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6300 North River Road Rosemont, IL 60018-4262
Phone 847/823-7186, 800/346-2267 Fax 847/823-8125 Fax-on-Demand 800/999-2939 Internet www.aaos.org



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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) welcomes this opportunity to comment on the Food and Drug Administration's (FDA) Premarket Guidance: Reprocessing and Reuse of Single Use Devices; Draft Guidance for Industry and FDA Staff (published in the Federal Register on June 1, 2001[Docket No. 01D-0232]).

The Academy wishes to thank the FDA for its willingness to discuss the concerns outlined in our letter submitted to this docket, dated August 6, 2001. The AAOS appreciates the FDA's concern for patient safety in the area of reprocessing and reuse of single use devices (SUDs). As advocates for our patients, the AAOS believes that patient safety should never be compromised and realizes that some devices may not be capable of being reprocessed. Nonetheless, the Academy believes that some single-use devices may be reprocessed safely and efficiently with no adverse consequences to patients.

The Academy has grave concerns about the adverse consequences the guidance and enforcement provisions may have on patients, payers, and providers in the health care system. Of particular concern to the AAOS in this matter is the apparent lack of scientific evidence necessitating the guidance, as well as the financial burden hospitals will incur, at the expense of patients and insurers, upon implementation. We hope that the agency will consider these important issues, as well as others outlined below. Specifically, the AAOS notes that:

- There is a conspicuous lack of scientific and empirical evidence necessitating the extent to which this guidance has been applied;
- The enforcement guidance does not pertain to ambulatory surgical centers which also reprocess single-use devices; this inconsistent application of the guidance does not address the public safety concern;
- The tremendous cost increase, especially to hospitals, warrants greater investigation into the end results of this guidance on the delivery of care;

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- A uniform standard for identifying and labeling single-use devices must be developed and consistently applied;
- Class I 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 patients;
- SUD reprocessing cannot be considered human experimentation due to the long history of safe reprocessing;
- Environmental consequences will be substantial as a result of the guidance document;
- The guidance document format is preferable to proposed rule making;
- There is no evidence of prion disease transmission during orthopaedic surgery.

LACK OF SCIENTIFIC EVIDENCE

The AAOS is troubled that the FDA's actions are not based on scientifically relevant studies. 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. Although investigative and corrective actions are indeed warranted in such cases, individual case reports are not sound foundation upon which to base encompassing regulatory guidelines. Clearly, incident case reports are beneficial in that detailed explanations provide insight into the reasons for device failure and opportunities for health care professionals to prevent them. Conclusions derived via the scientific method of hypothesis testing and objective data gathering will enable us to soundly identify any potential threat to patient safety involved with SUD reprocessing.

INCONSISTENT APPLICATION OF THE GUIDANCE TO ALL HEALTH CARE FACILITIES

In creating this guidance, FDA attempts to improve current measures to safeguard the public's health. The regulatory guidance and its enforcement priorities, however, do not support this apparent motive. This regulation applies only 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.

COST INCREASES WILL NEGATIVELY AFFECT PATIENT CARE

From a financial standpoint, hospitals anticipate that their costs for device expenditures will increase as a direct result of the FDA regulation. The AAOS realizes that the FDA is not mandated to consider cost implications, nonetheless this guidance has enormous financial consequences. The AAOS feels that the FDA has ignored the important financial ramifications of this regulation and how they will negatively affect patient care and the delivery of services. This guidance document has created an unintended adverse consequence for patients and society at large due to increased cost passed down to the consumer without any demonstrable patient benefit. The paperwork required under the guidance for the sterilization and reprocessing of even simple monoblock metallic devices is substantial, labor intensive, and requires personnel with advanced knowledge of FDA procedures. These financial constraints may reduce options

for hospitals attempting to decrease costs while still delivering high-quality care. As a result, hospitals may be forced into either expensive contractual arrangements with third party reprocessing firms, or the more costly alternative of disposing devices after one use, regardless of their capacity to be safely reprocessed. At this time, there is a conspicuous lack of third party reprocessors capable of reprocessing all of the devices addressed in the guidance. Hospitals may be forced to discard otherwise functional devices due to a lack of available options. The AAOS is very concerned that the cost of medical devices may adversely dictate the practice of medicine.

A UNIFORM STANDARD FOR LABELING MUST BE DEVELOPED AND IMPLEMENTED

Unfortunately for hospitals and providers, manufacturers arbitrarily label certain medical devices for single-use, and device pricing fluctuates within the industry. In the June 2000 GAO report Single Use Medical Devices (GAO/HEHS –00-123) " …FDA officials and health care personnel told us that they recalled that the labels of some devices were changed from "reusable" to "single use" in years past without significant design changes." It is obviously in the best financial interest of the manufacturer to label every device for single use in order to sell more units of devices. Safe reprocessing has been established for many devices, Class I orthopaedic devices included, for many years. It has been noted in the GAO report that manufacturers have offered pricing incentives to some hospitals promising to forgo reprocessing, leading to price savings of 50% or more per unit. This practice of offering substantial discounts to medical centers for promising not to reprocess devices systematically destroys the medical device reprocessing industry and, in turn, reduces reprocessing options for hospitals. The present lack of any regulation in the device manufacturing industry's labeling standards is, in fact, creating financial hardships upon those institutions purchasing devices, and will ultimately, adversely impact patient care.

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". Not withstanding issues of liability, the device industry has the opportunity to assist insurers, hospitals, and physicians as they strategize how to provide optimal care at reasonable cost in these financially challenging times. The Academy strongly encourages investigation and oversight into the medical device industry's labeling practices.

CLASS I ORTHOPAEDIC MONOBLOCK METALLIC DEVICES SHOULD BE EXEMPT FROM SINGLE- USE LABELING

The AAOS disagrees with the arbitrary labeling of Class I 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. The demonstrated safety record of reprocessed orthopaedic Class I devices is evident in the scientific literature. 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 all 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 orthopaedic devices demonstrates the efficient reuse of medical devices

with the utmost concern for patient safety. Customary in-house sterilization and reprocessing techniques enable medical centers to safely and economically restore and re-supply monoblock metallic devices in a timely fashion. The AAOS respectfully requests that Class I orthopaedic monoblock metallic medical devices be excluded from guidance enforcement provisions.

SUD REPROCESSING CANNOT BE CONSIDERED HUMAN EXPERIMENTATION

The Academy has observed with interest the related issues surrounding SUD reuse. A concern likening SUD reuse without informed consent to unethical human experimentation has been expressed. The AAOS notes the long history hospitals have in sterilizing and reprocessing instruments and devices for reuse in-house. For decades, hospitals have responsibly reprocessed items for the safe reuse on patients, as a matter of both practicality and efficiency. Technological developments in sterility techniques over the years have improved the process even more, allowing hospitals to safely reuse expensive devices and control costs. In essence, reprocessing has been a major function in all hospitals for quite some time; and has allowed the economical reuse of expensive devices without risk to the patient. Equating established reprocessing protocols with unethical human experimentation disregards the lengthy safety history most devices have acquired.

THE SUD GUIDANCE WILL HAVE AN ADVERSE ENVIRONMENTAL CONSEQUENCE

As an additional concern, the AAOS anticipates significant environmental consequences as a result of this regulation. Unnecessary disposal of devices demonstrated to be safely reprocessed will contribute to a substantial increase in medical waste. 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.

GUIDANCE DOCUMENT FORMAT IS PREFERABLE TO PROPOSED RULE MAKING

The AAOS commends FDA's implementation of guidance documents as dissemination tools in the process of rulemaking. The AAOS believes that the format of guidance documents is both more user friendly and more adaptable to change than is the proposed rule/final rule-making format.

THERE IS NO EVIDENCE OF PRION DISEASE TRANSMISSION DURING ORTHOPAEDIC SURGERY

Although not specifically addressed in this guidance, the AAOS would like to acknowledge the efforts of the FDA in preventing the transmission of transmissible spongiform encephalopathies (TSE), or diseases attributed to prions. The AAOS appreciates the concern for public safety and agrees that additional research resources are necessary to investigate these diseases. Nonetheless, the Academy specifically notes that there is no evidence of any transference of prion diseases during orthopaedic surgeries.

CONCLUSION

Due to the long history of safe reprocessing, the Academy urges the FDA to reconsider some provisions in the SUD guidance and enforcement provisions. The AAOS is aware that many entities will be affected by decisions made regarding the reprocessing of devices, and the AAOS looks forward to working closely with the FDA on these matters.

Sincerely,

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

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