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October 31, 2006

Re: FDA Docket 2006P-0085

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I oppose the petition to exempt cranial orthoses from the premarket notification requirements that typically apply to Class II devices.

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- I strongly agree with the FDA's determination on July 30, 1998 that cranial orthoses require regulation as Class II devices with special controls. This determination was made to provide reasonable assurance of the safety and effectiveness of these devices. The FDA identified a number of health risks inherent in the use of these devices, including the potential for skin breakdown, head and neck trauma, asphyxiation, eye trauma and impairments to brain growth and development.¹
- The FDA revisited and reiterated this determination in a letter dated September 13, 2000. Although the FDA determined that cranial helmets used solely for protection are Class I devices, the FDA reaffirmed that cranial orthoses intended to improve cranial symmetry and/or shape will continue to be classified as Class II devices and will continue to require premarket notification.²
- These are both recent determinations, and there is no meaningful evidence to suggest that the FDA should reverse its decisions. The FDA applied its four criteria for exemption determinations in the past to cranial orthoses, and there is insufficient evidence to change the FDA's determination.³
- For example, there remains insufficient evidence to demonstrate that the health risks associated with the inherent characteristics of cranial orthoses have changed since the FDA identified these risks (such as skin breakdown, head and neck trauma, asphyxiation, eye trauma and impairments to brain growth and development) in 1998.
- As another example, there is insufficient evidence to suggest that changes to the device (such as changes to the materials, weight or design of the device) would not materially increase the risk of injury or increase the risk of ineffective treatment. The Petitioner certainly did not fully address any of the FDA's four criteria, and the Petitioner did not

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¹ 63 Federal Register 40650 (July 30, 1998); 21 CFR Section 882.5970.

² Letter from Linda S. Kahan, FDA to C. Michael Schuch, President, American Orthotic and Prosthetic Association, dated September 13, 2000.

³ Specifically, the FDA considers the following factors: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials; (2) The characteristics of the device necessary for its safe and effective performance are well established; (3) Changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. 63 Federal Register 3143 (January 21, 1998).

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address the vast majority of the potential health risks identified by the FDA for cranial orthoses in the past.

- In fact, the FDA should be especially cautious because cranial orthoses are used to treat a vulnerable population of infant patients by shaping the rapid growth of their skulls during the initial months of life.
- I support the FDA's current position, and I urge the FDA to refrain from removing the existing premarket notification requirements for cranial orthoses.

It is also worth briefly addressing some of the misconceptions raised in the beginning of the Petitioner's letter.

- First, there is no meaningful evidence to suggest that ongoing innovation, development or patient access have been thwarted by the Class II designation. To the contrary, there is now widespread patient access to a superior level of orthoses and associated therapy.
- Second, the Petitioner states that cranial orthoses are manufactured primarily by "large national conglomerates." However, according to the FDA website, the FDA has cleared a total of 28 510(k)s for various cranial orthoses since 1998.⁴ Of this total, small, independent orthotic and prosthetic providers filed the clear majority of the applications. The FDA website indicates that 6 manufacturers, 6 hospitals and 10 orthotists have secured 510(k)s for cranial orthoses.⁵
- Third, the Petitioner also incorrectly suggests that price increases over the years have been the result of the FDA's regulation. To the extent that increases have occurred in the price of therapy with cranial remolding orthoses, the primary cause is the significant increase in the service-intensity of this therapy. In contrast to the 1980s and early 1990s, most treatment regimens for therapy with cranial orthoses now involve weekly followed by bi-monthly clinical visits with the treating orthotist, resulting in an additional 8 to 10 hours of professional time. Since cranial remolding orthoses are billed under HCPCS Level II codes, the cost of these clinical visits must be bundled together along with the cost of the product.

For the reasons discussed above, I believe the Petitioner's request is fundamentally flawed, failing to meet the criteria used for determinations under Section 510(m)(2) of FDAMA. I urge the FDA to reject the Petitioner's Citizen Petition.

Sincerely,



James W. Sherrill, CO, LO

⁴ U.S. Food and Drug Administration, August, 2006. Accessed at: <http://www.fda.gov/cdrh/index.html>.

⁵ Available at: <http://www.fda.gov/cdrh/index.html>

Division of Dockets Management (HFA-305)

Food and Drug Administration

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