

Federation of American Health Systems

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801 Pennsylvania Ave., NW Suite 245
Washington, DC 20004-2604

phone: 202-624-1500
fax: 202-737-6462

April 11, 2000

Larry D. Spears
Food and Drug Administration
Office of Human Resources and Management Services
Division of Management Systems and Policy
Dockets Management Branch
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

**Re: Draft Guidance on Enforcement Priorities for Single-Use Devices
Reprocessed by Third Parties and Hospitals - Docket No. 00D-0053**

Dear Mr. Spears:

The Federation of American Health Systems ("FAHS") is the national representative of over 1,700 privately owned or managed community hospitals and health systems throughout the United States. Our members range from small rural hospitals to large urban medical centers and offer a variety of services including acute hospital care, outpatient services, skilled nursing care, rehabilitation, and psychiatric care. The FAHS submits this comment letter in response to the notice by the Department of Health and Human Services ("HHS") Food and Drug Administration ("FDA") on the Reprocessing and Reuse of Single-Use Devices, published at 65 Fed. Reg. 7027 on February 11, 2000, and the "Draft Guidance on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" ("Draft Guidance") cited therein.

The FAHS has been monitoring this issue since it was brought to our attention with the announcement of the "Proposed Strategy on Reuse of Single Use Devices" ("Proposed Strategy") in the Federal Register of November 3, 1999 (64 FR 59782). In an effort to gain more information and provide input on the "Proposed Strategy," the FAHS participated in the December 14, 1999 Public Meeting on this topic. We have carefully reviewed the Draft Guidance on Enforcement Priorities and have a number of comments regarding the guidance.

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Enforcement Priorities Are No Substitute for a Reasonable Regulatory Scheme

Our first, and perhaps our most fundamental concern, involves the approach the FDA has taken in both the Proposed Strategy and the Draft Guidance. The FAHS appreciated the discussion in the Public Meeting regarding the need to approach the issue of the reprocessing of single-use devices (SUDs) based on the degree of risk posed by the “reprocessing.” However, we are concerned to see that in the Draft Guidance, the FDA has again drawn an untenable distinction between “enforcement priorities” and “regulatory requirements.” In other words, the FDA now says that “categorization of devices by risk would be used only to set enforcement priorities,” and by deduction, then, does not affect the actual level of regulation applied to the reprocessing of these devices. In our view, it would make much more sense to develop reprocessing regulations that are appropriate for the degree of risk involved in the reprocessing of specific categories of SUDs. The idea that rather than developing an appropriate level of regulation, the FDA would instead simply adjust its “enforcement priorities” leaves those who either reprocess devices directly or use devices reprocessed by others in a difficult bind. Do they have to comply with the regulations or don’t they? It sends a mixed signal. We would like to work with the FDA to develop a regulatory scheme for reprocessing, *not just enforcement priorities*, that are based on the degree of risk involved in reprocessing the various categories of devices.

Opened-But-Unused Devices Are Not Reprocessing

We strongly support the Draft Guidance’s proposal to exclude “opened-but-unused” devices from the enforcement priorities, however, are left with the same question noted above regarding their actual regulatory status. When the Draft Guidance says that the FDA will not take enforcement action with respect to these devices, it in no way clarifies what third party reprocessors and/or hospitals must do to be in compliance with the FDA regulations for opened-but-unused devices. We urge the FDA to clarify that opened-but-unused devices are not subject to the same level of regulation as “reprocessed” single-use devices. This clarification is particularly important given the definition of “reprocessing” included in the Draft Guidance’s Appendix A. Technically, parties could argue that re-sterilization of an opened-but-unused device fits into the definition set forth there. We do not believe this is the FDA’s intent and urge the Agency to clarify that re-sterilization of opened-but-unused devices is not included in the definition of reprocessing, as follows (underlined text is proposed to be added):

“Reprocessing: includes all operations performed to render a contaminated reusable or single-use device patient ready. The steps may include cleaning and disinfection/sterilization, but does not include sterilization or re-sterilization of an “opened-but-unused” device as defined above. The manufacturer of reusable devices

~~and~~ or single-use devices that are marketed as non-sterile should provide validated reprocessing/sterilization instructions in the labeling.”

We do think opened-but-unused devices are in a completely different category from “reprocessed” devices, because they have not been used on a patient and therefore do not incur all the cleaning and potential wear on the device such use would generate. Rather, we believe issues regarding re-sterilization of opened-but-unused devices should be addressed by the original equipment manufacturers in their labeling.

It is a common and well-known practice for hospitals to open SUDs prior to use and assemble them as part of customized procedure trays that contain several devices. In some instances, either where the device is not sold as “sterile,” or when it has been assembled into a procedure tray but is not used, an unused device must be sterilized/resterilized. This is essential preparation for medical procedures that prevents delays, minimizes risk of inadvertently using less than optimal equipment and devices, streamlines operations and provides protection from infection. Treating this process as “reprocessing” will impede these activities and sacrifice these benefits. Clear sterilization/resterilization instructions can address any patient safety risk issues and is the original equipment manufacturer’s obligation under the labeling provisions of food and drug law and regulation. Therefore, we also request that the FDA clarify that sterilization/resterilization of opened-but-unused SUDs is not subject to the FDA *regulatory scheme-- not just the enforcement priorities--* set forth for the reprocessing of SUDs.

FDA Must Establish a Level Playing Field

A second overarching concern relates to the scope of the Draft Guidance. In the Draft Guidance (page 4), the FDA indicates that the “enforcement priorities set forth in this guidance do not apply to: . . . 3. Health care facilities that are not hospitals.” The FDA goes on to note that it is aware that hospitals may not be the only health care facilities that reprocess devices labeled for single use, and intends to examine whether it should include other establishments that may reprocess SUDs.

FAHS has serious concerns with the FDA limiting its enforcement activity to hospitals and calls on the FDA to apply its requirements even-handedly. As an increasing amount of complicated care occurs outside of the traditional hospital setting, the FDA must ensure equity in patient care and regulatory oversight between and among delivery sites. To the extent this is an important patient safety issue in the hospital setting, we can only imagine that it would be as much if not more of an issue in other settings. In fact, some might even argue that given the broad range of quality assurance activity, oversight, accreditation and survey in the hospital setting, other sites would be in greater need of the FDA’s initial oversight.

Clarify No Evidence of Risk to Patient Health or Safety

The FAHS believes that the FDA should make clear the basis for its earlier approaches to this issue and the impetus for revising that approach. As indicated in the Public Meeting on December 14, 1999, and in Congressional testimony earlier this year, the FDA noted that there has not been evidence that reprocessing of SUDs presents a risk to the health and safety of patients. We think it is imperative that this foundation be clearly explained in the FDA Guidance in order to prevent any negative inference which might otherwise be assumed. Certainly, the FDA would not be “phasing-in” enforcement if it thought patient health and safety were at risk, but health care providers who have been under scrutiny regarding patient safety issues in so many areas feel we deserve a more explicit statement on this matter.

The FAHS would urge the FDA to include in the Final Guidance language such as:

“To date, the FDA has used its enforcement discretion not to enforce premarket review requirements against third-party reprocessors, and will continue to use the same enforcement discretion to “phase in” the enforcement of premarket review requirements against third-party reprocessors and hospitals, because the FDA has not found sufficient evidence to suggest that reprocessing, absent the FDA premarket review, presents a threat to public health.”

Require Manufacturers to Justify “Single Use” Label

In a regulatory scheme that seeks to regulate the reprocessing of “single-use devices”, it is imperative that when manufacturers choose to label devices “single use,” the label be an objectively defensible assertion and relay clear meaning to all stakeholders. This is *particularly* true now that so much more scrutiny, regulation and enforcement priority is being applied to the “reprocessing” of so-called “single use devices.” While we understand that there are some complexities attached to requiring manufacturers to justify the “single use” label, we assert that, given the financial and other incentives attached to potential inappropriate uses of this label, it is incumbent on manufacturers to work with the FDA and other stakeholders to ensure that single use labeling has meaning, and is not simply a convenient marketing tool.

Further, we understand that, in many cases, the exact same device marketed in the U.S. as “single label” is often marketed in other countries as a re-usable device. In addition, we are aware of devices that have historically been labeled as reusable, becoming “single use only” devices without a measurable change in the product. These kinds of contradictions indicate that clearer parameters surrounding the application of “single use” labeling are both necessary and well warranted. Manufacturers should be required to provide scientific evidence that demonstrates the reprocessing or re-sterilization techniques that purportedly compromise the integrity of its product.

We urge the FDA to develop criteria that must be met in order for a manufacturer to label a device as “single-use” and to incorporate those requirements into the final guidance on this topic. Until the “single-use” label has clear parameters, how can the FDA apply regulations and enforcement actions to implement and enforce it? The FDA should apply equal scrutiny and regulatory requirements to the classification or labeling of a device as “single-use,” as they do to enforcing that label.

Oversight Must be Appropriately Tailored and Non-Duplicative

In its Draft Guidance, the FDA has outlined a new regulatory scheme for hospitals engaged in reprocessing devices. Given the many oversight bodies that already review hospital procedures and standards, it is only prudent that the FDA work with these existing oversight entities (e.g. the Joint Commission on Accreditation of Health Care Organizations, and state survey agencies) to ensure compliance with reprocessing standards, develop models that are appropriate in the hospital setting and avoid duplication of effort.

Classification Scheme Must be Clear and Include an Appropriate Appeals Process

The FAHS believes that in a regulatory scheme based on the risk involved in the reprocessing of a device, the classification of devices should be more meaningful than it is in the scheme established in the Draft Guidance. In the Draft Guidance, it appears that the classification only affects the timeline for potential enforcement action, rather than the level of regulation, premarket review, etc. In either case, it is important that the proposed classification of devices into risk categories (high, moderate and low) must be based on clearly understandable parameters and the process by which devices are classified must be transparent. Reprocessors, those who utilize reprocessed devices, and patients need to be able to discern how a particular device is classified in order to effectively comply with relevant requirements on the appropriate time frame. Moreover, the FDA must establish and adequately notify all interested parties regarding an appropriate and timely appeals process for challenges regarding device categorization. If risk classification actually impacted the level of regulatory requirements, these matters take on even greater significance and would also mandate a need for the FDA to provide a meaningful opportunity to revisit and revise device categorization in appropriate circumstances, such as when new data becomes available.

Consensus Standards

The FDA’s historical treatment of reprocessed single use devices, and the issuance of the Draft Guidance suggest strongly that the Agency concurs that the reprocessing of single use devices is a permissible activity, provided that certain criteria are met. The FAHS is committed to the shared goal of safely reprocessing single-use labeled devices. To this end, we support efforts to create a research program to increase the body of literature available to stakeholders in order to ensure that reprocessing decisions are based on sound scientific evidence. We urge the FDA to work with hospitals, physicians, third-party re-processors, and

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other interested parties to develop consensus standards relating to the safe reprocessing of medical devices. We support a "community best practices" approach for low-risk device standards, and a more formal interdisciplinary approach for developing standards for high-risk devices.

Need for Education and Training on New Responsibilities

Because significant new responsibilities are being raised in this Guidance, it will be crucial for the FDA to work closely with hospitals to promote education and training on these new responsibilities.

We appreciate the opportunity to comment on the Draft Guidance and look forward to working with the FDA to develop an appropriate regulatory approach for the reprocessing of single- use devices.

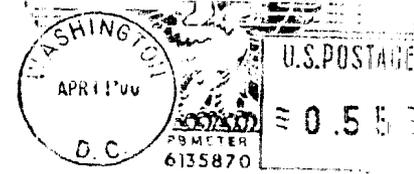
Sincerely,


Anne Berdahl
Assistant Vice President


Laura Steeves Gogal
Vice President and Chief Counsel

Federation of American Health Systems

801 Pennsylvania Avenue NW
Suite 245
Washington, DC 20004



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