



**Statement**

of

**Kevin J. Bozic, MD, MBA**
Member At-Large, Board of Directors
Chair, Health Care Systems Committee
American Association of Orthopaedic Surgeons
(AAOS)
American Association of Hip and Knee Surgeons
(AAHKS)
Associate Professor
University of California, San Francisco
Department of Orthopaedic Surgery and
Philip R. Lee Institute for Health Policy Studies

on

# Marketing or Medicine: Are Direct-to-Consumer Medical Device Ads Playing Doctor?

**Presented to the**
**Special Committee on Aging**
**U.S. Senate**

**September 17, 2008**

Good morning, Chairman Kohl, Ranking Member Smith and other distinguished members of the committee. My name is Dr. Kevin Bozic, and I speak to you today as a practicing orthopaedic surgeon and a health care services researcher from the Department of Orthopaedic Surgery and the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco.

I am also a member of the Board of Directors for the American Association of Orthopaedic Surgeons (AAOS) and the American Association of Hip and Knee Surgeons (AAHKS), and Chair of the AAOS Health Care Systems Committee. On behalf of the AAOS and the AAHKS, I thank you for providing me the opportunity to testify before you today on the issue of direct-to-consumer advertising (DTCA) of medical devices. This issue is of particular interest to me both as a practicing clinician and as a health care services researcher, and during the course of my testimony I will be referring to a 2007 study which I authored on the impact of direct-to-consumer advertising in orthopaedics.[1] The DTCA of medical devices and is just beginning to be scientifically studied, and there is sparse data in the published literature. This type of advertising proliferates on television, in print media such as newspapers, magazines, billboards, as well as on the Internet.

***Overview of Marketing in Medicine***

The Food and Drug Administration (FDA) regulation of DTC advertising began with the Federal Food, Drug and Cosmetic (FD&C Act) of 1938. However, prior to 1980, pharmaceutical manufacturers and representatives primarily directed their marketing efforts to health care professionals.

During the 1980's, the first print pharmaceutical advertising designed for consumers was distributed. The FDA instituted a moratorium on this practice in 1983, which was eventually lifted in 1985.[2] However, pharmaceutical companies did not resume DTC advertising efforts until around 1990. In 1997, the FDA issued a draft guidance document and a final guidance in 1999[3] on consumer-directed broadcast advertisements. The Agency required that advertising of medical products must not be false, misleading, or lacking in material fact. Additionally, the guidance stated that advertisements must present a fair balance of the risk and benefit information.

The 1999 guidance applies to marketing efforts for product specific advertising for prescription human and animal drugs and biological products for humans. The consumer-directed broadcast advertisement guidance is not intended to address the advertising of medical devices. As soon as this guidance was finalized, DTCA efforts increased significantly in 2000 and included the advertising of medical devices and technologies to orthopaedic consumers and patients.

Over the past decade, DTCA has increased dramatically with advertisements from medical device and pharmaceutical manufacturers, over-the-counter drugs, hospitals, insurers, providers, and fitness centers[4] all attempting to increase their market share.

In February of 2004, the FDA issued the first guidance for the DTCA of restricted medical devices.[5] At the same time, the FDA issued a guidance document on "help-seeking" communications by or on behalf of drug and device firms[6] in addition to a guidance document on the brief summary requirements for DTCA to disclose risk information in print media.[7]

DTCA offers manufacturers the opportunity to promote products and services directly to the patient, bypassing all other parties involved in the decision and authorization chain. When manufacturers advertise directly to the patient, it is the patient who then demands the product from their surgeon, who in turn makes a product demand of the manufacturer. While marketing activities are not always 100% successful, directing the marketing efforts to the larger audience will drive demand for the product to the surgeon through the patient.[8]

Proponents argue that DTCA offers many benefits by enhancing patient education efforts to create more informed patients, empowering patients with information regarding their health conditions and potential treatment options, de-stigmatizing certain health conditions, calling attention to untreated disorders, encouraging efficient dialogue between patients and physicians, and encouraging treatment adherence and compliance with treatment plans. Conversely, opponents claim that DTCA does not educate consumers, because the information contained in DTC ads is biased and misleading, and benefits of the drug or device are exaggerated and risks are at best downplayed.[6]

Additionally opponents argue that DTCA significantly strains the doctor-patient relationship by increasing the length of office visits and diminishing the role of the physician in clinical decision making.[9, 10] Opponents also contend that patient pressure could lead to excessive or inappropriate resource utilization and that clinicians could be led to venture outside their "comfort zone" in order to satisfy inappropriate patient requests for specific treatments. [2,9, 10, 11]

The AAOS continues to have concerns about the DTCA of restricted medical products. In 2004, AAOS appointed a Board of Directors level Task Force and issued a position statement on device and drug DTCA issues. The AAOS continues to examine DTCA and its subsequent effects on the physician-patient relationship and believes in the primacy of the physician-patient relationship. Physicians and patients are partners in health care and must reach informed decisions together.

"***Help-seeking" Advertising***

"Help-seeking" advertising should be differentiated from specific product endorsement advertising and may provide patients with useful educational information. The AAOS holds patient education as one of its most important objectives. *Your Orthopaedic Connection* on the AAOS' home page is an objective information source for patients, containing diagrams, text, and brochures written specifically for patients. Additionally, the AAOS has produced many patient education videos to generate a dialogue between patients and surgeons about what patients can anticipate during fracture care, joint

replacement surgery, or during the treatment of soft tissue injuries, amongst other orthopaedic procedures.

The National Institutes of Health (NIH) consensus conferences on Total Knee Replacement (2003) and Total Hip Replacement (1994) found strong evidence of disparities between racial and ethnic groups in content knowledge and surgical rates and that these underutilized therapies could greatly enhance the quality of life. According to a consensus report published by the NIH in 2004, only 9% to 13% of patients who potentially could benefit from a joint arthroplasty actually receive this highly effective treatment.[12] The AAOS realizes that there are significant health disparities in the U.S. and that education plays a vital role in bringing needed therapies to patients. "Help-seeking" advertising may aid in generating educational material and stimulate a patient to research their health condition and seek all available options with their health care practitioners.

***Differences between DCTA of drugs and DCTA of devices***

Although the effects of DTCA related to drugs have been studied extensively, there are substantial differences between DTCA related to pharmaceutical products and medical devices which make extrapolating the findings or conclusions inappropriate and misleading. First, there is a substantial difference in price between medical devices and prescription drugs. Second, medical devices are usually sold to hospitals, although surgeons are the primary decision makers and end users. Unlike prescription drugs, early adopters of new medical technologies, including physicians and hospitals, often promote their use of these technologies in an attempt to differentiate themselves in a competitive marketplace to attract patients who seek treatment from "high tech" or "cutting-edge" providers. However, when a surgeon decides to use a new device in their practice, additional training is often recommended, and there is a learning curve effect that can be associated with a higher rate of complications. Finally, the potential adverse consequences to the patient and the surgeon are considerable if an inappropriate or unfamiliar device or surgical technique is used, the choice of implant or procedure cannot be easily substituted if the result of surgery is unfavorable.

DTCA of devices may not inform patients about the differences in product design, composition of materials, strength of the devices, or proper clinical indications. Potential patients may not have access to post-market surveillance data or understand issues relating to device performance and safety. Surgeons choose devices to meet an individual patient's needs. For example, implant wear is a significant issue with devices used by orthopaedic surgeons. Patients may not be aware of the appropriateness of certain devices for their particular health conditions or health status.

There is considerable variability in medical devices beyond the FDA's Class I, II, and III distinctions. Some medical devices dissolve within the body, such as wrinkle fillers, other devices can be applied to the surface of the body and are removable, such as contact lenses, while many devices are surgically implanted and may be intended to reside within the patient for the lifetime of the patient. Surgically implanted devices have the gravest

consequences for the patient and surgeon should the device prove to be less than optimal. Nonetheless, the AAOS is not aware that the FDA makes that type of distinction when reviewing product advertising.

***DTCA lacks fair balance of benefit and risk information***

The practice of marketing medical devices directly to the consumer rather than to the physician has become the subject of significant debate. Many advertisements are incomprehensible to the American public, which studies have shown on average read at an eighth grade reading level.[13] Most information, particularly in print advertisements, is edited from the FDA approved labeling requirements targeted to health care professionals. Side effects and risk information are often formatted on the back of a print advertisement and are therefore, generally neglected by readers. Additionally, the font size of the print advertisement is significantly smaller when conveying risk information as opposed to the benefit information. Smaller font size is particularly difficult for seniors to read as their vision becomes less acute during the aging process.

The lack of fair balance in describing benefit and risk information in advertising is problematic. Potential benefit information is typically presented in layman's terms whereas risk information is downplayed by using medical jargon, using a very small font size, or increasing the speed of delivery of information in a voice-over announcement. Therefore, risk information is often not read, not comprehended, nor sometimes even reasonably visible.

***Increased spending, utilization, and sales***

Increasing procedure volume and costly new implant technologies have led to concerns among health policy makers regarding the costs associated with hip and knee replacement procedures, which currently represent the largest single procedural cost in the Medicare budget. As mentioned previously, the literature on DTC marketing and advertising of medical devices is just beginning to accrue. However, if we examine the published literature on drugs, we find evidence of the DTCA of drugs increases pharmaceutical sales.[14]

In 2005, U.S. health care spending grew 7.4 % to over $2 trillion dollars; much of that growth was attributable to increased spending on prescription drugs. Increased drug spending is due to three factors: increased utilization, increased prices, and the use of new, expensive medications.[15] DTCA is relegated to a concentrated subset of medications which tend to be the best selling drugs[16] with the top ten drugs accounting for 36 % of all DTCA spending in 2001.[17] According to a 2002 Government Accountability Office report, DTCA increases prescription drug sales and utilization.[18] DTCA also increases the sales in the entire class of drugs. For example, prescription drugs used to treat allergies would all increase in sales in response to the DTC advertisement of one allergy medication.

In a time of necessary fiscal responsibility, David M. Walker, former Comptroller General of the U.S., in testimony before the Budget Committee of the House of Representatives, listed health care expenditures as the biggest driver of the long-term fiscal challenge facing this nation.[19] In light of the national expenditure on Medicare Part D benefits, the cost-effectiveness of pharmaceutical medications is particularly important for long-term fiscal considerations.

***DTCA in Orthopaedics***

In our 2007 published study,[1] my co-authors and I evaluated the influence of DTCA in orthopaedics by surveying practicing orthopaedic surgeons who perform hip and knee replacement procedures and patients who where were scheduled to undergo hip or knee replacement surgery. The goals of our study were to evaluate the impact of DTCA on consumer demand, health services resource utilization, and the doctor-patient relationship in orthopaedics, including patient and surgeon awareness of and exposure to DTCA, their level of satisfaction with the quality and accuracy of information provided in DTCA, and their general opinions of the value of DTCA.

We found that DTC ads had a substantial influence on both patient and surgeon decision making. However, we also found that patients and surgeons differed considerably with respect to their opinions on the value of DTCA as a source of information regarding hip and knee replacement surgeries. The majority of surgeons believed patients who were exposed to DTCA were confused or misinformed about the appropriate treatment for their condition, had unrealistic expectations regarding the benefits of a specific type of procedure or implant, and requested types of surgery or implants that were not appropriate for them, whereas less than 1⁄3 of surgeon respondents believed patients who were exposed to DTCA were more educated regarding their condition or their treatment options.

In contrast, the majority of patient respondents believed advertisements educated them about their medical conditions and helped make them more aware of new technologies, joint implants, or types of surgeries, and only 18% of patients thought advertisements confused them about the appropriate treatment for their condition.

The differences between surgeon and patient perceptions of DTCA found in our study underscore the need to improve the dialogue between patients and surgeons regarding the treatment options for their condition to facilitate true shared decision making.

Some of the important findings of our study include:

- Greater than 98% of surgeon respondents had experience with patients who were exposed to DTCA.

- 74% of surgeon respondents believed that DTCA negatively impacted their relationships with their patients.

- 78% of surgeons believed that their patients were confused or misinformed about the appropriate treatment for their condition based on an advertisement, and 84% of surgeons believed patients who were exposed to DTCA had unrealistic expectations regarding the benefits of a specific type of procedure or implant.

- In contrast, only 18% of patients believed that DTC ads confused them about the appropriate treatment for their condition, and only 37% of patients believed that such ads were misleading in their claims.

- Only 5% of surgeons believed patients were more educated regarding the specific risks and benefits of joint replacement surgery as a result of exposure to DTCA, while the majority of patients surveyed believed that advertisement were helpful in educating them about potential health conditions and their treatment options.

- 52% of surgeons indicated that at times they felt pressured to use a particular brand of implant based on a patient request, and 74% of surgeons believed patients who had been exposed to DTCA at times tried to influence their treatment in a way that could be harmful to them,

- 60% of patients indicated that they had formed an opinion about the type of surgery or specific implant that was appropriate for them *before* consulting with a doctor, and 52% of patients indicated they were more likely to request a specific type of surgery or brand of implant from their surgeon after seeing or hearing an advertisement.

***2006 American Orthopaedic Association Annual meeting symposium on DTC Marketing***

The use of orthopaedic products requires a high level of clinical judgment, and it is that judgment that needs to be conveyed to the patient. Potential negative consequences of a patient-desired but inappropriate therapy may be significant since a poor outcome cannot be easily corrected. Influence on a surgeon to select an implant with which they lack familiarity may adversely affect the outcome of the surgical procedure.

Efforts to motivate patients to see physicians are most effective when the information conveyed in the DTCA truly informs, sets realistic expectations, and is not confusing to the consumer. Conversely, if a patient requests a specific treatment that the physician does not use or recommend, the patient's interaction with the manufacturer of that specific product has complicated their relationship with that physician. A survey on DTCA of attendees at a 2006 orthopaedic annual meeting was conducted as part of a symposium.[8]

Some of the findings of that survey include:

- DTCA seems to play a substantial role in surgeon and patient decision making in orthopaedics.

- 94% of attendees thought that DTCA would set unrealistic expectations regarding the potential benefits of a particular medical device, drug, or procedure.

- 84% of attendees believed that DTCA of orthopaedic products or procedures changes physicians' practices.

- Surgeons were concerned that a patient would change surgeons if the surgeon was unwilling to provide a specific brand of implant requested by a patient. Only 12% of attendees felt that no patient would switch surgeons while 88% of attendees felt that patients would change surgeons if the surgeon was unwilling to provide a specific brand of implant.

***Creation of a National Hip and Knee Implant Registry***

In general, surgeons have not reached consensus on the relative merits or performance of a particular medical device over another. Therefore, product specific DTC advertisements related to hip and knee replacement implants are presented out of context when they advocate for one particular device without presenting the range of product options or treatments. Only after collecting sufficient data in a rigorous manner could an evidence-based claim be made that a particular device offers relative benefits over another one in terms of implant longevity or patient function. Long term data collected over twenty years (or longer) may be needed to define optimal product performance and design characteristics. In this regard, the AAOS continues to work with other health care stakeholders in its efforts to develop a national hip and knee registry. The goals of this registry are to improve patient outcomes, decrease revision rates, and allow earlier identification of poorly performing implants. The U.S. joint replacement registry is intended to define best practices and provide an early warning system for hip and knee implants. A similar joint replacement registry in Sweden cut revision surgery rates in half by identifying best surgical practices and best-performing implants in total joint replacements.[20] A ten percent decrease in the number of revision hip and knee arthroplasties in 2005 would have saved the Centers for Medicare and Medicaid Services (CMS) over $100 million that year.

***Recommendations***

The Internet and the World Wide Web have led to a new generation of technologically savvy and empowered health care consumers who are taking a more active role in finding the best solution for wellness and health care. As surgeons, we applaud efforts by our patients to educate themselves regarding their health conditions and their potential treatment options. However, we believe it is important for patients to evaluate the source and the accuracy of information on which they base their opinions. Sound health care information that is supported by scientific evidence has the potential to enhance the dialogue between physicians and their patients and improve patient satisfaction and the overall quality of care we deliver. However, as our research has shown, biased information contained in direct-to-consumer advertisements promoting specific products

which are not supported by scientific evidence has the potential to cause tremendous harm to the doctor-patient relationship, to create unrealistic expectations among patients, to lead to overutilization of inappropriate and costly unproven medical technologies, which could have dire and expensive public health consequences.

While the marketing of medical devices directly to consumers continues to evolve, we believe that more scientific study needs to be conducted on the effects of medical device marketing on physicians and patients. Furthermore, the different advertising mediums, including newspapers, magazines, the Internet, television, and billboards may necessitate different levels of scrutiny from federal authorities. The AAOS and AAHKS believe that the DTCA of restricted medical products has the potential to create a distorted market, and therefore, we support greater restraint from the medical device industry and greater oversight from the FDA.

The AAOS and AAHKS offer the following specific recommendations to the Committee as it examines the consequences of the DTCA of medical devices.

1. We support ongoing research into the effects of DTCA on the physician-patient relationship, health care utilization and spending, patient safety, and cognitive science.

2. We support disease awareness and help seeking ads which seek to educate patients about their health conditions and the treatment options available to them, rather than product specific advertising. Claims made in product specific advertising related to medical devices are biased, frequently not supported by scientific evidence, and contribute to unrealistic patient expectations and inappropriate requests for specific procedures or implants, which may have grave public health consequences. Furthermore, product specific advertisements have the potential to strain the doctor-patient relationship and lead to inappropriate utilization of specific medical devices or surgical procedures.

3. We support the presentation of a fair balance of risk and benefit information in DTCA of medical devices.

4. We recommend that health care stakeholders should work together to improve the quality and accuracy of information contained in consumer-directed advertisements related to medical devices and surgical procedures.

5. We support increased resources for the FDA, in particular in the area of medical device advertising. AAOS is pleased that the FDA Science Board report has fueled the debate to substantially increase appropriations for the Agency.

6. We support an increased oversight from the FDA Center for Devices and Radiological Health advertising review staff on the DTCA of medical devices.

7. We recommend that the FDA track their reviews of the DTCA of medical devices and should prioritize their reviews.

8. We support a prohibition on DTCA and marketing of restricted medical products to children.

**********

I appreciate the opportunity to share our views with the Committee on issues related to the DTCA of medical devices, and I look forward to answering any questions you may have.

---

[1] Bozic, K.J., Smith, A. R., Hariri. S. et al. The Impact of Direct-to-Consumer Advertising in Orthopaedics. Clin Orthop Relat Res. 2007; May:458:202-19.
[2] R.A. Bell, R.L. Kravitz, M.S. Wilkes. Direct-to-consumer prescription drug advertising, 1989-1998: A content analysis of conditions, targets, inducements, and appeals. J Fam Pract. 2000;49, 329-35.
[3] Food and Drug Administration. Guidance for Industry: Consumer Directed Broadcast Advertisements. Division of Drug Marketing, Advertising and Communications, Aug.1999. Available at: http://www.fda.gov/cder/guidance/1804fnl.htm.
[4] Lyles. A. Direct Marketing of Pharmaceuticals to Consumers. Annual Reviews Public Health 2002; 23:73-91.
[5] Department of Health and Human Services, U.S. Food and Drug Administration. Draft guidance for industry and FDA consumer-directed broadcast advertising of restricted devices. February 10, 2004. Available at http://www.fda.gov/cdrh/comp/guidance/1513.pdf.
[6] Food and Drug Administration. Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms, Division of Drug Marketing, Advertising and Communications, Feb. 2004. Available at http://www.fda.gov/cder/guidance/6019dft.pdf
[7] Food and Drug Administration. Guidance for Industry: Brief summary: Disclosing risk information in consumer-directed print advertisements, Division of Drug Marketing, Advertising and Communications, Feb. 2004 Available at: http://www.fda.gov/cder/guidance/5669dft.pdf
[8] Schaffer, J.L, Bozic, K.J., Dorr, L.D., Miller, D.A., Nepola, J.V. An AOA Symposium: Direct to consumer marketing in orthopaedic surgery: boon or boondoggle. To be published in the J. Bone Joint Surg. Am.2008.
[9] Zachary, W.M., Dalen, J.E., Jackson, T.R. Clinicians' responses to direct-to-consumer advertising of prescription medications. Arch Intern Med; 2003: 163, 1808-12.
[10] Mintzes, B., Barer, M.L., Kravitz, R.L. Bassett, K. et. al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. Can Med Assoc J. 2003; 169, 405-12.
[11]. Bell, R.A., Kravitz, R.L., Wilkes, MS. Direct-to-consumer prescription drug advertising and the public. J Gen Intern Med.1999;14, 651-7.
[12] National Institutes of Health. NIH consensus statement on total knee replacement December 8-10, 2003. J Bone Joint Surg Am. 2004;86:1328-1335.
[13] Kutner, M, Greenberg, E, Jin, Y, Boyle, B, Hsu, Y, Dunleavy, E. Literacy in Everyday Life: Results from the 2003 National Assessment of Adult Literacy. April 2007. US Department of Education, NCES 2007-480.
[14] Donohue JM, Cevasco M. A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med. 2007. Aug 16;357(7):673-81.
[15] U.S. General Accounting Office. Prescription Drugs- FDA Oversight of Direct-to-Consumer Has Limitations. GAO-03-177, Oct. 2002.
[16] Ma, J, Stafford, RS, Cockburn, IM, Finkelstein, SN. A Statistical Analysis of the Magnitude and Composition of Drug Promotion in the United States in 1998. Clin Ther 25(5):1503-17, 2003.
[17] Impact of Direct-to-Consumer Advertising on Prescription Drug Spending. Kaiser Family Foundation. June 2003.
[18] Ibid, GAO-03-177.
[19] U.S. Government Accountability Office. 21st Century Addressing Long-Term Fiscal Challenges Must Include a Re-examination of Mandatory Spending. GAO-06-456T, Feb. 15, 2006.

[20] Malchau, H et al. The Swedish Total Hip Replacement Register.2002. J. Bone Joint Surg. Am., 84:2-20.