Smith & Nephew, Inc.
1090 Vermont Ave., NW, Suite 220
Washington, DC 20005
USA

T 1-202-898-2016
M 1-202-441-2342
F 1-901-566-7837

We are smith&nephew
www.smith-nephew.com

April 20, 2012

The Honorable Tom Coburn, M.D.
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

Dear Senator Coburn:

On behalf of Smith & Nephew, Inc., a global medical technology company with a significant presence in Oklahoma, I am writing to thank you for your leadership in introducing the "Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act of 2012"(S. 2292), or the "PATIENTS' FDA Act." We greatly appreciate your focus on ensuring that the Food and Drug Administration (FDA) clears pathways through which patients have timely access to cutting-edge medical devices. In particular, we commend you for including Section 506, Meeting the Device Needs of Individual Patients, which would allow for the reasonable manufacture of custom devices to serve certain patients' unique needs.

Smith & Nephew is dedicated to helping improve people's lives. With leadership positions in Orthopaedic Reconstruction, Advanced Wound Management, Sports Medicine, Trauma and Clinical Therapies, the Company has almost 11,000 employees and a presence in more than 90 countries, including more than 4,000 employees in the United States.

As you are aware, the current custom device exemption does not permit sufficient flexibility to enable medical device companies and our surgeon partners to meet the needs of the exemption's target population. If the need for a device presents more than once, the device can no longer be considered a custom device, requiring the manufacturer to have FDA approval or be evaluating the device in an IDE study. The clinical use of custom devices, however, is so limited that it is overly burdensome to apply for 510(k) clearance or premarket approval.

While it is the manufacturer's responsibility to design a range of device sizes and features to meet the majority of the population's anatomy, it is understood that the extremes of the population distribution are difficult to be included in the range of device sizes and are considered outliers. These outliers can introduce a worst case condition for testing and may not be feasible to be mass produced.

To meet these regulatory policy challenges, we strongly support Section 506 of the "PATIENTS' FDA Act." This provision would allow device manufacturers and our surgeon partners greater flexibility in attempting to address the unique anatomies of a very limited number of patients.

Thank you again for your leadership on this important issue.

Sincerely,

Paul A. Seltman
Sr. Vice President
Government Affairs & Reimbursement

cc: Members of the Senate Health, Education, Labor, and Pensions Committee