

TESTIMONY OF ED ROZYNSKI  
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U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS  
“Ensuring Safe Medicines and Medical Devices for Children”  
Tuesday, March 27, 2007 – 1:00 pm  
Room 430, Dirksen Senate Office Building

**Introduction**

Good afternoon. Chairman Dodd, Ranking Member Alexander, and Members of the Committee, my name is Ed Rozynski. I am Vice President of Global Government Affairs for Stryker Corporation (“Stryker”). On behalf of Stryker, an early supporter of this bill, I am pleased to present testimony today to support the “Pediatric Medical Device Safety and Improvement Act of 2007” (S. 830) and highlight the importance of ensuring the development of medical technologies for children.

Senator Dodd, we sincerely appreciate your leadership role on children’s issues and specifically on this landmark legislation. Like you and your colleagues, we want children to have access to the fullest and best range of possible medical treatments, even if that means doing or inventing something new just for them.

**Stryker and Its Commitment to Pediatric Populations**

Stryker is one of the world’s leading medical technology companies with the most broadly-based range of products in orthopaedics and a significant presence in the other medical specialties. Stryker Corporation is a Fortune 500 company with more than \$5 billion in revenue and more than 17,000 employees. Stryker is committed to bringing the best possible solutions to patients, surgeons, and health care systems throughout the world. This philosophy has placed Stryker at the forefront of medicine’s most promising breakthroughs in joint replacements, trauma, spine and micro implant systems, orthobiologics, powered surgical instruments, surgical navigation systems, endoscopic products, and patient handling and emergency medical equipment. Notably, Stryker’s products are used in over 80 percent of the hip and knee replacement procedures performed each year in the United States.

Stryker’s commitment to children is not new. Our company is a market leader in products of significance for children. We are the leading manufacturer of orthopaedic oncology prostheses in the United States and have a significant presence in other medical specialties with a high percentage of pediatric cases, including craniofacial deformities such as cleft lip and palate. We also take very seriously our responsibility to ensure that our devices are safe and effective for use in pediatric patients.

I’d like to take a few moments to tell you about some of our products that are commonly used in children.

## Oncology Prostheses and Craniomaxillofacial Technologies

There has been significant progress over the past two decades in the management of patients with musculoskeletal cancers that has improved both the survival rates and quality of life of afflicted individuals. Soft tissue and bone cancers represent less than one percent of all adult malignancies; however, they represent 15 percent of all malignancies in children. Twenty years ago, the standard treatment for any primary malignant bone and soft tissue sarcomas of the extremity was amputation of the affected arm or leg. Since that time, Stryker is proud to have partnered with leading orthopaedic oncology surgeons to develop limb-sparing, surgical solutions, including the implantation of a growing prosthesis that can be elongated to account for a child's growth.

Often, a child's only chance to beat these aggressive forms of cancer is the removal of most, if not all, of an entire bone. Stryker's implant and instrument technologies are designed to allow not only for bone replacement with a prosthetic device but also soft tissue reattachment, which is critical to enable limb function following surgery. In children, there is often the need to have several surgeries to elongate the prosthesis to keep up with their growth, and Stryker provides solutions to meet this need.



Osteosarcoma



Stryker GMRS Distal femoral prosthesis

As with cancer, the treatment of craniofacial deformities is an area in which Stryker also has significantly improved and broadened its range of available medical products and

solutions. With continued innovation of craniomaxillofacial technologies, Stryker hopes to continue to transform the lives of children facing challenges such as cleft lip and palate.

We take pride in partnering with and sponsoring a range of medical organizations, including Operation Smile, a non-profit organization dedicated to repairing childhood facial deformities around the world. Last year, Operation Smile was able to provide free cleft lip surgeries to 8,531 children in 23 countries. These surgeries – on average taking 45 minutes and costing \$240 per child – have a positive, lasting impact on the lives of pediatric patients and their families.

Finally, Mr. Chairman, I want to point out that children also suffer from other birth defects that, if left untreated, can cause permanent brain damage and/or severe disabilities. Craniosynostosis is a condition that results from premature fusion of the sutures or connections of the skull bones and has been estimated as a problem in three of every 10,000 live births. When this occurs, the pressure on a child's brain becomes an immediate threat to the organ's regular development. The surgical solution for this condition is deconstructing the skull and then reconstructing it to be normal in shape and size to permit normal growth. Stryker's Inion Baby™ system allows surgeons to effectively accomplish this procedure through polymer-based reabsorbable plates and screws specifically designed to reabsorb faster than the adult version of this product to accommodate the faster growth rates of children's bones. The Inion Baby™ system is also often used in cleft lip and palate surgeries.

### **Pediatric Device Legislation**

It is our sincere hope that the "Pediatric Medical Device Safety and Improvement Act of 2007" will further spur the evolution of novel health care solutions for children. This legislation provides a comprehensive approach for ensuring that children have access to medical devices that are manufactured with children's needs in mind.

First, the bill fosters the innovation of new pediatric devices. It authorizes new money to create a grant program to support the establishment of non-profit consortia to promote pediatric device development, including "matchmaking" between inventors and manufacturers. The bill also establishes a point of contact at the National Institutes of Health (NIH) to help innovators and physicians access funding for pediatric device development.

Second, the bill improves incentives for the development of devices for the pediatric market, which is very small. The cost of developing a new medical device and performing the required pre-market clinical studies can be enormous, often steering some manufacturers to serve larger, more established, and well known adult medical device markets.

Current law for Humanitarian Device Exemptions (HDEs) permits the Secretary of Health and Human Services to approve for use in up to 4,000 adults and/or children a

year a promising device that otherwise might not be approved. However, unlike for other FDA-approved medical devices, manufacturers are prohibited from making a profit on HDE products. The bill would lift the HDE profit restriction for new pediatric products only, in an effort to encourage more manufacturers to pursue the development of these products serving such small numbers of children.

Equalizing the incentives between pediatric HDE products and full market approval products in this way -- even if the costs per patient are higher -- likely will spur companies to develop pediatric products that they otherwise might not have. Moreover, these products might be targeted for pediatric populations with no other treatment options except through the HDE approval process. Therefore, it is important to provide incentives for surgeons, hospitals, and manufacturers so that they stick with innovative concepts for pediatric products to ensure that they make it from concept to reality.

Third, the bill facilitates the pooling and collection of more information about pediatric devices. Companies and other researchers are required to place certain pediatric postmarket studies and other research in a centralized, publicly available database so that information and solutions can be easily shared and analyzed. It also creates a mechanism to allow the Food and Drug Administration to track the number and type of certain higher-risk devices approved for use in children. In addition, the bill incorporates several recommendations made by the Institute of Medicine in its report on pediatric devices, including increasing the postmarket surveillance of medical devices used in children.

Senator Dodd, we applaud you for introducing this legislation and look forward to continuing to work with you on refining the bill and advocating for its passage into law this year.

## **Conclusion**

In closing, I would like to say that Stryker is committed to working with others to find more and better solutions to the often costly and unique health care challenges of children.

We see the hope and the benefit that our latest bone implants provide to children with cancerous tumors. In order to reach more children, Stryker has decided that we will find a way to provide much needed charitable assistance to families and patients who are undergoing treatment for pediatric bone cancers at selected NIH Comprehensive Cancer Care Centers in the United States. Specifically, we are looking for the best way to provide financial support for lodging, travel, and other non-healthcare expenses associated with travel to a Center of Excellence hospital for treatment – expenses not covered by health insurance and that often pose a serious impediment to a family’s ability to provide for a child’s care and recovery.

We intend to finalize our plans and to announce them within the next several months, perhaps, in coordination with the passage of a much needed pediatric device bill. We believe that Stryker’s charitable initiative will complement the advanced medical

technologies for children that Stryker already develops, and that all companies will be further encouraged to develop as a result of Chairman Dodd's legislation.

I thank the Committee for the opportunity to testify this afternoon, and I would be pleased to answer any questions the Committee may have.