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Dockets Management Branch, Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5603 Fishers Lane, Room 1061 (HFA-305)
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Docket Number - 99N-4491

We appreciate the opportunity to comment on the FDA's "Proposed Strategy on Reuse of Single-Use Devices". Comments were generated by the System-wide Infection Control Practitioners of Fairview Health Services. Fairview Health Services is a community based health system consisting of hospitals, clinics, nursing homes, a home care agency, pharmacies, behavioral health services and numerous other components of a system. Our comments are organized in response to the seven questions posed.

1. We feel that third-party reprocessors of Single-Use Devices (SUD's) should and must be regulated similar to the regulation issued to hospitals (November 11, 1977) that engage in reprocessing. Hospitals engaging in reprocessing assume a certain level of risk for this practice and while this risk may be shared with the third-party reprocessor, it is difficult to determine the level of shared risk if the reprocessor does not have standards and guidelines. Standards regulated processes afford an expectation that devices are adequately cleaned and sterilized and that device functionality, effectiveness and quality are maintained.
2. We support the use of categorization, using three categories rated by functionality and sterility. However, we also recommend that this categorization be built off of recognized classification systems and guidelines such as the Spaulding classification scheme and the 1996 APIC guideline for selection and use of disinfectants. Whatever classification system is proposed, it should be based on both safety and infectious risk factors.
3. We support the use of a "List of Frequently Reprocessed SUD's", but have no comment on the items in that list.

4. We do not support the notion that Original Equipment Manufacturers (OEM's) provide information on their labels about risks associated with re-use of SUD's. This implies that the reprocessed device is a lower or inferior quality product. The single use device should not be re-used unless it meets the same specifications and requirements as when used the first time.
5. We support the use of definitions, but suggest eliminating "d" reesterilization. Once determined safe for use, the principles and methods of sterilization should be the same whether the item is labeled reusable or SUD. The term reesterilization may suggest a variation from these established principles and methods.
6. We caution any group addressing the use of consensus standards. Consensus standards are OK if scientifically based validation studies/testing are conducted by an outside laboratory. Any reprocessing methodology/findings should be supported by research rather than a "consensus" based on third-party reprocessor's current practice.
7. We strongly support the development of a research program on reuse of SUD's. Many new avenues for quality health care are opened with the expansion of any research efforts.

Again, thank you for allowing us to provide input on this topic and we await further information on the FDA's proposed strategy.

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