



April 20, 2012

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

Dear Senator Coburn:

On behalf of the Spina Bifida Association (SBA), the only national patient advocacy organization working on behalf of the estimated 166,000 individuals who live with all forms of Spina Bifida and their families, I am writing to express our appreciation to you for introducing the “Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act of 2012” (S. 2292), or the “PATIENTS’ FDA Act.” This legislation will ensure that the Food and Drug Administration (FDA) clears pathways through which Spina Bifida patients have timely access to cutting-edge medical devices.

Every day, an estimated eight babies are born with Spina Bifida – the nation’s most common permanently disabling birth defect – which adversely impacts virtually every organ system. Each year 3,000 pregnancies are affected by Spina Bifida and 1,500 babies are born with this complicated and devastating condition. These children join the ranks of an estimated 166,000 individuals living with all forms of Spina Bifida, in needing ongoing, life-long comprehensive, quality medical care.

In particular, SBA commends 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. Those living with Spina Bifida will have a lifetime of orthopedic issues, which in some cases will require a custom device. For years, the orthopedic surgeon had been able to obtain the custom devices within 48 hours from device manufacturers. However, since FDA has changed its view of custom devices, manufacturers can no longer provide these surgeons with these products. 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 Spina Bifida patients.

Thank you again for introducing this important piece of legislation. Should you have any questions, or if we can be of any assistance, please do not hesitate to contact me at (202)-944-3285, Ext. 14, or Jeremy Scott at (202) 230-5197. We are looking forward to working with you throughout the 2nd Session of the 112th Congress.

Sincerely,

Cindy Brownstein
President and Chief Executive Officer
Spina Bifida Association

cc. Senate HELP Committee Members