

Warranties for Hip and Knee Implants
Consumers Union
Safe Patient Project
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Millions of Americans now have hip and knee implants, and thanks to aggressive marketing to younger consumers and aging Baby Boomers, demand for these surgeries will only grow. In 2011, doctors performed more than 711,000 knee replacement/reconstructions along with 464,000 hip replacements (total and partial).¹ Demand for hip and knee replacement surgery could reach 4 million a year by 2030, and more than 50% of patients will be under age 65.²

Why does that matter? Because younger people will need their implants to last a long time, but the vast majority of knee and hip implants do not come with a manufacturers' warranty.³

For other kinds of products, including other types of implants, the warranty specifies the length of time the manufacturer guarantees the item will last and gives consumers a process to address defects when they occur.⁴

According to recall data from the Food and Drug Administration (FDA), over the last ten years every major manufacturer of knee and hip implants has voluntarily recalled a product, or line of products, due to defects. Problems range from having the wrong size etched on the device to post-operative fracturing to early wear and delamination.⁵ Some designs proved to be fundamentally unsafe: entire lines of metal on metal hips have been recalled after thousands of patients had to have them removed.⁶

Most hip and knee implants are exempted from safety testing before they are put on the U.S. market. Only 1% of medical devices are approved through the more rigorous Premarket Approval Process which requires safety testing.⁷ Unlike Australia, there is no national U.S. registry that tracks which implants fail or a system to notify the patients who have them. As consumers line up for the promise to 'feel better, play longer' on their new joints, they are buying into a loosely regulated marketplace that can leave them holding the bag for costly and painful revision surgery when these implants fail or break.

When implants go bad, the cost of additional surgery to remove and replace the implant is now largely borne by patients (and their insurance companies or Medicare). Revision surgery costs more, is surgically demanding, results in longer hospital stays and often leads to additional revision surgeries.⁸ When patients outlive their implants, revision surgery is also required and they should have solid information about the expected lifespan of the device when making their initial decision to get a knee or hip replacement.

Since manufacturers are not required to report what percent of their products fail or even how often it happens, it's impossible to calculate the overall cost to Medicare, insurance companies or patients when implants turn out to be defective. It is estimated that nearly 18% of hip replacement and 8% of knee replacement surgeries performed in the U.S. are for revisions.⁹ The costs for revision procedures is likely in the hundreds of millions of dollars per year based on the huge volume of revisions performed.¹⁰

Manufacturers should bear their fair share of this cost, and assist consumers when their products fail. Warranties would do that. Consumers Union calls on the manufacturers of knee and hip implants sold in the United States to back their products with a 20-year warranty. A warranty will communicate to patients how long devices can be expected to last [“this is officially how long we will stand by our product”] and provide a straightforward process to replace a defective product with as little hassle and cost as possible. Transparency and clear lines of accountability will ultimately move companies to reduce defects and improve quality because it will be in their own financial best interest to do so.

Loopholes prevent FDA from adequately protecting consumers against defective implants

Unlike prescription drugs, which must be tested to demonstrate they are safe and effective before they are put on the market, most joint replacement products are not required to undergo rigorous pre-market testing. Medical devices like hip and knee implants do not have to be reviewed for safety by the FDA if they are similar to a product already on the market. Since most design changes are incremental, nearly every hip and knee currently being installed in patients is similar to something that came before it, and therefore device makers gain approval of their new implants through what is known as the FDA’s 510(k) clearance process (based on its “substantial equivalence” to a device already on the market). Under this section of federal law, implant makers do not need to provide evidence from clinical trials to demonstrate a product’s safety and effectiveness, as required by the FDA’s more rigorous “premarket approval” or PMA process¹¹

FDA’s premarket approval process, while rarely used, does appear to improve implant safety. The GAO surveyed device recalls from 2005-2009. Among all classes of devices that were eventually recalled, 87% had been approved through the 510(k) process, while only about 8% of the recalled devices went to market after the more rigorous Premarket Approval process.¹²

Instead of pre-market safety testing, the FDA primarily relies on “post-market” reporting to Medwatch, a system for physicians and patients to report problems with implants. When enough problems or “signals” are reported, FDA may send out notice to the companies and the companies can choose to voluntarily recall their products. This means virtually every hip and knee implant patient is an unwitting participant in a giant, “post market” test to see which products are actually safe and which ones turn out to be harmful or ineffective.

While FDA cannot require clinical safety testing for any product that is “substantially equivalent” to another implant, a 2012 amendment to federal law created a more streamlined process for the FDA to require clinical testing.¹³ In January 2013, the FDA proposed a reclassification of metal-on-metal hips, which, when finalized, would require more rigorous testing and reporting before the design could be marketed again.¹⁴

Defects happen

We know that hip and knee products can be defective - some have failed spectacularly, while defects limited to certain “lots” or components can also have serious implications for patients.

Imagine you just opened the box of a complicated piece of build-it-yourself furniture. You carefully lay out all the parts, you pull out the custom tools helpfully provided, and you read all the instructions until you feel you understand the steps. You start building it – only to find, when

you are well into the project, that some of the screws are the wrong size. Now imagine this is your surgeon, and the item under construction is your knee, and you are in the operating room under anesthetic.

Literally hundreds of knee components have been recalled since 2003,¹⁵ frequently because they ship with the wrong part, a wrong size part, a missing part, or a part built for the left side but etched as a “right” (or vice versa). Since most parts must be opened immediately before surgery to keep them sterile, these kinds of errors have serious implications for patients. Reasons for product recalls straight from the FDA’s own database include the following packaging issues (quoted verbatim):

- “Labeling Discrepancy -- Mislabeled and mis-etched as to size. Inserts were labeled and packaged as size Standard; 12.5mm Inserts but were actually a 10mm Inserts. Risks include but not limited to: a delay in the procedure while the proper component is located; and tight joint with constricted movement as a result of implantation of the wrong thickness of insert.”
- “The product contained screws with the incorrect length (incorrectly contained 15 mm length screws instead of the correct 5 mm length screws).”
- “Mislabeled--The product is not collared; although the label states that it is collared. A non-collared component will provide a reduced contact with bone interface and/or a delay in the procedure may be incurred while clarifying package contents.”
- “The firm is initiating a removal of one lot of the Bigliani/Flatow Humeral Provisional Stem (00-4301-012-17; lot 62283991) as the stems manufactured under the lot are 14mm x 170mm devices incorrectly etched and packaged as 12mm x 170mm devices.”
- “A box labeled as a Scorpio NRG Femoral Size 7 Right; may actually contain a Scorpio PS Femoral Size 5 Right.”
- “Zimmer had determined that two lots of these tibial implants have incorrectly positioned or missing flange plugs that were not seated in the device upon receipt to the customer. A missing flange plug could lead to a delay of surgery or possibility of wear leading to more surgery.”

And those specialized tools included in the product to facilitate installation are sometimes a problem as well.

- “The instrument may have been assembled improperly; which may result in reversed resection cuts on the femur and affect implant performance; resulting in the need for revision surgery.”
- “Triathlon Offset Adaptors may seize during surgery and the OR staff may be unable to disassemble the instrument using the removal tool.”
- “The standard Triathlon Femoral Stylus does not fit into the Specialty Sizers and the "R" and "L" markings on the Right Sizer are reversed.”
- “The instrument's sizing line is in the wrong place.”

Of course, some knee components have been recalled because they simply weren’t manufactured to spec or started to fail once installed in people.

- Fracture of SPIRALOK Anchors post op; requiring patient revision

- The firm has received complaints of loosening of the implanted device requiring revision surgery. There have been 114 MDRs filed all reported that the device loosened and the patient required additional surgery to replace the device.
- The device was cut to an incorrect angle; which may result in an incorrect bone cut.
- Raw material supplied by a third party used to manufacture various medical devices does not comply with metallurgical requirements outlines in ASTM standard for titanium surgical implants.
- An impurity in the metal may affect the strength of the screw; resulting in breakage and/or surgical delays.

Hip implant devices, tools and components have been recalled for similar reasons, but the story of the metal-on-metal hip is an abject lesson in the failings of our current oversight systems.

Metal on metal hip implants, where the ball and socket of the hip joint are both made of metal, were a popular innovation because they promised to last longer than other devices made with ceramic and plastic. Because the basic design was similar to previous hip replacement designs, the FDA allowed the new product to be fast tracked to the market without safety testing.¹⁶ It was popular: an estimated 755,000 Americans got these hips over the past decade.¹⁷

Some patients with the new hips started to report swelling at the site, along with unexpected symptoms like rash, cardiomyopathy, neurological problems, cognitive impairments, and more. It turned out that when metal rubbed against metal, chromium and cobalt ions were released from the surface, first into the hip itself and later into the bloodstream, causing these and other health problems. The metal being released into the nearby tissue sometimes caused damage to surrounding bone, tissue, muscles and nerves, making it difficult to replace the metal hip.¹⁸

Starting in 2004 and 2005, Johnson & Johnson introduced DePuy ASR and ASR XL metal on metal hips. As early as 2007, the Australian Joint Registry recorded unusually high revision rates for the DePuy ASR. DePuy stopped selling the ASR in Australia in 2009. The National Joint Registry of England and Wales identified similarly high revision rates.¹⁹

Even as scientific evidence mounted, patients in the U.S. continued to get all-metal hips implanted. In August of 2010, DePuy recalled all 93,000 ASR XL hips worldwide after it became clear that the device was failing far more often than average and producing serious injuries. While it's unclear how many people actually had to have their artificial hip removed, an article in the British Medical Journal called it "one of the biggest disasters in orthopaedic history."²⁰

Australian regulators spotted trouble with these hips early, in part because the country has a national device registry. The U.S. does not. Because the U.S. lacks a national device registry, U.S. doctors and patients don't learn about a recall in a systematic way and patients may not know to revisit their doctor to have their implant checked. The Australian Joint Replacement Registry allows officials to easily notify doctors about a recalled device, who can then notify their patients.²¹

The societal implications of failing knees and hips

Years ago, when implant patients were most often elders, the longevity of a new knee or hip may have mattered less than the immediate relief it provided from pain and diminished mobility. Today, people under the age of 65 routinely undergo hip or knee replacement, and they will likely remain active for 20 or 30 more years after their surgery. And, many people over 65 tend to be more active than in the past and are living longer.

Implant advertising is geared toward younger and athletic older audiences, as aging sports stars like former tennis player Billy Jean King promote knee replacements as a way to extend an active life. Researchers estimate that 50 percent of hip replacement patients are already under the age of 65, and soon the same will be true for patients with knee replacements.²²

Younger customers mean bigger business – and the hip and knee industry is big already. In 2012 worldwide revenue for hips reached \$5.8 billion and for knees another \$6.9 billion. Yearly, 1.4 million hip replacements and 1.1 million knee replacements are performed worldwide.²³

In the near future, Medicare hip and knee replacements could make up a significant percentage of all Medicare spending. Hospitals and surgeons are currently exploring cost control methods such as bundling all costs associated with a hip or knee replacement. The cost of a hip or knee implant can be as much as 50 percent of Medicare payment.²⁴

Younger patients are more likely to need revision surgery in their lifetimes simply because they are living longer with an implant. In addition to the increased cost, revision surgery is often more complicated than the original procedure. A patient cannot endure multiple revisions as more tissue and bone are destroyed with each surgery. According to one study, revision surgery resulted in more infections, longer hospital stays, and higher costs for the surgery.²⁵

A warranty would help make implants safer and spread costs more fairly

A strong warranty that gives consumers reasonable compensation when a joint fails will improve consumers' experience and encourage companies to make their products safer and more durable. Manufacturers should have some 'skin in the game' by guaranteeing that their products will last for at least 20 years, and not expect patients, insurers or taxpayer-supported health programs to pick up the cost for failed devices. As these products are marketed to younger and younger consumers, potential patients need information about the lifespan of their implant and a guarantee to back up company promises.

For most products on the market today, a manufacturer's warranty sets out how long the buyer can expect the product to work. If the product doesn't work or breaks during that time period, the consumer can request repair or replacement under the terms of the warranty. For hip and knee replacements, consumers expect the product to last 20 years, or even a lifetime. Of the people who responded to our detailed questions about their joint replacement, about two-thirds thought a 20 year or lifetime warranty was appropriate.²⁶

Hip and knee manufacturers claim this kind of system can't work for them, because problems people experience may not be due to product failure. Perhaps the patient gained weight, fell on the implant, or otherwise damaged it due to inappropriate activity; perhaps the failure was due to a surgical infection.²⁷ These debates are not new to any product on the market -- installers can make mistakes, consumers can drop appliances or use their vehicle inappropriately. Any good

warranty creates a procedure for resolving such disputes and getting consumers a replacement product with as little hassle and cost as possible.

Currently, there is only one implant manufacturer that provides any kind of warranty at all. The Biomet Oxford Partial Knee comes with a lifetime warranty. Biomet pays the cost of a replacement implant one time (parts) but does not include costs associated with replacement surgery (labor). Consumers Union believes this warranty is inadequate because it doesn't cover the associated costs to replace the implant. When a customer triggers an appliance warranty, or takes a car back to the dealership for a warranty repair, the warranty covers parts and labor because the labor associated with replacement is part of the cost of failure. A good knee or hip warranty should do the same.

Consumers Union believes a standard warranty should come with every knee and hip device. The warranty should be given to patients as part of the implant procedure and should meet the following basic requirements:

- Covers the implant for at least 20 years
- Covers the full costs of replacing the flawed device, including the device, surgeon and hospital costs as well as the related patient out of pocket costs.
- Does not require the failed device be replaced with the same product or a product from the original device maker if the product has been recalled by FDA or the company, is the subject of FDA warnings, is under investigation by the FDA or if the product is no longer being sold by the company.
- Establishes a clear system for patients to use, including a toll-free number and a registration number to track the claims process, with physicians charging the device company, not the patient.
- Does not require the patient pay out-of-pocket expenses; for example, the patient should not have to pay the device maker or surgeon first and get reimbursed later.
- Provides the patient with full information concerning a warranty claim denial and provides a process to allow the patient to appeal the decision.
- Does not limit or eliminate a patient's right to sue if they use the warranty.
- Does not disqualify patients across the board because they have specific diseases or illnesses that are not related to the failure of a device.
- Does not disqualify patients for normal activities, including falls.
- Does not disqualify patients due to information that is not routinely available to them, such as information that is on the device packaging or placed into their medical records and not routinely provided directly to the patients in the course of getting the implant.
- Patients do not waive the right to sue if they use the warranty.

For more information contact:
Suzanne Henry
506 West 14th. Street, Ste.A
Austin, TX 78701
512-651-2921

¹ Agency for Healthcare Quality Research, Healthcare cost and Utilization Project (HCUP): Outcomes for CCS principle category Arthroplasty of knee and hip replacements, total and partial, 2011 weighted national estimates from the HCUP Nationwide Inpatient Sample (NIS); <http://www.hcup-us.ahrq.gov/reports.jsp>

² Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ., "Future Young Patient Demand for Primary and Revision Joint Replacement." *Clinical Orthopedic Related Research*, 2009 Oct; 467(10):2606-12. doi: 10.1007/s11999-009-0834-6. Epub 2009 Apr 10. Also, Kurtz SM, Ong K, Lau E, Mowat F, Halpern M, "Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030," *Journal of Bone and Joint Surgery Am.*, April 2007; 89(4):780-5.

³ Consumers Union talked to representatives of the top six sellers of hip and knee implants and found only one offered a warranty on a hip or knee product: Biomet's Oxford Partial Knee Implant; <http://www.biomet.com/lessIsMore/lifetimeWarranty.cfm>

⁴ Examples of warranties for St. Jude's implantable products (<http://www.poweroveryourpain.com/warranty>), Biotronik (http://www.biotronikusa.com/global/assets/pdf/regulatory/warranties/W4011-C%205-08_Generic%20Pacemaker%20Warranty.pdf) and Boston Scientific Cardiac Pulse Generators (http://www.bostonscientific-international.com/templatedata/imports/HTML/PPR/warranty-pdf/358871-001_Elabel_Universal_PG_Warranty_US-OUS.pdf) and Medtronic diabetes products (<http://www.medtronicdiabetes.com/customer-support/tool-download-library/warranties>).

⁵ Consumers Union review of 10 years of hip and knee recalls from the FDA recall database, 2003 to 2013, accessed on 7/23/13 and 7/24/13 respectively. (<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/>)

⁶ Cohen, D., "Out of Joint: The story of the ASR;" *British Medical Journal*;342:d2905, May 14 2011

⁷ US Government Accountability Office, "FDA Should Take steps to ensure that high risk device types are approved through the most stringent premarket review process," GAO-09-190: January 2009

⁸ Ong KL, Lau E, Suggs J, Kurtz SM, Manley MT, "Risk of subsequent revision after primary and revision total joint arthroplasty," *Clinical Orthopedic Related Research.*, Nov 2010; 468(11): 3070-6. Also, Vincent KR, Vincent HK, Lee LW, Weng J, Alfano AP, "Outcomes after inpatient rehabilitation of primary and revision total hip arthroplasty." *Arch Phys Med Rehabil.* August 2006; 87:1026-32. Also, Lavernia C, Lee D, Hernandez V, "The increasing financial burden of knee revision surgery in the United States," *Clinical Orthopedic and Related Research*, May 2006: 446, pp 221-226..

⁹ Kurtz S, Mowat F, Ong K, Chan N, Lau E, Halpern M. "Prevalence of primary and revision total hip and knee arthroplasty in the United States from 1990 through 2002." *J Bone Joint Surg Am.* July 2005; 87(7):1487-1497.

¹⁰ Steiner C, Andrews R, Barrett M, Weiss A. *HCUP Projections: Mobility/Orthopedic Procedures 2011 to 2012*. 2012. HCUP Projections Report # 2012-03. ONLINE September 20, 2012. U.S. Agency for Healthcare Research and Quality, Available: <http://www.hcup-us.ahrq.gov/reports/projections/2012-03.pdf>. Estimated US hip revision incidence for all adults: 12,000 at the end of 2012, p. 47. Average hospital cost for all adults for hip replacement revision surgery estimated at \$24,500 at the end of 2012, p. 51. Estimated total cost of hip replacement revisions: \$294 million at the end of 2012. Estimated US knee revision incidence for all adults, 15,500 at the end of 2012, p. 75. Average hospital cost for all adults for knee replacement revision surgery estimated at \$25,000 at the end of 2012, p. 79. Estimated total cost of knee replacement revisions, \$387 million.

¹¹ 21 CFR 807 Subpart E ; Premarket Notification 510(k); <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=807>

¹² Government Accountability Office (GAO); June 2011; "FDA Should Enhance its Oversight of Recalls;"

<http://www.gao.gov/assets/320/319565.pdf>

¹³ Food and Drug Administration Safety and Innovation Act, Public Law 112-144, Sec. 608, pp 1055-1059, 112th Congress, July 9, 2012; <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf> .

¹⁴ Proposed Order for the reclassification of metal-on-metal hip joint to require filing of a premarket approval application (PMA); Jan. 18, 2013 <https://www.federalregister.gov/articles/2013/01/18/2013-01006/effective-date-of-requirement-for-premarket-approval-for-two-class-iii-preamendments-devices>

¹⁵ FDA recall database on knee replacements, 2003 to 2013 <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/> , accessed on [FIND DATE AND CONFIRM RANGE OF DATES FOR THIS AND FOOTNOTE 5 ABOVE]

¹⁶ Ardaugh B.; Graves S.; Redberg R; "The 510(k) Ancestry of a Metal-on-Metal Hip Implant;" *New England Journal of Medicine*, Jan. 10, 2013, 368:2, pp 97-100

¹⁷ Consumer Reports, "FDA cracks down on all-metal hip replacements;" Jan. 18, 2013 <http://www.consumerreports.org/cro/news/2013/01/fda-cracks-down-on-all-metal-hip-replacements/index.htm>

¹⁸ Food and Drug Administration, "Concerns about Metal-on Metal Hip Implants;" Jan. 17, 2013; <http://www.fda.gov/Medicaldevices/productsandmedicalprocedures/implantsandprosthetics/metalonmetalhipimplants/ucm241604.htm>

¹⁹ Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, "Recall of DePuy Orthopaedics ASR hip," May 16, 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm#recall>. Also, National Joint Registry for England and Wales, 7th Annual Report, 2010, p. 107

²⁰ Cohen, D., "Out of Joint: The story of the ASR;" *British Medical Journal*;342:d2905, May 14 2011. Also, Consumer Reports, "Dangerous Devices;" May, 2012.

²¹ Australian Orthopaedic Association National Joint Replacement Registry, "Patient Information;" <https://aoanjrr.dmac.adelaide.edu.au/documents/10180/11058/Patient%20Information?version=1.1&t=1362454366800>

²² Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ, "Future Young Patient Demand for Primary and Revision Joint Replacement," *Clin Orthop Relat Res.* 2009 Oct; 467(10):2606-12. doi: 10.1007/s11999-009-0834-6. Epub 2009 Apr 10.

²³ Orthoknow, "Orthopedic Industry Annual Report 2012;" June 2012. Full report available at <https://www.orthoworld.com/index.php/main/oiar>

²⁴ Rikkers, Laing, "A Surgeon's Look at Costs In Total Joint Arthroplasty," *Orthopedic and Dental Industry News*, March 31, 2006; http://www.healthpointcapital.com/research/2006/03/31/a_surgeons_look_at_costs_in_total_joint_arthroplasty/

²⁵ Ong KL, Lau E, Suggs J, Kurtz SM, Manley MT, "Risk of subsequent revision after primary and revision total joint arthroplasty," *Clinical Orthopedic Related Research.*, Nov 2010; 468(11): 3070-6.

²⁶ Of the more than 700 people who have experienced a hip or knee replacement and responded to Consumers Union's detailed questionnaire about warranties with us, 232 supported the idea of a 20 year warranty and 197 supported a lifetime warranty. This was not a scientific survey.

²⁷ Weyman, Andy, MD; Chief Medical Officer; Smith & Nephew; letter to Consumers Union in response to request to warranty their hip and knee implant products; July, 2013
