American Academy of Orthopaedic Surgeons®

AAOS American Association of Orthopaedic Surgeons®

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August 6, 2001

Bernard Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, MD 20852

Dear Dr. Schwetz,

On behalf of over 16,000 members, the American Academy of Orthopaedic Surgeons (AAOS) respectfully requests that the Food and Drug Administration (FDA) immediately delay implementation of the Class I, exempt single-use reprocessing enforcement provisions for hospitals and reprocessors. Section 510 of the Act; 21 CFR Part 807 requires hospitals and reprocessors of single-use devices to register and list with the FDA by the deadline of August 14, 2001.

AAOS has grave concerns about the regulatory guidance and enforcement provisions for some medical devices that are labeled for single-use, and hopes that the agency will revisit this important matter prior to the enforcement implementation. Specifically, the AAOS notes that:

- There is a lack of scientific and empirical evidence necessitating the extent to which these guidelines have been applied;
- The tremendous cost increase, especially to hospitals, warrants greater consideration before the issuance of these guidelines;
- The enforcement guidelines do not apply to ambulatory surgical centers which also reprocess single-use devices; this inconsistent application of the guidance does not seem to address the public safety concern;
- Class I exempt, such as monoblock metallic devices, (simple, uniform, solid metal devices without moving parts, joints, or attachments) should be exempt from single-use labeling, as reprocessing of these devices poses no risk to the patient;
- A uniform standard must be developed for identifying and labeling single-use devices.

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The AAOS is troubled that the FDA's actions are not based on scientific evidence. The Academy is aware of two high profile malfunctions of reprocessed non-Class I single-use labeled devices that were presented in the popular media, neither of which were orthopaedic devices. To date, there is no scientific evidence that patient safety has been compromised with any orthopaedic devices. Therefore, to apply a broad sweeping regulation to all devices does not seem equitable or to satisfy the scientific approach adopted by the FDA.

The AAOS firmly believes that medical devices must indeed be safe and efficacious; patient safety is of paramount concern and should never be compromised. To that end, the reprocessing record of non-Class I exempt orthopaedic devices demonstrates the efficient reuse of medical devices with the utmost concern for patient safety.

Hospitals anticipate that their costs for device expenditures will increase exponentially as a direct result of the FDA regulation. This final guidance document has created an unintended adverse consequence for patients and society at large due to increased cost passed down to the patient without demonstrable patient benefit. This can ultimately compromise the delivery of care. The AAOS feels that the FDA has not adequately considered the important financial ramifications of this regulation and how they will negatively affect patient care and the delivery of services. The AAOS is very concerned that the cost of medical devices may adversely dictate the practice of medicine.

The AAOS is aware that the single-use device regulation only applies to hospitals and third-party reprocessors. Reprocessing at physician's offices and surgical centers is not subject to the same requirements. If the premise of the regulation is to protect the health of the public, then this regulation fails on its foundation due to the fact that other health facilities are not subject to the same reprocessing scrutiny.

The AAOS objects to the labeling of Class I exempt devices, such as orthopaedic monoblock metallic devices including blades, reamers, knives, burrs and drill bits as single-use devices. These devices have been successfully sterilized and reprocessed for decades and may be used repeatedly with no adverse consequences. Manufacturers have arbitrarily labeled these devices for single-use. It is in the best financial interest of the manufacturer to label every device for single use in order to sell more units of devices. Interestingly, even devices that have an electric motor are labeled for single-use. The AAOS does not believe that any rationale exists to the labeling of such devices as "single-use". The AAOS specifically requests that orthopaedic monoblock metallic devices be exempt from single-use labeling.

Furthermore, due to a dramatic increase in medical waste, the AAOS anticipates significant environmental consequences as a result of this regulation. We are reminded that landfill space is a precious resource and that it is incumbent on each and every one of us to reduce, reuse, and recycle resources before disposing of them.

The AAOS does not foresee any adverse consequences to patient safety by delaying implementation of the enforcement guidelines for Class I exempt devices. We thank you for your consideration to delay implementation on this very important final guidance document so that the FDA can have more time to carefully evaluate the concerns raised in this letter. The Academy is aware that many entities will be affected by decisions made regarding the reprocessing of devices, and the AAOS looks forward to working with the FDA on this matter.

Sincerely,

William W. Tipton, Jr., MD
Executive Vice President

Cc: The Honorable Tommy G. Thompson
David Feigal, MD, MPH
Bernard Statland, MD, PhD
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