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September 21, 2006

**VIA HAND DELIVERY**

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

**Re: FDA Docket 2006P-0085  
Comments in Opposition to Exemption Petition**

Dear Sir or Madam:

The following comments are submitted in opposition to the petition for exemption of the Class II device "cranial orthoses" from premarket notification requirements under Section 510(m)(2) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) submitted by the American Association of Neurological Surgeons ("Petitioner") on July 6, 2006 (FDA Docket 2006P-0085).

We oppose the petition to exempt cranial orthoses from the premarket notification requirements associated with these Class II devices. Such an exemption would fail to provide reasonable assurance of the safety and effectiveness of these devices. The Petitioner fails to provide adequate information to reverse the decision that the Food and Drug Administration ("FDA") rendered recently in 1998 and subsequently revisited in 2000.

The FDA promulgated a notice on January 11, 1998 describing the FDA's factors for exempting Class II devices from premarket notification requirements under Section 510(m)(2).<sup>1</sup> At that time, the FDA applied these factors to identify several dozen Class II devices that are now exempt from premarket notification requirements.

After the FDA established and extensively applied these factors, the FDA subsequently determined on July 30, 1998 that cranial orthoses required regulation as

**2006P-0085**

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<sup>1</sup> 63 Federal Register 3143 (January 21, 1998).

Class II devices with special controls to provide reasonable assurance of the safety and effectiveness of these devices.<sup>2</sup>

The FDA revisited and reiterated this determination in 2000 in the context of a citizen's petition involving cranial helmets. The FDA distinguished cranial helmets used for protection from cranial orthoses used for remolding infants' growing skulls. In a letter dated September 13, 2000, the FDA determined that cranial helmets for protection are Class I devices, although a device that is intended to improve cranial symmetry and/or shape will continue to require premarket notification.<sup>3</sup>

Thus, the FDA already has considered the issue of classification and potential exemption of cranial orthoses in the recent past. The FDA rendered its initial decision after the FDA established the current criteria for considering such exemptions in 1998. In addition, the FDA subsequently revisited the issue in a related evaluation in 2000. These are both recent determinations, and there is no meaningful evidence to suggest that the FDA should reverse this decision.

In fact, the FDA should be especially cautious in removing any safeguards involving these devices, which are used to treat an especially vulnerable population of infant patients by shaping the rapid growth of their skulls during the initial months of life. The medical literature is just starting to report on the complexity of the medical conditions that result in the need for treatment with these devices. In addition, as the Petitioner highlights, one can expect a dramatic increase in the number of these patients in the near future.

The issues raised by the Petitioner are addressed in full below.

### **The Assertions Made by the Petitioner Regarding Patient Access and the Cost of Cranial Orthoses Are Inaccurate**

At the outset, the Petitioner makes several important assumptions and arguments that are simply inaccurate. In particular, the Petitioner states that cranial orthoses are manufactured primarily by "large national conglomerates," suggesting that access, innovation and cost competition are discouraged by the Class II designation. In fact, the opposite is true.

According to the FDA website, the FDA has cleared a total of 28 510(k)s for various cranial orthoses since 1998.<sup>4</sup> Of this total, the clear majority of the applications were filed by small, independent orthotic and prosthetic providers. The FDA website indicates that the 510(k) applications can be broken down as follows:

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<sup>2</sup> 63 Federal Register 40650 (July 30, 1998); 21 CFR Section 882.5970.

<sup>3</sup> Letter from Linda S. Kahan, FDA to C. Michael Schuch, President, American Orthotic and Prosthetic Association, dated September 13, 2000.

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

**510(k)s Cleared for Cranial Orthoses 1998 to Present**

FDA's Characterization of Entity	Number of Entities	Number of 510(k)s
Manufacturers	6	12
Hospitals	6	6
Orthotists (independent)	10	10

Source: <http://www.fda.gov/cdrh/index.html>

Several important conclusions can be drawn from this information. The 510(k) holders are quite diverse and clearly are not limited to "large national conglomerates." In fact, local hospitals and independent entities have filed the majority of the 510(k)s for cranial orthoses. 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.

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.

As a result, the Petitioner's justifications for requesting an exemption from the FDA's existing safeguards are flawed.

**FDA Exemption Factors for Consideration**

Each of the FDA's factors for consideration under Section 510(m)(2) are addressed below. In each instance, there is insufficient evidence to satisfy the FDA's factors for exempting a Class II device from premarket notification requirements.

***There is insufficient evidence to demonstrate that 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.***

The Petitioner fails to provide meaningful information regarding any history of false or misleading claims or of risks associated with the inherent characteristics of the device. The Petitioner provides eleven references in support of the petition. However, two of these articles discuss the issue of sudden infant death syndrome (rather than cranial orthoses), and three additional articles were published prior to the FDA's 1998 determination.

The six remaining articles submitted by the Petitioner do not provide definitive statements regarding the history of false or misleading claims that have occurred or that could occur in the absence of the current regulatory approach to these Class II devices.

In fact, the literature referenced by the Petitioner highlights the inherent risk of cranial orthoses and supports the FDA's concerns regarding the safety and efficacy of cranial orthoses. For example, the articles referenced by the Petitioner include the following statements:

These devices [cranial orthoses] are unique because they are applied to the rapidly growing infant cranium. They therefore represent an inherently greater risk than most other types of orthotics.<sup>5</sup>

The classification of the cranial orthosis as a Class II neurology device demonstrates that the FDA has recognized the potential adverse consequences if these devices are not used appropriately. These devices are unique in that they are being applied to an infant's rapidly growing cranium and thus present an inherently greater risk than many other types of orthotics....<sup>6</sup>

The Petitioner also fails to address the inherent characteristics of cranial orthoses that present numerous health risks identified previously by the FDA. In the FDA's 1998 determination regarding cranial orthoses, the FDA identified the following six risks to health associated with these Class II devices:<sup>7</sup>

- 1) Skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin;

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<sup>5</sup> Littlefield TR. Cranial remodeling devices: treatment of deformational plagiocephaly and postsurgical applications. *Semin Pediatr Neurol.* 2004, 11:268-277.

<sup>6</sup> Littlefield TR. Food and Drug Administration regulation of orthotic cranioplasty. *Cleft Palate—Cranioplasty Journal.* 2001, 38(4):337-340.

<sup>7</sup> 63 Federal Register 40650 (July 30, 1998).

- 2) Head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements;
- 3) Impairments of brain growth and development from mechanical restriction of cranial growth;
- 4) Asphyxiation due to mechanical failure, poor fit, and /or excessive weight that alters the infant's ability to lift the head;
- 5) Eye trauma due to mechanical failure, poor construction and/or inappropriate fit; and
- 6) Contact dermatitis due to the materials used in the construction of the device.

The Petitioner is silent regarding the vast majority of these health risks identified by the FDA for this vulnerable population of patients, and there is inadequate support for any change in the current regulation of these devices. Adequate information does not exist for the FDA to reverse its 1998 decision regarding the need for premarket notification for cranial orthoses.

Although the Petitioner portrays the clinical literature as more or less settled, recent studies highlight that serious impairments are associated with deformational plagiocephaly, including developmental, visual and bony deformities.<sup>8,9</sup> These clinical conditions requiring treatment with cranial orthoses are far more complicated and serious than the benign, cosmetic deformities described in the past. The FDA must remain mindful that this is a vulnerable patient population with clinical conditions, as well as long-term prognoses, that are far more serious and complex than suggested by the Petitioner.

***There is insufficient evidence to demonstrate that the characteristics of the device necessary for its safe and effective performance are well established***

With respect to this factor, the Petitioner simply asserts but does not comment upon the characteristics of the device necessary for safe and effective performance. The Petitioner also makes a brief reference to the indications for the device and the general clinical routines.

The Petitioner also does not describe how the FDA and caregivers can be assured that biocompatible materials are used, the straps will not become a choking hazard, and a

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<sup>8</sup> Kordestani RK, Patel S, Bard DE, Gurwitsch R, Panchal J. Neurodevelopmental delays in children with deformational plagiocephaly. *Plastic and Reconstructive Surgery*. 2006; 117:207-218.

<sup>9</sup> Siatkowski RM, Fortney AC, Sayeda AN, Cannon SL, Panchal J, Francel P, Feuer W, Ahmad W. Visual field defects in deformational posterior plagiocephaly. *Journal of the AAPOS*. 2005; 9:274-278

safe and effective design is employed to address the head shape deformity. Outside of the 510k procedures, no industry fabrication standards are documented for cranial remolding orthoses to ensure that the device will not cause skin breakdown and will be an appropriate weight and size for the young infant. Additionally, the Petitioner does not address the health risks described previously by the FDA for cranial orthoses (see above).

Certainly, there is insufficient information to conclude that adequate protections would exist in the absence of the current regulatory requirements for these Class II devices.

***There is insufficient evidence to demonstrate that the changes in the device that could affect safety and effectiveness will either: (a) be readily detectible by users by visual examination or other means such as routine testing before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.***

The basis for the Petitioner's confidence on this point is unclear. In dealing with the infant patient, subtle changes in the materials used, weight of the device or design of the device could have significant adverse impacts with respect to the health risks identified previously by the FDA. These health risks include:

- Skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin;
- Head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements;
- Impairments of brain growth and development from mechanical restriction of cranial growth;
- Asphyxiation due to mechanical failure, poor fit, and /or excessive weight that alters the infant's ability to lift the head;
- Eye trauma due to mechanical failure, poor construction and/or inappropriate fit; and
- Contact dermatitis due to the materials used in the construction of the device.<sup>10</sup>

At a minimum, there is insufficient information to conclude that adequate protections would exist in the absence of the current regulatory requirements for these Class II devices

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<sup>10</sup> 63 Federal Register 40650 (July 30, 1998).

***The Petitioner presents inadequate information to demonstrate that any changes to the device would not be likely to result in the device's classification.***

There are a number of innovative changes that are in the research and development stage for cranial orthoses, including potential changes in structure and material selection.

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We believe the Petitioner's request is fundamentally flawed, failing to meet the factors used for determinations under Section 510(m)(2) of FDAMA. We urge the FDA to reject the Petitioner's Citizen Petition.

Thank you for your consideration of this issue. We request the opportunity to respond to any additional questions that the FDA may have regarding this issue, as well as the opportunity to meet with FDA officials. I can be contacted at 202-624-7301 or [sstranne@pogolaw.com](mailto:sstranne@pogolaw.com).

Sincerely,



Steven K. Stranne, M.D., J.D.

cc: Mark Melkerson  
Director,  
General, Restorative and Neurological Devices Division