

Dockets Management Branch
HFA-305, Food and Drug Administration
Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Gentlepersons:

The American Association of Neurological Surgeons and Congress of Neurological Surgeons Forum on Drugs, Devices, and Biologics, sponsors of the petition (Docket 2006P-0085) to exempt cranial orthoses from class II regulation, would like to take the opportunity to discuss some of the points in the letter of Powell Goldstein dated Sept 21, 2006 submitted as part of the public comment process. As representatives of the medical profession and proponents of patient care, we take major exception to the letter. Although it is not stated who Powell Goldstein represents, we strongly believe they are council for one of the major helmet manufacturers, which as a group that has been the major benefactor of the FDA regulation of cranial molding helmets, as the patient population clearly has not been a benefactor in this process.

Based on the petition for exemption filed in 2000 by the American Orthotic and Prosthetic Association, and the current petition submitted by our group as representatives of this country's neurosurgeons and their patients, it is clear that the prescribers and producers of the devices feel that there is a very safe product profile. The 1998 decision by the FDA, which approved the 'de novo' application for Class II regulation of a device that had been employed for no less than two decades, has had significant negative impacts on patient care. The net result of the FDA regulation has been a marked increase in the cost of the device, which has directly benefited the large manufacturers at the expense of patients. We would like to outline our concerns with the Powell Goldstein letter below.

With regard to their first point, that most applications have been filed by small independent providers, this belies the true manufacturing trends. Twelve applications have been filed by manufacturers, whereas 16 have been filed by hospitals and orthotists. However, the hospitals and orthotists only produce for their local population of patients, whereas the manufacturers have a nationwide distribution network. For instance, Cranial Technologies, producers of the DOC band, lists 16 sites on their website alone, indicating this one manufacturer has as many distribution points as all of the hospitals and orthotists combined. It is important to note that prior to the FDA ruling it is likely that hundreds of orthotists were producing the helmet devices, and the net effect of the ruling has been that the vast majority of helmets are now outsourced to the major manufacturers. As prescribers of the devices, we are absolutely certain that this has led to a significant price increase with a concurrent falloff in low-income patient access. We do not believe that the service intensity before and after the 1998 regulations has changed, and do not feel that this is a justification for the increased price of the device, which we believe on average went up 400% in most markets. Pure and simple, the increased price is a result of a decrease in supply competition.

With regard to false and misleading claims, to the best of our knowledge there simply have been none. We are unable to provide 'meaningful information regarding any history of false or misleading claims', as the Powell Goldstein letter states, simply because it does not exist, and we do not feel this is a failing of the petition. Similarly, we do not provide substantial data on the "inherent characteristics of cranial orthoses that present numerous health risks identified previously by the FDA" for the same reason. These data do not exist. In the 'de novo' application process we believe that the risks were substantially over-stated. As a group we have treated thousands of these infants and are not aware of any health risks related to head and neck trauma, impairments of brain growth (which was in fact addressed in the petition, reference 5),

asphyxiation, or eye trauma. We do agree that there is a low risk of skin irritation and contact dermatitis, which is why we believe that these devices should be available only by prescription and under the supervision of a medical professional. Health care professionals that prescribe these devices are best able to monitor their effectiveness and safety, and are best able to understand the characteristics of the device needed for its safe and effective performance.

Although we do not believe that there will be substantial changes to this safe and effective device, we certainly agree that changes to the device should be monitored. We clearly state in the Limitation on Exemption section of the petition that “an exemption from the requirement of premarket notification for a cranial orthosis is only to apply to those devices that have characteristics of commercially distributed devices.... A cranial orthosis would not be exempt from premarket notification if it (1) has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type. If innovations come about that so change the device such that they are no longer consistent with the commercially distributed devices, these changes should be assessed fully for their safety and efficacy.”

We remain committed to representing the best interests of the patients we serve. We continue to feel that the benefactor of the FDA regulation has been industry, not patients, and we strongly hope that the the FDA appreciates the validity and urgency of the petition.

Sincerely,

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