

June 18, 2013

Andrew Ekdahl, President
DePuy Orthopaedics
700 Orthopaedic Drive
P.O. Box 988
Warsaw, IN 46580

Dear Mr. Ekdahl,

Consumers Union, the advocacy and public policy arm of Consumer Reports, is writing to urge DePuy Orthopaedics to offer a warranty with your knee and hip implants. We are asking the same of the other highest volume makers of these devices. Manufacturers of products that are implanted in the human body must have the highest standards for safety and durability, and a warranty demonstrates that the company stands behind its product. Besides indicating confidence in the safety and reliability of your products, a warranty can help guide a patient through the necessary steps to repair or replace a hip or knee implant if it fails. We believe:

- Patients have a right to know how long an implanted product will last.
- Warranties will improve the safety and performance of devices.
- Warranties will provide a clear process for replacing a failed device.

Consumers Union recently gathered personal stories from 3,000 patients who have had hip and knee replacements. We found that many people don't know key details about their device, such as the make and model of their implant or the number of years they should expect their hip or knee replacement to last. In general, they also don't know what to expect or do if revision surgery is needed on their implants -- having a warranty in place spells out the process available to them.

We also reviewed products made by the largest hip and knee device companies (including yours) and found only one knee implant product currently is sold with a warranty.

Specifically, we ask you to warranty your hip and knee implant products for at least 20 years, with the conditions for a fair warranty specified in the attached document. The manufacturer should provide documents regarding the warranty with the product, to be given to the patient as part of the implant procedure. Patients who must replace a flawed device endure many expenses. The warranty should cover full replacement costs of implants that fail, including those that break, crack, cease to function as intended or emit toxins into the body. A good

warranty should clearly explain the process for its activation, clarifying and streamlining the process for a patient to pursue revision surgery and hopefully repair the hip or knee quickly.

As you know, the number of hip and knee replacements is expected to increase significantly over the next 20 years. When revision surgeries are needed, they add significant costs to Medicare, the major payer for these products, and private insurers, as well as patients' out-of-pocket expenses.

Because of limited pre-market safety reviews and post-market safety oversight, we believe manufacturers of these products have an obligation to guarantee their products to their customers, just as other manufacturers do for products that are much less essential to consumers' lives. A warranty would cover the full replacement cost of a failed device, and the device maker should continue to work with the patient and surgeon if the device fails.

We hope DePuy Orthopaedics will take this opportunity to lead the way on this important public health issue, and we look forward to working with you to give patients assurances that their hip and knee implant products are of high enough quality to stand the test of time.

We are interested in discussing further with you or an appropriate company official the possibilities of offering warranties on your hip and knee devices. Please contact Suzanne Henry at (512) 477-4431, ext. 121 or shenry@consumer.org to set up a time to talk. We would appreciate a response by July 8, 2013.

Thank you for your consideration to stand firmly for the quality and safety of your products, and we look forward to speaking with you.

Sincerely,

A handwritten signature in black ink that reads "Lisa McGiffert". The signature is written in a cursive, flowing style.

Lisa McGiffert
Manager
Consumers Union Safe Patient Project
lmcgiffert@consumer.org
506 West 14th Street, Suite A
Austin, TX 78701

[Attachment](#)