TESTIMONY OF ED ROZYNSKI
VICE PRESIDENT, GLOBAL GOVERNMENT AFFAIRS
STRYKER CORPORATION

U.S. HOUSE OF REPRESENTATIVES ENERGY AND COMMERCE COMMITTEE
SUBCOMMITEE ON HEALTH
"Programs Affecting Safety and Innovation in Pediatric Therapies"
Tuesday, May 22, 2007 – 10:00 am
Room 2322, Rayburn House Office Building

**Introduction**

Good morning. Chairman Pallone, Ranking Member Deal, and Members of the Subcommittee, my name is Ed Rozynski. I am Vice President of Global Government Affairs for Stryker Corporation ("Stryker"). On behalf of Stryker, I am pleased to present testimony today in support of the "Pediatric Medical Device Safety and Improvement Act of 2007" (H.R. 1494), which would promote the development of medical technologies for children.

As an early supporter of the bill, we sincerely appreciate Congressmen Markey and Rogers' 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.

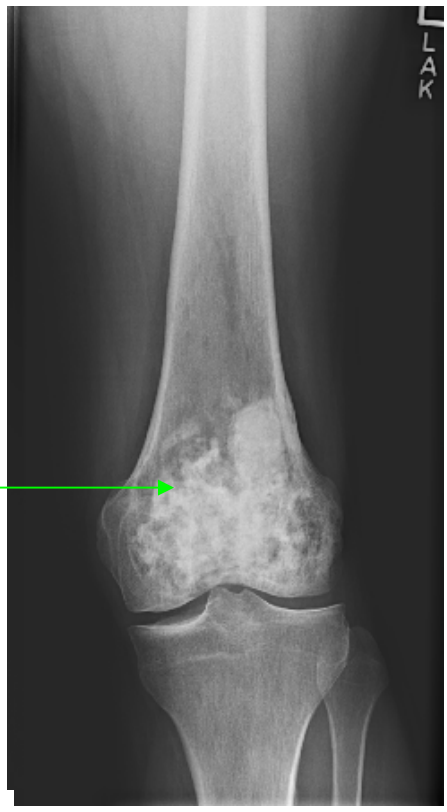
I would like to take a few moments to tell you about some of our products that are commonly used in children.

**Oncology Prostheses and Craniomaxillofacial Technologies**

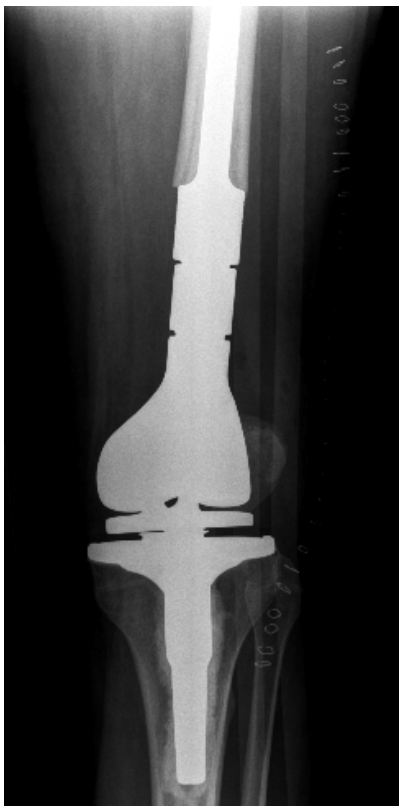
There has been significant progress over the past two decades in the management of patients with musculoskeletal cancers that has improved both the survival rates and quality of life of afflicted individuals. Soft tissue and bone cancers represent less than one percent of all adult malignancies; however, 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 form 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 while maintaining the cap of 4,000, in an effort to encourage more manufacturers to pursue the development of these products serving such small numbers of children.

Improving the incentives for pediatric HDE products 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 and turn them into a reality for young patients.

Third, the bill facilitates the pooling and collection of more information about pediatric devices. It requires companies and other researchers to place certain pediatric postmarket studies and 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. We are aware of ongoing discussions related to the postmarket surveillance provisions of the bill and hope successful resolution will be reached on this issue. This bill has twin goals that we support: bringing more pediatric medical devices to market and improving information about pediatric

devices. All stakeholders should work together to ensure that provisions of this bill are structured so that both goals may be achieved.

We applaud Congressmen Markey and Rogers for introducing this bill, and we thank all of the Members of the Subcommittee for considering this important legislation. We 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. For example, we see the hope and the benefit that our latest bone implants provide to children with cancerous tumors.

Additionally, in an effort to reach even more children, Stryker has decided that we will 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 travel, lodging, 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.

We believe that Stryker's charitable initiative will complement the advanced medical technologies for children that Stryker already develops and manufactures. It is our hope that we and other medical device companies will be further encouraged to develop more pediatric devices as a result of Congressmen Markey and Rogers' legislation.

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