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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Docket # 2006P-0085
Rockville, Maryland 20852

Children's Memorial Foundation
Children's Memorial
Research Center
Children's Surgical Foundation

RE: Docket # 2006P-0085 - Cranial Orthoses

Dear FDA Officials:

I am writing in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. This notice requested comments on the possibility of establishing an exemption from the premarket notification requirements for cranial remolding orthoses (headbands). These devices are used to improve cranial symmetry for babies with cranial molding from both surgical (craniosynostosis) and non-surgical (positional molding such as plagiocephaly) causes. The most common reason to use a cranial molding orthoses is positional plagiocephaly.

As a craniofacial surgeon very actively involved in the treatment of infants with deformational plagiocephaly, I strongly oppose this change. I sincerely believe that if cranial remolding orthoses are exempted from premarket notification requirements, it will create safety and effectiveness issues for babies that require cranial remolding orthoses. There are risks inherent in applying cranial orthoses to an infant's rapidly growing cranium, and it is ill-advised to remove the current level of safeguards in place to protect this vulnerable population of patients. The appropriate manufacture and management of these devices are critical to achieving the desired result. If either of these processes is not controlled, the desired result will not be achieved.

It is very important that we ensure the utmost protection for babies with head shape anomalies by maintaining stringent regulation as presently mandated by the FDA.

The petition by the AANS is short-sighted, and makes light of the potential problems that may result from head shape asymmetry. Head shape deformities are not the benign anomaly that the AANS petition implies. Recent research (attached) has documented that infants with plagiocephaly can have significant developmental delays, visual motor problems and jaw and facial asymmetry. The FDA's involvement with cranial remolding orthoses ensures that the necessary protocols and procedures are in place during the manufacturing process so that optimal outcomes can be achieved in this time-sensitive treatment. I strongly encourage you to deny the AANS petition and maintain the present FDA safeguards for cranial remolding orthoses as Class II Medical Devices.

Sincerely,

Frank A. Vicari, MD, FACS, FAAP
Director, Head Shape Evaluation Program
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FAV/crs

Enclosures

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