Legal Opinion Letter

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GREATER TRANSPARENCY NEEDED IN REPROCESSING OF MEDICAL DEVICES

by
The Honorable Bob Franks

Technological innovation continually produces new challenges to test our system of regulatory and legal safeguards. A current example involves the reprocessing of single-use devices (SUDs). Single-use devices are medical instruments designed, manufactured, and marketed to be used one time on one patient and then discarded. SUDs encompass a large range of devices including catheters, biopsy forceps, and trocars. Many are Class III "critical-use" instruments utilized in surgery and other invasive procedures.

In recent years, it has become common practice for third-party reprocessors to recover used SUDs, subject them to mass sterilization and refurbishing procedures, and distribute them to health-care institutions across the country. In relatively short order, SUD reprocessing has become big business: the industry's three largest reprocessors shipped over 4.6 million single-use devices in 2004. The problem with this practice is that single-use devices are designed by their manufacturers with the goal of being effective in their particular applications, not for ease of reprocessing. Many have features such as crevices, coils, meshes, and rough surfaces that render them difficult or impossible to adequately clean.

Another drawback lies in the fact that reprocessing often results in damage to the SUD. Few reprocessors have access to the original documentation revealing how a device is constructed and the characteristics of its materials. Such factors render it difficult for even the most stringent procedures to guarantee satisfactory levels of sterilization while maintaining material integrity, which can translate into increased risks for patients.

The integrity of the U.S. Food and Drug Administration's tracking of reprocessed SUD's has been lacking. Until August of 2006, reprocessing companies were not even obligated to identify their recycled products from the original devices through either labels or packaging. As a result, reprocessed items were simply mixed in with new devices, often without the knowledge of doctors and nurses. Under such circumstances, a failed SUD could easily be attributed in error to the original device manufacturer, rather than the company that reprocessed the device.

Regulatory efforts to address the reprocessing problem are evolving. Originally, reprocessing companies were required only to register with the government, meet production guidelines, and undergo spot inspections. More expansive requirements followed reports of infections, injuries, and mechanical failures. But, at the same time, a number of important factors have remained unaddressed. These include transparency among both reprocessors and end users, which would include effective labeling of reprocessed items, a strict chain of control giving all interested parties knowledge of when and how SUDs are used, and appropriate limitations on the number of times that a device can be reprocessed.

The existence of such gaps underscores the need for greater transparency in the reprocessing of single use devices. The reprocessing industry cannot be expected to police itself. Current safeguards are

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clearly unsatisfactory, leaving intervention by state government as a practical means of protecting the health and safety of its citizens. At this level of government, clear standards for the safe use of reprocessed devices could be established. Without them, a patient would be denied access to important information about their medical care.

We are not suggesting that reprocessing be banned, or asserting that reprocessed SUDs have no place in medical treatment. No doubt some devices can be safely and effectively reused. But the unknown level of risk and the absence of certain basic safeguards demand regulatory oversight backed by comprehensive legislation.

Strengthening state oversight and providing additional information to patients about SUDs is the major objective of PatientGUARD (Patient Groups United Against Reprocessing Dangers), a coalition of New Jersey health-care and patient advocacy groups. PatientGUARD includes a broad coalition of patient groups among its members, including: the Creutzfeldt-Jakob Disease Foundation, the Diabetes Foundation, the Epilepsy Foundation of New Jersey, the Family Resource Network, the Hyacinth AIDS Foundation, and the Caregivers Association of New Jersey.

Specifically, PatientGUARD is urging state lawmakers to enact the following patient protection measures:

1) Requiring informed written patient consent prior to using a reprocessed SUD;
2) Requiring healthcare facilities to inform physicians about their policies governing the use of reprocessed SUDs;
3) Providing physicians with the opportunity to reject using reprocessed SUDs;
4) Requiring that patient records include an inventory of reprocessed SUDs used in their treatment;
5) Establishing registration, tracking, and reporting procedures to monitor the distribution and use of reprocessed SUDs; and
6) Establishing liability among reprocessors for reprocessed SUD failures and injury.

The intent of these measures is to place SUD reprocessing within the framework of accepted medical ethics, in which the needs of the patient comprise the central element of health care. Dr. John H. Fielder of Villanova University, a professor of philosophy and an authority on medical ethics, made that case in his testimony before Congress:

> ...it is a long-standing tradition in ethics and law that patients have a right to decide what risks to take, and health care professionals have the obligation to inform them of the risks and benefits of alternative treatments. In cases where patients are exposed to a significant risk, ethics requires that they be informed of the benefits of treatment, the risks, and the alternatives. Since patients treated with reprocessed single-use devices are also exposed to a significant risk, it is enlightening to construct a consent form for this procedure... The form would have to state that the potential harms include the possibility of transmission of TB and hepatitis C, very serious diseases, and possible functional changes or failures. What are the alternatives? Besides nontreatment and any other less invasive procedures, you could be treated with a new device at no extra cost to you and avoid these potential complications.

Dr. Fielder's analysis makes it clear that nothing extraordinary is required to meet the SUD challenge. Regulatory safeguards based on customary medical ethics can provide a sufficient corrective. Patients have a right to make informed decisions regarding their health care. The PatientGUARD proposal provides that right.

At the close of his testimony before Congress, Dr. Fielder stated that the current regime of SUD reprocessing "...amounts to an extensive medical experiment without patient benefit, knowledge, or consent."

It's time that open-ended experiment was brought to an end.

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