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## Cardiac Catheter Reuse in An Era of Reform: Cost-Efficiency and Regulatory Policy in the Face of Scientific Uncertainty

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Cardiac Catheter Reuse in An Era of Reform:  
Cost-Efficiency and Regulatory Policy in the Face of Scientific Uncertainty

## 4040k~ Introduction

Cardiac catheters have become an essential element of current cardiovascular practice with several hundred thousand used each year in both diagnostic and angioplasty procedures. Like many other disposable devices they are also increasingly being reused as hospitals attempt to cut costs.<sup>1</sup> The general progression of device reuse seems to follow rather directly the rise in the expense of medical equipment and procedures. For example, in 1976, only 14% of United States' hospitals reported reusing single-use devices, while in 1982, 90% of hospitals admitted practicing reuse.<sup>2</sup> As for the government's regulation of such reuse, 1981 saw the FDA issuing guidelines practically proscribing the reuse of catheters when their average cost was only \$10-\$25.<sup>3</sup> Even as late as 1987, however, only 2.4 full-time FDA employees and \$19,000 were dedicated to monitoring the reuse of nondurable devices.<sup>4</sup> The General Accounting Office concluded that the FDA knew of less than 1% of medical device problems occurring in hospitals.<sup>5</sup> On the heels of the longstanding debate about the reuse of hemodialyzers and the Safe Medical Devices Act of 1990 and 1992 Medical Device Amendments, it appears as if the FDA is more receptive to tightening regulatory control over medical device reuse.

This paper will address the increasing cost-containment incentives to reuse cardiac catheters, countervailing scientific uncertainty about attendant health risks and finally, several proposals for a regulatory scheme addressed at both manufacturers and hospitals to better ensure the safety and efficacy of previously designated single use only devices.

## I. Cost Containment Incentives to Reuse Catheters

Cardiac catheters serve as an excellent model for predicting what the practice of reuse may do for cost containment programs, since they are both relatively expensive and frequently used.<sup>6</sup> Catheters are also one of the few devices which have several manufacturers currently in competition for an ever cost-conscious health care market. Recent estimates suggest that millions of dollars could be saved by hospitals each year if each catheter were reused only once. But there is also a healthy dose of skepticism surrounding reuse, because in an time when the majority of hospital patients are becoming capitation fee patients<sup>7</sup>, cutting millions of dollars in costs means one thing for the hospital -profit. Cost-cutting motives on the part of Medicare and other third party payors have also been influential, leading to increased hemodialyzer reuse in the mid1980s. In 1981, 90% of dialyzers were single-use, while now over 70% are reused, up to 12 times.<sup>8</sup>

Statistics obtained from the Brigham and Women's Hospital in Boston show that the cost savings for one reuse of the more frequently ordered cardiac catheters would be \$175,500, after expenses for a sterilization technician and resterilizing materials.<sup>9</sup> If Brigham and Women's were to follow current trends of reuse (use up to 5 times), savings could be upwards of \$1 million dollars annually. When one considers that more than 300,000 angioplasty procedures were performed in the United States in 1990, the potential cost savings appear to be magnanimous.<sup>10</sup>

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Cost savings to hospitals and patients, one of the primary goals of reuse, should not be mis-characterized as a simple game of subtracting the number of units no longer required to be purchased. There are many costs associated with reuse including, but not limited to increased labor costs, supply costs, machine time for cleaning, repackaging, storage, and quality assurance documentation.<sup>11</sup> These costs when considered along with the cost of administrative red tape and further scientific studies may greatly minimize the benefits currently foreseen.

Reuse is not desirable from the standpoint of most manufacturers. They argue that while cost containment is a noble goal, and the possibility of reusing products may merit further examination, some devices simply cannot survive more than one use, and in the face of scientific uncertainty should not see more than one use. From a cost-containment perspective, manufacturers also warn that widespread reuse may drive up prices as companies anticipate lower sales due to multiple uses. Competition will become driven by the tensile strength of the catheter (in many cases already overdesigned), how many resterilizations it can withstand, accompanying diagnostic software, or sterilization contracts to an outlying facility to reduce hospital liability for sterilization mishaps.

One glaring exception appears to be Minntech Corporation which has designed a PTCA reprocessing machine which was launched overseas in August, 1993 and for which the company is now approval in the United States. Minntech catheters are identified during reprocessing with a serial number attached to the device's proximal end so users can keep track of the number of

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reuses, with the company recommending no more than five uses. Minntech estimates that should catheter reuse in the United States and other countries eventually approximate that of Europe, the market could be worth about \$27 million.<sup>2</sup>

To prevent reuse, some manufacturers and health officials have suggested marketing devices that will not survive more than one use. This approach has several drawbacks, most notably the need for new pre-market notification filings (510(k)s) or perhaps pre-market approval applications. Development costs to the manufacturer would likely be substantial and result in a more expensive product for the consumer. Furthermore, there is the threat that physicians may simply tinker with these modified devices to attempt their reuse, perhaps injuring or killing patients.

Finally, it is unclear what the legal ramifications may be if the government or institutions begin mandating device reuse to achieve cost-containment benefits. In the 1986 case, Wickline v. State of California<sup>3</sup>, the court attempted to determine the legal responsibility that a third party payor has for harm caused to a patient when a cost containment program is applied in a manner which is alleged to have affected the implementation of the treating physician's medical judgment.<sup>4</sup> The court held that as long as an individual physician could overrule the institution's cost-containment policy through some sort of review process, the third party payor should not be held liable for patient injury. In the realm of device reuse, however, chances are that any one physician will not know

whether the catheter she is using has been recycled or is new. The stage for this type of suit has already been set with HCFA threatening to withhold reimbursement from hospitals who don't reuse hemodialyzers. Somewhat inconsistent with their cost-containment mandate, however, when they do reimburse for these products The amount paid is the same whether it is a new device used or one used for the tenth time.

#### **U. Scientific Uncertainty and Health Risks Associated with Reuse**

One concern of biomedical engineers and central processing departments involves the potential for inadequate sterilization, resulting in infection. EtO (ethylene oxide) sterilization is the most common method of industrial and hospital catheter sterilization, but it is incapable of sterilizing proteins such as blood and organic debris that may be left behind in the catheter after use. As a result, if the catheter is improperly cleaned before sterilization, those proteins can then be passed to the next patient upon reuse. In addition, EtO sterilization is controversial given its toxicity if residual particles are found after improper aeration. Given the possibility of improper implementation and toxicity, there is a growing fear among the scientific community that hospitals will regard a given reprocessing method as acceptable until adverse reactions are reported, and that methods with more dangerous properties may become popular.<sup>15</sup>

Most sterilization methods are approved and detailed by industrial sterilization companies, but there are several problems unique to in-hospital

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sterilization that are of some concern to the public safety, not the least of which include the threat of AIDS or hepatitis B transmission. First, hospitals are not required to validate any product they process; many merely rely upon information they receive from either the sterilant producer, the product manufacturer or both.<sup>6</sup> Secondly, most hospitals do not have the luxury of sterilizing one product per machine and often vary their loads in both content and packaging. An Ohio study comparing industrial and hospital reuse processing techniques demonstrated that hospital sterilization necessitated extending device aeration time by 46 hours, and exposure time by some 75 minutes.<sup>7</sup> Suggestions for hospitals also included implementation of dedicated loading, using biological monitors in each load, post-sterilization microscopic inspection and increased glove use.<sup>8</sup> Finally, there is concern regarding the quality of sterilization technicians. The qualifications for a laboratory aide in the cardiac catheter lab at many hospitals require only the ability to read, write, and follow verbal and written instructions, and a high school diploma. Most knowledge required to perform these tasks will be acquired through on the job training, but the 2-3 is sheet of detailed instructions for each catheter could be confusing to those with a scientific background.

In addition to concerns about sterilization, the physical integrity of catheters and angioplasty balloons in particular is uncertain upon reuse. A British study in the early 1980s revealed that while 8% of balloon angioplasty devices experienced a rupture after the first use, nearly 62% had ruptured after



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the fourth use. At that time British hospitals were known to reuse the devices as many as 18 times. Most importantly, reuse demonstrated a reduced life span of the device in that it was capable of performing less than one half the average inflation/deflation cycles that one could attain with a new catheter.<sup>20</sup>

While rupture is easily detectable, a recent study at the University of Wisconsin examined more subtle problems with the physical, electrical and mechanical integrity of Webster/Mansfield deflectable catheters after reuse.<sup>21</sup> The primary reason for catheter rejection in the study was found to be glue separation, short of causing the device to fail, from the tip electrode, allowing glue to be released into the bloodstream and blood to collect in the space left behind in the catheter.<sup>22</sup> This deterioration precluded proper cleansing, rendering the catheter unfit for further use. On the basis of their findings, the researchers at Wisconsin suggested that these catheters be used no more than five times.<sup>~</sup> Apart from glue separation, no other major failures of the device occurred indicating that the integrity of the Mansfield/Webster ablation catheter performs rather well under reuse conditions. However, the study was limited to one specific catheter, and efforts must be made to study the safety and efficacy of all before a change in FDA policy is warranted to further permit reuse. Currently, the Wisconsin and similar studies appear to be garnering attention and the testing methods are being employed at hospitals such as the Brigham and Women's Hospital in Boston. Brigham and Women's hospital is unique perhaps, in its efforts to implement stringent continuous quality improvement measures

including semi-annual electron microscopy tests, detailed reuse documentation, and loose particle testing. Indications of inadequate reprocessing will cause the reuse program to cease and the procedures reevaluated.<sup>24</sup>

Due to the lack of comprehensive catheter studies involving comparison testing among sterilants, aeration times, and various brand products, and given the range of possible deleterious health effects; further regulation of catheter reuse must be implemented to examine whether the current level of uncertainty about the scientific desirability of reuse can be minimized. No one knows what the possible health risks of catheter reuse could entail, as studies examining patient reactions have been limited to fever, chills and hypotension.<sup>25</sup>

While some argue that science should drive regulatory policy, rather than the reverse, both sides have demonstrated an unwillingness to pursue the matter to the detriment of the patient.

### III. Regulatory **P**olicy

#### **A. Current**

Despite growing cries of cost-containment and the fear associated with scientific uncertainty, the current regulatory stance of the FDA regarding device reuse is quite limited. In fact, the only device currently regulated is the dialysis hemodialyzer, which is vastly different than a cardiac catheter. Hemodialyzer reuse is only authorized for the same patient in order to eliminate the risk of infectious disease transmission. Also the population of hemodialyzer patients is

much smaller than the number requiring catheterization procedures each year. Moreover, there is no evidence that a reused catheter can meet the same standards of a first time use, whereas reused hemodialyzers have been shown to be more effective for many patients. Finally, regulations promulgated under the guidance of HCFA stated that information given to patients using hemodialyzers should include the risks and benefits of reuse, while those receiving reused catheters are not notified **26**

Aside from the formal rulemaking involved with the hemodialyzer, the current means of handling reuse problems is limited to the Medical Device Reports (MDR) and labeling. In the past several months, the MDR system has undergone recent changes which could effect institutional reuse policies.<sup>27</sup> The institution of Section H of new reporting form 3500A, to be completed by device manufacturers, now requires a designation that the adverse event involved the initial use or reuse of a device, which should improve the quantity and quality of reuse data available to the FDA.~ Furthermore, user facilities will be required to provide similar information in another section of the form, perhaps inducing hospitals without explicit reuse protocols to develop them.<sup>29</sup> The increased attention now paid to reuse through these forms, and as evidenced by FDA responses to comments in the Federal Register suggest that the agency has recognized that in the past inadequate provisions have been made for collecting and correlating all salient information to determine and identify the root cause of, and all factors contributing to adverse events and the implications of reuse as

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one of those factors.<sup>30</sup> Even under this new system, user facilities need only report deaths to the FDA, with all other events solely referred to the manufacturer upon receiving information or otherwise becoming aware that a device has caused significant harm.<sup>31</sup>

Follow-up letters were sent to the manufacturer indicating that the frequency and severity of this event would be periodically monitored to determine if other action is necessary.<sup>32</sup> This phrase appears in almost every MDR report, yet there is no indication in FDA guidelines or reports as to how often follow up is conducted or if it has ever revealed further violations. One senses that follow up is rare given the reluctance of the FDA to strictly monitor the device realm, and the general lack of resources to adequately monitor changes in sterilization procedures or hospital protocols.

Recent MDR reports involving cardiac catheters include reports of EtO sterilization weakening adhesive bonds allowing the catheter to stretch and bend abnormally.<sup>33</sup> The catheter had been EtO processed 3 times by the hospital and the laboratory staff then noticed a wire outside the catheter. Warnings issued to C.R. Bard in 1992-3 revolved around incidences of reused Peripheral Transluminal Angioplasty Catheters' (PTCA) tips breaking off inside patients, at least one of which was unrecoverable. This reuse occurred despite explicit warnings on the label reading, this catheter is for one time use only; do not reuse or resterilize for any reason.<sup>34</sup> Moreover, the catheter had been used for the dilatation of a cystic duct, not an indicated use of the product.

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Along with MDRs, labeling requirements imposed upon manufacturers by the FDA have been only marginally effective, although changes are evident and do show promise for improvement. In 1989, the FDA released manufacturer guidelines for medical devices regarding sterile device labeling.<sup>35</sup> These guidelines recommend the labeling of any changes in the physical characteristics of the device that may result from reprocessing which affect its safety, effectiveness, or performance; and limit on the number of times resterilization and reuse can be done without affecting the safety or effectiveness of the device.<sup>36</sup> While recognizing that some manufacturers include labeling to advise against reuse, the FDA suggests that where reuse is common practice, manufacturers should provide information about resterilization techniques anyway.<sup>37</sup> In fact, the agency has decided that some devices that have been marketed and labeled for single use will no longer be generally acceptable to the agency, while others will be required to supplant their labels with a warning against reuse.<sup>38</sup>

Hemodialyzer manufacturers, for instance, have been called upon by both the FDA and Congress through agency guidelines to justify their single use only labels, and it is not farfetched that the same scrutiny may soon fall upon the catheter industry.<sup>39</sup> This increased pressure will require manufacturers to either provide scientific data on effective sterilization methods or prove that the item cannot be reused in order to maintain their labeling status. Data will be compiled both through the 510(k) process and via heightened surveillance and regulatory oversight of [the manufacturer's] customers' practices.

The Health Industry Manufacturers Association (HIMA) believes that reuse concerns should be reviewed by an expert panel before single use only labeling is prohibited to ensure consensus on appropriate methods of safe and effective reuse.<sup>41</sup> HIMA said that it will be difficult to give adequate directions to users since so many different sterilization modes are used by hospitals. The organization has even threatened to challenge the FDA's legal authority to make the guideline binding, and individual companies have considered suing as well fearing further liability with respect to labeling instructions. Recent FDA statements, however, seem to signal a move towards stricter monitoring of device reuse and formal regulations could be forthcoming. One such indication is the FDA's shift from merely encouraging manufacturers to eliminate single use labeling, to requesting the submission of detailed plans for re-labeling.

Hospitals would likely welcome more labeling information as they are constantly requesting guidelines or instructions for product reuse. Not only do hospitals wish to limit their legal liability, but more hospitals are seeking to develop stringent in-house protocols as part of continuous quality improvement programs. Under current guidelines prohibiting manufacturers from giving specific advice unless a particular sterilization method has been validated, hospitals are left to trial and error methods of reuse processing.

#### B. Proposals **for Future Regulatory Action**

While HIMA and unofficial statements by the FDA have long warned that

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if you reuse a disposable medical device, you bear responsibility for if safety and effectiveness, there have been no cases in which a hospital or physician has been prosecuted, reprimanded, or even warned on record as being a remanufacturer. While it is true that some large hospitals are developing detailed protocols for reuse without being labeled manufacturers, many simply will not force regulatory-type controls upon themselves unless the federal government clearly designates them a manufacturer.

One reason for mandating manufacturer status for hospitals reusing disposable devices is to foster further development of written reuse protocols and better reuse documentation. A 1987 survey of all Canadian hospitals showed that 86% of those hospitals with more than 200 beds reused single use only devices regularly, with 20% admitting reuse of disposable catheters. Despite this high incidence of reuse, only 38% of those regularly reusing disposable devices had written reuse or sterilization procedures, and only 32% had mechanisms in place to determine the number of times a device had been used. Perhaps if hospitals attained manufacturer status, these statistics and comparable ones in the United States would show a marked increase in quality assurance programs and reuse documentation. In addition to general improvement of hospital reuse protocols, once a hospital or physician is deemed a manufacturer for reusing disposable devices, it would enable the government to levy civil penalties of up to \$15,000 per violation or up to \$1 million in any given proceeding, and mandate adherence to good manufacturing practices (GMPs) - Adherence to GMPs would require

simulated use testing, where practical, upon finished devices to assure that device specifications are met and sterilization is being properly completed.<sup>~</sup>

The issue of how to bring hospitals or physicians within the definition of manufacturer is not difficult. First, courts have been reluctant to read any term in the Food, Drug and Cosmetic Act narrowly given its broad public mandate to protect the health and safety of the citizenry. Secondly, the term manufacturer already has been interpreted within the GMP regulations to include assigners, contract sterilizers, specification developers and initial distributors of imported devices, - and the list does not appear to be exhaustive.<sup>47</sup> Other issues associated with manufacturer status, however, are more intractable. For instance, if GMPs are imposed upon hospitals, compliance reviews by the FDA would be nearly impossible given the limited resources of the agency. Furthermore, JCAHO and state medical associations simply cannot be relied upon to conduct these reviews due to bias, and the omnipresent fear that by shooting one of their own they, too, will become targets.

A more manageable solution would be the imposition of manufacturer status coordinated with a modified GMP standard requiring hospitals to submit detailed reuse protocols, reports of all adverse events regardless of their severity, and immediate notification of any changes in sterilization or reuse practice. A necessary accompaniment would be prompt FDA response to adverse events, which could perhaps be delegated to state health agencies on an as needed basis. The Brigham and Women's Hospital in Boston, MA sets a good example for other



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major health care institutions by requiring that any product for which staff wish to approve reuse, a proposal must be submitted and approved by the Product Standardization Committee who will issue a proper protocol with supporting documentation to be kept on file in the Department of Clinical Engineering.

While a bit more radical, another solution to the reuse dilemma would be to change the Food Drug and Cosmetic Act or its interpretation to designate that a reused single-use device is per se excluded from being a substantial equivalent of the original device. Substantial equivalence is currently defined in terms of safety and effectiveness, but is met if a product can demonstrate that it has the same intended use and same technological characteristics as a pre-Amendment device.<sup>49</sup> This new exclusion should require the reused device to be tested under a pre-market approval (PMA) system as a class III device leading to the clinical trials not yet conducted under the present system. However, if this is too taxing on the FDA and hospitals, at the very least, additional studies should be required to properly classify such devices as Class II with special controls. A statutory amendment might not even be required, with a regulation sufficing. The FDA could merely state that unless the material integrity of the device can be proven to be as safe as effective as when used the first time, it fails to meet the substantial equivalence definition. These changes would be consistent with the legislative history of the Medical Device Amendments of 1976 which states that the purpose is to encourage the research and development of medical devices, but also to be sure that the FDA has proper authority to regulate that process so that

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Americans are not put at risk from the use of unsafe and ineffective medical

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devices.

The primary problem with the substantial equivalence approach is the additional time and information necessary for premarket approval given the FDA's belief that, premarket clearance or approval generally should only be necessary for those changes that require physical alteration of the device that could significantly affect its safety or effectiveness.<sup>52</sup> The FDA much prefers 510(k) reviews for medical devices in order to save time and paperwork. In fact expedited 510(k) review was promised to device manufacturers filing before November 1, 1992?~ Given that between 1976 and 1983 more than 3,000 510(k)s were submitted for cardiovascular devices, the chance that an inferior product unable to withstand reuse is on the market seems significant?~ New hybrid 5 L0(k)s may be of some help in preventing new products from being reused, but are of little help for those already being reused in the market.

A third term in the Food Drug and Cosmetic Act which could be changed to afford more control over reused catheters and other devices is intended use. Now defined as the, objective intent of the persons legally responsible for the labeling of the devices, intended use can be demonstrated if, with the knowledge of such persons or their representatives, I an article isi offered and used for a purpose for which it is neither labeled nor advertised.<sup>55</sup> Tightening up this definition to prevent manufacturers from being held liable for the unique and unauthorized actions of a particular facility may be a useful deterrent to some

reuse.

The issue here is with whom lies the right to establish intended uses for a product, and how best to avoid patient deception when reused devices are used upon them. Unlike drugs where a doctor may use an approved drug for an unapproved use given the longstanding FDA position that it is not the business of the FDA to encroach upon the practice of medicine or pharmacy, not all or even many doctors are trained in biomedical engineering?<sup>7</sup> Even support for the pharmacy exception has been waning as the practice of pharmacy has changed in the past several decades. In Retkwa v. Orentreich<sup>57</sup>, a physician recompounded a liquid silicone compound for injections to alleviate a particular disease and the court held substance was to be considered a new device and thus placed in Class III, without premarket approval. As a result, the product was found to be adulterated and held for sale within the meaning of the Food Drug and Cosmetic Act?<sup>8</sup>

A final option, perhaps best utilized in conjunction with one or more of the aforementioned proposals, is to pave the way for manufacturers to sue hospitals and physicians for patent infringement when they reuse a device. Mallinckrodt Inc. v. Medipart, Inc.<sup>59</sup>. decided in 1992 started the debate by stating that a buyer could be prohibited from reusing a patented single-use only medical device if the manufacturer's restriction was reasonably within the patent grant and not just for anticompetitive reasons. Mallinckrodt, the manufacturer sued a servicing company for processing the devices for reuse.

The benefit of using the patent law to deter reuse of catheters is that the federal government's involvement would be minimized, limited only to the patent grant, leaving the enforcement mechanism to disgruntled manufacturers. It is unclear whether manufacturers will take advantage of this option, however, knowing that they may lose a significant part of their market as a result of such suits. Furthermore, the threat of patent suits may lead to a decline in voluntary reporting of reuse at many hospitals or the quality of MDRs.

#### Conclusion

Cardiac catheter reuse for both diagnostic and angioplasty procedures could provide financial breaks to hospitals, although no one is sure as to how much will be saved long-term. The potential costs associated with injured patients and public scandal in the face of tragedy, however, may well supersede those cost-containment benefits. Comprehensive scientific studies have not been conducted and despite nearly two decades of medical device regulation, the issue of reuse lingers in a regulatory void. If reuse is not addressed head-on by the medical and FDA communities, it is likely that if and when a medical disaster occurs, an ill-planned, overly restrictive legislative response will be forthcoming. By no means should reuse be prohibited, but the unwitting patient on the operating table deserves to know that the catheter on the tray, while used nine times before, is safe, effective, and under the watchful eye of the FDA.

## Endnotes

1. An IHPA Survey conducted in 1984 found that cardiac catheters are the second most frequently reused medical device just behind hemodialyzers, with 31% of those hospitals responding admitting reuse of catheters and their guide wires. S. Perry, et al. Reuse of Medical Devices Intended for Single Use only 1 HEALTH CARE INSTRUM. 4,6 (1985).
2. J. Kahan, Medical Device Reuse - The Controversy Continues 282 Clinica 14 (June 12, 1987).
3. J. Jacobson, et al. Fever Chills and Hypotension Following Cardiac Catheterization with Single and Multiple Use Disposable Catheters 9 CATHETERIZATION AND CARDIOVASCULAR DIAGNOSIS 39 (1983).
4. The Gray Sheet, FOOD DRUG COSM. REP. November 16, 1987.
5. H. Holstein, Safe Medical Devices Act of 1990: Postmarket Surveillance, Medical Device Reporting, and Other Postmarket Issues, 46 FOOD DRUG AND COSM. LAW J.165,166 March 1991.
6. See Table A, attached.
7. Capitation fee patients pay a flat fee for all of their health services over the course of a year. Thus, the less procedures performed by hospitals or clinics, the more money the institution has to distribute as profits to its physicians and corporate officials.
8. G. Borzo, Dialysis market shifts to Peritoneal Dialysis 54 HEALTH INDUST. TODAY 1,3. May 1991.
9. See Table A, attached.
10. Technology Assessment Reports, 9 INT'L JL. OF TECH. ASSESSMENT IN HEALTH CARE 597. Summer 1993.
11. One proposed validation study on resterilizing cardiac catheters was estimated to cost nearly \$3500 initially (excluding the catheters themselves), \$600 per load sent thereafter for routine reprocessing, and annual revalidations. PROPOSAL FROM STERILIZATION TECHNICAL SERVICES TO DEPT. OF CLINICAL ENGINEERING, Brigham and Women's Hospital, Boston, MA. October 14, 1993.
12. The Gray Sheet, FOOD DRUG COSM. REP. June 28, 1993.

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13. 239 Cal.Rptr. 810 (1986). (Third party payor rejected extended length of stay for patient who subsequently was forced to have leg amputated due to onset of infection)
14. Id at 810.
15. J. Kahan and J. Gibbs, Reusing Disposable Medical Devices: Legal and Economic Consequences ENGINEERING IN MED. AND BIOL. MAG 32, 33 (June 1985).
16. M. Reichert, Appropriate Reuse of Single-Use Medical Devices: A Case Study, Jan/Feb. JL. HOSP. SUPPLY PROC. DISTRIB. 31 (1985).
17. Id. at 36.
18. Id.
19. Brigham and Women's Hospital Job Description — Laboratory Aide, February 22, 1993.
20. 284 BRITISH MED. JL. 707 (1982).
21. A. Boaz, et al., Repeated Use of Ablation Catheters: A Prospective study Nov. JL. OF AMER. COLL. OF CARDIOLOGY 1367 (1993).
22. Id. (This glue separation occurred in 25% of the catheters tested) See also P. Bentolila, et al., Effects of Reuse on the Physical Characteristics of Angiographic Catheters 14 JL. OF MED. ENGINEERING AND TECH. 254 (1990). (indicating evidence of debris in 2 of 18 reused catheters studied, and a propensity for polyamide catheters to display more surface ruptures than either polyurethane or polyethylene)
23. Brigham and Women's Hospital of Boston limits reuse of the same catheters to three times. (Hospital Catheterization Policy — 1993).
24. Catheter Reuse - Biomedical Engineering, Proposal for Testing Protocol at Brigham and Women's Hospital in Boston, MA. 1993.
25. J.A. Jacobson, et al., Fever, Chills, and Hypotension Following Cardiac Catheterization with Single and Multiple-Use Disposable Catheters 9 CATHETERIZATION AND CARDIOVASCULAR DIAGNOSIS 39 (1983).
26. 42 C.F.R. §405.2136(b) (1993)
27. §519(b)(1)(A),(B), and (C) of the Food Drug and Cosmetic Act. (1993).
28. 58 FED. REG. 31,596—01 (May 26, 1993).

29. ~ proposed regulation 56 FED. REG. 60,024 (Nov. 26, 1991), and 58 FED. REG. 64,001—01 (1993).
30. 58 FED. REG. 61,952—01 (1993).
31. See 21 C.F.R. §803 (1993).
32. MED. DEVICE REP. FDA MDR List (June 1993).
33. MED. DEVICES REP., FDA MDR List (June 1993). FDA No. M225473  
(Cardiovascular Imaging Systems diagnostic catheter malfunction in March, 1991).
34. MED. DEVICES REP., FDA MDR List (June 1993). FDA No. M223020.
35. FDA Publication 89-4203. August 1989. Labeling Regulatory Requirements for Medical Devices.
36. Id.
37. See 21 C.F.R. §801.4 (1993) which states that where a manufacturer knows.., that a device introduced into interstate commerce by him is to be used for conditions, purposes or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.
38. The Gray Sheet. FOOD DRUG COSM. REP. (December 13, 1993).  
Typically a manufacturer will be notified by a hospital of its desire to reuse a specific product and for instructions for proper reesterilization and assurances that the product will withstand reprocessing. Upon gaining assistance from the manufacturer an independent sterilization service will often be asked to test those methods for residual materials upon reprocessing, material and mechanical integrity, and biocompatibility. Once completed, the hospital can produce a reasonable protocol to shield itself from potential liability.
39. FDA draft guidance on premarket testing and labeling for reuse of hemodialyzers The Gray Sheet, FOOD DRUG COSM. REP. (Nov. 8, 1993).
40. FDA's Rulemaking Alternatives May Elicit Litigation The Gray Sheet, FOOD DRUG COSM. REP. (December 13, 1993). See also 19 DEVICES AND DIAGNOSTICS LTR. (December 11, 1992).
41. See suora note 2, at 14. HIMA stated in a 1986 position paper that reuse should occur unless the reused device can meet the same safety and efficacy standards as a new device.
42. FDA May be Sued by Industry on Device Reuse Stance, 19 DEVICES AND DIAGNOSTICS LTR. 2 (November 20, 1992).

43. N. Reichert, Reuse of Single Use Devices STERILIZATION TECH. FOR THE HEALTH CARE FACILITY (1993). See also FDA Policy Guide No. 7124—16 (1981).
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45. §303(f)(1)(A), Food Drug and Cosm. Act (1993).
46. 21 C.F.R. §820.160 (1993).
47. 21 C.F.R. §820.3 (1993).
48. Reprocessing of 'Single-Use' (Disposable) Medical Devices and Supplies Task Committee on Reprocessing, Brigham and Women's Hospital, Boston, MA. (Dec. 1985).
49. §§513(f)(1)(A)(ii), 513(i)(1)(A)(i),(ii) of the Food Drug and Cosmetic Act (1993).
50. §513(e)(1) of the Food Drug and Cosmetic Act states that based upon new information regarding a device, the Secretary may upon his own initiative or upon petition of an interested person, by regulation, change the classification of the device and revoke any §514 or §515 requirement with respect to that device.
51. S.Rep. No. 94—33, 94th Cong., 2d Sess. 2 (1976), 1976 U.S.C.C.A.N. 1070—71.
52. 57 FED. REG. 22,971—01 (1992). See also 21 C.F.R. §807.81(a)(3) (1993).
53. Id.
54. J. Gibbs, B. Mackler, Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield 22 TORT & INS. L.J. 194,202 (1987).
55. The Gray Sheet, FOOD DRUG COSM. REP. November 8, 1993. See also 21 C.F.R. Part 801.109(c) regarding labeling for a product's intended use.
56. Congressional deferral to physician's right to practice medicine was limited to allowing use of authorized drugs in unauthorized manners. Retkwa v. Orentreich, 584 N.Y.S.2d 710 (1992).
57. 584 N.Y.S.2d 710 (1992)
58. The plaintiff was also permitted to use this information to further her malpractice claim based on a theory of informed consent



4. The doctor did not tell her of the unapproved status of the device.

59. 976 F.2d 700 (C.A.Fed. Ill. 1992).

Table A — CARDIAC LAB CATHETERS: Medical Devices - January 25,  
1993 Number of Orders

Devices	Now	If Reused	Unit Saved	Unit Price	Savings
Radio Ablation Cath	100	30	70	\$750	52,500
Staiford Bioptones	reused			—	0
Millar Catheters	reused			—	0
Pacemaker Kits	2	1	1	\$7000	7,000
Open PTCA Balloons	0	0	1	\$715	715
Open DVI Cutting	0	0	1	\$1,175	1,175
Quadpolar Catheters	480	150	330	\$230	75,900
Tripolar Catheters	145	40	105	\$215	22,575
Hexapolar Catheters	75	25	50	\$255	12,750
Octapolar Catheters	20	7	13	\$255	3,315
Decapolar Catheters	75	25	50	\$255	12,750
Dynamic Tip Cath	20	6	14	\$425	5,950
Special Design Cath	10	3	7	\$270	1,890
Open Lumen Cath	10	3	7	\$255	1,785
Mansfield/Webster #120059	5	2	3	\$400	1,200
#120006	5	2	3	\$450	1,350
#120010	5	2	3	\$450	1,350
1120003	5	2	3	\$450	1,350
#140020	5	2	3	\$485	1,455
1120000	5	2	3	\$430	1,290
1160068	5	2	3	\$200	600
#160073	5	2	3	\$200	600
TOTALS:			673	\$14,865	207,500

Reusable Savings:

Expenses: 1. Manpower.50 FTE 2. Supplies  
- 14,000  
- 18,000  
Estimated Total Savings  
**\$175,500**