

September 5, 2013

Andy Weyman, MD
Chief Medical Officer
Advanced Surgical Devices Division, Smith & Nephew
150 Minuteman Road
Andover, MA 01810

RE: Response to Smith & Nephew letter dated July 1, 2013

Dear Dr. Weyman:

Thank you for your prompt and thorough response to our request for Smith & Nephew to warranty your hip and knee implants. We would very much like to continue this dialogue with you. Our goal is for potential patients to clearly understand how long they should expect these devices to last when they work properly and the steps to take when they do not. Ultimately we seek to improve the quality and safety of hip and knee implants.

The number of hip and knee implant surgeries is projected to grow significantly in the coming decades -- due in part to aging baby boomers who will likely live longer than their parents as well as the use of implants by younger and more active people. We believe that these consumers have a right to know how long their device will last and deserve a warranty to back up these claims. They need something more solid than vague estimates so they can realistically consider the consequences of multiple revisions throughout their lifetimes.

We recognize that these implants are complex but your company should be able to provide a straightforward warranty based on the extensive information you have on the performance of your products. It's true that the effectiveness of medical implants can be influenced by a variety of factors and we think it is critical for patients to understand these variables when they are contemplating surgery. We are not calling on Smith & Nephew to cover the cost of device failures regardless of the cause. We are asking your company to cover the costs of replacing a failed device when it is clearly a result of a product defect. All product warranties have exclusions for factors that are beyond the manufacturer's control and a medical implant warranty would be no different.

Your letter acknowledges that you already have personnel dedicated to evaluating claims when a device fails to determine whether a product defect is responsible for the failure. While you note that it can be difficult to determine the root cause of a device failure, you clearly have the ability to make these determinations. We're simply asking you to spell out this process in a warranty and to indicate how long patients are eligible to file a claim entitling them to have replacement costs covered by your company. Since Smith & Nephew is already processing these claims and assuming responsibility for replacement costs when the device is at fault, then you should have no objection to offering a warranty that details this process in a more official manner.

Now, patients are completely in the dark about how such claims will be handled and what their expectations should be regarding how your company will resolve these issues. When something goes wrong with their device, they are faced with an unknown and unspecified process on top of often debilitating physical problems. A warranty can spell out what it does and doesn't cover and make clear that factors beyond your control (for example surgical error) are not covered. By providing specific steps for them to take when the device fails, the warranty will help patients better understand what their expectations *should be* when it comes to filing a claim regarding a problem device.

Our recent communications with hundreds of people with hip and knee implants reveal an understanding of the unique issues involved and they overwhelmingly support having a warranty to protect them in case they receive a flawed device. About two-thirds of knee and hip implant patients who recently responded to a Consumers Union survey said that device makers should provide a warranty for 20 years or for a lifetime.

As your letter notes, Smith & Nephew monitors the performance of its devices based on your own research and other available sources. While each patient's experience is unique, this data should provide your company with the information you need to determine how long you are willing to stand by your products. If you do not have the confidence to do so, then Smith & Nephew should refrain from making vague promises in your marketing materials about how long devices should last and surgeons should not be giving patients estimates that are not backed by evidence.

Thank you again for your quick response to our request. As your letter suggested, we have had discussions with AdvaMed regarding a group meeting with AdvaMed and all of the companies, but due to anti-competitive issues, this will not be possible. We hope you, or your designated staff, will agree to a meeting or a conference call with us on this subject as soon as possible. If there is a different person within your company with whom we should communicate, please let us know.

Sincerely,



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