
**Testimony of Ami Gadhia**

**Concerning the Direct-to-Consumer Advertisements for Implantable Medical Devices**

**Special Committee on Aging**

**United States Senate**

**September 17, 2008**

Good morning, Chairman Kohl, Ranking Member Smith, and members of the Committee. My name is Ami Gadhia, and I am Policy Counsel with Consumers Union[1], the non-profit publisher of *Consumer Reports* magazine. I am here today to testify about direct-to-consumer (DTC) advertisements for implantable medical devices and the safety and health concerns related thereto. Consumers Union commends the Committee for holding today's hearing on this critical consumer safety issue.

## I. INTRODUCTION

Most people are familiar with direct to consumer, or "DTC" advertisements for prescription drugs. We see them on television almost every day, marketing a broad array of pharmaceuticals. Now, DTC ads for implantable medical devices[2] such as knee and hip replacement hardware and heart valves, are also appearing on our televisions. Unfortunately, injuries and deaths related to medical devices are also manifesting themselves. In a December 2007 article entitled, "Medical devices: Problems on the rise," our publication *Consumer Reports* noted that "reports of deaths linked to medical devices are at an all-time high, with 2,712 fatality reports in 2006, more than double the number in 1997."[3]

The *Consumer Reports* article also notes that in September 2007, "FDA issued its own report for its fiscal year 2006, saying it had seen a 25 percent increase in adverse events linked to medical devices over FY 2005, including 2,830 deaths, 116,086 injuries, and 96,485 device

[1] Consumers Union (CU) is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and its other publications and websites have a total subscription of approximately 8.6 million. *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] This testimony pertains only to *implantable* medical devices, and not to medical devices such as bandages or contact lenses.

[3] "Medical Devices: Problems on the rise," *Consumer Reports*, December 2007.

malfunctions."[4]

A number of studies show significant injury, including healthcare-acquired infections (HAIs), following implant surgeries. Both HAIs and device failure can and do cause death or serious morbidity and expense.

These injury and death statistics point to the need for regulation of the claims made in, and the warning information transmitted through, the advertising of the devices. While FDA review and regulation of DTC prescription drug advertisements are still in their infancy, the agency currently conducts almost no oversight of DTC advertisements for implantable medical devices. Consumers Union thus strongly urges Congress to require FDA to conduct the same oversight and regulation of DTC ads for implantable medical devices as the agency is now authorized to do for DTC drug ads as well as expand their review of all of these ads. I will explain the scope of the problem with DTC advertising for medical devices, and then I will discuss CU's recommendations to address the problem.

## II. DANGERS ASSOCIATED WITH IMPLANTABLE MEDICAL DEVICES

### A. Studies show significant injury, morbidity, and mortality following implant surgeries

In June 2006, *Consumer Reports* published an article entitled, "Joint replacement: 1,001 patients tell you what your doctor can't," in which we noted that:

> "Five percent of respondents reported getting an infection shortly after surgery, a significantly higher rate than reported in some major studies."

The aforementioned December 2007 *Consumer Reports* article again makes the point that there are serious consumer issues with the placement and use of some of these devices.

[4] See footnote 3.

The CDC's National Nosocomial Infections Surveillance (NNIS) System Report clearly shows hip and knee prosthesis surgery to be a serious source of infection, in some cases a high-risk source, and in some of the NNIS reporting hospitals, the infection rate may run as high as 5 percent or more.[5]

Considering deadly Methicillin-resistant *Staphylococcus* aureus (MRSA) infections alone, according to the Agency for Healthcare Research and Quality (AHRQ), 'complication of device, implant or graft' was the third most common of the 'principal diagnoses for hospital stays with MRSA infection in 2004'. While this category includes skin grafts, clearly devices and implants contribute to the total of 23,500 reported 'stays with MRSA infection' for 2004.[6]

Between 1991 and 2001 a study was performed on the 222,684 cases of total knee replacements in California. In the first 90 days of discharge, the study found 1,176 deaths (0.53% rate), 1,586 infections (0.71%), and 914 pulmonary emboli (0.41%). The rates were significantly higher when surgery was performed in low-volume hospitals or on above-average age or patients with other complicating conditions.[7]

A 2007 Health Affairs article (citing a Medline Plus website) stated:

> More than 600,000 total knee replacements (TKRs) are performed worldwide each year; this number will likely rise because of the aging population and the expanding clinical indications. In most cases, TKR can relieve a patient's knee pain, increase the joint's range of motion, and improve quality of life. Nevertheless, the surgery carries risks of potentially life-threatening complications, including anesthesia-related problems, wound and joint infections, deep venous thromboses, injury to nerves and blood vessels around the knee, and the potential for future surgical revision.[8]

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[5] NNIS System Report, data summary from January 1992 through June 2004, issued October 2004. Am J. Infect Control 2004; 32:470-485.

[6] AHRQ, Healthcare Cost and Utilization Project (H-CUP) Statistical Brief #35, July 2007, p. 8.

[7] SooHoo Nelson F; Lieberman Jay R; Ko Clifford Y; Zingmond David , "Factors predicting complication rates following total knee replacement," J Bone Joint Surg Am 2006 Mar; 88(3): 480-485.

[8] Peter Juhn, Audrey Phillips, and Kathy Buto, "Balancing Modern Medical Benefits and Risks," Health Affairs, Vol. 26, No. 3, May/June 2007, p. 648.

Our own review of the ads currently being aired also indicates to us that the target population for these devices is getting younger. For this younger population in particular, the expected lifespan of a device is a critical piece of information.[9]

Another recent study reviewed 2003 nationwide U.S. data to determine the incidences of primary total, partial, and revision hip replacements, and to assess short-term outcomes and factors associated with those outcomes.[10] This study found about a third of a million such hip procedures. The in-hospital mortality rates associated with these three procedures were 0.33%, 3.04%, and 0.84%, respectively. The perioperative complication rates associated with the three procedures were 0.68%, 1.36%, and 1.08% respectively, for deep vein thrombosis or pulmonary embolism; 0.28%, 1.88%, and 1.27% for decubitus ulcer; and 0.05%, 0.06%, and 0.25% for postoperative infection. Rates of readmission for any cause within 90 days ran between 9% for total replacement to 21% for partial. These are very serious operations, infections occur, and consumers need to consider these side effects.[11]

### B. Real-life examples from people who suffered deadly infections after knee and hip replacement surgery

For approximately four years, Consumers Union has been working through its Stop Hospital Infections campaign at the state level to enact legislation to require hospitals to publicly report their healthcare acquired infection rates. To date, 24 states have enacted public disclosure and anti-infection laws. These laws vary in their details, but they all are designed to empower consumers and health care providers to call attention to the HAI problem and to take steps to lower the rate of infection.

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[9] http://www.knbc.com/health/13213147/detail.html; http://www.journeytkr.com/commercial.cfm

[10] Zhan Chunliu; Kaczmarek Ronald; Loyo-Berrios Nilsa; Sangl Judith; Bright Roselie A., "Incidence and short-term outcomes of primary and revision hip replacement in the United States," J Bone Joint Surg Am. 2007 Mar; 89(3): 526-33.

[11] See footnote 10.

We are also working at the Federal level in support of legislation to establish a national HAI reporting program (HR 1174) and to call special attention to the growing problem of infections caused by MRSA (HR 4214/S 2278).

Our Stop Hospital Infection campaign has been fueled by the experiences and stories of our readership. We have accumulated approximately 2,000 stories of individuals and family members who have suffered injury and often death due to HAIs. A significant number of these cases occurred following hip and knee transplantation surgery. Many of these stories demonstrate that these HAIs have resulted in terrible pain and suffering, and in too many cases, death.

## III. THE NEED FOR FDA REGULATION AND OVERSIGHT OF DTCA FOR IMPLANTABLE MEDICAL DEVICES

### A. Examples of Advertisements that Fail to Provide Adequate Warnings of Side Effects, and Especially Fail to Warn of Infection

A Wall Street Journal article published April 10, 2007, entitled "New Medical-Device Ads; Old Concerns, Can a Knee Implant Be Sold This Way. And Should It Be?" describes the growth of medical device direct-to-consumer (DTC) ads. The warnings of side effects are generally non-existent or minimal, saying such things as 'there are potential risks' and 'potential for complications.' We found no advertisement that advised consumers of the very real possibility of deadly infection or to seek out surgical facilities with low infection rates.

For example, while Biomet's website lists a separate risk page and seems unusual in giving a full paragraph to possible complications, their website video advertisement (http://www.biomet.com/patients/oxford.cfm), featuring Mary Lou Retton, fails to mention (as of September 11, 2008) infection or how serious the side effects can be.

Other websites that offered relatively little or no warnings that we could easily see in clicking

through the site are:

-- http://www.genderknee.com

--http://www.aboutstryker.com/files/StrykerCommercial06.wmv

--http://www.journeytkr.com/commercial.cfm

### B. Financial Arrangements That May Discourage the Delivery of Side Effect Warnings

It is also important that advertisements carry a warning of the potential for infection, morbidity, and mortality as a result of surgery and implantation, because the system of payments between many device companies and surgeons creates financial incentives to conduct the surgery. These same incentives to use various devices may well have the effect of minimizing warnings and cautioning patients about other solutions (such as weight loss, pain medication, physical therapy, etc.). Our concern is based on recent reports of huge consulting fees to certain surgeons. A 2007 Wall Street Journal Health Blog posting reported that nationally, "more than 40 surgeons or groups each received at least $1 million in payments" in 2007.[12] A 2007 Indianapolis Star article stated that "Federal prosecutors said the industry has a long history of showering gifts on surgeons, making it necessary for companies to fully disclose all of their consulting contracts….the U.S. Attorney's spokesman said the Justice Department is continuing its investigation 'into the practice of certain doctors.'"[13]

We raise the issue of industry "consulting fees," because it calls into question the objectivity of the physician "learned intermediaries" to fully inform patients of the downsides of such surgeries. This potential problem is another reason to require advertisements to carry

[12] http://blogs.wsj.com/health/2007/10/31/device-makers-post-payments-to-docs-online/?mod=WSJBlog

[13] John Russell, "Docs bristle at suggestion of kickbacks; Feds probe orthopedic surgeons' fees from artificial device makers," Indianapolis Star, November 12, 2007.

warnings.

Other Department of Health and Human Services agencies recognize the importance of fighting HAIs and empowering consumers to understand the dangers of infection and the efforts individual facilities are taking to fight infection. For example, as part of the hospital payment update program, hospitals must report three anti-infection process measures, which are then reported on the CMS website, under "Hospital Compare." The three measures are (1) whether an antibiotic is started during the hour before surgery, (2) whether the correct antibiotic is used, and (3) whether it is discontinued at an appropriate time after surgery. While Consumers Union believes it is most important to report actual infection rates, we do urge consumers to check this website to see how hospitals perform on these process measures. We believe it is important because we have found within a single state, variations among hospitals in good practice of as much as 80 percentage points.

It is also worth pointing out that the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases provides some pamphlet-type information to consumers, such as "Joint Replacement Surgery and You; Information for Multicultural Communities." We do not know how many consumers use or read these materials, but it is interesting to note that on page 8 of this 16-page publication, the first major side effect listed is infection, but the description utterly fails to adequately warn[14] of how serious—how fatal—this problem can be:

> "Joint replacement is usually a success in more than 90 percent of people who have it. When problems do occur, most are treatable. Possible problems include:
>
> > Infection: Areas in the wound or around the new joint may get infected. It may happen while in the hospital or after you go home. It may even occur years later. Minor infections in the wound are usually treated with drugs. Deep infections

[14] "Joint Replacement Surgery and You; Information for Multicultural Communities," U.S. Dept. of Health and Human Services, pg. 8. This omission is particularly distressing in a publication aimed at the minority populations, since MRSA is a particularly serious problem in some of these communities.

may need a second operation to treat the infection or replace the joint."

Clearly, these warnings do not convey the medical horror described by some of our readers in the personal stories we have received through our Stop Hospital Infections Campaign.

## IV. RECOMMENDATIONS

### A. FDA Expected to Do More to Include Warnings in Advertisements

Given these significant concerns, how can FDA ensure that direct-to-consumer ads for medical devices do not mislead the public? Oversight and regulation, including that which FDA is now empowered to do for prescription drugs DTCAs under Section 503B of the FDAAA, could improve consumer safety and outcomes. Specifically, CU makes the following recommendations:

- FDA should be required to mandate that all print and electronic advertisements, including Internet advertisements, for implantable devices such as knee, hip, heart, valves, cosmetic implants, and other devices, warn consumers about: 1) the very real danger of health care-acquired infections that can and do result from surgery and follow-up care; and 2) the expected life span of the device before failure occurs.
- CU supports better oversight of medical devices ads (as we do for drugs), including an FDA review process before the ads are issued.
- FDA needs more resources for reviewing DTC ads and taking enforcement action when advertisements are unlawfully misleading, deceptive or unbalanced. Often, FDA does not issue a warning letter until months after a deceptive or misleading ad has been widely aired.

- Last week FDA posted a new web page on DTC drug ads which includes a presentation on how consumers can tell a "legal" drug ad from an illegal one and direct actions that people can take to report issues they might have with any ad they see. However, this service only deals with drugs and we believe that implantable devices should get similar attention.

Section 503B of the FDA Amendments Act of 2007 includes stronger authorities for the FDA to require pre-review and specific disclosures to ensure that consumers are warned in DTC advertisements about potential dangers and side effects. We urge FDA to use these authorities, as well as its existing authorities, to review device implant advertisements and require that they warn of the specific dangers of infection, and advise patients to ask questions about infection rates and anti-infection practices at the facility where the implantation will take place.

## V. CONCLUSION

There is no question that many implantable medical devices can restore high quality-of-life for patients who have been suffering. CU does not in any way intend to discourage those in pain and facing loss of mobility or other serious problems from seeking out medical advice on implants. But we do believe that unintended side effects, and deaths, can be minimized if the public is better educated about the risks involved and about facilities that are not demonstrating the highest level of anti-infection practices. The law requires that for all DTC ads for prescription drugs, the claimed benefits must be accompanied by balanced warnings of the risks of using the drug. The same requirement should be applied to devices. Requiring information about the danger of infection from surgery in implantable device advertisements will speed the day that America’s surgical centers and hospitals address this life-and-death problem.