REPORT OF THE COUNCIL ON SCIENTIFIC AFFAIRS

CSA Report 3-I-00

Subject: Reprocessing of Single-Use Medical Devices (Resolutions 514, I-99, and 525, A-00)

Presented by: Michael A. Williams, MD, Chair

Referred to: Reference Committee E (C. Alvin Head, MD, Chair)

Resolution 514 (I-99) introduced by the Society of Cardiovascular and Interventional Radiology at the 1999 Interim Meeting, and referred to the Board of Trustees, asks:

> That our American Medical Association (AMA) express to the Food and Drug Administration (FDA) and other appropriate entities its opposition to the recycling of single-use medical devices.

Resolution 525 (A-00) introduced by the Nevada Delegation at the 2000 Annual Meeting, and referred to the Board of Trustees, asks:

> That our AMA review and study the practices related to designating single use medical products and the growing practice of recycling such products with an emphasis on the implications of these practices for patient safety; and
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> That our AMA develop guidelines for the use of recycled medical products which had previously been designated for single use.

The reprocessing of single-use medical devices has been an expanding industry since the introduction of the concept in the late 1970s. Recently, this practice has come under significant scrutiny by health care providers, the news media, and the general public. This led the Food and Drug Administration (FDA) to revise its enforcement priorities for single-use devices (SUDs) reprocessed by third parties and hospitals. This report examines this new enforcement guidance in detail and discusses its potential impact on hospitals and physicians. It also briefly discusses the data on the safety and efficacy of reprocessed single-use medical devices and highlights the congressional bills seeking to legislate the use of such devices. Finally, the report provides several recommendations.

METHODS

- Literature searches in the MEDLINE database for articles published between 1990 to 1999 using the search term "single-use device" qualified with the terms "reprocessing," or "recycling," or "safety," yielded a combined total of 498 references. One hundred and sixty-seven English-language references contained information relevant to the safety, efficacy and regulation of reprocessing of SUDs and were examined further. Additional references were culled from the bibliographies of these pertinent references.
- Lexis/Nexis news databases were searched for current developments using the search strategy "single-use medical devices AND reprocessing."

- The World Wide Web was searched for information using the search strategy "single-use medical devices AND reprocessing."

REPROCESSING OF SINGLE-USE MEDICAL DEVICES

Reprocessing of single-use medical devices has occurred since the late 1970s when electrode catheters were reprocessed.[1,2] Over the next 20 years, the number of different single-use medical devices that are reprocessed has grown to approximately 200, ranging from cardiovascular to orthopedic devices.[1,3] However, before the shift to the use of SUDs occurred, medical devices were generally considered to be reusable; ie, could be used and reprocessed multiple times.[1,4] Such reuse of medical devices was facilitated by the fact that they were usually made from glass, metal, or rubber, and recycling these devices simply meant soaking them in a disinfectant solution such as glutaraldehyde after a thorough cleaning.[1,5]

However, original equipment manufacturers (OEMs) began to market and sell "single-use" medical devices, citing an increased market demand for disposable devices. This was also facilitated by the arrival of new plastics and of new sterilization technology, such as the use of ethylene oxide. Regardless, hospitals began to observe that the new "disposable" devices did not appear to be any different from the previous "reusable" devices. Furthermore, the provision of instructions by some OEMs to hospitals on how to re-sterilize an opened, but unused, SUD served to heighten the suspicion that SUDs could indeed be safely reprocessed and reused.[4,6,7] Additionally, some major OEMs have "recycling" programs offering to sell "remanufactured" devices for reduced prices to health care institutions that return their SUDs to the OEMs.[4] It became obvious that costs could be saved if hospitals need only pay full price for an SUD once and then obtain additional uses from the device by paying a lower price to have it reprocessed. Thus, hospitals began to study the costs that might be saved by reprocessing SUDs themselves or through third-party reprocessors. As an increasing number of hospitals decided that reuse was an effective cost-saving measure, and as more scientific data emerged to indicate that certain SUDs when properly reprocessed were safe and effective, the practice of reprocessing SUDs expanded. Increased reprocessing of SUDs also resulted in a decrease in medical waste and its associated costs.[1,4,8]

As the benefits became more obvious to hospitals, the list of reprocessed SUDs began to expand to include increasingly complex single-use medical devices, such as balloon angioplasty and other cardiac catheters. These devices are more complex and require more cleaning and disinfecting techniques, which include actions such as wiping the device of visible soil at the point of use, containing and transporting the device to a decontamination or sterilization work area, and/or performing a terminal microbicidal process like sterilization.[5] As a result, an industry of third-party reprocessors emerged to cater to the hospitals' reprocessing needs. As this industry expanded, and the number of single-use medical devices being reprocessed increased, several concerns began to be raised, including patient safety, informed consent, equivalent manufacturing standards for the OEMs and the reprocessing companies, and potential ethical issues of SUD reuse.[1,4,5,9,10] Concerns were also raised regarding public perception of the reuse of SUDs since such reprocessing is strictly a cost-saving and waste-reduction practice with little direct benefit to patient care.

As a result of this attention, the FDA and the Association for the Advancement of Medical Instrumentation cosponsored a conference in May 1999 on the practice of reprocessing and reusing SUDs. Following this, the FDA held a public stakeholder forum in December 1999 to solicit input on new guidelines for the reprocessing of SUDs.[11] After this forum, the FDA released two new draft guidances in February 2000 and made these drafts available for public

comment.[12,13] In response to the resulting public comments from more than 150 stakeholders, the FDA's Center for Devices and Radiologic Health released the final guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" on August 2, 2000.[3]

Reprocessing of Single-Use Medical Devices: Current Status

For a reprocessed device to be used in a patient, that device must be clean, sterilized, and functional following reprocessing. Cleanliness is extremely important, as any remaining biologic residue can be potentially harmful to the patient in whom the device is used. Also, this residue may provide residual bacteria a shelter from the sterilizing process thus compromising the sterility of the reprocessed device. As such, third-party reprocessors assert that they choose devices to reprocess very carefully, rejecting devices that cannot be cleaned well or may be damaged by the sterilization or reprocessing procedures.[4]

Generally, the sequence of events in reprocessing is similar.[4] Reprocessors follow specific guidelines or established procedures that may be issued by professional organizations (including medical specialty societies), or the OEMs themselves, which have been shown to be effective in reprocessing the device safely. Following collection after use, the device is rinsed repeatedly and cleaned by the hospital prior to reprocessing. At the reprocessing facility (in-house or third-party), the device is further cleaned, refurbished, inspected for quality and function, and then sterilized. At third-party reprocessors, devices from different hospitals are not mixed with each other and the hospitals receive back the same devices they submitted for reprocessing. According to the reprocessing industry, many devices are rejected prior to reprocessing because they have been damaged and are thus unsuitable. The number of times a device has been reprocessed is also recorded and every type of device will only be reprocessed a defined number of times. Finally, reprocessors also resterilize open but unused SUDs. These are not covered by the new FDA enforcement guidance.

Appendix A provides the FDA's list of SUDs that are currently being reprocessed.[3] While this list is probably not comprehensive, it does provide an idea of the type and number of SUDs that are currently being reprocessed. However, while many devices are being reprocessed, the reprocessing industry is only a small part of the medical device industry. The FDA estimates that there are only 13 third-party reprocessing firms and that only about 20% to 30% of hospitals actively reprocess SUDs.[4] Other reports indicate about 50% of hospitals are engaged in some reprocessing of SUDs.[14] Additionally, reprocessors will typically only reprocess limited types of SUDs and will seldom reprocess many different types.[4] There are no data yet on how the new FDA guidance issued in August 2000 will affect these numbers.

There is some concern that in the absence of regulation of the reprocessing industry, the potential for adverse events exists.[15] This opinion has been expressed by the OEMs[16] and recently has been repeated in the popular press.[17,18] Therefore, the FDA felt that precautions were necessary and thus revisited the manner by which it regulates reprocessed devices.

THE NEW FOOD AND DRUG ADMINISTRATION ENFORCEMENT GUIDANCE

Background

The FDA Center for Devices and Radiologic Health's new guidance for enforcement priorities for SUDs reprocessed by third parties and hospitals provides advice to these entities about their responsibility as manufacturers engaged in reprocessing devices labeled for single use under the

federal Food, Drug and Cosmetic (FDC) Act.[3] With this new guidance, all the regulatory requirements currently applicable to the OEMs, including premarket submission requirements, will be enforced on third-party reprocessors and hospitals.

It is important to realize that this does not imply that the FDA, prior to this guidance, never regulated third-party reprocessors. In fact, third-party reprocessors and hospitals that reprocess medical devices are categorized by the FDA as device manufacturers (similar to the original equipment manufacturers) and thus are required to comply with good manufacturing practices, FDA inspection, and manufacturers' adverse event reporting procedures. However, while the FDA has enforced these requirements with respect to the third-party reprocessors, it has not enforced them with respect to hospitals or other health care institutions that reprocess SUDs. Additionally, the FDA has not required third-party reprocessors nor hospitals to seek premarket approval for the reprocessed devices, another regulatory requirement necessary for OEMs.[3,4] The reason is that until now the FDA has felt that the reprocessing of SUDs has not posed a significant risk to public health.[1,3] Thus, the FDA exercised what it termed "regulatory discretion" to allow the reprocessing of single-use medical devices to proceed. The FDA retains the authority to immediately stop any practice that threatens public health but has not had to do so with SUD reprocessing.[4]

With regard to the premarket approval process, OEMs have complained to the FDA that by not enforcing this requirement on third-party reprocessors and hospitals, the FDA is placing a competitive disadvantage on the OEMs. OEMs that wish to sell a reusable device are required to provide data to the FDA via the premarket approval process (either on a form 510[k] or through a premarket application) indicating that the device can be safely reprocessed for additional use. As it stands, third-party reprocessors are reprocessing SUDs without seeking premarket approval from the FDA, and thus are technically producing "adulterated" devices. The third-party reprocessors strongly believe that the current regulatory framework, with its emphasis on quality control (adherence to good manufacturing practices, adverse event reporting, etc), is adequate. They do not believe that enforcing premarket requirements on them will increase the safety of reprocessed medical devices, saying there is "strong evidence of the safety of medical device reprocessing."[19] On the other hand, the OEMs believe that the reprocessing of SUDs is unsafe and potentially harmful to patients,[16] but there are little scientific data to support this claim. Many incidents that the news media have attributed to the reprocessing of SUDs have been unrelated to the reprocessing event or did not involve proper reprocessing techniques such as those performed by third-party reprocessors.[4]

"Single-Use" Labeling

It is important to understand the basis of the labeling of a medical device as single-use only. The FDA can evaluate premarket applications to sell new devices only in terms of the device's intended use as indicated on the label.[20] Accordingly, OEMs that wish to market a device as single-use need only show that it can be used safely and effectively once; there is no requirement to show that the device can be used more than once.[4,21] Thus the single-use label is not based on any data indicating that the device cannot be used safely and effectively more than once.[21] For an OEM to market a device as reusable, it would be required to submit a premarket application demonstrating scientifically that the device will perform safely and effectively when reprocessed and reused. OEMs would also be required to provide information on how the device is to be properly recycled for reuse.[4] This is a more complicated and costly process for the OEMs and thus any device for which the OEM did not seek to secure FDA approval as reusable must be marketed and labeled for single-use.

The Enforcement Guidance and its Implementation

While the FDA guidance emphasizes the lack of scientific data indicating that reprocessing of SUDs is unsafe, the FDA says that comments from stakeholders in response to its draft guidance generally support the decision to enforce more regulation of the reprocessing industry, in light of its expansion.[3] Additionally, other than comments received from OEMs, the FDA states that comments were not in favor of banning the reprocessing of SUDs.[3]

Following issuance of the August 2000 guidance, the FDA will begin to phase in enforcement of premarket submission requirements based on the classification of the medical device being reprocessed. The classification scheme is an established standard system with which all device manufacturers and many device users are familiar. It is published in the Code of Federal Regulations (CFR) and loosely reflects the risk of the medical device and the information necessary for the FDA to approve its marketing when first introduced for sale.[22] Thus class I devices are lower risk devices that are subject only to the general controls authorized by sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the federal FDC Act.[22] A device is placed in class I if (1) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (2) there are insufficient data to ensure that general controls are sufficient or to establish special controls to provide assurance of the safety and effectiveness of the device, but the device is not life-sustaining or for a use that is of substantial importance in preventing impairment of human health, and this use does not present potential risk of injury or illness. Many class I devices are thus exempt from the premarket approval requirements.[1]

Class II devices are or will be subject to special controls.[22] Thus, a device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, such as the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, and other appropriate actions.

Class III devices are those for which premarket approval is or will be required.[22] A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness. Alternatively, devices are class III if insufficient information exists to show that the application of special controls would provide assurance of their safety and effectiveness, and if, in addition, the device is life-supporting or for a use that is of substantial importance in preventing impairment of human health, or if the device presents a reasonable risk of injury or illness. Appendix A provides the classification of the SUDs that are currently reprocessed as well as the CFR reference for that classification.

The FDA intends to enforce premarket submission requirements within 6 months of the date of issuance of the enforcement guidance for all class III devices; within 12 months for all class II non-exempt devices; and within 18 months for all class I non-exempt devices.[3] The FDA will evaluate at a later date, on a case-by-case basis, the need to revoke exemptions from premarket submission requirements for class I and class II devices that are currently exempt and will base this decision on whether premarket submission for those devices is required to ensure their safety and efficacy after reprocessing. Despite the phase-in of the enforcement practices, the FDA retains the right to immediately take action should any particular product be shown to result in significant harm.

The new enforcement guidance does not apply to:

1. Permanently implantable pacemakers (covered separately under another guidance);
2. "Opened-but-unused" SUDS;
3. Health care facilities that are not hospitals; or
4. Hemodialyzers (covered separately under another guidance).

The FDA is thus limiting its new enforcement guidance to third-party reprocessors and hospitals but expects to evaluate other establishments that reprocess SUDs later.

With the new enforcement guidance, third-party reprocessors and hospitals are now required to adhere to the requirements of the federal FDC Act for device manufacturers, which are:

1. Registration and Listing;
2. Medical Device Reporting;
3. Medical Device Tracking;
4. Medical Device Corrections and Removals;
5. Quality System Regulation;
6. Labeling; and
7. Premarket Requirements.

Again, the first 5 requirements are already being enforced on third-party reprocessors, and the reprocessed devices meet the intent of the labeling requirement because they carry the original labeling of the OEMs. The new guidance now also enforces the first 5 requirements for hospitals that are performing reprocessing. As hospitals are the most disadvantaged by these new enforcement priorities, the FDA has given them one year to begin implementation of the first 5 requirements of the FDC Act, and will continue to enforce these requirements on third-party reprocessors. Labeling requirements will change with the new FDA guidance because reprocessed devices will have to be labeled accordingly.

The FDA will phase in enforcement of the premarket requirement (the seventh requirement) for both third-party reprocessors and hospitals over a period of time, depending on the classification of the device in question. For example, reprocessors of class III devices will now have 6 months to file a complete premarket submission with the FDA while reprocessors of class II non-exempt devices will now have 12 months to file a 510(k) submission. The FDA's rationale for its phase-in approach is that:

1. It believes the health risk associated with reprocessed SUDs varies with each device and the agency's regulatory activities should be implemented in accordance with the devices' CFR classification;
2. A phase-in implementation period may avoid any unintended and unpredictable consequences, such as potential shortages in certain hospitals that would be caused by an agency decision to immediately enforce all the requirements;
3. Establishments, such as hospitals, may be unfamiliar with FDA regulations and a phased-in implementation period will allow these facilities time to learn about the requirements and to develop programs to comply; and
4. The FDA's limited resources do not permit immediate enforcement of all regulatory requirements on third-party and hospital reprocessors.

However, the FDA also states it does not believe that phasing in the implementation of the requirements will endanger public health because there is no evidence at this time to demonstrate that reprocessing and reuse of SUDs is posing any imminent danger to public health.

THE SAFETY OF REPROCESSING SINGLE-USE MEDICAL DEVICES

Insufficient data are available to make any conclusive statement regarding the safety and efficacy of all reprocessed SUDs. However, for many specific SUDs that are reprocessed data show that when done properly, the practice is safe and results in significant cost savings to hospitals.[4,23-25] These devices include electrophysiologic catheters,[26-29] argon beam coagulation probes,[30] angioplasty catheters,[28] percutaneous transluminal coronary angioplasty catheters,[31,32] laparoscopic instruments,[33,34] perfusion cannulae,[35,36] and pulse oximeter probes.[37] Third-party reprocessors and hospitals recognize that other, more complex SUDs are difficult to clean or sterilize effectively, and thus avoid reprocessing these devices. For example, gastrointestinal biopsy forceps, which are very long and have hollow tubes and delicate mechanisms, are notoriously difficult to completely clean and sterilize and are seldom reprocessed.[4] It is important to continue research to determine characteristics of SUDs that make them safe for reprocessing, and to determine better methods of reprocessing.

Electrophysiologic catheters have been reprocessed for 20 years now and many peer-reviewed studies have found no evidence that the effectiveness of reprocessed catheters is compromised, that the sterility of the reprocessed catheters is of concern, or that the incidence of infection is increased.[2,26,28,29,38-41] There have been case reports of reprocessed cardiac catheters failing, the most notable being a report to the FDA through its Medical Device Reporting (MDR) system wherein the surface electrode of a reprocessed orthogonal catheter broke loose and became lodged in the patient's heart.[42] This platinum tip was not removed and the patient remained symptom-free. However, other similar incidents, documented by the FDA's MDR system, occurred with new catheters.[43,44]

An FDA review of all MDR reports between August 19, 1996, and December 7, 1999, revealed that 464 adverse reports out of 300,000 total reports could be associated with SUDs. Two hundred and nineteen were associated with hemodialyzers reused in the same patient and these devices are excluded from the new FDA enforcement guidelines. The remaining 245 reports involved about 70 different product types. Generally, the FDA states that this extensive review revealed no pattern of failures with reused SUDs that differs from patterns observed with the initial use of SUDs.[1,4,21] However, the FDA concedes there are significant weaknesses in the MDR reporting system and has stipulated that this is one of the reasons why more regulatory oversight is warranted.[1,3] For example, MDR reports cannot provide accurate assessments of failure rates, regardless of the type of medical device. Single-use devices are often not labeled as such in MDR reports. Specifically, failures associated with reprocessed SUDs may not be reported once it is realized that the device was reprocessed, and cross-infection resulting from an improperly reprocessed SUD can be hard to trace back to the reprocessed device.[1,4] Thus, it is necessary that medical device failures, especially that of SUDs, be properly reported to the FDA so that surveillance of adverse events can be improved. This data will enhance the safety of the reprocessing of such devices (if the failure was due to reprocessing) and will also serve to determine whether reprocessing of specific devices truly increases the risk to the patient.

A search of the peer-reviewed literature yielded no data to indicate that the reprocessing of SUDs has led to an increase in infection risks and, in fact, the limited studies available indicate that properly reprocessed SUDs can be safely reused with no infection risks.[45,46] In support, the Centers for Disease Control and Prevention (CDC) has stated it is unaware of any data indicating

that infections occur from SUD reuse and has reiterated that hospital infection surveillance programs would have detected such infections if they were present.[4,47] The FDA states that "to date, [it has] seen no documented evidence that treatment of patients with, or other patient use of, these reprocessed devices, has caused adverse clinical outcomes."[48] The FDA also notes "[it] has been unable to find clear evidence of adverse patient outcomes associated with the reuse of an SUD from any source."[49] However, it is acknowledged that the establishment of recognized standards and guidelines for the reprocessing of SUDs will only enhance the reuse of SUDs.[5] In fact, for medical devices that are intended for reuse, adherence to established reprocessing guidelines ensures that the risks to patients from the reprocessed devices are minimal.[50-53]

However, there are few established guidelines for reprocessing SUDs.[54] For those that have proper guidelines, these guidelines may not necessarily be followed or there may be an equipment malfunction or human error.[55-57] These situations can lead to adverse events. It is important to recognize that unused devices are also susceptible to defects in the manufacturing process resulting in malfunction and/or lack of sterility.[58] Even with the new FDA enforcement guidance, it is critical that properly researched, scientifically validated reprocessing guidelines exist for the SUD in question. Thus, it is important that proper reprocessing guidelines be made available, publicized, and adhered to by device reprocessors.

Finally, the CDC Hospitals Infection Program has stated that there is no evidence that the reprocessing of SUDs is a threat to public health.[4] William Jarvis, MD, Chief of the Epidemiology Branch at the CDC, has in fact been quoted as saying it would be amazing if the reprocessing of SUDs were a major public health problem and the leading hospitals have failed to realize it.[59]

CONGRESSIONAL ACTION ON THE REPROCESSING OF SINGLE-USE DEVICES

Senator Richard Durbin (D-IL) and Representative Anna Eshoo (D-CA) have introduced bills in the Senate (S. 1542) and the House (H.R. 3148) to legislate the reprocessing of single-use medical devices.[60,61] These companion bills seek to amend the federal FDC Act to require that:

1. Any reprocessor of SUDs, upon first engaging in such reprocessing and for each year in which such reprocessor continues to so engage, register with the Secretary of Health and Human Services and provide all required information; and for each such year, submit to the Secretary a list of devices labeled for single use that the entity is reprocessing, including names of original manufacturers and specific models;
2. Each such reprocessor: (1) provide such information to each person or establishment that uses such device; and (2) demonstrate the device's safety and effectiveness;
3. Every person or establishment that uses a class II or III reprocessed medical device for the provision of medical care to individuals seek informed patient consent for such use, and include a record of such use in the individual's medical record;
4. A report be made from the Secretary to specified congressional committees on the safety and efficacy of the reprocessing of devices labeled for single use;
5. The Secretary modify the MEDWATCH forms to facilitate the reporting of safety and efficacy information.

These bills were both introduced prior to the new FDA enforcement guidance and prior to a General Accounting Office report issued in June 2000 stating that there is no evidence of decreased safety with reprocessed devices. Regardless, both bills have been referred and are currently in the appropriate Senate and House (sub)committees.[60,61]

The new FDA enforcement guidance covers the most important aspects of both these bills especially with respect to ensuring patient safety via increased regulation of SUD reprocessing (the intent of points 1, 2, 4, and 5 above). One requirement of both bills is not directly covered by the new FDA guidance and its presence on the bills is problematic. This is the mandate for informed consent by every person or establishment that uses a class II or III reprocessed medical device. With respect to reprocessed devices, there has been no legal precedence in courts as to whether informed consent should be obtained prior to reusing SUDs.[62,63] Generally speaking, the physician, not the hospital, is responsible for obtaining informed consent of the patient. For non-research purposes, the need to obtain informed consent depends on the scope of disclosure that is required in the area or jurisdiction in which the physician practices, and in part on whether the jurisdiction has adopted a patient-based or physician-based standard for scope of disclosure.

With the physician-based standard, the medical community establishes the standard for whether reprocessed devices can be used in treatment.[62,63] With reprocessed SUDs, this has not happened and thus no standard exists.[62,63] A patient-based standard would establish the right of a patient to decide between the use of a new device or the use of a reprocessed device, where the use of a reprocessed device presents a significantly different material risk to a reasonable patient.[62,63] This "material risk" would be determined by the existing scientific evidence, and by the current reprocessing technology. For reprocessed SUDs, the material risk would be determined by the following 4 points:[62,63]

1. The specific SUD in question;
2. The scientific evidence demonstrating the safety and efficacy, or lack thereof, of the reprocessed SUD;
3. Whether reuse would pose a greater risk than the alternatives; that is, initial use of an SUD or use of a reusable device; and
4. Whether reprocessing and reuse protocols would constitute a significant risk to the patient.

Accordingly, a legislative mandate for informed consent for all class II or III reprocessed SUDs would not be not supported by the scientific evidence demonstrating that certain reprocessed SUDs are safe and efficacious when properly reprocessed. For the subset of devices for which there is scientific data indicating that use of the reprocessed SUD would not pose a significant material risk to patients, informed consent may not be necessary.[64] The Senate bill (S. 1542) and the House bill (H.R. 3148) would require informed consent to be obtained for all devices, regardless of the scientific evidence.

For devices for which insufficient scientific evidence of safety and efficacy exists, informed consent may be indicated. In many situations, physicians may be unaware they may be using reprocessed SUDs.[65] In these cases, efforts may have to be made to ensure that all physicians are aware of whether they will be utilizing reprocessed SUDs in their surgical or medical procedures. The labeling requirements of the FDA enforcement guidance should address this concern. Reprocessed SUDs will be labeled as such, and will also be labeled as FDA-approved for reuse. This should help clarify the informed consent situation, because a device labeled as reprocessed and approved for reuse should relieve the material risk issue for the physician. Alternatively, a label on a reprocessed SUD clearly indicating risks associated with its use will help a physician provide the proper informed consent to his or her patient. As such, regulatory guidance on the reprocessing of SUDs appears to be the better alternative than legislative action at this time.

OPINIONS OF OTHER MEDICAL/PROFESSIONAL ORGANIZATIONS

The attention given to the new FDA enforcement guidance (and the congressional bills) led many other medical specialty societies/organizations to release comments and policy statements on the subject. A search of the Web sites of medical organizations found no statement in support of banning the reprocessing of SUDs. In fact, some organizations had statements supporting the prior FDA enforcement decisions. However, most statements were in support of proper FDA supervision/regulation of the reprocessing procedure and many were opposed to legislative action with regard to reprocessing of SUDs. Many organizations feel that there must be adequate protocols for the proper reprocessing of SUDs and many offered to participate in efforts to generate such protocols. Finally, several professional organizations feel that OEMs should be made to clarify the single-use label and that if they have data indicating that their SUDs can be reprocessed, that data should be made available to improve the reprocessing protocol. The opinions, statements, and policies of the different professional organizations are summarized in Appendix B.

POTENTIAL IMPACT OF THE NEW ENFORCEMENT GUIDANCE ON PHYSICIANS AND HOSPITALS

The FDA's new enforcement guidance imposes new and significant requirements on reprocessors of SUDs but at the same time grants specific ways to obtain FDA approval for reprocessing an SUD. Thus, it is difficult at this time to judge the effect of the new guidance on hospitals and physicians. Until third-party reprocessors and hospitals learn to work with the FDA requirements, it is possible that the extent of reprocessing may decrease leading to an increase in costs for new SUDs. Additionally, this may cause temporary shortages of certain SUDs, again leading to potential cost increases.[4] If so, all of these costs will have to be dealt with in some manner, whether by insurance or Medicare increases, or by being added to the hospital's budget.[66]

Some hospitals have informed the General Accounting Office that the amount of in-house reprocessing will likely decrease, as hospitals choose to use third-party reprocessors rather than work through the new enforcement guidance.[4] Indeed, some third-party reprocessors also told the General Accounting Office that they anticipated a rise in business.[4] This would then increase the cost to hospitals of reprocessing, which again may have implications for hospitals' budgets.

The enforcement guidance, after its requirements are met, now provides FDA approval of reprocessed SUDs as safe and efficacious. This could potentially remove the necessity of informed consent for the physician when using an FDA-approved reprocessed device, as reuse of the SUD should pose no greater "material risk" than the initial use of the same SUD.

SUMMARY

As of September 2000, there are no scientific data indicating that the proper reprocessing of specific single-use medical devices results in increased risk to patients. However, there are certain complex SUDs that are difficult to clean and reprocess and therefore should be regulated more closely or should not be reprocessed. Additionally, there are no consensus guidelines for the reprocessing of certain SUDs, and where guidelines exist, there have been instances when they have not been followed. Thus, it is appropriate that the FDA examine its regulation of the reprocessing industry. The new FDA enforcement guidance released on August 2, 2000, provides a satisfactory framework for increased regulation of the reprocessing of SUDs but must continue to evolve based on the emergence of new data on the safety of reprocessed devices. Further

research to provide this data is critical. The Council on Scientific Affairs recommends that the FDA should be given an ample period of time to determine the outcomes of its enforcement guidance on single-use device reprocessing before legislative regulation is considered.

RECOMMENDATIONS

The Council on Scientific Affairs recommends that the following statements be adopted in lieu of Resolution 514 (I-99) and Resolution 525 (A-00) and that the remainder of this report be filed.

1. That our AMA support the Food and Drug Administration (FDA) guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" that was issued on August 2, 2000. **(New HOD Policy)**

2. That our AMA urge the FDA to continue to revise the guidance as new data on the safety and efficacy of reprocessed single-use devices emerge. **(Directive to Take Action)**

3. That our AMA support the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry. **(New HOD Policy)**

4. That our AMA encourage increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices. **(New HOD Policy)**

5. That our AMA urge Congress that the FDA should be given an ample period of time to determine the outcomes of its enforcement guidance on single-use device reprocessing before legislative regulation is considered. **(Directive to Take Action)**

6. That our AMA support the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved. **(New HOD Policy)**

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Appendix A: Single-Use Medical Devices that are reprocessed (reproduced from the FDA's Guidance)

	[redacted]					
1	Cardiovascular	Cuff, Blood-Pressure	870.1120	N	510(k)	II
2	Cardiovascular	Catheter, Angiography	870.1200	N	510(k)	II
3	Cardiovascular	Catheter, Electrode Recording, Or Probe, Electrode Recording	870.1220	N	510(k)	II
4	Cardiovascular	Catheter, Intracardiac Mapping, High-Density Array	870.1220	N	510(k)	II
5	Cardiovascular	Catheter, Oximeter, Fiberoptic	870.1230	N	510(k)	II
6	Cardiovascular	Catheter, Steerable	870.1280	N	510(k)	II
7	Cardiovascular	System, Catheter Control, Steerable	870.1290	N	510(k)	II
8	Cardiovascular	Wire, Guide, Catheter	870.1330	N	510(k)	II
9	Cardiovascular	Needle, Angiographic	870.1390	N	510(k)	II
10	Cardiovascular	Trocar	870.1390	N	510(k)	II
11	Cardiovascular	Actuator, Syringe, Injector Type	870.1670	N	510(k)	II
12	Cardiovascular	Oximeter	870.2700	N	510(k)	II
13	Cardiovascular	Oximeter, Tissue Saturation	870.2700	N	510(k)	II
14	Cardiovascular	System, Balloon, Intra-Aortic And Control	870.3535	N	510(k)	III
15	Cardiovascular	Clamp, Vascular	870.4450	N	510(k)	II
16	Cardiovascular	Device, Stabilizer,Heart	870.4500	Y	N/A	I
17	Cardiovascular	Stripper, Vein, External	870.4885	N	510(k)	II
18	Cardiovascular	Sleeve, Limb, Compressible	870.5800	N	510(k)	II
19	Cardiovascular	Syringes	870.1670	N	510(k)	II
20	Cardiovascular	Catheter, Percutaneous Transluminal Angioplasty (PTA)	Unclassified	N	510(k)	II
21	Cardiovascular	Catheters, Transluminal Coronary Angioplasty, Percutaneous & Operative (PTCA)	Unclassified	N	PMA	III
22	Cardiovascular	Electrode, Percutaneous, Conduction Tissue Ablation	Unclassified	N	PMA	III
23	Dental	Bur, Dental	872.3240	Y	N/A	I
24	Dental	Saw, Bone, Ac-Powered	872.4120	N	510(k)	II
25	Dental	Drill, Bone, Powered	872.4120	N	510(k)	II
26	Dental	Driver, Wire, and Bone Drill, Manual	872.4120	N	510(k)	II

27	Dental	Drill, Dental, Intraoral	872.4130	Y	N/A	I
28	Dental	Bracket, Metal, Orthodontic	872.5410	Y	N/A	I
29	Dental	Bracket, Plastic, Orthodontic	872.5470	N	510(k)	II
30	ENT	Bur	874.4140	Y	N/A	I
31	ENT	Laser, Microsurgical Argon, For Uses Other Than Otology, Including Laryngology & General Use In Otolaryngology	874.4490	N	510(k)	II
32	ENT	Laser, Microsurgical Argon, For Use In Otology	874.4490	N	510(k)	II
33	ENT	Laser, ENT Microsurgical Carbon-Dioxide	874.4500	N	510(k)	II
34	ENT	Forceps, Biopsy, Bronchoscope (Non-Rigid)	874.4680	N	510(k)	II
35	ENT	Forceps, Biopsy, Bronchoscope (Rigid)	874.4680	N	510(k)	II
36	Gastroenterology/ Urology	Instrument, Biopsy, Mechanical, Gastrointestinal	876.1075	N	510(k)	II
37	Gastroenterology/ Urology	Set, Biopsy Needle And Needle, Gastro-Urology	876.1075	N	510(k)	II
38	Gastroenterology/ Urology	Punch, Biopsy	876.1075	N	510(k)	II
39	Gastroenterology/ Urology	Forceps, Biopsy, Non-Electric	876.1075	Y	N/A	I
40	Gastroenterology/ Urology	Cover, Biopsy Forceps	876.1075	Y	N/A	I
41	Gastroenterology/ Urology	Instrument, Biopsy	876.1075	N	510(k)	II
42	Gastroenterology/ Urology	Brush, Cytology, For Endoscope	876.1500	N	510(k)	II
43	Gastroenterology/ Urology	Needle, Pneumoperitoneum, Spring Loaded	876.1500	N	510(k)	II
44	Gastroenterology/ Urology	Needle, Pneumoperitoneum, Simple	876.1500	N	510(k)	II
45	Gastroenterology/ Urology	Endoscope and/or accessories	876.1500	N	510(k)	II
46	Gastroenterology/ Urology	Balloons/Baskets, Extraction	876.1500	N	510(k)	II
47	Gastroenterology/ Urology	Electrode, Electrosurgical, Active, Urological	876.4300	N	510(k)	II
48	Gastroenterology/ Urology	Snare, Flexible	876.4300	N	510(k)	II

49	Gastroenterology/ Urology	Electrode, Flexible Suction Coagulator	876.4300	N	510(k)	II
50	Gastroenterology/ Urology	Forceps, Biopsy, Electric	876.4300	N	510(k)	II
51	Gastroenterology/ Urology	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)	876.4300	N	510(k)	II
52	Gastroenterology/ Urology	Biliary Sphincterotomes	876.4300	N	510(k)	II
53	Gastroenterology/ Urology	Dislodger, Stone, Basket, Ureteral, Metal	876.4680	Y	N/A	II
54	Gastroenterology/ Urology	Dislodger, Stone, Flexible	876.4680	Y	N/A	II
55	Gastroenterology/ Urology	Snare, Non-Electrical	876.4730	Y	N/A	I
56	Gastroenterology/ Urology	Holder, Needle	876.4730	Y	N/A	I
57	Gastroenterology/ Urology	Trocar, Gastro-Urology	876.5090	N	510(k)	II
58	Gastroenterology/ Urology	Catheter, Urological	876.5130	N	510(k)	II
59	Gastroenterology/ Urology	Accessories, Blood Circuit, Hemodialysis	876.5820	N	510(k)	II
60	General Hospital	Mattress, Flotation Therapy, Non-Powered	880.5150	Y	N/A	I
61	General Hospital	Lift, Patient, Non-Ac-Powered	880.5510	Y	N/A	I
62	General Hospital	Mattress, Air Flotation, Alternating Pressure	880.5550	Y	N/A	II
63	General Hospital	Mattress, Water, Temperature Regulated	880.5560	Y	N/A	I
64	General Hospital	Needle, Hypodermic, Single Lumen	880.5570	N	510(k)	II
65	General Hospital	Syringe, Piston	880.5860	N	510(k)	II
66	General Hospital	Cover, Mattress (Medical Purposes)	880.6190	Y	N/A	I
67	General Hospital	Scissors, Medical, Disposable	880.6820	Y	N/A	I
68	General Hospital	Syringe, Irrigating	880.6960	Y	N/A	I
69	General Hospital	Pump, Infusion, Implanted, Programmable	Unclassified	N	PMA	III
70	General Hospital	Pump, Infusion, Implanted, Non-Programmable	Unclassified	N	PMA	III
71	General Hospital	Device, Needle Destruction	Unclassified	N	PMA	III
72	Infection Control	Gowns, Surgical	878.4040	N	510(k)	II
73	Laboratory	Lancets, Blood	878.4800	Y	N/A	I
74	Neurology	Instrument, Clip Forming/Cutting	882.4190	Y	N/A	I

75	Neurology	Drills, Burrs, Trephines & Accessories (Manual)	882.4300	N	510(k)	II
76	Neurology	Drills, Burrs, Trephines & Accessories (Compound, Powered)	882.4305	N	510(k)	II
77	Neurology	Drills, Burrs, Trephines & Accessories (Simple, Powered)	882.4310	N	510(k)	II
78	OB/GYN	Laparoscope, Gynecologic	884.1720	N	510(k)	II, **I
79	OB/GYN	Laparoscopic Dissectors	884.1720	Y	N/A	I
80	OB/GYN	Laparoscopic Graspers	884.1720	Y	N/A	I
81	OB/GYN	Trocar	884.1720	N	510(k)	II
82	OB/GYN	Insufflator, Laparoscopic	884.1730	N	510(k)	II
83	OB/GYN	Electrocautery, Endoscopic And Accessories	884.4100	N	510(k)	II
84	OB/GYN	Electrocautery, Gynecologic (and Accessories)	884.4120	N	510(k)	II
85	OB/GYN	Coagulator-Cutter, Endoscopic, Bipolar (and Accessories)	884.4150	N	510(k)	II
86	OB/GYN	Coagulator, Laparoscopic, Unipolar (and Accessories)	884.4160	N	510(k)	II
87	OB/GYN	Coagulator, Hysteroscopic (and Accessories)	884.4160	N	510(k)	II
88	OB/GYN	Coagulator, Culdoscopic (and Accessories)	884.4160	N	510(k)	II
89	OB/GYN	Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)	884.4160	N	510(k)	II
90	OB/GYN	Scissors, Umbilical	884.4520	Y	N/A	I
91	OB/GYN	Scissors, Episiotomy	884.4520	Y	N/A	I
92	OB/GYN	Forceps, Biopsy, Gynecological	884.4530	Y	N/A	I
93	OB/GYN	Laparoscopic Scissors	884.1720	Y	N/A	I
94	Ophthalmic	Endoilluminator	876.1500	N	510(k)	II
95	Ophthalmic	Drapes, Surgical	878.4370	N	510(k)	II
96	Ophthalmic	Keratome Blade	886.4370	N	510(k)	I
97	Ophthalmic	Knife, Ophthalmic	886.4350	Y	N/A	I
98	Ophthalmic	Unit, Phacofragmentation	886.4670	N	510(k)	II
99	Ophthalmic	Fluidic,	886.4670	N	510(k)	II

100	Ophthalmic	Phacoemulsification/ Phacofragmentation Phacoemulsification	886.4670	N	510(k)	II
101	Orthopedics	Needle Saw Blades	878.4820	Y	N/A	I
102	Orthopedics	Surgical Drills	878.4820	Y	N/A	I
103	Orthopedics	Arthroscope	888.1100	N	510(k)	II **I
104	Orthopedics	Component, Traction, Invasive	888.3040	N	510(k)	II
105	Orthopedics	Scissors	888.4540	Y	N/A	I
106	Orthopedics	Reamer	888.4540	Y	N/A	I
107	Orthopedics	Knife, Orthopedic	888.4540	Y	N/A	I
108	Orthopedics	Burr	888.4540	Y	N/A	I
109	Orthopedics	Bit, Drill	888.4540	Y	N/A	I
110	Orthopedics	Rongeur	888.4540	Y	N/A	I
111	Orthopedics	Trephine	888.4540	Y	N/A	I
112	Orthopedics	Countersink	888.4540	Y	N/A	I
113	Orthopedics	Tap, Bone	888.4540	Y	N/A	I
114	Orthopedics	Staple Driver	888.4540	Y	N/A	I
115	Orthopedics	Holder, Needle	888.4540	Y	N/A	I
116	Orthopedics	Manual Surgical Instrument	888.4540	Y	N/A	I
117	Orthopedics	Carpal Tunnel Blade	888.4540	Y	N/A	I
118	Plastic Surgery	Stapler	878.4800	Y	N/A	I
119	Physical Medicine	Cable, Electrode	890.1175	Y	N/A	I
120	Physical Medicine	Joint, Shoulder, External Limb Component	890.3420	Y	N/A	I
121	Physical Medicine	Joint, Hip, External Limb Component	890.3420	Y	N/A	I
122	Physical Medicine	Joint, Knee, External Limb Component	890.3420	Y	N/A	I
123	Physical Medicine	Unit, Wrist, External Limb Component, Mechanical	890.3420	Y	N/A	I
124	Respiratory	Circuits, Respiratory Therapy And Anesthesia Breathing	868.5240	Y	N/A	I
125	Respiratory	Catheters, Oral And Nasal	868.5350	Y	N/A	I
126	Respiratory	Masks, Gas	868.5550	Y	N/A	I
127	Respiratory	Breathing Mouthpiece	868.5620	Y	N/A	I
128	Respiratory	Catheter, Tracheobronchial Suction	868.6810	Y	N/A	I

129	Respiratory	Tube, Tracheal	868.5730	N	510(k)	II
130	Respiratory	Changer, Endotracheal Tube	Unclassified	N	PMA	III
131	Surgery	Laparoscope, General & Plastic Surgery	876.1500	N	510(k)	II
132	Surgery	Endoscopic Blades	876.1500	N	510(k)	II
133	Surgery	Endoscopic Guidewires	876.1500	N	510(k)	II
134	Surgery	Splint, Extremity, Inflatable, External	878.3900	Y	N/A	I
135	Surgery	Splint, Extremity, Noninflatable, External	878.3910	Y	N/A	I
136	Surgery	Unit, Electrosurgical And Coagulation, With Accessories	878.4400	N	510(k)	II
137	Surgery	Electrosurgical Device	878.4400	N	510(k)	II
138	Surgery	Device, Electrosurgical, Cutting & Coagulation & Accessories	878.4400	N	510(k)	II
139	Surgery	Apparatus, Electrosurgical	878.4400	N	510(k)	II
140	Surgery	Electrode, Electrosurgical	878.4400	N	510(k)	II
141	Surgery	Needle, Biopsy, Cardiovascular	878.4800	Y	N/A	I
142	Surgery	Knife, Surgical	878.4800	Y	N/A	I
143	Surgery	Apparatus, Suturing, Stomach and Intestinal	878.4800	Y	N/A	I
144	Surgery	Lancet, Blood	878.4800	Y	N/A	I
145	Surgery	Chisel, Surgical, Manual	878.4800	Y	N/A	I
146	Surgery	Curette, Surgical	878.4800	Y	N/A	I
147	Surgery	Cutter, Surgical	878.4800	Y	N/A	I
148	Surgery	Rasp, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
149	Surgery	Retractor, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
150	Surgery	Snare, Surgical	878.4800	Y	N/A	I
151	Surgery	Spatula, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
152	Surgery	Stapler, Surgical	878.4800	Y	N/A	I
153	Surgery	Stripper, Vein, Disposable	878.4800	Y	N/A	I
154	Surgery	Hook, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
155	Surgery	Gouge, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
156	Surgery	Dissector, Surgical,	878.4800	Y	N/A	I

		General & Plastic Surgery				
157	Surgery	Clamp, Surgical, General & Plastic Surgery	878.4800	Y	N/A	I
158	Surgery	Saw, Manual And Accessories	878.4800	Y	N/A	I
159	Surgery	Scalpel, One-Piece	878.4800	Y	N/A	I
160	Surgery	Handle, Scalpel	878.4800	Y	N/A	I
161	Surgery	Brush, Biopsy, General & Plastic Surgery	878.4800	Y	N/A	I
162	Surgery	Applier, Staple, Surgical,	878.4800	Y	N/A	I
163	Surgery	Forceps, General & Plastic Surgery	878.4800	Y	N/A	I
164	Surgery	Blade, Scalpel	878.4800	Y	N/A	I
165	Surgery	Retractor, Manual	878.4800	Y	N/A	I
166	Surgery	Saw, Manual, And Accessories	878.4800	Y	N/A	I
167	Surgery	Applier, Hemostatic Clip	878.4800	Y	N/A	I
168	Surgery	Saw	878.4800	Y	N/A	I
169	Surgery	Forceps	878.4800	Y	N/A	I
170	Surgery	Curette	878.4800	Y	N/A	I
171	Surgery	Rasp	878.4800	Y	N/A	I
172	Surgery	Instrument, Cutting, Orthopedic	878.4800	Y	N/A	I
173	Surgery	Osteotome	878.4800	Y	N/A	I
174	Surgery	Clamp	878.4800	Y	N/A	I
175	Surgery	Retractor	878.4800	Y	N/A	I
176	Surgery	Spatula, Orthopedic	878.4800	Y	N/A	I
177	Surgery	Chisel, Mastoid	878.4800	Y	N/A	I
178	Surgery	Instrument, Surgical, Disposable	878.4800	Y	N/A	I
179	Surgery	Hook, Bone	878.4800	Y	N/A	I
180	Surgery	Scissors, General Use, Surgical	878.4800	Y	N/A	I
181	Surgery	Instrument, Manual, General Surgical	878.4800	Y	N/A	I
182	Surgery	Instrument, Manual, Surgical, General Use	878.4800	Y	N/A	I
183	Surgery	Laser Instrument, Surgical, Powered	878.4810	N	510(k)	II
184	Surgery	Blade, Saw, Surgical, Cardiovascular	878.4820	Y	N/A	I
185	Surgery	Saw, Electrically Powered	878.4820	Y	N/A	I
186	Surgery	Motor, Surgical Instrument, Pneumatic Powered	878.4820	Y	N/A	I
187	Surgery	Motor, Surgical Instrument, Ac-Powered	878.4820	Y	N/A	I

188	Surgery	Blade, Saw, General & Plastic Surgery, Surgical	878.4820	Y	N/A	I
189	Surgery	Dermatome	878.4820	Y	N/A	I
190	Surgery	Bur, Surgical, General & Plastic Surgery	878.4820	Y	N/A	I
191	Surgery	Bit, Surgical	878.4820	Y	N/A	I
192	Surgery	Saw, Powered, And Accessories	878.4820	Y	N/A	I
193	Surgery	Chisel (Osteotome)	878.4820	Y	N/A	I
194	Surgery	Saw, Pneumatically Powered	878.4820	Y	N/A	I
195	Surgery	Burr	878.4820	Y	N/A	I
196	Surgery	Tourniquet, Nonpneumatic	878.5900	Y	N/A	I
197	Surgery	Tourniquet, Pneumatic	878.5910	Y	N/A	I
198	Surgery	Endoscopic Staplers	888.4540	Y	N/A	I
199	Surgery	Trocar	874.4420	Y	N/A	I
200	Surgery	Trocar	876.5090, 876.1500, 870.1390	N	510(k)	II
201	Surgery	Electrosurgical Electrodes/Handles/ Pencils	876.4300, 878.4400	N	510(k)	II
202	Surgery	Surgical Cutting Accessories	878.4800, 874.4420	Y	N/A	I

Appendix B: Opinions of other medical/professional organizations

The **American College of Cardiology** (ACC) states that legislation as proposed by bills S. 1542 and H.R. 3148 is unwarranted.[59] Additionally, the ACC emphasizes that reprocessing is safe and is a practice that hospitals and physicians have relied on for more than 20 years. The ACC urges Congress to defer to the FDA regulatory function with respect to reprocessing of SUDs and supports the FDA increasing its regulatory oversight of reprocessing of SUDs as long as its regulations are based on the best available science.[59]

The **North American Society of Pacing and Electrophysiology** (NASPE) shares the views of the ACC and in fact provided joint testimony with the ACC to the Senate Committee on Health, Education, Labor and Pensions.[66] The NASPE and ACC summarized their comments by stating:

> [T]he reprocessing and reuse of EP catheters is safe and ... the FDA has issued a proposed strategy which when implemented will provide a scientific and risk-based approach to regulating the practice of reprocessing by hospitals and third-party reprocessors.

The NASPE also emphasizes that the designation of a device as "single-use" is a choice of the manufacturer and not an FDA requirement.[66] The NASPE comments that requiring informed consent when using reprocessed electrophysiological catheters is unwarranted and points out the difficulty with such a mandate. For example, physicians currently are not required to inform patients before using devices that have been the subject of an MDR report.[66]

The **American Society for Gastrointestinal Endoscopy's** (ASGE) position is:

> The American Society for Gastrointestinal Endoscopy (ASGE) is committed to the safe, effective and economical practice of gastrointestinal endoscopy and believes that the decision to reuse medical accessories in the setting of gastrointestinal endoscopy should be individualized to the practice of the physician or institution. If a reprocessing company is utilized, the company should be registered with the FDA. The ASGE supports further research on the reuse of medical accessories.

The AGSE supports many features of the FDA's regulatory strategy and hopes that regulatory decisions will be made based on hard data.[67]

The **American College of Surgeons** (ACS) in general supports the FDA's effort to increase regulation of the reprocessing of SUDs. It emphasizes:

> [T]he viability of reprocessed devices and the benefits and detriments to patient care associated with their reuse are crucial issues that must be carefully assessed. Surgeons-often unaware of the reuse status of the sterilized instruments in a surgical tray-must accept on faith that the hospital has taken the necessary precautions to prepare the operating room and its equipment for providing safe and high-quality surgical care.[65]

ACS also emphasizes that any decision:

> to restrict the use of reprocessed SUDs must be based on sound data if FDA is to produce truly credible and effective regulations.[68]

The ACS also asks the FDA to consider having OEMs provide information on their labels about risks associated with reuse of their SUDs as they are concerned that manufacturers currently have no incentive to provide thorough and accurate information that could encourage purchasers to reprocess devices rather than purchase new ones.

The **American Gastroenterological Association** (AGA) states that the labeling of medical devices that can be reprocessed as "single-use":

> increases the cost of care without necessarily increasing the patients' safety.[69]

Additionally, the AGA states:

> In fact, current Medicare practice-expense reimbursement policies are based on the assumption that these items are used multiple times. Further, a review of the literature finds no increased risk to patients as long as cleaning/sterilization protocols are followed.[69]

Thus, the AGA has issued the following policy statement:

1. Without data demonstrating the risk of infectious transmission, degradation of utility or other safety concerns with reuse of medical devices, Congress should not act to prohibit reuse of these devices.
2. The FDA should disclose data from the original equipment manufacturers (OEMs) on which claims of "single use" were made.
3. Proper reprocessing procedures should be defined by the OEMs. Furthermore, methods to assure the continued utility of reusable devices should be described and made available to end-users

The **Association for Professionals in Infection Control and Epidemiology** (APIC) maintains a neutral position on the issue of reuse of SUDs.[70] APIC is in support only of stricter regulation for the reprocessing of critical devices, and has been engaged in dialogue with the FDA and other stakeholders on this issue. APIC states in its response to the FDA's draft enforcement guidance that the:

> FDA should initiate a review process that is science-based and leads to the quantification of risk. This should clearly identify risk stratification for the wide range of products that are currently being reprocessed. We believe that efficacy data and procedural data (on the reprocessing itself) should be available. APIC would support regulating third-party reprocessors in the same manner as OEMs, where risk is scientifically demonstrated.[71]

Additionally, APIC believes that it is appropriate to allow reprocessors to declare conformity to a recognized reprocessing standard and supports the development of consensus standards for the reuse, reprocessing and resterilization of SUDs. With regard to informed consent, APIC says that informed consent is not indicated for all medical interventions and that traditionally, informed consent includes discussion of morbidity and mortality rates associated with a procedure. Since health care facilities using reprocessed SUDs consider them safe and efficacious, APIC believes that some indication would be needed of when use of a reprocessed SUD would require informed consent.[71] APIC believes that reprocessing must remain a viable option for users while also being safe and effective for the patients.[70]

The **American Hospital Association** (AHA) in its comments on the FDA's efforts to regulate reprocessing of SUDs states that it is clear that the medical community, reprocessors, and OEMs lack the data needed to properly assess reuse.[72] Thus, the AHA strongly supports more research conducted specifically on reuse of SUDs. The AHA also recommends that this research be directed at high-risk or more complex devices and that all such research be peer-reviewed and published.[72] With regard to consensus reprocessing guidelines, the AHA believes they are important but emphasizes that they should depend on the risk categorization of the SUD.[72] Thus, consensus guidelines for high-risk devices should be developed by an interdisciplinary advisory panel of health care professionals and device manufacturers. The AHA also expressed concern about the current use of the label "single-use" and strongly supports that OEMs be required to label SUDs with information about the risks associated with reuse. This labeling should be premised on a body of scientific evidence setting out the quantifiable risk associated with resterilization, reprocessing, and reuse of that particular device. The OEM, knowing the most about the device, is best qualified to perform this task. Finally, the AHA disagrees with the enforcement guidance's treatment of hospitals as similar to third-party reprocessors. The AHA feels that hospitals are already under very high levels of external regulatory and other oversight and internal controls. Thus, the imposition of more, and potentially redundant, regulations on hospitals would be burdensome.[72]

In a position statement from 1998,[73] the **Society of Gastroenterology Nurses and Associates** (SGNA) says that the appropriateness of reuse of single-use medical devices must be examined on a device-by-device basis. The risks of reuse will depend on the application of the device, how it has been handled during use, and how it is reprocessed in preparation for the next patient. Critical instruments carry a much higher level of risk in reuse than do non-critical or semi-critical devices. Thus the SGNA issued the following policy:

> In the absence of clear regulatory guidelines for reuse of single-use devices, based on current scientifically-based literature, and taking into consideration concerns for patient safety and ethical practice, the Society of Gastroenterology Nurses and Associates, Inc. supports the position that critical medical devices labeled for single-use should not be reused.[73]

The **Association of periOperative Registered Nurses** (AORN) has the following opinion on reprocessing of SUDs:[74]

> Three issues must be considered when making a decision regarding reprocessing a disposable medical device: the device's function and safety after reprocessing, the legal and ethical issues associated with the device, and economic concerns. Each single-use medical device should be considered on an individual basis after carefully validating the safety and efficacy of the item after reprocessing. A single-use medical device that cannot be cleaned, sterilized, or disinfected without damage to its integrity and/or function should not be reprocessed.[74]

The AORN does not recommend reprocessing SUDs unless manufacturers provide written instructions for resterilizing them, or unless the health care facility can demonstrate and document that the patient's safety and the medical device's effectiveness and integrity are not compromised. AORN also provides some steps that should be undertaken when reprocessing an SUD, concluding that validation of the safety, efficacy, and integrity of a reprocessed device should be based on an established reuse-testing protocol.

The **American Society for Healthcare Central Service Professionals** (ASHCSP) is a professional organization that promotes effective health care central service and sterile processing and inventory management practices. In responding to the FDA enforcement guidance, the ASHCSP stated its concern that other non-acute health care facilities would be exempt from the guidance, saying that these health care facilities often lack the necessary resources and protocols to ensure safe and effective reprocessing of single-use items.[75] ASHCSP also states its concern that hospitals would then be at a competitive disadvantage with the other health care facilities.[75] Regarding labeling requirements, the ASHCSP states:

> There are no standards in place which guide multi use vs. single use labeling. An OEM should not be permitted to label a device for single use if it is aware of safe and effective reprocessing and sterilization procedures...The device label should include the number of times the device will perform without failure as validated by the OEM...OEMs should be required to provide instructions for acceptable, validated methods of sterilization and/or resterilization for all devices.[75]

Finally, in a response to proposed legislation on the reprocessing of single-use medical devices, the ASHCSP reemphasizes that reprocessing of SUDs is a complex issue that cannot be solved with a broad approach. It feels that hospitals should have the prerogative to determine whether or not the reprocessing of disposable devices is appropriate for their facility. However, the decision to reuse internally should be made only if the facility has the capabilities to ensure the necessary steps are taken to preserve patient safety and device integrity. ASHCSP supports a regulatory approach that considers the classification of, complexity of, and ability to clean a medical device and treats reuse, reprocessing, and resterilization separately.[76]