

ATTACHMENT H

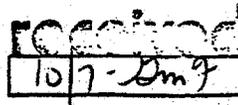


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1999



Larry R. Pilot, Esq.
McKenna & Cuneo, L.L.P.
Counsel to Petitioner
Medical Device Manufacturers Association
1900 K Street, N.W.
Washington, D.C. 20006

Re: Docket No.. 99P-1516/CP 1

Dear Mr. Pilot:

This letter is in response to your citizen petition on behalf of the Medical Device Manufacturers Association (MDMA), dated May 20, 1999, requesting that the Food and Drug Administration (FDA) issue a proposed regulation identifying reprocessed single use devices as banned devices and that such proposed regulation be made effective upon its publication in the Federal Register. As stated, the petition applies to practitioners, institutions, and reproprocessors. Thank you for the detailed petition and the issues you raised. We regret the delay in responding.

The petition requests that FDA issue a proposed regulation to ban the practice of reprocessing single use devices and to make the ban effective on the date of publication of the proposed regulation in the Federal Register. The stated grounds for the petition included a statement that the "complexity of these devices for their intended use severely constricts any possibility of cleaning and sterilizing the device in order to restore it to its original unused condition." Your letter also stated that manufacturers are required to obtain PMA approval or 510(k) clearance for their devices and that "FDA required labeling" for such devices must state that they are for single use and are not to be reused. You stated that this requirement must be met in the absence of information provided to FDA demonstrating that reprocessing will not adversely affect product safety or effectiveness.

FDA has carefully reviewed your petition to ban the reprocessing of single use devices, and we are denying it. The Agency does not believe that banning is the appropriate action to address the many and varied issues tied to this practice. Our reasoning follows.

There is no clear evidence that reprocessing presents "an unreasonable and substantial risk of illness or injury," which is one of the criteria for banning a medical device. FDA

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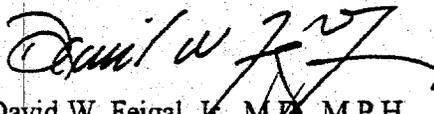
has received adverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported. In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source. Therefore, the "unreasonable and substantial risk" criterion has not been met.

According to the banning provision of the Federal Food, Drug and Cosmetic Act, Section 516, another criterion that can be used for taking such an action is substantial deception. As your petition suggests, it would be difficult to establish whether deception with respect to reprocessed devices has occurred and who was the target of that deception. Even if we did establish a basis to claim substantial deception, the statutory option of banning does not seem to be an appropriate response. There is no evidence to date supporting any such danger to individual health from the reuse of products that have been labeled for only a single use. This burden has not been met.

While FDA will not support a banning action, we believe that a significant re-evaluation of FDA's position with regard to the reuse of single use devices is in order. During the May 1999 AAMI/FDA Reuse Conference, FDA committed to provide a formal response to the conference in a Federal Register notice by October 1999. We plan to honor that commitment. Our Federal Register statement will address the direction of FDA's thinking with regard to key issues and concerns raised at the May conference, such as data generation, premarket submissions, and labeling. We encourage you and your client, MDMA, to be active participants in reviewing and responding to the upcoming Federal Register notice and any other document that FDA may issue on this subject.

If you have any questions, please contact Larry Spears at 301-594-4646, Ext. 151.

Sincerely yours,



David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and
Radiological Health