**Background**

Single-use medical devices (SUDs) are usually made of non-renewable petrochemicals and/or metals. Most, but not all, SUDs are presented as sterile products, with the requisite barrier packaging material. Since the devices are intended to be used only once, both they and their packaging contribute to the solid waste stream. Few of these products are suitable for recycling, because they are considered biohazardous after use, are of composite material or have no after-market for the raw material. All are made of virgin material, in that federal regulations all but preempt the use of recycled material in medical devices that will be in contact with human tissue.

On the face of it, it seems that reusing these products makes good environmental sense, by reducing the consumption of non-renewable resources and reducing solid waste. Indeed, some have claimed such in marketing their reprocessing services to hospitals. However, it is important to note that the only reduction in solid waste is the delay in adding the original product to the waste stream. If the device is intended for sterile use, it must be packaged again, and the method chosen may have more mass than the original, which was specifically designed for that product.

The reuse of medical devices labeled as SUDs has become a common tactic for cost cutting in today’s financially constrained provider community. This practice has gone on sub rosa for many years, with few institutions or professionals candidly acknowledging its presence. Over the past five or six years, an entire industry has grown up to service this need, in the form of third-party or commercial reprocessors.

Reuse of SUDs has gained the attention of the media, state and federal legislators and the U.S. Food and Drug Administration (FDA). At the request of the U.S. Congress, the General Accounting Office recently issued a report on the practice, finding that little data exist on problems with reuse, but that may be because of lack of means to identify adverse events. The report supports the general concern that there is a strong theoretical potential for patient harm and that the practice should be regulated.

Given the founding principles of HCWH, including “first, do no harm,” should HCWH and this conference encourage the reuse of SUDs? And, if so, to what extent should environmental issues be part of the decision making process?

**Problem Statement**

Over the course of the last 25 years, many SUDs have entered the market. The decision to market an SUD rather than a reusable device may be made for several reasons:

- It may not be feasible to make the device out of reusable materials and achieve the desired function.
- It may not be possible to design a device to both achieve the desired function, and allow patient-safe reprocessing. That is, the device may not be able to be cleaned or sterilized repeatedly with no degradation in performance. A corollary to this is the issue of designing a product that can be reprocessed using the equipment and procedures currently available in the hospital setting.

Requiring special equipment for reprocessing
could be a barrier to market entry and acceptance.

- Starting with an SUD may allow innovations to enter the market more quickly than they would if a carefully engineered reusable were required.
- Manufacturers may wish to control or limit their liability for product failure by making a product an SUD, rather than depending upon providers to do everything required for reprocessing and ongoing maintenance of a device. This would come into play when failure of the device in use might be harmful to the patient or the operator.
- Likewise, providers may require single-use designs for patient or staff safety reasons.
- Initially, in the old cost-plus health care reimbursement days, SUDs were preferred because they allowed direct pass through of expense to insurance payers.
- And, of course, SUDs may be more profitable to the manufacturer than well designed reusable products.

All of these reasons have or had legitimacy in our culture. However, the time has come to reevaluate those choices.

Likewise, the reprocessing of SUDs has raised many questions. Some of them are related to the above issues:

- How does one ensure that an SUD that was not designed with cleaning or resterilization in mind is, indeed, safe for the next patient from both an infection control and functional perspective?
- How does one control the reprocessing of especially complex items to make sure that the desired results are achieved every time?
- Does the patient have a right to know that a device labeled as an SUD is being reused on them? Do they have a right to refuse without jeopardizing their care?
- What is the environmental impact of reprocessing? And, is this better or worse than continuing to use the SUD only once?
- In the end, does this process really save money for the institution? Experience has shown that this needs to be examined on a case-by-case basis both at the point of decision and within a year after reprocessing begins. Assumptions made at the time of decision may not play out in reality.

Under pressure from Congress and the media, the FDA issued final guidance on August 2, 2000 that will address the first three questions on this list. While the title of the document says “guidance”, the effect is regulatory, because the text explains how the agency will now interpret and enforce existing regulations to cover this practice. These regulations apply to all third-party reprocessors and hospitals, but do not apply to non-hospital affiliated clinics, ambulatory surgery facilities, or physicians or other providers’ offices. They also do not apply to opened, but unused SUDs that may be resterilized only, with no cleaning needed.

Hemodialyzer membranes are also exempted, even though they are commonly reused for the same patient, because they are already covered by other regulations.

The regulations effectively make it impractical for most hospitals to consider reprocessing SUDs themselves, because of the significant regulatory hurdles that must be negotiated to do so. Specifically, every hospital that does its own reprocessing of any device labeled as single-use (except opened but unused ones) must comply with all of the requirements of a manufacturer of medical devices, including:

- Registration as a manufacturer with the FDA
- Listing of any and all devices reprocessed at any facility within the health care organization
- Mandatory adverse event reporting for any reprocessed device
- Tracking of devices
- Correction of complaints or problems, with documentation
- Removal of defective product
- Labeling requirements as specified by other regulations
- Compliance with the Quality System Regulation (formerly known as GMP).

It is this last requirement that may prove the most difficult, in that it demands a total rethinking of the processing department, with control and documentation of procedures and supplies that are not usually seen in healthcare facilities. Third-party reprocessors are already subject to all of these regulations. Hospitals that reprocess will have to comply by August 1, 2001.

In addition, all reproprocessors must meet the pre-market requirements for assuring the safety and efficacy of reprocessed medical devices. In most cases, this would mean submission of documentation of substantial equivalency with a device currently on the market (a so-called 510(k) submission, named for the section of the Food, Drug & Cosmetic Act that applies). A few
devices may require a pre-market approval submission (PMA), which is much more stringent. These later would be limited to devices that represent substantial risk to patient or provider safety when used as directed. The pre-market submission requirements are phased in over 18 months. Reprocessors need to submit for all Class III medical devices within 6 months; Class II, within 12 months; and, Class I, within 18 months. The work involved in amassing the information required for pre-market submissions is substantial and unfamiliar to hospitals. Third-party reprocessors have not had to comply with this part of the medical device regulations until now.

The good news of this regulation is that, once fully implemented, it will remove doubts about the safety and efficacy of devices that are approved for reprocessing. This will also eliminate the need for consideration of informed consent for those devices, as they will be assumed to be as safe and effective as the original. The net effect will be that hospitals choosing to reuse SUDs will probably do so only through a registered third-party commercial reprocessor.

The regulation does not address the other concerns noted for the reuse of SUDs. Therefore, the following scenarios are proposed for addressing this total issue:

**Solution**

**Scenario 1:**
**If resources were not an issue**
In an ideal world, healthcare providers and institutions could move toward sustainability by having the following precepts in place, both institutionally and with the appropriate group purchasing organization (GPO):

1. We would have the following available when making a decision on any product:
   - The manufacturer’s justification for making the device single-use, if it is so.
   - Life cycle environmental impact studies on the device and the technologies used to manufacture it, whether an SUD or reusable.
   - Accurate estimations of use-life, if reusable.
   - Valid life cycle costing of the alternatives in use.
   - GPO’s would use their collective resources to evaluate this information, since no one hospital is likely to have the expertise to do so on every product.

2. We would choose SUDs only when the technology does not support making the product reusable, or the environmental impact is less than that of a reusable.

3. We would insist that mercury, PVC and DEHP not be used in manufacturing or construction of any medical device, whether reusable or an SUD.

4. We would reevaluate each of the SUD’s currently used in our institution and, where it made sense, push manufacturers to develop reusable alternatives using the collective force of the market place.

5. We would not reprocess SUDs, nor send them to third parties for processing (See 2 above).

6. We would carefully control the use of products to prevent wastage of opened, but unused devices. This would involve staff and physician education, and perhaps some assistance from manufacturers with regard to packaging design, quantities in a package, and the provision of reusable devices as size determination trials for surgical implants.

7. For packaging of either an SUD or a reusable, we would choose the least amount of packaging (in terms of solid waste) that still provides protection of the contents (sterility barrier and physical protection, as needed).

8. We would choose all products (reusable or single-use) based on safety, efficacy and environmental impact, before considering cost.

**Scenario 2:**
**Best case – leading to substantial results**
The following steps could be taken to address environmental concerns associated with SUDs, while still taking the constrained resources of today’s marketplace into account:

1. We would establish a working group within each institution or at the GPO level evaluate SUDs currently used within the system, beginning with the items used most often. This evaluation would ask the following:
   a. Are there patient or worker safety issues that would preclude considering a reusable, if one were available (e.g. syringes and hollow bore needles need to remain disposable)?
   b. Are there reusables on the market that should be considered as alternatives?
   c. Is this a device that would lend itself to reprocessing, if such were available (e.g. the device is not deformed, damaged or consumed in use)?
   d. Are there third-party reprocessors that can handle this device? One quick way to answer
that is to look at the listings of items from several third-party reprocessors (they must have these to comply with current FDA regulations).

2. Based on this evaluation of each product, we would determine any action steps needed to move toward reusables or reuse. This process will move quickly for some products and be slow for others. Starting with the high volume items may allow for some quick impact on solid waste and other environmental issues without having to complete the whole list of purchases first.

3. If third-party reprocessing were an option for a product, we would ask the status of their pre-market submission process. We would prefer to wait until the FDA has fully implemented the regulation to assure that patients will not be harmed. We will deal only with FDA registered reprocessors.

4. We will consider packaging in every product evaluation, including that from third-party reprocessors of SUDs. We will provide feedback and attempt to influence manufacturers to minimize packaging and use environmentally friendly materials (preferably recyclable) in packaging.

5. We would communicate to all suppliers that we would prefer reusable products when they can meet the patient care need. We would ask corporate levels of manufacturers to tell us why specific products are made disposable, to heighten the awareness of our concern. We would indicate that we would not expect reusables to cost more, when considering total use-life and reprocessing costs.

6. We would carefully control the use of products to prevent wastage of opened, but unused devices. We would continue or initiate staff and physician education in areas such as the OR, L&D and the ED, to encourage opening only those devices that will be used, rather than preparing for a worst case scenario each time. We would provide feedback to manufacturers with regard to packaging design, quantities in a package, and the provision of reusable devices as trials for implants.

7. If our community has a recycling program, we will provide separate waste containers in areas of high usage to capture paper and other clean, recyclable packaging material from both SUDs and reusable products.

8. We would survey what SUDs are being reprocessed in-house, remembering to consult all departments and considering all devices, not just those initially sold as sterile.

9. If currently reprocessing SUDs in-house, we would develop a phase-out plan to comply with August 1, 2001 deadline. In rare circumstances, some institutions may decide to register as manufacturers and comply with the regulation.

**Scenario 3- Quick fixes for some impact now**

At a minimum, every institution should be doing the following:

1. If a commercial reprocessor is currently processing devices, we would ask the status of their pre-market submission process. We would prefer to wait until the FDA has fully implemented the regulation before initiating any new reprocessing of items to assure that patients will not be harmed. We will deal only with FDA registered reprocessors.

2. We would communicate to all suppliers that we would prefer reusable products when they can meet the patient care need. We would ask corporate levels of manufacturers to tell us why specific products are made disposable, to heighten the awareness of our concern. We would indicate that we would not expect reusables to cost more, when considering total use-life and reprocessing costs.

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Resource on Current FDA Activity

The FDA Center for Devices and Radiological Health website at: www.fda.gov/cdrh

- Click on “pre-market issues” to see what is involved in 510(k) process.
- Click on “post-market issues” to see the regulations regarding registration, listing, tracking, reporting, corrections and removals, and the Quality System regulation.

Endnotes
