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August 2, 2001

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The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services
Attn: Room 601
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson,

We write to you on a matter of importance and urgency.

On August 14, 2001 the Food and Drug Administration ("FDA") will commence with certain enforcement activities regarding reprocessing of Single Use Medical Devices ("SUDs"). This commencement date was set in an earlier Guidance to Industry and FDA Staff on Enforcement Priorities for SUDs ("SUDs Guidance"). This Guidance applies to all risk classes of SUDs.

We strongly urge the Department of Health and Human Services ("HHS") to delay enforcement, as it applies to the very lowest risk category of SUDs, Class I devices, for one-year to allow HHS time to:

- Complete a detailed analysis specific to Class I devices of the actual health and safety consequences of the SUDs Guidance, and the cost and benefits involved;
- Address potential unintended consequences we believe could arise from immediate commencement of enforcement;
- Initiate consultation among the FDA, the Centers for Medicaid and Medicare Services ("CMS") and the Centers for Disease Control and Prevention ("CDC") to achieve a consistent policy position; and
- Examine the need for criteria with respect to the labeling of devices as "single use only".

We believe that the Department of Health and Human Services possess the clear legal authority to, prior to August 14, 2001, revise the SUDs Guidance to delay for one year the enforcement for Class I SUDs.

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BACKGROUND

All SUDs are placed into one of three Classes based upon the risk each presents to the public. Class I devices are the lowest risk devices. Examples of Class I devices include drill bits, scissors and saw blades. Currently, Original Equipment manufacturers ("OEMs") have the discretion to label the devices they manufacture for single use without any established criteria or oversight. It is well accepted by all, including the FDA, that some of these devices labeled "single-use devices" by OEMs can be efficiently cleaned and sterilized with absolutely no risk to patient safety. For years, hospitals across the nation have engaged in such activity.

A regulatory scheme currently exists that has been applied in full to OEMs, and in part to third party reprocessors. Hospitals have not been subject to regulatory oversight or enforcement by FDA for their reprocessing activities in the past. The regulatory scheme has two components: (1) A set of comprehensive administrative/reporting requirements and internal process controls, referred to as the "non pre-market requirements" or "general controls"; and (2) Specific notice and/or approval processes required prior to marketing and use of the device, referred to as "pre-market requirements."

The SUDs Guidance sets enforcement dates that enforce this regulatory scheme for the first time in hospitals. The SUDs Guidance, as now drafted, phases in the pre-market requirements for hospitals on a risk based approach. For Class III devices the enforcement date was February 14, 2001, for Class II devices it is August 14, 2001, and for Class I devices it is February 14, 2002. However, for the non pre-market requirements, the enforcement date for hospitals in the current SUDs Guidance is not phased in by risk, but rather takes effect for all device classes on August 14, 2001.

We expect that many hospitals will find both the non pre-market and pre-market regulatory requirements too burdensome to continue any SUDs reprocessing. For example, Mayo Foundation, after careful review, has arrived at that conclusion. The General Accounting Office ("GAO"), which submitted a report on this topic in June 2000 ("GAO Report") similarly concluded, "hospitals will be much less likely to maintain in-house SUD reprocessing operations under the new framework." Thus, hospitals have two viable choices: (1) Discard the SUD after one use and purchase a new one, or (2) Send the SUD to a third party reprocessor that is able to comply with the complex regulatory structure.

A one-year delay in implementing the SUD Guidance for appropriate Class I devices poses no demonstrated risk to patients. The GAO Report on SUDs reprocessing stated that "[t]he infection control and patient safety experts we consulted told us that the reprocessing of certain SUDs is not a demonstrated health risk, and SUD reprocessing is seen as safe by many associations representing health care professionals. Several reports of patient adverse events allegedly related to SUD reprocessing that we investigated were inaccurate, not relevant to the debate, or difficult to interpret."

In addition, GAO reported that"[h]ospital infection experts at CDC told us that the evidence showed that SUD reprocessing poses minimal, if any, public health risk. The CDC experts said that they were not aware of patient illnesses caused by SUD reuse in the last decade. The head epidemiologist of CDC's Hospital Infection Program told us that although CDC does not specifically monitor SUD reuse, he was confident hospital infection surveillance systems would have uncovered infections resulting from SUD reuse if they had occurred. Risk management professionals told us that the hospitals they worked with had not received any claims of patient injury caused by the use of reprocessed SUDs."

In fairness, the GAO Report also stated, "the limitations of the information available about SUD reprocessing argue for monitoring of the practice. FDA researchers, original device manufacturers, and third party reprocessors all agree that many types of SUDs cannot be reprocessed safely."

The GAO Report further noted that "FDA has asked HCFA [now CMS] and JCAHO for assistance in monitoring SUD reprocessing in hospitals. We found that neither HCFA nor JCAHO plans to make a substantial contribution to this effort in the near term."

Moreover, little, if any, appropriate consideration has been given to the enormous cost impact of this SUD Guidance on hospitals and the potential lack of capacity of third-party processors to meet anticipated demands for their services. With respect to cost, according to the GAO Report, when a hospital reprocesses a SUD itself, the cost is approximately 10% the cost of a new device, and when a third party reprocessor is used, the cost is approximately 50% the cost of a new device. The GAO Report found that the hospitals they contacted with active cardiology services for SUDs reprocessing gave estimates of savings ranging from $200,000 to $1 million per year.

Mayo Foundation has undertaken a detailed cost study to isolate the impact solely related to low risk Class I devices if the enforcement takes place as scheduled. Mayo Foundation found an annual impact of $1.3 million.

With respect to available capacity, as of June 2000, FDA had identified only 13 reprocessing companies in the United States, although it suspects that more are in operation. Further, reprocessors typically reprocess only a few types of SUDs. Thus, the actual capacity of third party reprocessors at this point in time is a significant open question.

RATIONALE

We want to stress the limited nature of our current request and provide supporting rationale for it:

- **MINIMAL IMPACT**: This request involves only the devices FDA has classified as the lowest risk. For the pre-market portions of the SUDs Guidance, FDA originally adopted a phased approach based upon classification of the device. The requested

action would bring a similar phased approach to the non pre-market part of the regulatory scheme.

- **ABSENCE OF RISK ANALYSIS:** As noted, Mayo Foundation has completed a detailed analysis to isolate the impact on Class I devices. Mayo Foundation found an approximate $1.3 million annual impact. Clearly, the Class I device issue itself runs well into the $100s of millions when considered nationwide. The fiscal impact should be viewed in the context of two other facts: (1) The opinion of respected health care professionals and organizations that no patient risk will be eliminated by immediate commencement or enforcement for Class I devices; and (2) the admitted lack of evidence that any patient risk (particularly in the Class I setting) does exist. We believe these facts combined with the very large fiscal impact lead to the conclusion that the SUDs Guidance deserves a second and more thorough analysis that is specifically directed at Class I devices. No such specific and detailed analysis has been completed to our knowledge. It should also be noted that the FDA has been without a Commissioner for most of the period since the SUD Guidance was originally issued, thus limiting the amount of Cabinet or Sub-Cabinet level scrutiny that this issue has received since issuance.

- **UNINTENDED CONSEQUENCES:** While the FDA is no doubt acting with the motive of patient safety in mind, the potential for adverse consequences to patients has not been adequately addressed in the Class I setting. The potential for exponential increases in the costs of some devices may mean that surgeons may not be able to use certain devices in some circumstances. Further, the status and capacity of the third party reprocessing market in the United States is very unclear. This uncertainty further suggests that all the consequences attendant to Class I enforcement need to be better understood.

- **POLICY HARMONIZATION:** One of the key roles of the Secretary is to achieve policy harmonization across the diverse units that make up HHS. As is pointed out in the GAO Report, it does not seem that policy harmony exists between CMS, FDA and CDC on this issue. A delay for Class I devices is appropriate while uniform policy thinking and strategies are developed within HHS. .

AUTHORITY

The Secretary possesses the authority to proceed with the requested action prior to August 14, 2001. In fact, the relevant statutory scheme creates a responsibility for the Secretary to revise FDA guidance documents as needed. 21 USC § 371(h) specifically authorizes the development of guidance documents in the administration of the Food, Drug and Cosmetic Act. However, "such documents do not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration." 21 USC § 371(h)(1)(a).

21 USC § 371(h)(2) specifically requires the following:

"The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents."

Last September, 21 CFR § 10.115 was promulgated outlining "Good Guidance Practices" for FDA and HHS's implementation of 21 USC § 371(h). 21 CFR § 10.115(k) speaks to "how will FDA review and revise existing guidance documents." 21 CFR § 10.115(k)(1) states that "The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn." Also, according to 21 CFR § 10.115(k), suggestions to revise a guidance document may be submitted pursuant to the instructions in 21 CFR § 10.115(f)(3). In accord with that direction, this letter is also being submitted to the Dockets Management Branch.

In sum, both 21 USC § 371(h) and 21 CFR § 10.115(k) authorize HHS to undertake the requested action in this letter.

CONCLUSION

While the underlying issues in this policy area are indeed large, we want to reiterate that the actual requested action at this time is fairly minor. We ask only for a reasonable delay to address the important issues and questions outlined above. We urge you to act favorably upon this request, and would be pleased to respond to any questions you or your staff may have on the forgoing. Please feel free to contact Mr. Bruce Kelly, Director of Government Relations for Mayo Foundation, at (202) 416-1742.

Sincerely,

Mayo Foundation

American Academy of Orthopedic Surgeons

American Hospital Association

cc: Mr. Robert Wood, Chief of Staff
Ms. Mary Kay Mantho, Advisor to the Secretary
Lawrence Wiley, Deputy General Counsel

Guidance Document Submission
Dockets Management Branch
5630 Fishers Lane
Room 1061
Rockville, MD 20852