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Lisa McGiffert
Manager
Consumers Union Safe Patient Project
506 West 14th Street, Suite A
Austin, TX 78701

Dear Ms, McGiffert,

Thank you for your letter regarding the warranty of medical devices, This is a significant, complex topic that we have carefully considered in recent years, and we welcome your contribution to the conversation,

As you have probably found in your research, joint replacement surgery is among the most successful procedures available for the restoration of the body's natural function, However, while some patients have implants functioning as expected more than 30 years after surgery, others require a follow-up procedure relatively soon after their initial surgery, perhaps earlier than they and their surgeon had anticipated, The full set of potential reasons for revision surgery are too numerous to list here, but include infection, loosening, dislocation, metal allergy, pre-existing comorbidities (i.e" diabetes), implant alignment, weight gain, and inappropriate levels of physical activity not in accordance with the rehabilitation protocol.

Against this backdrop, it may not be practical to offer a joint replacement warranty that is meaningful, relative to how patients understand traditional warranties for consumer goods, A warranty that excludes these mechanisms of failure would be more narrowly written than patients might expect.

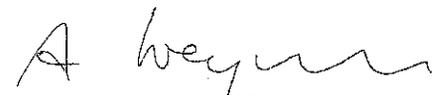
Just as determining the root cause of a patient needing revision surgery is difficult, it is also difficult to generalize regarding how long a procedure might bring relief and restore quality of life for a patient. As each patient is different and there are so many variables involved, surgeons often can only give broad predictions when setting expectations for their joint replacement candidates,

Smith & Nephew has a long, proud history of designing innovative solutions for addressing advanced knee and hip pain, and we monitor the performance of our implants in all available data sources, including patient registries, peer-reviewed publications and clinical studies. For instance, we lab-tested our VERILAST[®] Technology for knee replacement, and found it reduces wear by 98-percent compared to traditional implant materials. And when VERILAST Technology is used in hip replacement, clinical data shows it outperforms all other bearing surface materials in terms of implant survivorship. This data is publically available.

Smith & Nephew has dedicated personnel to examine any claims where our implant is suspected of being the cause of a surgery's failure. And in cases where our device was found to be at fault we have generally supported patients needing a revision procedure.

I hope that I have outlined our position clearly and that you can appreciate that this is a complicated subject. We look forward to learning about your findings from other device manufacturers and also suggest that you engage with some of our industry stakeholders, such as the American Association of Orthopedic Surgeons and AdvaMed.

Sincerely,



Andy Weymann, MD
Chief Medical Officer
Advanced Surgical Devices Division, Smith & Nephew