December 11, 2007

Divison of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Citizen Petition

Consumers Union, the independent, non-profit publisher of *Consumer Reports*[1] submits this petition pursuant to section 4(d) of the Administrative Procedures Act, 5 U.S.C. 553(e), and 21 CFR 10.25, 21 CFR Part 202, and PL 110-85 (Sec. 901(d), creating a new FDCA section 503B, Pre-review of Television Advertisements).

Action Requested

Consumers Union (CU) requests the Food and Drug Administration to require 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

> --the very real danger of health care-acquired infections that can and do result from surgery and follow-up care, and
>
> --the expected life span of the device before failure occurs,

both of which can and do cause death or serious morbidity and expense.[2]

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[1] Consumers Union 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 and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports and ConsumerReports.org, with approximately 6.5 million combined paid circulation, regularly carry 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. EXPERT • INDEPENDENT • NONPROFIT®

[2] The December 2007 issue of Consumer Reports discusses the rise in reports of serious problems from various heart implantation devices, but does not discuss the serious problem of surgical infection. See attached article "Medical devices Problems on the rise."

Some health care facilities do a better job than others in preventing infections and some make this information available to the public as a result of State laws or voluntary disclosure. Therefore, we ask that all such implanted device advertisements require a warning such as the following:

> "The surgery and care involved in the placement of this device may result in an infection, or other adverse events, that can lead to death or injury. Be sure to ask your doctor and hospital about infection rates at the facility where the surgery will be performed. In addition, ask your doctor about the long-term failure rates so that you are aware of when the implant is likely to need to be replaced."

In reviewing these implantable device advertisements and websites, we are concerned that the danger of adverse side effects—including death—are consistently understated, and we hope that the FDA will review the quality of all device ads. But for purposes of this petition, we are only asking that consumers be given clear warnings about the dangers of infection during and following such surgery and information about how long the devices are likely to last, and that consumers be advised to seek out facilities with the strongest anti-infection programs and devices with long-term data about failure rates.

There is no question that many of these devices can restore high quality-of-life in patients who have been suffering. We do not in any way intend to discourage those in pain and facing loss of mobility, etc., from seeking out medical advice on implants. But we do believe that unintended side effects, which can include death, can be minimized if the public is better educated to avoid facilities which are not practicing the highest level of anti-infection practices. Placing information about the danger of infection from surgery in device advertisements will speed the day that America's surgical centers and hospitals address this life-and-death problem.

Statement of Grounds

Below we discuss data and give examples of

--death and injury from infection following implant surgery, and

--device implant advertisements that fail to give adequate notice of these dangerous side effects.

Studies show significant injury, morbidity and mortality following implant surgeries

In June 2006 our publication Consumer Reports carried an article, "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. We can't tell from

> our survey whether those were serious deep-tissue infections or less worrisome surface infections. But those rates are consistent with what Consumer Reports has found when we surveyed subscribers about their hospital stays for various procedures in the past [described in a January 2003 hospital safety article]."

While we could not determine what type of infections those were from the survey responses, the rate of infection was consistent with our earlier, January 2003 "hospital safety" article.

Our December, 2007 issue includes an article (attached) entitled “Medical devices Problems on the Rise,” that again makes the point that there are serious consumer issues with the placement and use of some of these devices.

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.[3]

Considering just the deadly Methicillin-resistant staphylococcus aureus (MRSA) infection, 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.’[4]

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 co-morbidity patients.[5]

A recent 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,

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[3] NNIS System Report, data summary from January 1992 through June 2004, issued October 2004. Am J. Infect Control 2004; 32:470-485.
[4] AHRQ, Healthcare Cost and Utilization Project (H-CUP) Statistical Brief #35, July 2007, p. 8.
[5] 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.

> deep venous thromboses, injury to nerves and blood vessels around the knee, and the potential for future surgical revision.[6]

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.[7] 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. Clearly, these are very serious operations, infections occur, and consumers need to consider these side effects.

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 health care acquired infection (HAI) rates. To date, 20 states have enacted public disclosure and anti-infection laws. These laws vary in their details but 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.

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 Methicillin-resistant staphylococcus aureus, or 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 families who have suffered injury and often death due to HAIs. A significant number of these cases occurred following hip and knee transplantation surgery.

Attachment #1 is a sample of the type of reports we have received. As anyone can see, these HAIs have resulted in terrible pain and suffering, and in too many cases, death.

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

[7] 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.

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. It is reported that nationally, "more than 40 surgeons or groups each received at least $1 million in payments" in 2007.

> "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.'"[8]

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 warnings.

Other Government Agencies are Responding to the Danger of HAIs But More Needs to be Done by the FDA to Warn Consumers

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 an 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.

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

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

16-page publication, the first major side effect listed is infection, but the description utterly fails to adequately warn[9] 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 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 Attachment #1.

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

The attached Wall Street Journal article of 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. While we have no specific data on the amount being spent on such ads, we believe from our personal observations that there are numerous device implant advertisements by manufacturers and individual surgical physician groups.

Attached are several recent examples of print ads in major and minor national publications. Television advertisements are similar. 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.

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 November 28, 2007) infection or how serious the side effects can be. Other websites which offered relatively little or no warnings that we could easily see in clicking through the site are

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

[9] 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.

--http://www.genderknee.com

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

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FDA Expected to Do More to Include Warnings in Advertisements

The FDA Amendments Act of 2007 (PL 110-85) creates a new section 503B, which 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. Clearly, Congress expects stronger FDA oversight of these advertisements. We urge you to use this authority, and 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.

Environmental Impact

We believe that pursuant to section 21 CFR 25.30(a), this petition is excluded from the requirement for an environmental impact statement.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

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Attachment #1

Examples of some of the Consumers Union readers who have 'shared their stories' of infection following hip or knee replacement

Northern California

In Feb. 2006, my father had a hip replacement and contracted Methicillin Resistant Staphylococcus Aureus (MRSA). Kaiser Permanente Hospital had to replace the hip 3 times to get the infection under control. He also contracted Pneumonia and Urinary Tract Infections during his stay at this hospital. He continues to fight the Pneumonia and constant Urinary tract infections. This whole experience has been a nightmare…. This happened in Feb. 2006. It is now Jan. 2007 and my father is still in a nursing home and will never walk again or come home…..

Michigan

I went to Bronson Hospital in Kalamazoo, Michigan to have a knee scope before I was to have a knee replacement. After I went home from this procedure, I started to have a lot of pain in my leg that I had the scope in. I had only been home three days. Within a few minutes the pain was so terrible that I was rushed to the Battle Creek Medical Hospital, close to my home. I was in so much pain that I was not aware that I was being sent by ambulance back to Kalamazoo, to intensive care at Borgess Hospital. They had a special unit to try and save my life.

I spent three weeks in intensive care. My doctors did not think I would live. However, a team of infectious doctors that worked diligently to save me. I was later told that I had gotten this dreadfully painful disease from a dirty instrument. I suffered pain for six months and was unable to walk without a walker for three months. It took me three more years of constant doctors appointments before I could even consider to get my knee replaced.

I will be getting knee replacement during February of 2007. I was told that my doctor will be treating the cement with antibiotics, so this will not happen again. Due to this incident, I will always be susceptible to infection for the rest of my life.

Northern California

I was given a hip replacement on April 21, discharged to a rehab site on April 25, and returned home May 5. On May 16 I was re-admitted to the hospital with a severe staph-Pos infection in the operated site, and had to undergo a second surgery in which some of the new hip had to be replaced. After one week in isolation I was fitted with a "Pic Line," and had to self-administer antibiotics for six weeks. My recovery was very slow, and I have been told I will never be completely free of a re-occurrence of the infection.

Kansas

I was 45, single and healthy, when I had a hip replacement in 2003. I was told that I didn't have to worry about a Staph infection, because I was young and healthy. Recovery from the hip replacement was very difficult and I had a lot of pain. I went to see the surgeon every week, wondering why I hurt so bad, and why I couldn't walk around very well. He would take an X-ray, show it to me and tell me everything was fine, and send me home. At 6 weeks, I was home alone, and my hip popped out from the infection. I have never felt anything so excruciating in my life. I returned to the hospital for 8 days, 2 operations, 2 blood transfusions, and very little information. I was on 3 IV infusions and 3 oral antibiotics a day, for almost 4 months. I now have Lymphedema, permanent damage to my lower lymphatic system, from the infection. I will be dealing with compression hose, pain, lymphatic drainage, wrapping both legs and stomach every day, and great risk of a new infection, for the rest of my life.

Massachusetts

My mother has had artificial hips since age 17. As they wear they have been replaced. In 2002 she had a replacement done and after was told she had a staph infection. After several months on Vancomicine they decided they would have to remove the components. While she had a "hanging hip" her good hip dislocated and they operated on that hip. After 4 months they said her cultures were clear of infection and put the hip back in. Last fall they found infection again and took the hip back out. This time they said it was an entrococcus infection and they didn't know how she got it. She was again put on the Vanco. And recently was told she was reading to have her hip put back in on 3/17/05. Well last Monday they told her she has VRE in the good hip and now they want to take that one out too and possibly both knees as well! She is giving up hope.

Arizona

[I had had a] total knee for 16 years and had worn out the plastic pads. I went for PT approximately 2 weeks after surgery and my therapist called my doctor twice to tell him that my knee felt very warm and that he should look at it. About 5 months after the surgery, I had to check myself into urgent care, as I could not put any weight on that knee due to the pain. I had a temperature of 104 degrees and was given morphine and transferred to a hospital. There they did blood tests and determined that I had Staph infection that had spread into my blood. I was then transferred to the hospital that did the revision surgery. My orthopedic doctor withdrew the puss from my knee, did athroscopic

surgery to clean out the knee. Then in another surgery removed all of the total knee hardware….

Arizona

My 81 year old mother broke her hip in April of 2004, had a partial hip replacement and was recovering well. Six weeks after the surgery, her hands swelled and turned red and painful. She was readmitted and given many tests including nuclear medicine in order to find the site of the infection. The physicians believed she had a bacteremia, but could never determine just what caused it. Her white cell count soon after admittance was over 20,000. She was hospitalized for over 100 days. During her stay, she acquired 6 or 7 nosocomial infections. First she acquired a Vancomcycin Resistant Enterococcus urinary tract infection. She also got Klebsiella, MRSA, and Pseudomonas aeruginosa urinary tract infections. Also, because she was on total parenteral nutrition for so long she suffered candidaemia. Finally, due to the number of antibiotics she received, she acquired highly resistant Clostridium difficile diarrhea. She lost a great deal of weight because of the multiple infections and never recovered enough to go home…..