly, those for prescription drugs.

Advertisements for medical devices, for which the FDA does have statutory authority to regulate the promotion of, must also do two things: (1) state the established name of the medical device; and (2) contain “a brief statement of the intended uses of the device and *relevant* warnings” and precautions regarding safety—side effects of the device, precautions when using the device, and contraindications for employing the device.²¹ These are minimum requirements; under the terms of the PMA, additional specific advertising restrictions or requirements may be imposed on the manufacturer.²²

The brief-statement requirement of the restricted medical device advertising requirement has undergone some adjustment by the FDA. The FDA issued draft guidance in 2004 to help medical device manufacturers who advertise their restricted medical devices directly to consumers.²³ It contained recommendations for content that closely mimics prescription DTCA requirements governing broadcast media such as television, radio, and telephone-based advertising.²⁴ DTCA would comply with the FDA’s guidance if it:

disclose[d] the most serious and most common risks associated with the device in either the audio or audio and visual parts of the presentation, and [made] adequate provision for dissemination of the approved package labeling in connection with the broadcast presentation (e.g., reprinting the labeling in magazine advertisements

20. *Id.* § 352(q)(1).

21. *Id.* § 352(r) (emphasis added).

22. *Id.* § 360e(d)(B)(ii).

23. U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA: CONSUMER-DIRECTED BROADCAST ADVERTISING OF RESTRICTED DEVICES (2004), *available at* <http://www.fda.gov/ohrms/dockets/98fr/04d-0042-gdl0003.pdf>. Although this draft guidance document has been withdrawn for administrative reasons, the underlying statutory provisions remain unchanged and so the steps discussed in the document are still relevant to industry for purposes of complying with the statutory requirements.

24. *See id.*; *see also* U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), *available at* <http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3627b2bl.pdf> (covering advertising of prescription drugs).

and/or providing an 800 number that viewers can call to request that it be read or mailed to them).²⁵

How well does this regulatory scheme play out in the real world? To answer this question, some data should be reviewed and commentary should be made about what the world of DTCA of restricted, surgically implanted medical devices looks like in the United States in 2012.

III. SOME OBSERVATIONS ON RESTRICTED, SURGICALLY IMPLANTED MEDICAL DEVICES DTCA: HOW MUCH IS OUT THERE, WHO IS DOING THE ADVERTISING, AND WHERE DOES THE ADVERTISING APPEAR?

At the time of this writing, there were no substantive data published in either medical literature or law journals on the prevalence and characteristics of the relatively new phenomenon of DTCA of restricted, surgically implanted medical devices. The topic of DTCA of medical devices, whether restricted, implantable, or otherwise, has without question been a below-the-radar-screen issue when compared to the decades-old controversy over DTCA of prescription pharmaceuticals. For example, the definitive casebook on food and drug law²⁶ devotes less than a paragraph to promotion of devices, whereas DTCA of prescription drugs merits more than fifty pages of text and commentary. The text, *Medical Device Regulation & Compliance*, edited by Terman and O'Flaherty, provides a definition of advertising and labeling and, later in the text, provides an accurate and concise summary of the statutory requirements that must be met by such advertising but otherwise does not discuss the topic in any depth.²⁷

This author's preliminary observations²⁸ in 2009 represented the first attempt to begin to define some of the legal issues surrounding this area of food and drug law. That publication explored some of the unique aspects of the involvement of the

25. Jeffrey K. Shapiro, *Labeling and Advertising of Medical Devices*, in *PROMOTION OF BIOMEDICAL PRODUCTS: REGULATORY CONSIDERATIONS* 1, 14 (Thomas E. Colonna & Jeffrey K. Shapiro eds., 2006).

26. See PETER BARTON HUTT, RICHARD A. MERILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* (3d ed. 2008).

27. Evan P. Phelps, *Medical Device Labeling and Advertising*, in *MEDICAL DEVICE REGULATION & COMPLIANCE* 23, 24, 32 (Stephen D. Terman & Neil F. O'Flaherty eds., 2010).

28. Bruce Patsner, *Problems Associated with Direct-to-Consumer Advertising (DTCA) of Restricted, Implantable Medical Devices: Should the Current Regulatory Approach be Changed?*, 64 *FOOD & DRUG L.J.* 1 (2009).

medical profession (physicians, surgical groups, hospitals) in advertising for high-technology, surgically implanted medical devices on behalf of industry; discussed some of the problems with the information gap consumers face in interpreting the information (if any) contained in an advertisement for a restricted, surgically implanted medical device;²⁹ and, lastly, commented at great length on current FDA guidelines and issues facing the FDA in regulating DTCA of devices. Aside from one sentence about state regulatory actions against physicians (and, by implication, hospitals and medical centers) who fraudulently promote the unproven efficacy and safety benefits of some devices, much of the focus was on potential First Amendment issues.

All well and good, but the relative scarcity of writing on DTCA of devices raises two other important issues, which have also not been addressed. The first is the paucity of information about the prevalence of DTCA of restricted, surgically implanted medical devices: How much advertising is an average consumer exposed to? Who is doing the advertising, and where is the advertising (television, radio, magazines, billboards) being done? In addressing this first question, it is important to keep in mind that we are talking about the promotion of medical devices to consumers, not to physicians.

The second question derives from the first question: If the advertising itself and the entity doing the advertising for restricted, surgically implanted medical devices differ significantly from the DTCA of prescription drugs, then whose regulatory problem is it, the FDA's or the states'? In other words, if most or all of the promoting is done not by the medical device industry itself, but rather by surrogates such as physicians, surgical groups, hospitals, and academic medical centers, then the FDA should not be held accountable for failing to police the promotion. And, if this is the case, then prevention of consumer fraud, not protection of the First Amendment rights of corporations against government encroachment, is where the battle line should be drawn.

A. *Prevalence and Publications*

During a three-month period of time when the author was consulting, traveling cross-country, living in three major metropolitan areas (New York, Houston, and Denver), and

29. *Id.* at 38.

researching and drafting this manuscript, a determined effort was made to look for any advertising for restricted, surgically implanted medical devices in the United States in order to get a sense of how much advertising of such devices an average adult might be exposed to, and how it compared to DTCA of prescription drugs.³⁰ Particular attention was paid to who was doing the advertising (surgeon or surgical group, hospital, medical center) and what medium such advertising appeared in. Travel during the summer of 2012 included airline flights (three flights from New Jersey to California, three flights from Texas to Colorado, three flights from New Jersey to Texas, and one flight from New York to Florida) and three cross-country drives (Colorado to Texas, Texas to Boston, and New Jersey to Colorado). With the exception of the Pacific Northwest, every area of the United States was visited. When not traveling, the author watched a minimum of six hours of non-cable television a day and listened to two hours of afternoon radio five days a week.³¹ Air travel involved a steady exposure to in-flight and airport magazines; interstate auto travel involved exposure to billboards. The Internet was specifically excluded from this observation set. No DTCA of restricted, surgically implanted medical devices was observed in any national newspapers, though the only paper read on a daily basis was *The New York Times*.

Although no effort was made to perform a definitive quantitative, statistical analysis of the differences among advertising for different medical products, three observations about DTCA of these select restricted medical devices could easily, and definitively, be made. Based on these observations, there are clearly some very unique aspects of the manner in which medical devices, particularly surgical and surgically implanted devices, are promoted to consumers when compared to the manner in which prescription drugs are advertised.

First, the amount of DTCA of medical devices one is exposed to on a daily basis is much, much lower than the amount one is exposed to of advertising to consumers for prescription drugs. During the ninety days of observation, fewer than three dozen

30. The number of advertisements in the United States for over-the-counter preparations involving the gastrointestinal tract and its manifestations—flatulence, diarrhea, constipation, hemorrhoids, and acid reflux—one is exposed to in three months simply defies mathematics.

31. The author does not recommend this level of exposure to advertising or television as part of a healthy lifestyle.

different medical device ads were seen compared to literally hundreds of drug ads seen each week. Average citizens are exposed to prescription drug promotions on a daily and constant basis whether one watches television, listens to radio, or reads magazines. Second, during three months of looking, the author was able to find only one DTCA for a restricted, surgically implanted medical device by the manufacturer itself;³² all other advertisements were by individual surgeons, subspecialty surgical groups, hospitals, or large medical centers.³³ This finding was not surprising. The notion of industry advertising by medical professional surrogates was emphasized in legal writings on DTCA of medical devices,³⁴ and it represents one of the major differences (other than sheer volume of advertising) between DTCA of prescription drugs and devices.

Third, and just as important as the phenomenon of surrogate advertising, is the medium in which DTCA of restricted, implantable medical devices takes place. Unlike advertising for prescription and over-the-counter drugs, which has an overwhelming presence on television,³⁵ DTCA of restricted,

32. This was an advertisement for an artificial knee by Stryker Corporation. The advertisement consisted of a group of elderly men attempting to bowl with oval bowling balls. The point of the advertisement was ostensibly to point out that since the human knee is round (not oval) the artificial knee you have implanted should be round as well. This advertisement contained no other vital information (efficacy, safety, or a picture of the actual artificial knee device itself) and assumed that (1) the human knee joint is round and (2) an average non-medical person would know this. Although an average person might know that the kneecap is round, it is not clear how the concept of round actually matches up to a joint that is a hinge. A similar ad is available online. See Stryker Corp., *GetAroundKnee Bowling TV Commercial*, YOUTUBE (July 26, 2012), <http://www.youtube.com/watch?v=anrTJMwED5I>.

33. The particular surgeons, surgical groups, hospitals, or academic medical centers are somewhat region-specific when one looks at billboard advertising and radio advertising, although it is not rare to find advertisements for nationally prominent medical centers (such as MD Anderson Cancer Center in Houston) and their technologies on billboards in neighboring states such as Oklahoma, Arkansas, and Louisiana from which they draw out-of-state patients. In-flight airline magazines, such as Southwest Airlines, carry advertisements for local surgical groups (depending on the route) as well as larger specialty groups and hospitals, which are attempting to expand their referral group nationally.

34. See Patsner, *supra* note 28, at 19.

35. There is a large amount of DTCA of prescription and over-the-counter drugs as well as dietary supplements in consumer magazines, though the drugs advertised depend on the magazines (e.g., birth control pills and hormone replacement therapy in women's magazines and erectile dysfunction drugs and supplements in magazines which men are more likely to read).

surgically implanted medical devices is a very rare occurrence on television. In the three-month period of observation of surgically implanted medical device advertisements, only one of the promotions took place on television; this was the solitary advertisement by the manufacturer itself. It is entirely possible to never see or hear DTCA for medical devices (particularly restricted, surgically implanted medical devices) on television or radio for months at a stretch.

However, if one travels on major interstate highways, particularly near large urban areas or near academic medical centers, one can see billboards for hospitals or academic medical centers advertising their cutting-edge medical technologies (e.g., gamma-knife radiation therapy units, robotic surgical systems, spinal implants). Billboard advertisements by the manufacturer of radiation therapy machines may also be observed in prominent places near passenger drop-off points at major airports, though these billboards are not for surgically implanted devices and provide no useful information other than the name of the company and a picture of the machine.³⁶ By contrast, highway billboard advertisements for prescription drugs are rarely seen. The one common area in which both prescription drugs ads and ads for restricted, surgically implanted medical devices are seen³⁷ seems to be in magazines, airline magazines in particular.

In summary, advertisements for restricted, surgically implanted medical devices are rarely television ads, are almost always by a member or institution of the medical profession that markets the device to prospective patients, and occur much, much less commonly than ads for prescription drugs. The ads themselves—the type of ad, the content of the ad, and the accuracy of the ad—as well as the FDA statutory requirements for content of a DTCA, will now be examined.

36. For example, the author has observed an advertisement at the Logan International Airport (Bos.) by Variant for their radiation therapy products.

37. For example, the August 2012 issue of *Spirit* (Southwest Airlines' in-flight magazine) contained no ads for prescription drugs, but it had medical device ads for Saint Thomas Hospital (Nashville, TN) and the Unity System for brain surgery (manufacturer not specified) as well as the infuriating spread of "the best Lasik Surgeons in America" with the disclaimer in small print at the top, "These doctors are among . . ." Advertising for surgeons, and advertising for medical devices, go hand in hand. Advertisement, *The Best Lasik Surgeons in America*, SPIRIT, Aug. 2012, at 123.

B. Content and Accuracy of Information

The content of the observed medical device advertisements to consumers appears to be diametrically opposed to that seen for prescription drug promotions. Perhaps because of who is doing the advertising—a surgical group, hospital, or academic medical center—the content of the advertisement is invariably limited to the name of the medical device product, often accompanied by either a picture of the device itself, a physician/surgeon who is presumably involved in using or inserting the device, or both, as well as the affiliate institution or medical group where they are based. The name of the manufacturer may or may not be prominently placed, and the indications (i.e., specific medical or surgical conditions for which patients might be able to judge if they are a suitable candidate) usually are absent. Most importantly, there is a universal absence of any information related to safety or risk.

In three months of constant travel and observation of (the few visible) restricted, surgically implanted medical device DTCA in the United States, the author did not see a single promotion that complied with the recommendations the FDA issued in its 2004 guidance document.³⁸ The only televised DTCA by the manufacturer of the medical device itself, which was observed during the entire ninety-day observation period by the author, was a New York City area prime-time advertisement by Stryker for its implantable artificial knee medical device. The advertisement comprised a group of elderly men at a bowling alley attempting to knock down pins with an oval, instead of a round, bowling bowl. The ostensible purpose of the ad was that the Stryker artificial knee was better than alternatives (not mentioned) because it was round instead of oblong, just like the knee. The ad failed to mention indications for use of the device, contraindications to use of the device, risks associated with insertion of the medical device, how long the device would last. The ad also did not contain an advisory warning (to talk to your physician/surgeon), contact information for the company, or a website to visit.³⁹

By contrast, a routine printed or televised prescription drug advertisement contains enormous amounts of printed or broadcast

38. See U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., *supra* note 23.

39. Stryker Corp., *supra* note 32.

safety information as well as the indications for the drug. The drug advertisements always have a 1-800 number to dial for more information about the drug, a website to go to in order to obtain safety and efficacy information about the drug, as well as the labeled indication for use of the drug, and a statement to contact your physician to discuss questions about whether the drug is right for you.⁴⁰ The absurdity of the medical device ad as either educational or informative, in addition to its gross failure to comply with regulatory requirements, is only exacerbated by the fact that the knee is a hinge joint and that the only structure in the knee that is ovoid (the knee cap or patella) is neither perfectly round nor oval (it's almost square) and has no equivalent structure in an artificial knee at all. This further assumes the average consumer would know something about the structure and function of the normal knee, or would have to mistakenly believe that the knee is round.

C. What Does the Limited Data Show?

There is no published data at the time of this writing on how accurate DTCA of restricted, surgically implanted medical devices is. There is some published data on the accuracy of DTCA of robotic surgical systems—complicated medical devices, which, though not restricted devices, are complex prescription devices that are temporarily inserted into the body during minimally invasive surgical procedures. The ability of hospitals and surgeons/surgical groups to offer advanced laparoscopic surgical services is a cornerstone of marketing advanced surgical programs in surgical oncology, gynecology, urology, and other medical specialties and, along with interventional cardiology services (coronary artery stents, minimally invasive aneurysm, and heart valve repairs) are among the most profitable items for hospitals, academic medical centers, and surgical specialty groups.

40. There are specific content requirements for DTCA of prescription drugs in broadcast media as well as the basic requirements for promotional labeling and prescription drug advertising contained in 21 C.F.R. § 201.100(d). *See also How Can an Ad Violate the Law?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/UCM076768.htm#law_violation_how (last updated Sept. 13, 2012). Though one might disagree with the degree to which pharmaceutical manufacturers strictly adhere to such guidelines and with the notion of whether DTCA should be allowed at all, there is little controversy at present with efforts of prescription drug manufacturers to provide safety risk information in their advertisements to consumers.

Many of the specialty surgical services noted use the da Vinci robotic surgical system developed by Intuitive Surgical, Inc.⁴¹ DTCA by surgeons and hospitals has been an ongoing activity for more than half a decade. At this point, some data has accumulated on how this particular prescription medical device is promoted to consumers in the field of women's cancer services, the surgical specialty that has the longest and most expansive experience with use of the medical device. The little data available is not encouraging. Because of current trends in marketing to consumers, all of the investigations have focused on internet-based promotions, such as hospital websites.

In a paper⁴² presented at the March 2012 annual meeting of the Society of Gynecologic Oncology—the oldest and most prestigious international organization in the world devoted exclusively to gynecologic cancer—investigators from Columbia University College of Physicians and Surgeons in New York City, and Carolinas Medical Center in Charlotte, North Carolina analyzed the content, quality, and accuracy of information provided on hospital websites about robotic gynecologic surgery. The study was a systematic analysis of randomly chosen hospitals with more than 200 beds; the chosen hospitals evaluated were predominately in (moving from east to west) New York, Pennsylvania, Georgia, Illinois, Colorado, and California.⁴³ The authors analyzed the promotions of a robotic surgical system medical device for information on clinical claims of effectiveness, assertions of institutional superiority, ease of access to information about the medical device, and use of emotionally driven marketing.⁴⁴ More than half of the advertising was for cancer-related conditions, and between one-half and two-thirds of the promotions used either stock photographs or stock narratives from the manufacturer.⁴⁵ One-third of the websites specifically mentioned the name of the company in promotions for da Vinci

41. See generally INTUITIVE SURGICAL, <http://www.intuitivesurgical.com> (last visited Jan. 25, 2013).

42. Maria B. Schiavone et al., *The Commercialization of Robotic Surgery: Unsubstantiated Marketing of Gynecologic Surgery by Hospitals*, 207 AM. J. OBSTETRICS & GYNECOLOGY 174.e1 (2012).

43. *Id.* at 174.e1–.e2.

44. *Id.* at 174.e2–.e3. The analysis in the paper was based on descriptive statistics. *Id.* at 174.e2.

45. *Id.* at 174.e2–.e3.

hysterectomy for benign surgical conditions.⁴⁶ Over 6% of promotions for gynecologic-cancer surgery specifically mentioned “improved cancer outcomes” despite a paucity of published data that demonstrates that patients who undergo robotic surgery, as opposed to more conventional surgery, actually have higher cure rates for their malignancy.⁴⁷

Superiority claims were supported by evidence-based data in fewer than 15% of advertisements.⁴⁸ Cost (3.7% of promotions), complications (1.6% of claims), and operating time compared to conventional surgery (3.7% of advertisements) were rarely, if ever, discussed.⁴⁹ The conclusions of the authors in this first-of-its-kind marketing analysis were that “[m]arketing of robotic gynecologic surgery [by hospitals] is widespread. Much of the content [of this marketing] is not based on high-quality data, fails to present alternative procedures, and relies on stock text and images” from the manufacturer of surgical robots.⁵⁰ Potential limitations and costs are rarely presented to patients.⁵¹ The low incidence of medical-device-related, complication-rate reporting and the virtual total absence of medical-device-related safety information strongly suggests that there is no realistic attempt for such DTCA to comply with the FDA statutory requirements.

Recent expert commentary⁵² by prominent academicians in obstetrics and gynecology has also pointed out that hospital promotions for robotic surgery on billboards and the Internet provide misleading information to patients and consumers. Much of the content of the promotions is provided by the manufacturers, does not provide accurate evidence-based information, and provides either false information about benefits and complications or ignores the risks and costs altogether. As things currently stand, manufacturers of devices do have to comply with statutory requirements for balance of information and content, but rarely have to do so since they rarely advertise; the medical groups need

46. *Id.*

47. *Id.* at 174.e3 (finding 6.3% of promotions described improved cancer outcomes and 9.4% of promotions described higher lymph node yields).

48. *Id.*

49. *Id.*

50. *Id.* at 174.e1.

51. *Id.* at 174.e3.

52. *See, e.g.,* Andrew M. Kaunitz, *The Promotion of Robotic Gynecologic Surgery by Hospitals: Are Our Patients Being Misled?*, MEDSCAPE (Oct. 12, 2012), <http://www.medscape.com/viewarticle/772325>.

not comply with statutory requirements for information and rarely bother to, even though they do almost all of the advertising.

IV. THE OTHER CORE ISSUE: INFORMATION AND EDUCATION

The focus in this article thus far has been on the structure of DTCA for prescription, restricted, surgically implanted medical devices in the United States. As has been shown, the amount of DTCA and the source of the advertising differ for medical devices and for prescription drugs. Even though the FDA statutory requirements are similar for broadcast and magazine promotions for drugs and devices, the former generally comply, while the latter do not.

All of this raises an interesting, though largely hypothetical, opportunity to analyze some of the restriction of commercial speech issues, which have plagued both the FDA and the pharmaceutical industry over the past twenty years, as they might apply to the medical devices industry. What if the medical device industry *was* to make a determined effort to actively do the majority of the DTCA of its products on its own without using hospitals and surgical groups as surrogates? What information should be contained in the ads in order to comply with the FDA regulations and recommendations regarding effectiveness and risks for the products? Would simply meeting the same requirements pharmaceutical manufacturers have to meet in broadcast advertisements (e.g., a 1-800 number, balanced presentation of risks and benefits with significant, safety issues emphasized, etc.) be adequate, or are there limitations on the availability of critical information that the medical-device industry cannot control that might prevent the manufacturers from ever being able to provide information about safety sufficiently educational for consumers? And if the ads cannot ever be adequately educational, do the promotions deserve the same level of commercial-speech protection as the promotions for prescription drugs by commercial-drug manufacturers? I will briefly address these issues prior to summing up my conclusions.

A comprehensive review of all of the information defects inherent in any attempt to provide information necessary to meet statutory requirements for a fair and balanced presentation of all of the relevant efficacy and safety issues for a complex, restricted, surgically implanted medical device is beyond the scope of this article. The following discussion may be viewed as both a summary

of the information that should appear and an explanation of why such information cannot appear (i.e., it is not available).⁵³

Consumers are generally unaware of the indications and characteristics of medical devices until they become patients. Unlike the packaging for prescription pharmaceuticals, there is no patient package insert⁵⁴ for restricted, surgically implanted medical devices for patients to read so that they may become familiar with the indications for the devices as well as the major safety risks and complications for the devices themselves. Most of these devices are employed by the physicians to whom patients are referred, so providing a statement in an advertisement that one should contact his or her physician is less meaningful in the context of a restricted, surgically implanted medical device. The primary care physician from whom the patient gets the referral is virtually never a surgeon and, unlike the situation with routine prescribing of prescription drugs, is unlikely to be familiar with the mechanics and problems with the device. General practice physicians are unlikely to know enough about complicated medical devices to be able to meaningfully counsel patients.

Physicians in medical school have extensive and mandatory exposure to pharmacology and pharmaceuticals from the first two years of medical school on, but no standardized instruction or exposure to complex medical devices until they do surgical rotations. Physicians, as a rule, know less about devices than they do about pharmaceuticals, just as consumers do. Surgeons (and consumers) themselves have no equivalent to the Physician Desk Reference for prescription drugs for prescription medical devices; there is no readily available source of information or compendium of medical device labels that may be consulted by patients prior to having such a device inserted into their body. Patients would need to be very familiar with the standard medical, non-surgical treatments of their medical conditions in order to know if and when they are appropriate candidates for surgically implanted medical devices.

There is no evidence that either consumers or physicians are aware of the contours of the medical device approval process at the FDA in general, or of the fact that some surgically implanted

53. Some of this material has been described in greater detail in the one existing law review article on the subject of DTCA of restricted Class III medical devices. See Patsner, *supra* note 28.

54. 21 C.F.R. pt. 201 (2012).

devices can be marketed in the United States without undergoing extensive testing for safety and effectiveness. Nor is long-term safety and efficacy data (e.g., how long will the newest type of hip implant last?) a routine part of the medical device marketing approval process, even if the device has a PMA—comparative effectiveness data is sorely lacking. Another complicating factor is that the approvals for drugs at the Center for Drug Evaluation and Research and biologicals at the Center for Biologics Evaluation and Research are at least almost always made by physicians, whereas at the Center for Devices and Radiological Health, the ultimate decision for devices is frequently made by non-medical personnel, such as engineers, who neither understand clinical medicine nor are trained to balance clinical medical efficacy versus patient medical safety.

Even if these defects—labeling; the medical device approval process; physician training and exposure to complex medical devices; the FDA's numerous problems with the way it approves or clears medical devices for marketing in the United States; and the virtual lack of long-term safety and device failure rate for restricted, surgically implanted medical devices—could all be corrected, there is still the problem of the lack of information on surgical and hospital experience, performance, and complication rates. There is a profound lack of reliable, useful information on surgical outcomes using devices for individual surgeons, surgical groups, hospitals, surgical centers, and academic medical centers, which can allow consumers to determine the comparative skill and safety for restricted, implantable medical devices. This is an inherent defect for both physicians and consumers, and unique for devices compared to drugs. In the absence of such information, fair balance and meaningful content requirements for a restricted, surgically implanted medical device for DTCA cannot be met.

Even this short list and discussion illustrates that there are significant obstacles to providing the requisite relevant safety and efficacy information for a complex medical device in a DTCA. Some of the defects, such as the lack of availability and transparency about surgeons and hospitals, are clearly outside the ability of either a medical device manufacturer or the FDA to access or control. This would be true even if referring physicians were eminently knowledgeable about medical devices and even if the problems in the medical device approval process did not exist. But, if the primary justification for protecting the commercial speech

rights of manufacturers of pharmaceuticals, vaccines, medical devices and other medical products regulated by the FDA is that the advertisements and promotions are educational and fully informative about relative risks and benefits,⁵⁵ the protection may not be deserved if the advertisements cannot be educational in the way in which DTCAs of prescription drugs are.

At present, the purported educational purpose of DTCA cannot be met because of the inherent information defects and limitations on information for consumers. All of this raises another interesting question, which is beyond the scope of this article but worth considering: Do consumers/patients lose anything by not being exposed to DTCA for medical devices? At present, there is no way to know. But one could argue that the absence of such advertising does not adversely impact overall consumer health and in fact might actually be of some benefit. DTCA of prescription drugs is illegal in all Western European countries and this does not seem to have adversely impacted the health of the patient population in those countries at all.

V. CONCLUSION: IS THERE A PROBLEM WITH DTCA OF MEDICAL DEVICES? IF SO, WHOSE PROBLEM IS IT AND HOW SHOULD IT BE SOLVED?

The medical device industry is likely going to continue to promote high-tech, profitable, restricted, surgically implantable medical devices directly to consumers in billboard and magazine advertisements for the foreseeable future via promotion by surgeons and hospitals/medical centers. The interests of the manufacturers and subspecialty healthcare providers are aligned because the promotion of high technology goes hand in hand with marketing and profits.

The volume of DTCA in television and other broadcast media (aside from the Internet) is minimal at the moment. One explanation for the relative paucity of broadcast advertising by medical device manufacturers is that they are content to let the

55. The *Central Hudson* test does not predicate its protection of commercial speech on the fact that advertisements must be truly educational, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), though one could argue that if advertisements are not educational at all then they are purely to generate demand for products. In fact, the Supreme Court has allowed potentially misleading information to survive so long as it is accompanied by a disclaimer. The Court does not cite evidence establishing the usefulness of disclaimers.

medical profession do most of the advertising for them. Another explanation is that television advertising may be too expensive for surgeons and hospitals to aggressively market in, unlike the pharmaceutical industry, which has vastly greater financial resources and is willing to devote up to twenty percent or more of its revenues to marketing activities. A third alternative is that the Internet is cheaper, easier, more widespread, and essentially unregulated. There is no substantive research on Internet-based advertising for the complicated restricted surgically implantable devices we have discussed here.

If medical professionals were required to meet FDA statutory standards for their advertisements, the information provided by the manufacturer in current advertisements would not be in compliance. There is no evidence, however, that this situation has created problems with the FDA for medical device manufacturers. It is a virtual certainty that these advertisements will never be able to meet the statutory requirements for either fair and balanced information or contain all of the relevant information that a consumer would need in order to make a truly educated decision regarding the appropriateness of the device for themselves even if the medical device manufacturers decided to do most of the advertising themselves. The reasons for this are not completely under the FDA's or the medical device industry's control because, unlike pharmaceuticals, it is impossible to separate effectiveness and safety of a device from the surgeon and affiliate institution due to an almost total lack of transparency. Even if there were transparency of medical provider/institution performance and safety information, there is still the lack of safety information for those devices reaching consumers via 510(k) clearance.

The deficiencies in information are global in the sense that they apply to all restricted medical devices that are implanted by surgeons in health care facilities (hospitals or surgical centers) and insurmountable in the sense that there is no way to separate the effectiveness and safety of the device from either the non-surgical alternatives or the competence and safety of the surgeon and the facility. The lack of transparency of information regarding the comparative effectiveness of competing medical devices, of devices versus non-surgical alternatives, or of meaningful, accurate information on the relative abilities and outcomes for surgeons simply makes the matter worse.

If most of the advertising for these complex devices is done by the medical profession, not industry, the burden of responsibility for protecting patients and consumers from misleading, false, or grossly inadequate advertising is not the FDA's problem, but rather falls on the individual states, and their respective state medical boards and attorneys general. Unlike the situation in advertising and promotion for prescription pharmaceuticals, the main problem is not the First Amendment and attempts by the FDA to protect public health by restriction of manufacturers' commercial speech. The problem in advertising of restricted, surgically implanted medical devices is consumer fraud and the regulation of the medical profession at the state level.

Whether the situation whereby the medical profession does virtually all of the advertising and promotion to consumers exists because it is easier or cheaper; or because of the structure and competition among hospitals; or because of the close ties or capture of the medical profession and hospitals by the medical devices industry; or because the industry has determined that it can make an end-run around the regulations by letting medical surrogates do the advertising; or if it is because medical device manufacturers have determined that information defects cannot be overcome if they do the advertising; or some combination of these is unknown. What is known is that DTCA of complex, restricted, surgically implanted medical devices is very different than that for prescription drugs. So different, in fact, that neither the FDA nor the First Amendment are where the enforcement battles are likely to (or should) be fought.