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From: Rick Sites [ricks@OHANET.org]
Sent: Tuesday, April 11, 2000 5:10 PM
To: 'fdadockets@oc.fda.gov'
Subject: Reuse of Single-Use Devices; Docket No. 00D-0053



Comment on Device
Reuse.doc

Attached are the comments of the Ohio Hospital Association on Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme and on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (February 8, 2000):

<<Comment on Device Reuse.doc>>

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

Attn: Docket Officer
Docket No. 00D-0053

Re: Comments of Ohio Hospital Association on Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme and on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (February 8, 2000)

Ladies and Gentlemen:

Recently, the Food and Drug Administration (FDA) issued two proposed draft Guidances, on Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme and on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. The Ohio Hospital Association (OHA) supports efforts by hospitals and by the FDA to ensure and enhance patient safety, which is the foremost concern of our hospital members.

OHA is the trade association of hospitals in Ohio. Virtually every hospital and hospital system in Ohio is a member of our association. We represent approximately 185 hospitals, 40 hospital systems, and about 1200 personal members in affiliated societies representing such disciplines as nursing, health law, risk management, and patient advocacy. We appreciate the opportunity, on behalf of our many members, to submit written comments on both draft Guidances.

After recognizing the profound impact that the draft Guidances would have on hospitals, our Risk and Insurance Management Committee recommended that OHA participate with the FDA in addressing the issue of the reuse of medical devices currently labeled, or otherwise intended, for single use. We would like to join the American Hospital Association (AHA) in expressing our thoughts on this issue, and we endorse the comments made by AHA in regard to these two draft Guidances.

Guidance on Review Prioritization

We support the FDA's efforts to base its enforcement of pre-market requirements on the level of risk associated with the reuse of a device intended for single use. The risks of infection and

failure of performance are critical in determining whether reprocessing is appropriate and whether reuse of a reprocessed device can be safe and effective. While we applaud the FDA's carefully considered approach to risk categorization, we urge that the process of determining such risk categorization be cautious and deliberate.

1. Information used and specific determinations made in assessing a particular device's risk categorization should be publicly available.

The FDA has outlined, with flowcharts and lists of questions, the process by which devices intended for single use will be categorized according to risk. The questions to be considered in the flowcharts are largely subjective in nature. As such, all answers to flowchart questions for a particular device, and any documentation supporting those answers, should be published and made publicly available. Thus, the entire process should be transparent.

2. Multidisciplinary panels of professionals should assist the FDA in determining individual device risk.

As a further means of augmenting the process of determining risk category, OHA recommends that the FDA work with a multidisciplinary panel of professionals in determining the final list of single-use devices and their risk categories. In this way, additional evidence regarding safety or effectiveness or developing consensus standards could be considered in an established, timely fashion by the FDA, to add this evidence to the record and potentially change a particular device's risk categorization.

The transparency of this process and the participation of qualified professionals would facilitate greater cooperation between manufacturers, reprocessors, hospitals, and the FDA in ensuring that particular devices are regulated appropriately, enhancing our common goal of device effectiveness and patient safety while minimizing regulatory burden for both the FDA and the regulated parties.

Guidance on Enforcement Priorities

We would like to present a number of specific concerns about the enforcement priorities regarding single-use devices.

1. The high costs that hospitals must bear under this standard may be unnecessary since hospitals already face significant oversight regarding quality of care and patient safety.

Many of the FDA's concerns relating to quality of care and patient safety may already be adequately handled by existing hospital regulations. Any additional concerns could be addressed through enhanced oversight by entities that already monitor hospitals, like the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). As David W. Feigal, MD, the Director of the FDA's Center for Devices and Radiological Health, stated in testimony to the House Subcommittee on Oversight and Investigations, Committee on Commerce, on February 10, the FDA will require the assistance of organizations like JCAHO to enforce these new standards.

2. Hospitals face high costs as a result of these proposed Guidances.

If the FDA proceeds with plans to enforce all pre-market requirements on hospitals that reprocess devices, these hospitals face two sets of additional costs. Investing scarce resources toward compliance with pre-market application requirements would diminish any cost savings hospitals realize by reprocessing single-use devices. The cost of using a device labeled for single use only once is prohibitive, so hospitals will continue to reprocess devices. However, in light of these additional costs, many hospitals will likely discontinue internal reprocessing activities and pay more for this service to reprocessors. Due to the increased demand resulting from implementation of these draft Guidances, the prices of reprocessing will increase, leading to further hospital expenses. As a result, these standards for single-use devices would serve only to increase the costs of care to hospitals without significantly adding to the already safe and effective reprocessing activities in which hospitals engage.

3. The phased-in enforcement delays fail to provide adequate time for hospitals to comply with post-market requirements.

Hospitals would have six months to prepare themselves for enforcement of the post-market requirements. However, hospitals face significant difficulty keeping up with this mandate, in light of the challenges posed by encountering a new set of regulatory requirements, on top of the many current regulatory mandates imposed on hospitals. The FDA should extend this time period.

4. The phased-in enforcement delays fail to provide adequate time to prevent a shortage of high-risk devices.

The brief delay in the enforcement of these Guidances for high-risk devices could very well be insufficient to allow for compliance with pre-market submission requirements. Such delays could imperil the health of patients whose care requires the use of high-risk devices. The FDA should extend this time period.

5. To level the playing field for hospitals, any reprocessing standards should also apply to other providers engaged in reprocessing.

A number of individual providers and facilities perform internal reprocessing of single-use devices, including physician offices, group practices, ambulatory surgical centers, and other healthcare entities. Hospitals would encounter a competitive disadvantage if they alone among this group must comply with costly reprocessing standards. This disadvantage would be especially unjust in light of the increased resources and facilities available to hospitals that already allow them to ensure greater safety and effectiveness of reprocessed devices.

6. The proposed Guidance wisely excludes "opened but unused" devices, but the FDA should require manufacturers to provide resterilization instructions for these devices.

There is no scientific evidence establishing a public health risk with the reprocessing of "opened but unused" single-use devices. Since they have never been used, reprocessing these

devices raises far fewer concerns than the reprocessing of used devices. To ensure the continued safety of this reprocessing, the FDA should require manufacturers to provide resterilization instructions for these devices.

7. Low risk devices should be exempted from FDA oversight, with their safety guarded by reprocessing consensus standards.

The reuse of some medical devices provides such a low risk to patients that the costs entailed by FDA oversight far outweigh any benefits. To ensure that low risk devices remain safe and effective after reprocessing, the FDA should endorse the development and dissemination of reprocessing consensus standards based on community best practices. Professional associations representing physicians, hospitals, sterile processing professionals, infection control professionals, and reprocessors could lend their expertise to the development of these standards.

8. Manufacturers should be required to justify single-use labeling using scientific standards.

Currently no standards govern the labeling of devices as "single use only." To make such warnings meaningful, the FDA should apply uniform standards to manufacturers that require justification of such a label. Manufacturers would not be permitted to apply such a label if they are aware of safe and effective reprocessing and resterilization procedures. As a corollary, manufacturers should be required to provide instructions for acceptable, validated methods of resterilization for all devices.

9. Subjecting hospitals to manufacturer device reporting requirements would be costly and redundant, in light of existing hospital reporting requirements.

Hospitals already must comply with reporting requirements as outlined in the Safe Medical Devices Act. Adding to the burden of hospitals the reporting requirements of device manufacturer would result in redundant, inefficient use of hospital and government resources. As such, the FDA should limit any new hospital reporting obligations to specific, non-duplicative requirements.

We commend the FDA on its efforts to ensure the maintenance of device effectiveness and patient safety with the reuse of single-use medical devices. We urge that the FDA examine existing hospital regulations, the costs to hospitals of these new regulatory standards, and the current safety and effectiveness of reused devices, in weighing the costs and benefits of these proposed Guidances. We believe our comments can assist the FDA in this process.

The Ohio Hospital Association joins the American Hospital Association in its expression of the concerns of hospitals regarding the two proposed Guidances regarding the reprocessing and reuse of single-use medical devices. We look forward to cooperating with the FDA in applying carefully considered standards that apply burdens sparingly and equally to all parties that reprocess devices.

Thank you for your attention to our comments.

Sincerely,

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