

## NASPE POLICY STATEMENT

# Reprocessing of Electrophysiology Catheters: Clinical Studies, Regulations, and Recommendations. A Report of the NASPE Task Force on Reprocessing of Electrophysiological Catheters

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### Introduction

The reuse of medical devices labeled for single use evokes concern because of the possibility that this practice may increase procedural risks for patients. The debate over this controversial issue extends well beyond the area of electrophysiological studies and is clouded by financial incentives for hospitals, manufacturers, and reproprocessors. It is compounded by the ambiguous criteria for "single use" labels and doubt about the uniformity of reprocessing standards. The broad scope of single use devices (SUDs) that are frequently reprocessed is shown in Table I.<sup>1</sup> These devices vary considerably in their materials, technical complexity, fragility, and risk of reuse.

On February 10, 2000, the Subcommittee on Oversight and Investigations of the Committee on Commerce of the United States House of Representatives presided over a hearing to examine the risks to patients, the need for informed consent when SUDs are reused, regulatory fairness, and appropriate regulatory measures.<sup>2</sup> A subsequent hearing by the Senate Committee on Health, Education, Labor, and Pensions included the General Accounting Office (GAO) report on medical SUDs. The purpose of this North American Society of Pacing and Electrophysiology (NASPE) policy statement is to examine the basis of concerns about reprocessing catheters and the measures proposed by the Food and Drug Administration (FDA) to address this issue.

### Development of Single Use Labels and Reprocessing Policies

Prior to the late 1970s most medical devices were considered "reusable" and were hand wiped, soaked in disinfectants, and resterilized by heat. As the demand for disposable equipment rose, hospital administrators and physicians began to notice that some products labeled "single use only" were similar to devices that had been formerly distributed as "reusable." For example, a letter written by USCI Cardiology & Radiology Products to a hospital explained that although USCI had decided to change the label on a particular device from reusable to single use, it had made no structural changes to the device. Specifically, USCI stated "our manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner they have been in the past."<sup>3</sup>

In response to what many physicians and hospital administrators perceived as an arbitrary labeling policy, the practice of reprocessing SUDs evolved to reduce costs and the amount of medical waste generated by the use of disposable devices. As this practice encompassed critical devices such as electrophysiological catheters, the complexity of decontamination and sterilization procedures increased. The role of hospital committees made up of physicians, nurses, infection control specialists, risk managers, hospital lawyers, and professional reproprocessors evolved to monitor the safety of reesterilization methods. Many hospital administrations believed this practice was safe, some made use of third party reproprocessors, and others abandoned the practice altogether. Concerns about reprocessing often pertain

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**Table I.**

## Frequently Reprocessed Single Use Devices

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Surgical saw blades
Surgical drills
Laparoscopy scissors
Orthodontic (metal) braces
Electrophysiological catheters
Electrosurgical electrodes and pencils
Respiratory therapy and anesthesia breathing circuits
Endotracheal tubes
Balloon angioplasty catheters
Biopsy forceps

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to liability, the institution's technical expertise, or the cost that quality assurance programs entail.

According to the *FDA Compliance Policy Guide*, hospitals that reprocess SUDs assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized.<sup>4</sup> They also have the responsibility to confirm that device safety, effectiveness, and quality are maintained. In essence, hospitals or third parties that reprocess SUDs become "manufacturers" and are subject to the same regulatory requirements as other manufacturers, including premarket requirements. To date, the FDA has not actively enforced premarket requirements against third parties, and with regard to electrophysiological catheters opinions differ as to what these requirements should entail.

Third party reprocessors are currently required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation.<sup>5</sup> These extensive regulations require the reprocessors to (1) control and monitor production processes to ensure that a device conforms to its specifications, (2) validate with a high degree of assurance that reprocessing methods ensure that specified requirements are met, and (3) establish and maintain procedures for reprocessed device acceptance to ensure that each production run, lot, or batch meets acceptance criteria. A functional difference between reprocessors and manufacturers is that reprocessors test every reprocessed device before sending it back to a hospital, whereas the original manufacturers test only a sample of their products. The purpose of these requirements is to assure that the reprocessed device is clean, sterile, and able to perform its originally intended clinical function. These regulations also stipulate that third party reprocessors must make all required information and data available for inspection by the FDA.

In his testimony to the Subcommittee on Oversight and Regulations, Dr. Robert O'Halla, Vice President of Regulatory Affairs for the Medi-

cal and Diagnostic Group at Johnson and Johnson, and Chairman of the Association of Disposable Device Manufacturers (ADDM) provided alarming data that raises serious concern that hospitals do not uniformly abide by the Quality System Regulation. He testified that ADDM members retrieved 1,000 reprocessed devices from hospitals where they were awaiting use in patients. Approximately 75% of the samples failed inspection due to the presence of blood or proteinaceous matter, bacterial contamination, functional failures, or defective packaging leading to nonsterile devices.<sup>6</sup> One of the photographs presented by Mr. O'Halla to the subcommittee illustrated tissue residue that had not been removed from an electrophysiological catheter during cleaning. His testimony points to the need for closer oversight of reprocessing and the need for uniform standards to which third party reprocessors and hospitals would be accountable.

#### The Basis and Impact of Single Use Labeling

No FDA regulations or formal standards distinguish the quality or functionality of reusable devices from SUDs. The discretion to label a device for single use lies solely with the device manufacturer. In his testimony during the subcommittee hearing, Dr. David Feigal, Director of the Center for Devices and Radiological Health at the FDA, acknowledged that it has been the FDA's practice to take a manufacturer's request for single use labels at face value and to evaluate how that device would perform as single use.<sup>7</sup> The FDA evaluates a device relative to its intended use by the manufacturer. Its approval of a device for single use means that the device can be used safely once; however, the single use label does not specify that the device cannot be used safely and reliably more than once if it is reprocessed appropriately.

The Federal Food, Drug, and Cosmetic (FDC) Act requires that all new medical devices be approved by the FDA through the premarket notification (510k) or premarket approval (PMA) process. Under the FDA's rules, reprocessing modifies a SUD by changing its intended use to multiple use. The implications are that reprocessors of SUDs become manufacturers under the FDC Act and are subject to its regulatory requirements, including premarket notification requirements. In a letter dated July 9, 1999, the FDA stated that "third-party reprocessing of devices labeled for single use is unlawful unless those engaged in these practices comply with all regulatory requirements for manufacturers including premarket notification requirements."<sup>8</sup> In the same letter the FDA qualified its position by stating "FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements, until a new FDA reprocessing position is adopted.

The most significant regulatory requirement, at this time, is compliance with the newly developed Quality System Regulation.”

The impact of arbitrary single use labels is that an entire industry has developed to reprocess these devices, but the legality of current practices is ambiguous. The reproducers should be subject to the FDC Act, but the FDA’s decision to use “regulatory discretion” in enforcing these provisions has been confusing to physicians and hospitals. A more cohesive policy is required.

**Review of Published Studies Regarding The Reuse of Electrophysiological Catheters**

The issues pertaining to the safety and efficacy of reusing catheters focus on the risk of transmitting an infection from one patient to another and the structural and functional integrity of a catheter that is used more than once. While resterilization procedures are well established for most catheter designs, objective measures of catheter integrity are not as well documented. Some catheters are subjected to very little stress during a procedure, while the deflectability or maneuverability of others may change considerably. Moreover, the process of resterilization may affect materials used in the design of the catheter and could have an impact on function. A few published studies have evaluated the safety of reusing catheters for electrophysiological studies and have addressed some of these issues.

O’Donoghue and Platia<sup>9</sup> surveyed 12 medical centers to determine the safety of reusing catheters. The incidence of infection related to a total of 14,640 electrophysiological studies involving 48,075 catheter uses was reported. At three centers, catheters were automatically discarded after a single use. These centers carried out 1,245 electrophysiological studies using 3,125 catheters. At the other nine centers, the catheters were sterilized for reuse. There were 13,395 studies using 44,950 catheters in the reuse group. The incidence of bacteremia (blood borne infection) and superficial skin infection at the site of catheter insertion is shown in Table II. The authors concluded that sterilization and reuse of the catheters used in this study did not result in an increase in the risk of infection. They felt the catheters were sufficiently durable to be reused well in excess of five times, and that one-time use of such catheters appeared to be an unnecessary and expensive policy.

Dunnigan et al.<sup>10</sup> obtained similar results in a prospective study that evaluated catheter reuse over a 5-year period during which 178 catheters were used 1,576 times for 847 electrophysiological studies. Detailed records of catheter testing and use were maintained. No complications were encountered during the study period. All reused catheters functioned for cardiac pacing and

<b>Group</b>	<b>Bacteremia</b>	<b>Superficial Skin</b>
Single use catheters 1,245 studies 3,125 catheters	1 (0.03%)	1 (0.03%)
Reused catheters 13,395 studies 44,950 catheters	8 (0.018%)	1 (0.002%)

recording of cardiac electrical signals. Surveillance cultures and biological indicators revealed that adequate sterilization procedures were used. The authors concluded that electrophysiological catheters may be safely reused provided a thorough cleaning, testing, and record keeping system is instituted. They also concluded that the practice of reusing catheters would result in substantial cost savings to hospitals.

The prior studies were conducted in patients undergoing diagnostic electrophysiological studies before the advent of deflectable catheters and arrhythmia ablation procedures. Avital et al.<sup>11</sup> prospectively investigated the time course of electrical, physical, and mechanical changes in ablation catheters to determine the affect of reuse on safety and efficacy. They studied 69 ablation catheters made by a single manufacturer that were used in 336 procedures. Testing of *physical integrity* consisted of visual and stereoscopic (X30 magnification) examination of handle function, catheter shaft, and the deflectable tip. Specific attention was paid to the ablation electrode attachment to the catheter shaft, and the ablation tip electrode was scrutinized for pitting. The *electrical integrity* of the catheters was measured by electrical resistance from the handle connector to the recording rings and to the tip electrode. Deflection and torque measurements were made to assess *mechanical integrity*.

During the course of this study, 36 (52%) catheters were rejected at some point because of mechanical or electrical failure. Eighteen catheters were repeatedly sterilized and 11 of the catheters were used  $\geq 10$  times. The most common reasons for catheter rejection were tip electrode glue separation after  $4.3 \pm 4.3$  uses and loss of deflection after  $5.0 \pm 3.3$  uses. The glue that covers the most proximal portion of the distal electrode is shiny and uniform before any use. The application of radiofrequency energy causes a rise in tissue temperature and the electrode tip is heated secondarily. Small fractions of glue were missing and may have been released into the bloodstream. Catheters

with blood that collected in this space could not be properly cleaned. There was no evidence that the tip to shaft attachment was affected by the outer glue separation; however, the possibility that the attachment of the tip electrode was weakened by the glue separation could not be excluded. Electrical discontinuity was observed after  $10.0 \pm 3.7$  uses. There was no significant decrease in the catheter torquing ability that determines the steering responsiveness of the catheter. The medical records of 140 patients who had arrhythmia ablation procedures in this study revealed only one (0.7%) case of local infection at the insertion site that was treated effectively by antibiotics. There were no other complications.

Avital et al.<sup>11</sup> concluded that the catheter model used in this study could be reused an average of five times. They recommended that after each use catheters be carefully examined under magnification with special attention to the tip electrode. They also recommended that the catheters be tested for deflection and electrical integrity after each use.

As part of an internal quality review process Aton et al.<sup>12</sup> determined the effects of reprocessing on mechanical integrity, sterility, and chemical residuals to establish and validate an institutional policy for reuse. A total of 12 commercially available catheters from two manufacturers were analyzed. Eleven of the catheters were randomly selected from the catheter inventory of the clinical electrophysiological laboratory after being used one to four times. They were manually cleaned, repackaged, and gas sterilized with ethylene oxide. To assess the *sterility* of reused catheters, three were cut into 2-inch segments, placed in bacterial culture media, and incubated for 5 days. Six of the catheters were analyzed for chemical residuals after gas sterilization. Two catheters were examined for evidence of component failure. Visual inspection and microscopy were used to determine the *mechanical integrity* of the catheter surface, and x-ray inspection was performed to assess interior structures.

The study results of Aton et al.<sup>12</sup> showed no bacterial growth detected on any of the cultures, which indicated that reprocessed electrode catheters are effectively sterilized. The chemical analysis demonstrated that the concentrations of ethylene oxide detected in extraction liquid exceeded standards established by the FDA. Microscopic examination of reprocessed catheters demonstrated inconsequential metal and fiber particulates on the catheter surface and at some electrode to catheter interfaces. Fluid entrapment around the distal pole may occur in catheters with tip electrodes. The shaft of the catheters and the electrodes remained intact. There was no evidence of electrical discontinuity, and the integrity

of the internal structures was confirmed by x-ray inspection. The authors concluded that with the sterilization techniques frequently used by hospitals, the potential for chemical residual contamination might exist after sterilization with ethylene oxide.

### Limitations of Available Clinical Data

The criticisms that can be made of these studies are that one was a retrospective survey that depended on the memory of those who responded.<sup>9</sup> It is possible that isolated events escaped the attention of the participants in the survey or they may have forgotten complicating events. The other prospective studies involved smaller numbers of patients.<sup>10-12</sup> The methodology of these studies varied and is unlikely to meet standards that are presently being considered by the FDA. Moreover, the catheters used in each of these studies are older designs. Because changes in materials or deflection mechanisms might have a significant impact on the durability of electrophysiological catheters, it should not be assumed that prior safety data is applicable to new catheter designs.

### Medical Device Reports

Medical Device Reports contain information about three catheters that broke with dislodgment of an electrode in the patient. One of these involved a reprocessed catheter and the other two appear to be new single use catheters.

1. Report #1062310-199-0001. A reprocessed orthogonal electrophysiological catheter was used without incident until it was removed from the heart. The physician felt some resistance during removal of the catheter. A subsequent X ray showed a small electrode fragment lodged in the wall of the right atrium. It was presumed that a single platinum electrode mounted on the surface of the catheter might have been compromised during reprocessing. The surgical consultant decided that removal of the fragment was not indicated and the patient remained free of symptoms.

2. Report #4501350000-1995-0088. A new deflectable ablation catheter was being positioned in the right atrium when the catheter tip was noted to be detached and wedged in the coronary sinus. The patient was observed overnight and discharged the following day without any reported symptoms.

3. Report #6000087-1998-00002. A small fragment of the distal tip in proximity to the electrode side of a new catheter broke away, and the fragment could not be located. Further details are not available.

There is concern that physicians do not consistently report complications and that the limited number of Medical Device Reports underesti-

mates the problem. Moreover, it is difficult to evaluate Medical Device Reports because the system for indexing the complications is cumbersome and it is not always clear whether the reported device was reprocessed or new. Despite these limitations, the Medical Device Reports have drawn attention to defects in new products. The question is if the handful of cases involving reused devices are representative. In his testimony to the Subcommittee on Oversight and Investigations, Mr. Vern Feltner, President of Alliance Medical Corporation and a member of the Association of Medical Device Reprocessors, testified that from January 1997 to March 1999 three medical device reports were filed concerning devices reprocessed by AMDR companies. In the same reporting period Boston Scientific, Johnson & Johnson, Mallinckrodt, and Tyco had in excess of 16,000 Medical Device reports associated with 11,827 device malfunctions, 2,509 patient injuries, and 163 deaths.<sup>13</sup> Dr. David Feigal, representing the FDA, testified that from August 1996 through December 1999, the Medical Device Reports revealed that out of 300,000 adverse events, 464 could possibly be attributed to reuse of an SUD. These reports spanned approximately 70 different types of products and showed no discernable pattern of failure with reused SUDs, which differed from patterns observed with the initial use of SUDs.<sup>14</sup> Based on these data it appears that significant complications are being reported to the FDA, but there are no disproportionate complications resulting from the reuse of SUDs.

### **Transmissible Spongiform Encephalopathies: A Dilemma for Reprocessors**

Human spongiform encephalopathies are degenerative diseases of the central nervous system that include Kuru, Gerstmann-Sträussler-Scheinker syndrome, fatal familial insomnia, and Creutzfeldt-Jakob disease. There is no immunization or known treatment for any of these diseases. The nature of the infectious agent is still under study. Prions, which appear to be the infectious agent, are proteins that contain no DNA or RNA. These unique pathogens, which are smaller than viruses, have incubation periods from months to as long as 40 years. The pathogenic forms of prions replicate by transforming normal cellular prion proteins into aberrant proteins that accumulate in the central nervous system.<sup>15</sup>

Fortunately, human spongiform encephalopathies are rare. The incidence is estimated to be only 1 per million, but the incidence of new variant Creutzfeldt-Jakob disease is rising at a rate of 23% in the United Kingdom, presumably due to consumption of meat contaminated with bovine spongiform encephalopathy.<sup>16,17</sup> There is con-

cern that unrecognized carriers might contaminate surgical instruments or blood products because there are no effective screening tests. The infectious agents are quite resistant to inactivation and can survive autoclaving regimens used to sterilize surgical instruments.<sup>18,19</sup> They are also resistant to ethylene oxide, formalin, iodofor, and many other common agents used to decontaminate surgical supplies.<sup>18</sup> Nondisposable surgical instruments should be decontaminated by soaking in 1N sodium hydroxide or undiluted sodium hypochlorite for 1 hour and then autoclaved for 1 hour at 134°C.<sup>18</sup> These methods are not applicable to electrophysiological catheters.

As of 1998, 103 documented cases of iatrogenically transmitted Creutzfeldt-Jakob disease were attributable to transplantation of brain, pituitary, or ocular tissue.<sup>20</sup> This is almost certainly due to the high levels of an infectious agent in the central nervous system, but lymphatic tissue is also highly infective, and the infectious agent is widespread throughout the body. The risk of transmission through human blood products is not resolved. No epidemiological studies have incriminated blood transfusions, and transfusion of human blood has not transmitted the disease in susceptible animal hosts.<sup>21</sup> Nonetheless, there are anecdotal reports that patients have developed Creutzfeldt-Jakob disease after transfusions of contaminated blood.<sup>22</sup> Based on these data, NASPE recommends that laboratories should never reprocess catheters that have been used in patients with known prion disease or unexplained dementia.

How can we be certain that prion diseases are not transmitted from unrecognized carriers? This question has much broader implications than the FDA's current focus. It would affect the reuse of clamps, retractors, and other expensive items that are exempted from the new regulations. It could also affect transfusion of blood products or organ transplants. There are probably about 300 patients with prion disease in the United States (incidence 1 per million). According to the Centers for Disease Control, the incidence in the United States has not changed over the past decade and in people < 30 years of age it remains < 5 per billion.<sup>23</sup> In essence, a policy banning all reusable surgical supplies would be based on a low risk. In the case of electrophysiological studies, the risk of a fatal complication is about 0.1%. The risk of contracting prion disease from reused catheters adds an additional risk that is probably in the range of 1 in several million. Is this an acceptable risk? Should it alter clinical practices? To date, neither the FDA nor the Centers for Disease Control and Prevention (CDC) has taken a formal position on this issue. If they do, any standards they develop for reesterilization of electrophysiological catheters would be

made in the broader context of if any surgical instruments should be reused.

### GAO Report

The GAO report submitted during the Senate hearing on June 20, 2000 was entitled *Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted*.<sup>24</sup> The GAO reviewed the relevant scientific literature, met with FDA officials, examined FDA documents and documents submitted to the FDA by interested parties, interviewed officials at the CDC and the Health Care Financing Administration, gathered information from other experts in government and industry, contacted third party reprocessing companies, and interviewed physicians, hospital administrators, and other health care providers. They concluded that neither the FDA nor any other organization has accurate information about the number of facilities that use reprocessed SUDs or the types of these devices that are reprocessed. They point out that it is difficult to assess the validity of surveys because the response rates are low and some hospitals are unwilling to acknowledge that they reuse devices.

Many health care personnel advised the GAO that some SUDs can safely be reused.<sup>14</sup> The GAO found mistrust over the single use label because the FDA does not require manufacturers to support the designation of single use, there is a perception that financial incentives influence the designation of single use, and the FDA's requirements for SUDs are thought to be less extensive than those for reusable devices. The GAO also found contradictions within the manufacturers' practices that contribute to widespread skepticism. Some companies have programs to "remanufacture" SUDs and others provide guidelines for hospitals to reprocess the devices. Moreover, in a 1998 United States District Court case, the judge found that the manufacturer's only purposes in labeling a device for single use were to comply with the FDA's requirements and to limit its own liability from reuse, not to prevent a hospital from using the device more than once.<sup>25</sup>

The GAO report concluded that some SUDs can be safely reprocessed and reused on other patients, and notes that some patient adverse events allegedly related to SUDs are inaccurate. They specifically cited the clinical literature supporting the safety of reprocessing electrophysiological catheters. The GAO was advised by hospital infection control practitioners, risk management executives, and patient safety experts that careful reprocessing of SUDs that can be properly cleaned and sterilized does not pose a risk to patient health. The report quotes experts from the CDC who said that they were not aware of any infec-

tions caused by reuse in the last decade. The CDC expressed confidence that hospital infection surveillance systems would detect a significant risk associated with this practice.

Although the GAO report found little evidence of harm arising from reprocessing, it found instances where standard procedures were not always followed correctly. It notes reports by the device manufacturers who found damaged, unclean, or unsterile devices taken from hospital stocks that had been reprocessed by the hospitals or third party reprocessing firms. The GAO is concerned that surveillance programs may underreport problems, and that it is difficult to trace infections back to the use of a specific device. The GAO report concludes that some SUDs can be safely reprocessed; however, the practice is not invariably safe and further oversight by the FDA is needed to protect the public safety.

### Informed Consent

One of the concerns raised during the United States House of Representatives subcommittee hearing is that patients are not informed when reprocessed catheters are used. The analogy to "truth in advertising" requirements is that patients have a right to know, and that physicians should not be reluctant to disclose this information to the patient. It was clear that the subcommittee is particularly concerned about any perception of duplicity when informed consent is obtained. The testimony from two ethicists focused on the perspective that patients should be informed of substantive risks. One ethicist concluded that patients should be advised when reused SUDs are used because the risks have not been adequately studied.<sup>26</sup> The second ethicist concluded that the need to obtain informed consent for reused SUDs depends on if the physician believes there is an appreciable risk to patient.<sup>27</sup> He maintained that use of a reprocessed SUD should be disclosed to the patient if it poses a significant risk; however, if it is determined that the risks are minimal, the process of trying to disclose these risks could actually hinder the integrity of informed consent by promoting irrational concerns.

To put this issue in perspective, physicians do not routinely obtain consent for the second use of a device that is labeled "reusable" because this is not associated with substantive risk. Moreover, physicians are not compelled to inform patients before using devices that have been the subject of a Medical Device Report or Warning Letter from the FDA. Physicians do not generally advise patients that medical devices are subject to recalls, nor can they exclude the possibility that devices used in the procedure could be recalled in the future. In these cases informed consent is influenced

by the physician's judgement about the level of risk relative to the inherent risk of the procedure.

In the case of electrophysiological studies, the risk of a life-threatening or fatal complication is in the range of 1:1,000.<sup>28</sup> Certain other risks may be higher depending on the nature of the procedure. The risk of reusing electrophysiological catheters appears to be so low that no reasonable estimate has been identified. Relative to the overall risk of the procedure, the risk of reusing electrophysiological catheters is insignificant. If the use of reprocessed devices is not associated with material risk, then there is no ethical reason why this issue must be added to the long list of risks known to be associated with the procedure. Patients should be informed if they ask about the hospital's policy, and they have the right to request that reprocessed catheters not be used. The decision to include this discussion when informed consent is obtained should be determined by the attending physician.

#### FDA Guidance Document

The FDA issued a document August 2, 2000 entitled *Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals*.<sup>29</sup> This document provides guidance to third party and hospital reprocessors about their responsibility as manufacturers engaged in reprocessing devices labeled for single use. The FDA has made it clear that third party and hospital reprocessors are subject to all the regulatory requirements currently applicable to original equipment manufacturers. This document evolved from a proposed strategy that was published in November 1999. In addition to publishing the proposed strategy for public comment, the FDA also sponsored a teleconference on November 10, 1999, and convened an open public meeting on December 14, 1999. Representatives from NASPE participated in these discussions. As a result of comments and discussion about the proposed strategy, the FDA revised its regulatory strategy as follows:

1. Devices will be classified according to the Code of Federal Regulations (Class I, II, or III) to set enforcement priorities for premarket submission requirements.

2. The FDA intends to enforce premarket submission requirements within 6 months for all Class III devices (ablation catheters) and within 12 months for Class II (diagnostic electrophysiological catheters) devices.

3. For hospital reprocessors, the FDA will establish a 12-month phase in for active enforcement of non-premarket requirements (registration, listing, medical device reporting, tracking, corrections and removals, quality system regulations, la-

beling). The agency will use this period to educate hospitals about their regulatory obligations.

The FDA's objective is to ensure a regulatory program based on science that protects public health with requirements that are equitable to all parties.

The new regulations require third party and hospital reprocessors to register with the FDA as a reprocessor and list the devices they intend to reprocess. Reprocessors will not be subject to Medical Device Tracking regulations unless the FDA issues an order for the specific device being reprocessed. The reprocessors will be required to notify the FDA if they have any reason to suspect that a device or batch of devices was defective and required removal from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. All reprocessors will be required to adhere to current good manufacturing practice requirements set forth in the Quality System Regulations. These requirements include design controls, corrective and preventive actions, and validation procedures. The FDA's general labeling requirements must also be met.

Premarket requirements for reprocessed devices are still under review and may be particularly controversial. Class III devices require either a premarket notification (510k) submission or a PMA application. The classification regulation for each type of Class III device indicates if a PMA application is required. The FDA has indicated that ablation catheters will require PMA applications. These applications must include valid scientific evidence that demonstrates the safety and effectiveness of the reprocessed device. It is not yet clear if clinical data will be required to reprocess ablation catheters. The requirements for diagnostic electrophysiological catheters will generally fall into the category of a premarket notification (510k), which must contain enough information for the FDA to determine if the device is substantially equivalent to a legally marketed predicate device. Premarket (510k) submissions and PMA applications are device specific, so the FDA will require a 510k or PMA for each device unless they are convinced that closely related variations of the same type of device should be grouped in one submission or application. *The FDA intends to take immediate enforcement action against third party and hospital reprocessors that fail to make any submissions or submit incomplete applications following the end of the phase in periods.*

#### Impact of Reuse Policies on Physicians, Hospitals, Manufacturers, and Reprocessors

Most electrophysiological laboratories are staffed and administered by hospital employees.

The cost of supplies and maintenance for electrophysiological laboratories is also paid from hospital budgets. Most physicians who perform electrophysiological studies have no direct or indirect personnel financial gain from cost saving measures that are targeted by the hospital. In cases where physicians do have a financial incentive to reuse catheters, such as a freestanding laboratory owned by the physician or his group, there may be a conflict of interest when catheters are reused.

The cost savings realized by hospitals that reuse electrophysiological catheters depend on the volume of procedures and whether catheters are reprocessed internally or through a commercial reprocessing company. As a general rule, reprocessing companies charge 50% of the original cost of the catheter each time the catheter is reprocessed.<sup>15</sup> Allowing for an 85%–90% pass rate for each reprocessing cycle for a maximum of six uses per catheter (resterilized a maximum of five times), hospitals can reduce their catheter costs by about 35%. According to the GAO report, hospitals may save from \$200,000 to \$1,000,000 annually by reprocessing catheters.<sup>24</sup> The total savings at smaller medical centers would be substantially less, but for large and small hospitals this practice is a significant cost reducing measure at a time of escalating costs and declining reimbursement. An indirect financial benefit is that the competition from reprocessors probably forces manufacturers to hold their costs down.

One impact of the proposed FDA regulations for reuse of electrophysiological catheters is that hospitals will almost certainly be forced out of reprocessing the catheters themselves. The FDA's new regulatory requirements<sup>29</sup> will exceed the administrative or technical resources of most hospitals. This might shift reprocessing of catheters to commercial vendors, or hospitals may simply abandon reuse of electrophysiological catheters. Whether commercial vendors can meet the regulatory standards and remain profitable will depend on the standards that are developed.

The impact of reuse of SUDs on manufacturers is obvious. It can be assumed that widespread resterilization practices have a significant impact on the sales of new products. This must adversely affect the manufacturers' profit margins and the money available for research and development. The manufacturers are also exposed to potential liability if their products are reused and the patient suffers harm due to a component failure for a device that was labeled "single use only." Finally, while manufacturers and reprocessors are subject to regulatory standards, manufacturers claim that they are held to a different set of standards than the reprocessors. The FDA's proposed policy would bring a uniform set of standards that should address this concern.

### **Senate Bill 1542 and House of Representatives Bill 3148**

In response to public concern over reprocessing of medical devices, legislation has been introduced by Senator Richard Durbin (S.1542) and Representatives Anna Eshoo and Fred Upton (H.R. 3148) that would require any person who reprocesses a medical device to comply with certain safety requirements. These nearly identical proposals are based on the perception that some reprocessed medical devices labeled for single use have been associated with serious injury and that reprocessed medical devices labeled for single use have the potential to cause injury. They also take the position that reprocessed medical devices labeled for single use are being used on patients without their knowledge, against original manufacturers warning, and without a determination by the FDA that such devices are safe and effective. The purpose of these bills is to require the FDA to implement all provisions of the FDC Act, including premarket safety controls, and to require the informed consent of patients prior to using reprocessed devices such as electrophysiological catheters. Reprocessors would be required to demonstrate that a reprocessed device is safe and effective or substantially equivalent to a device already deemed to be safe and effective. The bills also contain provisions for all reprocessors to register with the government and tighten documentation requirements.

The full impact of these well-intended amendments is difficult to assess. They would clearly increase the documentation required for reprocessing SUDs and might set the standards for PMA at levels that would discourage reprocessing of electrophysiological catheters altogether. They do not address the fact that some devices appear to be designated for single use because of marketing as opposed to safety decisions, nor do they recognize the role of existing guidelines specified in the Quality System Regulation. Moreover, the FDA already has the authority to regulate reprocessing and is working with NASPE, the American College of Cardiology (ACC), manufacturers, and reprocessors to implement policies that would address the stipulations outlined in these proposals. NASPE has expressed concern over the bills because of their potential to add new and unnecessary regulatory requirements.

### **Conclusion**

#### **NASPE's Position on Reuse of Electrophysiological Catheters**

1. NASPE adheres to the principle that reuse of electrophysiological catheters is a safe and cost effective practice provided that they are meticulously cleaned, sterilized, and inspected in accordance with accepted standards of practice as spec-

ified by the FDA. The exception is when catheters have been used in patients with human spongiform encephalopathies such as Cruetzfeldt-Jakob disease. In these cases, no catheters should be reused because conventional reprocessing methods that are applicable to electrophysiological catheters cannot eliminate contamination that is transmissible to other patients.

2. NASPE recognizes the FDA's responsibility to provide regulatory oversight so that uniform quality control standards are applied and the public welfare is protected when electrophysiological catheters are reprocessed.

3. NASPE supports the FDA's initiative to provide a framework for the safe reuse of electrophysiological catheters. NASPE will work with the ACC, the FDA, original manufacturers, and reprocessors to refine standards that can be applied to reprocessing medical devices.

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