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January 5, 2000

Docket No. 99N-4491
 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

Dear Sir or Madam:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to submit these comments on the Food and Drug Administration's (FDA) proposed strategy on reuse of medical devices currently labeled for single use. In recent months there has been extensive public debate over the reuse of single use devices (SUDs). ASGE applauds FDA's effort to listen to all viewpoints. We concur with FDA that the "primary goal is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science."

ASGE represents more than 6500 physicians who specialize in the use of endoscopy in the diagnosis, treatment and management of gastrointestinal diseases and conditions. Our members are obligated to "do no harm" when providing medical care to their patients. This means that they avoid actions they know to be harmful and continually examine their practices using the best science available, making alterations in those practices when warranted by scientific evidence.

The reuse of SUDs is not new. FDA first provided guidance to hospitals in 1977 on this issue. Over the years it has applied limited regulatory standards to the companies that reprocess devices. A number of the devices used by gastroenterologists that are labeled single use by the manufacturer are now reprocessed either by hospitals or third party reprocessors and used with no apparent compromise to the safety of patients. Recently, however, several parties have questioned the adequacy of FDA's regulatory activity in this area.

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ASGE believes that the scientific data on reprocessing to date suggests that some medical devices used in gastrointestinal endoscopy that manufacturers have labeled as single use can be reprocessed safely, achieving sterility without loss of function. There is peer-reviewed research published in respected medical journals to suggest that these practices are safe. It must be noted, however, that these studies are relatively few in number and have been conducted by a limited number of investigators. Additional larger controlled studies are needed to validate this information.

FDA's own records do not reveal a pattern of problems with reprocessing of accessories for gastrointestinal endoscopy, nor is there evidence of infection risk in the medical literature or in the records of the Centers for Disease Control. Studies offered in contradiction have been largely unpublished and lack peer review. Those that have been published are small and have appeared only in abstract form or in relatively obscure journals. In the absence of appropriate review by independent peer reviewers, it is difficult to determine the merits of this material.

Given the conflicting viewpoints, the ASGE believes that more data would be helpful to all parties. Therefore, we recommend that FDA act quickly on its recommendations to develop a research program on the reuse of SUDs. ASGE would be pleased to work cooperatively with FDA in such an effort. With such information in hand, FDA will more easily be able to determine the extent of regulation needed for reprocessing and thereby focus its regulatory attention where it may be most needed.

ASGE believes that the concept of a risk-based regulatory system has merit. However, risk should be determined based on the best available science that has examined the question of whether or not the reprocessing of a specific medical device poses an increased risk to patient safety. While the proposed "Risk Categorization Scheme (RCS)" is an admirable attempt at determining risk, the implicit assumptions of the algorithms ultimately result in classifications that do not reflect the available scientific data in the medical literature. As we interpret the proposal, it appears that virtually all GI endoscopic accessories would fall into the high-risk category, which is at odds with the medical literature and the experience of the FDA and CDC described previously. ASGE does not believe that the scientific evidence would support the classification of these GI devices as "high risk".

The algorithm determining risk of infection (Flowchart 1) relies heavily on the assumption that design characteristics of devices, such as narrow lumens or interlocking parts, preclude safe reprocessing. While these characteristics probably increase the difficulty of the process, published studies have been submitted to FDA showing that these characteristics do not inherently preclude safe and effective sterilization of medical devices. Yet this aspect of the flowchart alone guarantees that devices incorporating these design features would be labeled as high risk. The postmarket information segment of the algorithm is subjective and does not establish a clinically relevant, objective threshold based on scientific data. Yet this segment also has the ability to catapult a device into a high-risk category, again seemingly without objective scientific

data. The algorithm goes on to include functional characteristics that are already addressed in the second algorithm pertaining to instrument function.

Flowchart 2 attempts to address the risk of a performance change. ASGE strongly supports and would contribute to the establishment of CDRH performance standards for GI devices. However, due to the proprietary nature of these devices, the absence of performance tests recommended by the OEM should not inherently result in a higher risk classification. The key component of this algorithm relies heavily on the assumption that a device that cannot be evaluated solely by visual inspection results in increased risk. Yet ASGE has submitted published studies demonstrating that devices can maintain their electrical integrity or flow characteristics, even when reprocessed 7-10 times. The threshold question, we believe, should be the risk to the patient if the device fails. In the case of GI endoscopy the patient risk from device failure is almost non-existent. This is true of new and reprocessed devices. If an endoscopic accessory fails during a procedure, the physician simply halts the procedure and replaces the defective product. The patient is not exposed to any risk.

The current debate has also shown that there is too little agreement on terminology. ASGE agrees that more clarity and precision in the definition of terms would be helpful. FDA could play an important role in bringing the parties together to forge agreement on the meaning of these terms. For example, the decision to label a product as "single use" is now left to the discretion of the manufacturer. There are no common criteria for using this designation. Clinicians do not know whether such labeling is based on scientific, regulatory or marketing concerns. The information would be more useful to clinicians if the manufacturers demonstrated and reported why a particular device is not suitable for reprocessing or if the device reprocessors demonstrated and reported the effectiveness of their reprocessing.

The FDA's proposed strategy is a beginning, not an endpoint. ASGE believes that the FDA's statement demonstrates convincingly that better information is needed if FDA is to provide effective regulation in this area. Therefore, we urge FDA to place a priority on data collection and scientific study. As the data develop, FDA can adjust its requirements as necessary to ensure continued public confidence in the use of any reprocessed medical devices.

ASGE urges careful consideration of these recommendations. We look forward to continuing to work with FDA and all other interested parties on this important issue.

Sincerely,



James T. Frakes, M.D.
President



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