MEDICAL DEVICE SAFETY: HOW FDA REGULATES THE REPROCESSING OF SUPPOSEDLY SINGLE-USE DEVICES

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

SEPTEMBER 26, 2006

Serial No. 109–190

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

30–528 PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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TUESDAY, SEPTEMBER 26, 2006,

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:40 a.m., in room 2157, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis, Mica, Gutknecht, Porter, Foxx, Schmidt, Waxman, Owens, Towns, Cummings, Kucinich, and Norton.

Staff present: David Marin, staff director; Larry Halloran, deputy staff director; Keith Ausbrook, chief counsel; A. Brooke Bennett, counsel; Susie Schulte, professional staff member; Michael Galindo and Benjamin Chance, clerks; Karen Lightfoot, minority communications director/senior policy advisor; Stephen Cha, minority professional staff member; Sarah Despres, minority counsel; Early Green, minority chief clerk; and Jean Gosa, minority assistant clerk.

Chairman TOM DAVIS. I apologize for being a couple of minutes late. I want to welcome everybody to today's hearing on the Food and Drug Administration's regulation of reprocessed single-use devices.

The purpose of this hearing is to assess FDA's oversight of the reprocessing industry and determine what, if any, additional measures are needed to assure reprocessed SUDs are effective and safe. FDA is responsible for approving these devices. Manufacturers choose to submit applications for single-use only designation as opposed to multi-use designation. FDA, however, allows reprocessed SUDs to be marketed if they are substantially equivalent to the original device.

Many of you may not be aware that several commonly used medical devices are cleaned and resterilized to be used by hospitals more than once. Devices such as catheters, biopsy forceps, and surgical tools are often designated for one-time use, but hospitals routinely pay to have them reprocessed to cut costs and reduce medical waste. For example, new biopsy forceps can cost $60, yet reused forceps can cost as little as $15. Savings from use of reprocessed devices can be significant.

Original device manufacturers have said, however, they cannot guarantee the safety of SUDs once they are reprocessed and re-

used. Reprocessors contend there is no sufficient or credible evidence to indicate the use of reprocessed medical devices is riskier than the use of new ones. Hospitals may save overhead costs, but what is the cost of patient's health? That is just one of the many questions we are going to ask today.

The committee's interest began with a series of articles in the Washington Post that reported many instances of patient injury associated with the use of defective and unsterile reprocessed devices. Mr. Waxman and I wrote to the FDA, asking for information on device safety regulations and the adequacy of adverse event data. The FDA responded that the data in hand did not establish a clear causal link between reprocessed devices and subsequent adverse health effects, but we need to know whether that is because the reprocessed devices are safe or because MedWatch, the adverse event monitoring system, is too passive or insensitive to capture subtle but potentially deadly trends.

Today's hearing will question whether FDA's current MedWatch reporting system can accurately capture adverse events resulting from reprocessed devices. We will ask FDA how new labeling requirements under the Medical Device User Fee and Modernization Act are working to help improve the MedWatch system. Effective last month, reprocessed devices are required to be stamped or tagged with a label indicating they have been reprocessed. Previously, only the packaging was required to identify the device was reprocessed, and most doctors were unaware devices were reprocessed as packaging is often removed prior to use in the operating room.

Now look, I realize some of our witnesses will say it is too early to clearly determine what impact the new labeling requirement will have on adverse event reporting, and that is OK. Today's hearing will not be the committee's final look at the issue.

Mr. Waxman and I have asked GAO to update its June 2000 report on SUDs. GAO's initial report found little harm from reuse but recommended additional oversight by the FDA. Because FDA regulation of the industry has increased significantly since 2000, the committee asked GAO to specifically examine the safety of SUD reprocessing, the adequacy of FDA's oversight, and how reprocessed SUDs compare to original devices. GAO has accepted this request, but they have not yet initiated work.

Before we move to our first panel, I am going to express my disappointment in the original device manufacturing industry. We have no device makers testifying today because they preferred to speak through their trade association, AdvaMed. Specifically, C.R. Bard, a company from Murray Hill, NJ, was invited to testify, but they declined to appear. We would have preferred to have direct testimony from companies so they would be able to provide specific examples and commentary regarding their specific devices. Despite the committee's disappointment with the lack of original device manufacturer witnesses, we will continue our discussions with those companies.

We have the reprocessors represented by SterilMed and Ascent Healthcare Solutions, the two largest companies in the business, ready to testify today, and I want to thank them for appearing.

I look forward to your testimony from both panels on this important issue.

[The prepared statement of Chairman Tom Davis follows:]

Chairman Tom Davis
Opening Statement
"Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices"
September 26, 2006

Good morning. Welcome to today's hearing on the Food and Drug Administration's (FDA) regulation of reprocessed single-use devices (S.U.D.). The purpose of this hearing is to assess FDA's oversight of the reprocessing industry and to determine what, if any, additional measures are needed to ensure reprocessed SUDs are effective and safe. FDA is responsible for approving these devices. Manufacturers choose to submit applications for single-use only designation as opposed to a multi-use designation. FDA, however, allows reprocessed SUDs to be marketed if they are "substantially equivalent" to the original device.

Many of you may not be aware that several commonly used medical devices are cleaned and resterilized to be used by hospitals more than once. Devices such as catheters, biopsy forceps, and surgical tools are often designated for one-time use, but hospitals routinely pay to have them reprocessed to cut costs and reduce medical waste. For example, new biopsy forceps can cost $60, yet reused forceps can cost as little as $15. Savings from use of reprocessed devices can be significant.

Original device manufacturers have said, however, they cannot guarantee the safety of SUDs once they are reprocessed and reused. Reprocessors contend there is no sufficient or credible evidence to indicate the use of reprocessed medical devices is riskier than the use of new ones. Hospitals may save overhead costs but is it at a cost to patient health? This is just one of the many questions we'll be asking our witnesses today.

The Committee's interest in this issue began with a series of articles in the Washington Post that reported many instances of patient injury associated with the use of defective or unsterile reprocessed devices. Mr. Waxman and I wrote to the FDA asking for information on device safety regulation and the adequacy of adverse event data. The FDA responded that the data in hand did not establish a clear causal link between reprocessed devices and subsequent adverse health effects. But we need to know whether that's because the reprocessed devices are safe or because MedWatch, the adverse event monitoring system, is too passive or insensitive to capture subtle but potentially deadly trends.

Today's hearing will question whether FDA's current MedWatch reporting system can accurately capture adverse events resulting from reprocessed devices. We'll ask FDA how new labeling requirements, under the Medical Device User Fee and Modernization Act, are working to help improve the MedWatch system. Effective last month, reprocessed devices are required to be stamped or tagged with a label indicating they've been reprocessed. Previously, only the packaging was required to identify the

device as reprocessed, and most doctors were unaware devices were reprocessed as packaging is often removed prior to use in the operating room.

I realize some of our witnesses will say it's too early to clearly determine what impact the new labeling requirement will have on adverse event reporting—and that's OK. Today's hearing will not be the Committee's final look at this issue. Mr. Waxman and I have asked GAO to update its June 2000 report on SUDs. GAO's initial report found little harm from reuse but recommended additional oversight by the FDA. Because FDA regulation of the industry has increased significantly since 2000, the Committee asked GAO to specifically examine the safety of SUD reprocessing, the adequacy of FDA's oversight, and how reprocessed SUDs compare to original devices. GAO has accepted this request but has not yet initiated work.

Before we move to our first panel, I have to express my disappointment in the original device manufacturing industry. We have no device makers testifying today because they preferred to speak through their trade association, AdvaMed. Specifically, C.R. Bard, a company from Murray Hill, New Jersey, was invited to testify but declined to appear before the Committee. We would have preferred to have direct testimony from companies so they would be able to provide specific examples and commentary regarding their specific devices. Despite the Committee's disappointment with the lack of an original device manufacturer witness, we will continue our discussions with those companies. We have the reprocessors represented by SterilMed and Ascent Healthcare Solutions, the two largest companies in the business, ready to testify today and I thank them for appearing. I look forward to the testimony today from both panels on this important issue.

Chairman TOM DAVIS. I would now recognize Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman for holding today's hearing on the safety of reprocessed medical devices.

FDA's oversight of medical devices is an important issue that does not get sufficient attention. Medical devices can be as critical to a patient's care as the drugs they are prescribed. There are devices that keep the heart beating, to measure the level of oxygen in blood, to deliver pain medication, and to test blood pressure. When devices fail, there can be very serious consequences including death.

Today's hearing is focused on the risks of reprocessed medical devices, but the safety risks posed by medical devices are by no means limited to reprocessed devices. One example is the recent manufacturing defects in brand new implantable cardiac defibrillators. These are devices that are implanted into people with heart problems and that can save a person's life by shocking a nonfunctioning heart back into rhythm. Even after one major manufacturer of defibrillators learned that some of its devices were flawed, the company did not inform physicians or the public, and the faulty defibrillators continued to be surgically implanted.

Eventually, there was an after the fact recall, but by this time, the faulty defibrillators had already been implanted and patients were put into the position of having to live with defibrillators that could fail or undergoing another surgery to have them replaced. That is a terrible position for anyone to be in.

In recent years, there has been a concerted effort to strengthen FDA regulation of reprocessed devices. A series of congressional hearings and a GAO investigation showed that this was an area that needed more regulation. FDA then asserted its jurisdiction over device reprocessors, subjecting them to the same standards as other device manufacturers, and in 2002 and in 2005, Congress imposed additional requirements on the manufacturers. The last of the new rules for reprocessed devices went into effect in August. As a result, we no longer have a regulatory scheme that allows devices to be cleaned and reused with no oversight. Under the law, reprocessed devices are actually more tightly regulated now than their single-use counterparts.

I understand that the original equipment manufacturers do not like reprocessing. They have an economic concern about this practice. The practice of reprocessing cuts into their profits and often forces them to lower their prices to stay competitive. Their agenda, however, should not be our agenda.

The safety concerns with reprocessed devices have to be understood within the broader context of device safety. Under the FDA's current regulatory scheme for reprocessed devices, FDA assures us that a reprocessed device will meet the same exact standards as the original device. It must be just as strong and just as sterile as it was the first time it was used. So, as we question FDA's ability to assure that reprocessed devices are safe and effective, as we should, we must recognize that we are, in effect, questioning FDA's ability to ensure that all devices are safe and effective.

We will hear today that FDA is not devoting enough resources to enforcing the requirements that apply to reprocessed devices. I share these concerns.

I want to learn how the new regulations for manufacturers of reprocessed devices are being implemented, and I hope we will do everything we can to urge FDA to be more effective bringing enforcement actions for violations of the regulations governing reprocessed devices. But we must recognize that FDA's failure to protect the public extends beyond reprocessed devices. The reality is that FDA is also not doing a good job protecting Americans from the dangers of new devices, and it is the original devices, not reprocessed ones, that cause the largest number of deaths and injuries.

I issued a report in June that revealed that FDA enforcement actions have declined significantly under the Bush administration. Among FDA's regulatory centers, the Center for Devices and Radiological Health saw the biggest decline in enforcement with a 65 percent drop in the number of warning letters it issued from 2000 to 2005. This report made clear that in the last 5 years, FDA has chosen to ignore the advice of its own staff, has taken far fewer enforcement actions than in previous years, and has left the industry to police itself.

In order to put the issue of reprocessed medical devices into the broader context of device safety, I requested that Dr. Peter Lurie from Public Citizen be invited to testify. For reasons that I do not understand, my request was denied. Dr. Lurie is a consumer advocate with no financial stake in this issue. He would have provided an important public health perspective to today's hearing, and it is unfortunate he was not allowed to participate.

Americans rely on the FDA to make sure that the foods they eat, the drugs they take, and the devices that they need are safe and effective. Unfortunately, recent tragedies like the faulty defibrillators have shaken consumers' confidence that FDA is effectively fulfilling this role.

I look forward to learning from our witnesses today steps we can take to strengthen FDA's oversight of all medical devices so that we can have this faith restored. I thank the witnesses for coming.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

Statement of
Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
"Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices."

September 26, 2006

Mr. Chairman, thank you for holding today's hearing on the safety of reprocessed medical devices. FDA's oversight of medical devices is an important issue that does not get sufficient attention.

Medical devices can be as critical to a patients' care as the drugs they are prescribed. There are devices to keep the heart beating, to measure the level of oxygen in blood, to deliver pain medication, and to test blood pressure. And when devices fail, there can be very serious consequences, including death.

Today's hearing is focused on the risks of "reprocessed" medical devices, but the safety risks posed by medical devices are by no means limited to reprocessed devices. One example is the recent manufacturing defects in brand-new implantable cardiac defibrillators. These are devices that are implanted into people with heart problems and that can save a person's life by shocking a nonfunctioning heart back into rhythm. Even after one major manufacturer of defibrillators learned

that some of its devices were flawed, the company did not inform physicians or the public, and the faulty defibrillators continued to be surgically implanted.

Eventually, there was an after-the-fact recall. But by this time, the faulty defibrillators had already been implanted, and patients were put in the position of having to live with defibrillators that could fail or undergoing another surgery to have them replaced. That is a terrible position for anyone to be in.

In recent years, there has been a concerted effort to strengthen FDA regulation of reprocessed devices. A series of congressional hearings and a GAO investigation showed that this was an area that needed more regulation. FDA then asserted its jurisdiction over device reprocessors, subjecting them to the same standards as other device manufacturers. And in 2002 and 2005 Congress imposed additional requirements on the manufacturers. The last of the new rules for reprocessed devices went into effect in August.

As a result, we no longer have a regulatory scheme that allows devices to be cleaned and reused with no oversight. Under the law, reprocessed devices are actually more tightly regulated now than their single-use counterparts.

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I look forward to learning from our witnesses today steps we can take to strengthen FDA's oversight of all medical devices, so that we can have this faith restored.

I thank the witnesses for coming

Chairman TOM DAVIS. Thank you.

Any other Members wish to make opening statements?

Mrs. Schmidt.

Mrs. SCHMIDT. Thank you, Mr. Chairman. I will be brief. I really appreciate the opportunity to have this hearing today. I first became aware of the issue of using reprocessed single-use medical devices in my own district with people that had concerns over the fact that patients may not know these devices are being used, doctors may not know that these devices are being used, and the quality of them being reprocessed.

I look forward to an insightful debate on this issue. The concern and the bottom line that I have is that when a patient seeks medical treatment that the best care is being provided, the safest care is being provided, and that the patient understands that when a reused device is going to be used, that they know the ramifications of that.

I thank you very much for the opportunity to learn more about this.

Chairman TOM DAVIS. Thank you very much.

Any other Members wish to make opening statements?

If not, we will proceed to our first panel. We have Dr. Daniel Schultz, the Director of the Center for Devices and Radiological at the Food and Drug Administration.

Dr. Schultz, thank you for being here. Why don't you just remain standing, and I will swear you in.

[Witness sworn.]

Chairman TOM DAVIS. Thank you.

You have a light in front of you that turns orange after 4 minutes, red after 5. Your entire statement is part of the record, and questions will be based on your entire written statement. Thanks for being with us.

STATEMENT OF DR. DANIEL G. SCHULTZ, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

Dr. SCHULTZ. Good morning, Mr. Chairman, members of the committee.

My name is Dan Schultz. I am Director of the Center for Devices and Radiological Health at the Food and Drug Administration. The safety of medical devices is of utmost importance to the agency, and I appreciate the opportunity to discuss the safety and effectiveness and manufacturing quality of reprocessed single-use devices or SUDs.

My written testimony includes an overview of our regulatory authority for medical devices. FDA classifies medical devices into Class I, II, and III, based on risk, Class III being the highest risk. Currently, only Class I and II single-use device types have been cleared by FDA for reprocessing.

Let me provide some background on the regulation of reprocessed devices. In August 2000, FDA issued guidance enforcement priorities for single-use devices reprocessed by third parties in hospitals. Again, this was prior to any specific legislation on this issue. It was based on a series of meetings that we held and input from stake-

holders, which suggested that there was interest in having closer regulation on this topic.

This guidance set forth FDA's priorities for enforcing pre-market submission and post-market requirements for manufacturers who wish to market reprocessed SUDs. The guidance document stated that any third party and hospital reprocessor should comply with requirements pertaining to registration and listing, medical device reporting, medical device tracking, medical device corrections and removals, the quality system regulation, labeling, and pre-market submission. Essentially, at that time, reprocessors were placed on the same regulatory framework as the OEMs.

Prior to issuance of this guidance, reprocessors were not consistently held accountable to any of these requirements. In 2002, with enactment of MDUFMA, Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data that exceeded the requirements for OEMs. Certain reprocessed SUD types that present the greatest potential risk of infection and inadequate performance following reprocessing and that were previously exempt from pre-market submission were no longer exempt.

MDUFMA also created a new type of pre-market submission called a pre-market report for Class III reprocessed SUDs that otherwise would have required a pre-market approval application. MDUFMA also required a change to FDA's MedWatch voluntary and mandatory reporting forms to identify adverse events involving reprocessed SUDs. As of August 1, 2006, MDUFMA also requires reprocessed SUDs to bear the name, abbreviation, symbol of the reprocessor, either on the device itself, on an attachment, or a detachable label.

Under the FD&C Act, before introducing a device to market, manufacturers must submit a notification of 510(k) and obtain FDA clearance unless the device has been exempted. MDUFMA required FDA to identify previously exempt device types that, if processed as an SUD, would now require 510(k) submission including the submission of validation data. In addition, MDUFMA required the FDA identify SUDs already subject to 510(k) pre-market requirements but that would now also require the submission of validation data. Validation data include cleaning and sterilization and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate after the maximum number of times the device is intended to be reprocessed.

On June 1, 2004, FDA issued Guidance for Industry and FDA Staff, MDUFMA 2002, Validation Data in Pre-market Notification for Reprocessed Single-Use Medical Devices. This document describes the types of validation data that FDA expects to be submitted on cleaning, sterilization, and functional performance, the timeframe for FDA's review of these submissions, and what actions the agency intends to take if it finds a reprocessed SUD to be not substantially equivalent.

As of September 2006, FDA has received 200 pre-market notification submissions for reprocessed SUDs, each covering from a single to as many as several hundred device models. Approximately 67 percent have been cleared by the agency. The remaining were not cleared for reasons such as inadequate validation data, lack of nec-

essary information from the reprocessor, withdrawal of the application, or lack of response to FDA's request for data. Just to give you some perspective on this and put it in context, of the total number of 510(k)'s that we received, approximately 88 percent of all those are cleared.

Inspections serve as a bridge between pre and post-market activities. On the average, FDA has conducted inspections of reprocessor firms once every 2 years, a rate considerably higher than the one in every 4 years for OEMs. All known reprocessing firms have been inspected within the last 2 years. FDA continues to evaluate newly registered firms to confirm whether they are performing SUD reprocessing and updates its inspectional plan as required.

Post-market; post-market monitoring of device-related adverse events and product problems is accomplished through the MDR system. MDR reports include deaths, serious injury, and device malfunctions. Healthcare facilities are required to report deaths suspected to be device-related to both FDA and the manufacturer/reprocessor and serious injuries to the manufacturer/reprocessor. FDA also receives voluntary reports generally from healthcare professionals through its MedWatch reporting system. CDRH receives approximately 200,000 device-related adverse event reports per year.

Can I continue? Oh, sorry.

As you know, on January 24, 2006, I and others briefed the committee staff about SUD reprocessing. We searched our Manufacturer and User Facility Device Experience data base for reports from October 22, 2003, which is when the MDUFMA legislation went into effect, to December 13, 2005, that were coded as adverse events associated with reprocessed SUDs. Analysis of these reports did not disclose a clear link between a reprocessed SUD and subsequent patient injury or death.

In July 2006, the agency updated the search to include all reports between October 2003, and July 2006. FDA has received a total of 434 reports and, of these, approximately 65 reports involved or were suspected to involve reprocessed SUDs. These AEs may be associated with reprocessing. They may also be associated with the medical condition of the patient, the medical procedure, or other confounding factors. We are seeing that the same types of adverse events reported to be associated with the use of SUDs are similar for new, non-reprocessed devices.

To learn more about how reprocessing was actually occurring from a user standpoint, we conducted a survey under our Medical Product Device Safety Network or MedSun. FDA's MedSun is comprised of over 350 hospitals that identify and report device problems, and this is a more active surveillance system as opposed to the MAUDE system which is a much more passive system. Representatives from more than 50 of these facilities provided feedback on their experience with reprocessed SUDs to FDA staff. In general, participants had a favorable view of reprocessed SUDs. There were no reports with specific problems with SUD-related infections, and participants did not report a greater concern with mechanical problems associated with reprocessed SUDs compared to non-reprocessed SUDs.

I would like to emphasize, however, that one of the statements, and there was some variability in terms of the comments that we got, but one of the statements that was clear and was totally consistent was the idea that it was, that they found it necessary and desirable for FDA to have a strong oversight over this process.

The agency continues to review and assess the practice of reprocessing SUDs. I have some specifics in my written summary.

Just yesterday, FDA published rules amending certain classification regulations for reprocessed SUDs formerly exempt from premarket, those previously subjected to pre-market notification, and for which validation data are now necessary in a 510(k). These amendments will help reprocessors and other stakeholders to know which devices are being reprocessed and allow them to submit the data that they need to demonstrate that their device is substantially equivalent.

We have also recently updated our Web site. We have also recently initiated a dedicated post-market team to look specifically at the adverse events associated with reprocessing, and we continue to update our inspection plan to make sure that we are inspecting all of the reprocessors on a regular basis.

Available data show that certain—and I emphasize the word, certain—SUDs can be reprocessed with a reasonable assurance of safety and effectiveness. FDA believes that reprocessed SUDs, that meet FDA's regulatory requirements are as safe and effective as their predicate. The law and regulations in place are designed to protect the public health by assuring that reprocessing is based on sound science. We continue to monitor the performance of these devices and to assess and refine our ability to regulate them appropriately.

Mr. Chairman, I apologize for running over. Thank you again for the opportunity to address this important topic.

[The prepared statement of Dr. Schultz follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DANIEL SCHULTZ, M.D., DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2006

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I consider device safety to be of utmost importance and appreciate your invitation and the opportunity to discuss this issue. Let me say at the outset that I believe FDA currently has many tools to ensure the safety, effectiveness, and manufacturing quality of reprocessed, single-use devices (SUDs).

FDA has been actively engaged in the SUD reuse issue for some time, and our efforts have included research, outreach, pre-market review, inspections, and compliance investigations. We have held numerous public meetings and conferences with industry, healthcare professionals, and consumers over the years to determine the extent, magnitude, and changing nature of this practice. FDA has carefully evaluated and conducted research to develop the scientific basis for addressing SUD reprocessing. We have inspected third party reprocessors, evaluated and investigated reports of patient injuries, and reviewed numerous pre-market submissions. Taken together, the Agency believes that these efforts have provided, and will continue to provide, reasonable assurance of safety and effectiveness of reprocessed SUDs for patients.

BACKGROUND

I will begin with a brief overview of our regulatory authorities for medical devices. A medical device as defined by Federal law encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and

complex devices such as implantable defibrillators and robotic equipment for minimally invasive surgery.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic (FD&C) Act gave FDA specific authority to regulate the safety and effectiveness of medical devices. Medical devices are assigned to one of three "classes." Class I is the lowest risk category of device and includes items such as adhesive bandages. Class II, or medium-risk category of device, includes devices such as intravenous catheters and powered wheelchairs. Class III is the highest risk category of device and includes devices such as heart valves and coronary stents.

THE REGULATION OF REPROCESSED SINGLE USE MEDICAL DEVICES

The reprocessing of SUDs is legally permissible in the United States under the FD&C Act. Currently, only Class I and II SUD device types have been cleared by FDA for reprocessing. No Class III SUDs have been cleared/approved for reprocessing.

In August 2000, FDA issued a guidance document for industry and staff entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." This document set forth FDA's priorities for enforcing pre-market submission and post-market requirements for manufacturers who wished to market reprocessed SUDs. The guidance document stated that any third party or hospital reprocessor should comply with requirements pertaining to: registration and listing, medical device reporting, medical device tracking, medical device corrections and

removals, the quality system regulation, labeling, and pre-market submission. Essentially, third party firms and hospitals reprocessing SUDs were placed in the same regulatory framework as original equipment manufacturers (OEMs).

Prior to issuance of this guidance, reprocessing of SUDs was frequently performed by hospital personnel without regulatory oversight or regard to the level of device risk. In addition, many third party reprocessors contracted with hospitals to perform similar tasks and these contractors did not consistently adhere to FDA's Good Manufacturing Practice Requirements.

CHANGES ENACTED WITH MDUFMA

In 2002, with enactment of the Medical Device User Fee and Modernization Act (MDUFMA), Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the Agency that exceeded the requirements for OEMs. In addition to the requirements specified in our 2000 Guidance Document, certain reprocessed SUD types that potentially could pose the greatest risk of infection and inadequate performance following reprocessing and that were previously exempt from any pre-market submission requirements, are no longer exempt.

MDUFMA also created a new type of pre-market submission, called a "pre-market report" (PMR), for Class III reprocessed SUDs that otherwise would have required a pre-market approval application. Among other information, a PMR must include validation

data regarding cleaning, sterilization, and functional performance of the reprocessed device to ensure it is substantially equivalent to a legally marketed device. To date, only one PMR has been submitted to the Agency and it was later withdrawn by the firm.

In addition, MDUFMA required a change to FDA's MedWatch voluntary and mandatory reporting forms (Forms 3500 and 3500A, respectively) to facilitate the reporting of adverse events involving reprocessed SUDs.

Finally, MDUFMA required, as of August 1, 2006, that reprocessed SUDs prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device and whether the device has been marked by the OEM.

PRE-MARKET REVIEW OF REPROCESSED SUDs

Under the FD&C Act, before introducing a device to market, manufacturers must submit a Notification of Intent to Market a Device (510k) and obtain FDA clearance, unless the device has been exempted. MDUFMA required FDA to identify previously 510(k)-exempt device types that, if reprocessed as a SUD, would now require 510(k) pre-market review, including the submission of validation data. In addition, MDUFMA required that FDA identify SUDs that were already subject to 510(k) pre-market requirements, but that would now also require the submission of validation data. Required validation data include cleaning and sterilization data, and functional performance data demonstrating

that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed.

The criteria used to determine which reprocessed SUD types would no longer be exempt from pre-market notification requirements and would require 510(k)s with validation data, and which reprocessed SUDs already subject to the 510(k) requirements also would now be subject to the additional requirement of validation data are available on the Internet at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/03-10413.html.*

Using these criteria, FDA identified all previously exempt "critical" and "semi-critical" devices that were high-risk. These devices would no longer be exempt from 510(k) requirements and SUD reprocessors of these device types would be required to submit 510(k)s with validation data and receive clearance in order to continue marketing these devices.

In addition, the requirements and the lists of devices that were newly subject to these requirements were published in the *Federal Register*. FDA has added other reprocessed SUD types to these lists as we become aware of information that warrants their inclusion.

On June 1, 2004, FDA issued a revised "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Pre-market Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices." This

document describes the types of validation data that FDA recommends be submitted on cleaning, sterilization, and functional performance of certain reprocessed SUDs to ensure that they are substantially equivalent to the predicate device. Additionally, this document describes the timeframe for FDA's reviews of these validation data submissions, and what actions the Agency intends to take if it finds a reprocessed SUD to be Not Substantially Equivalent (NSE) to the predicate device.

As of September 2006, FDA has received nearly 200 pre-market notification 510(k) submissions for reprocessed SUDs. These submissions cover from one, to as many as several hundred, device models. Of the almost 200 submissions, approximately 67 percent have been cleared by FDA. The remaining were not cleared for such reasons as inadequate validation data, lack of necessary information from the reprocessor, withdrawal of the application by the submitter, or lack of response to FDA's request for data. (Approximately 88 percent of 510(k)s for all other devices are cleared and approximately 3.4 percent are found NSE to the predicate device.)

COMPLIANCE ACTIVITIES

FDA's inspectional program serves as a bridge between pre- and post-market activities. Since 2000, on average, FDA has conducted inspections of reprocessor firms once every two years, a rate considerably higher than the one inspection in four years for OEMs. Of the seven firms currently known to be reprocessing, all have been inspected within the last two years. FDA continues to evaluate newly registered firms to confirm whether they are performing SUD reprocessing and updates its inspectional plan as required.

POST-MARKET SURVEILLANCE FOR REPROCESSED SUDs

Post-market monitoring of device-related adverse events (AEs) and product problems is accomplished through the Medical Device Reporting (MDR) system. MDR reports include deaths, serious injuries, and device malfunctions. Healthcare facilities are required to report deaths suspected to be device-related to both FDA and the manufacturer/reprocessor. They are required to report serious injuries to the manufacturer/reprocessor.

FDA also receives voluntary reports, generally from healthcare professionals, through its MedWatch reporting system. As previously mentioned, under MDUFMA, the MedWatch reporting form 3500A was revised to include a data entry field (D8) to ask if the device associated with the reported event was a reprocessed SUD. This question was added to the form to enhance the Agency's ability to quickly identify and investigate reports of problems associated with reprocessed SUDs.

FDA responds to reports of death or serious injury by investigating the report and taking appropriate follow-up actions as needed. Follow-up actions may include enforcement actions and/or the issuance of a public health notification to alert the healthcare community of the Agency's concerns.

As you know, on January 24, 2006, I and others briefed this Committee about SUD reprocessing. At that time, we provided background information including the current

regulatory framework and AE data. Specifically, we searched our Manufacturer and User Facility Device Experience (MAUDE) database for reports from October 22, 2003, to December 13, 2005, that were coded as adverse events associated with reprocessed SUDs. The search produced 176 reports of death, serious injury, and/or device malfunction; however, analysis of these reports did not disclose a clear causative link between a reprocessed SUD and subsequent patient injury or death.

In July 2006, the Agency updated the search to include all reports entered into the MDR, MAUDE, and MedWatch databases between December 2005 and July 2006. FDA has received a total of approximately 434 reports, including MedWatch forms, where the reprocessed SUD field was checked "yes." Our analysis of these reports determined that many of the devices were not reprocessed SUDs. Rather, they were implanted devices or devices that were designed to be re-usable and, therefore, were not reprocessed SUDs. Of the 434 reports, approximately 65 reports actually involved or were suspected to involve reprocessed SUDs, and were reviewed by FDA. The final analysis of the reports found that the types of adverse events reported to be associated with the use of SUDs were the same types of events that also are being reported for new, non-reprocessed devices. Therefore, it was unclear whether the device, the medical condition of the patient, the medical procedure, or other confounding factors caused or contributed to the adverse event.

FEEDBACK FROM A SAMPLING OF MEDSUN HOSPITAL FACILITIES THAT USE REPROCESSED SUDs

FDA's Medical Product Safety Device Network (MedSun) is comprised of over 350 hospitals that have been recruited and specifically trained to identify and report device problems. The hospitals in this program are broadly representative of U.S. healthcare facilities. FDA staff talked with representatives from more than 50 of these facilities to obtain feedback on their experience with using reprocessed SUDs.

The MedSun respondents who gave us feedback represented various occupations in hospitals, including materials management, biomedical and clinical engineering, risk management, infection control, surgical services, nursing staff, supply utilization, and equipment management. Staff being interviewed responded overwhelmingly that they view the use of reprocessed SUDs as providing a significant cost savings to their facilities and as being an environmentally sound practice.

There was considerable variation in the devices being reprocessed at the various facilities and the degree of acceptance of this practice by individual practitioners within the facilities. None of the participants we spoke with reported specific problems with SUD-related infections, but they also pointed out that, if an infection occurred, it would be difficult to discern whether the reprocessed SUD was the cause. It also is interesting to note that the participants did not report a greater concern with mechanical problems associated with reprocessed SUDs compared to un-reprocessed SUDs. In general, the participants had a favorable view of reprocessed SUDs used in their facilities. They also stated that they relied heavily on FDA oversight to ensure safety and effectiveness and to provide objective information on reprocessed SUDs.

ONGOING FDA ACTIVITIES

The Agency continues to review and assess the practice of reprocessing SUDs.

- CDRH established an active internal work group to ensure that review scientists remain current with the evolving scientific literature and new consensus standards that are relevant to the reprocessing of SUDs.
- CDRH has convened a second work group, called the "Post-market Issue Action Team," to develop a long-term strategy for monitoring, evaluating, and communicating information about reused SUDs.
- CDRH continues to submit reprocessor inspection requests to the Office of Regulatory Affairs to schedule inspections of reprocessor facilities to assess conformance with the Quality System Regulation.
- CDRH periodically updates its reuse webpage so that healthcare facilities and providers will have current information on legally marketed, reprocessed SUDs. Recently, easy-to-read tables listing FDA requirements for specific reprocessed SUD types were added to the website. In addition, we improved accessibility and added instructions to the publicly searchable FDA pre-market databases. These databases allow the user to search in real-time for recent and past clearances. (*http://www.fda.gov/cdrh/reuse/index.html*)
- CDRH regularly updates guidance to industry and FDA reviewers on validation data requirements for reprocessed SUDS.
- CDRH regularly updates the list of reprocessed SUDs subject to the additional pre-market requirements imposed by MDUFMA.

- CDRH is conducting research to develop/establish "acceptable" SUD cleaning criteria.
- CDRH is collaborating with two local healthcare facilities to help monitor changes in the design of some SUDs and identify new SUDs being reprocessed.

On September 25, 2006, FDA published two rules: the direct final rule for Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; and a proposed rule for Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Companion to Direct Final Rule (proposed rule). These amendments will help ensure that reprocessors submit the data, including cleaning, sterilization, and functional performance data, needed to demonstrate that their device is substantially equivalent to the predicate device.

CONCLUSION

Available data show that SUDs can be reprocessed with a reasonable assurance of safety and effectiveness. FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device. The law and regulations in place are designed to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on sound science. FDA continues to monitor the performance of these devices and to assess and refine our ability to regulate these devices appropriately.

Mr. Chairman, thank you again for the opportunity to address this important topic. I will be happy to answer any questions.

Chairman TOM DAVIS. Thank you very much.

I am going to start the questioning with Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, I don't have a question so much as a comment.

I am delighted the FDA is taking some of these issues seriously, but I just want to make sure that we don't overstate the danger here. I just don't want consumers to believe that there is real risk.

In your professional judgment, how many American consumers have been injured by some of these reused technologies?

Dr. SCHULTZ. I wish I could give you an exact count; I can't.

Again, we have looked at all of the reports that have been submitted to us, most of the reports, and we were given specific authority to designate those reports as whether they are reprocessed or non-reprocessed. Unfortunately, a lot of those reports were incorrectly designated. When we looked at them specifically one by one, of those that remained, there certainly are some that could have been associated with reprocessing, but based on the data and actually the in-depth analysis of those individual reports, as I said, it is very difficult to precisely, precisely define which ones were, in fact, associated with the reprocessing versus the device or the overall procedure. I apologize for not being able to give you a more specific answer, but that is the honest answer of what we currently know.

Mr. GUTKNECHT. My point really is, Mr. Chairman and Members, I think we have to put this in some context. The unfortunate fact is that somewhere between 6,000 and 10,000 Americans die every year in hospitals as a result of either getting the wrong medication or an infection which they actually caught while they were in the hospital. In the very rare circumstance of that infection, did that have anything to do with a reprocessed medical device?

I think it is important we have this hearing, Mr. Chairman, but I think we have to put it in context. No. 1, we don't have very good data, and second, the data that we do have doesn't suggest that American consumers, American patients are at any undue risk because of the reprocessing of medical devices.

I know in talking to some of the healthcare people in my district and in the State, they do want to use these because they can see significant savings rather than having to buy all new equipment. If it were up to the device manufacturers, there would be no reprocessing at all.

So the only thing I would say—and I want to thank you for your testimony—is that the evidence here is pretty scant that there is real harm being done to American consumers by this technology.

I yield back.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. Thank you, Dr. Schultz, for your presentation.

As I mentioned in my opening comments, I didn't really want to restrict my comments to reprocessed devices alone because in some ways there is a blur between the two. I do want to ask you about what your office is doing regarding device safety generally.

I mentioned in my opening comments the cardiac defibrillators made by Guidant. The New York Times broke the story about the Guidant pacemakers. There was little movement by your agency to

look further into the company, despite reports of short circuits for years preceding this effort. Your agency, in fact, knew about these problems for years before the New York Times story. Can you explain your agency's delay in action?

Dr. SCHULTZ. Yes, we have looked at that very carefully, Mr. Waxman, because obviously it was an issue that concerned us a lot as well.

One of the things that we have done over the course of the last year is to look at all the different ways that we get input regarding medical devices, and I think what we found is that we get input from a lot of different sources. We get input from patient reports. We get input from inspections. We get input from reports that manufacturers are required to submit as part of their routine postmarket reporting, especially on PMA devices. I think one of the things that we have found is that it is very difficult sometimes to, what I call, connect the dots and to be able to put together the information, the patient report information, the inspectional information, and the updated manufacturing information.

Mr. WAXMAN. Notwithstanding that, obviously you have to connect the dots before you do something, but I guess one of the sources of information is reading the newspaper because they seemed to come up with a story that connected the story in advance of the FDA.

I wonder if this is part of the problem. FDA's enforcement actions have declined under the Bush administration. In fact, your Center on Devices had the greatest drop with 65 percent fewer warning letters in 2005 than in 2000. How can you explain such a sharp dropoff in enforcement during a time of increasing problems in devices such as implantable pacemakers and defibrillators?

Dr. SCHULTZ. Well, I am not sure that, I am not sure I would characterize it as increasing problems, and in terms of the 65 percent number, I don't have that number in front of me, but I certainly would take you, that that is, in fact, the number. I think that one of the things that we have been asked to do is to make sure that the warning letters that we do send out are consistent and are reviewed at higher levels to make sure that they are, in fact, consistent so that we are not sending warning letters to some companies as opposed to other companies.

Other than that, I can tell you that the people that I work with and the people that are in my center are constantly looking at problems related to manufacturing and submitting appropriate, what I consider to be appropriate action items to deal with those problems. Sometimes they are warning letters. Sometimes they may be so-called untitled letters where we feel that some of those corrections can be made in other ways. Sometimes they are injunctions. Sometimes they are seizures.

Mr. WAXMAN. Have you ever had your staff recommend enforcement action and then send it up to other higher levels than the FDA and have it turned it down?

Dr. SCHULTZ. I am sure that there are instances where warning letters have gone through different layers of review and have not gone forward. I can't tell you specifically.

Mr. WAXMAN. Maybe you can get us some information for the record.

Dr. SCHULTZ. We can do that. We can do that.

Mr. WAXMAN. MDUFMA required FDA to develop a list of reprocessed devices for which companies would be required to submit supplemental validation data. Can you walk us through the process FDA used to select the devices on that list?

Dr. SCHULTZ. Sure; basically, we used sort of a dual approach. One was using the so-called Spaulding criteria where we looked at the inherent risk of that particular type of device in terms of what part of the body it came in contact with. Under those criteria, there are certain types of devices that touch normally sterile parts of the body, for instance, the inside of the abdominal cavity or the chest cavity; there are other what is called semi-critical devices which touch mucosal surfaces such as the inside of the gastrointestinal tract or the inside of the respiratory tract; and then there are low risk devices which basically come in contact with intact skin.

So we looked at that. We sort of used that as a starting point, and then we also looked at the device itself. There are some devices that are relatively simple and straightforward in terms of how they could be cleaned and how they could be sterilized, and we tried to gauge the complexity of the device and how difficult it would be to reprocess in conjunction with the criticality of how the device was being used.

So we combined those two sets of criteria and came up with a list of what we thought were the most important, the most urgent to regulate, and then sort of worked our way down from there.

Mr. WAXMAN. Thank you.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you.

Mrs. Schmidt.

Mrs. SCHMIDT. Thank you, Mr. Chairman. I have a few questions.

I think the first and the most basic that I have is I have a little trouble with if something is designed for single use, how can it be reprocessed too for dual use?

Let me give you an analogy. In auto racing, there is a difference between drag cars and cars that go around and around on a track. Drag cars' engines are built for a single use, a single time, and then they get rebuilt. They are not built to go more than once. If these devices are being built to go one time, how can they be reprocessed and be safe?

Dr. SCHULTZ. OK; I am not an expert on car racing, but what I would tell you is when we look at any product, whether it be a reprocessed product or a non-reprocessed product, we don't make a decision sort of before the fact as to whether or not that particular product can or can't be used in that particular manner. What we do is we say, OK, you want to do this. You want to label your product to be used in such a way. You must provide us with the data that shows that, in fact, that can happen safely and effectively.

You are right; I think in some cases, there are single-use devices that cannot and should not be reprocessed. But what we have found in terms of our own review process, not what somebody tells us or doesn't tell us but in terms of our own review process is that, in fact, some devices—again, I tried to be careful in my testimony that certain devices, we believe, can be reprocessed safely and ef-

fectively—that some devices, in fact, can be used more than once if they are properly reprocessed. And we clear those devices if, and only if, the manufacturer, in this case, reprocessor, provides us with data to demonstrate that is, in fact, the case and they have to tell us, in fact, how often the device can be reprocessed safely.

Mrs. SCHMIDT. Mr. Chairman, may I have two more questions?

Chairman TOM DAVIS. Yes, go ahead.

Mrs. SCHMIDT. Thank you.

The second one I have is on the labeling of the devices.

Dr. SCHULTZ. Right.

Mrs. SCHMIDT. Last winter, I had the opportunity to actually review some of these devices, and it would be very, very hard for anyone including a physician to figure out whether the device was new or reprocessed because, in some cases, there is just a little teeny dot on the instrument to note that it is a reprocessed instrument.

Dr. SCHULTZ. Right.

Mrs. SCHMIDT. What kind of labeling do you have in place?

Dr. SCHULTZ. The new statute with regards to device labeling, as was mentioned in some of the opening comments, went into effect on August 6th. I think there was a recognition by Congress that there needed to be a clearer designation of those devices that are reprocessed versus those devices that are, in fact, being used for the first time, and that was something that needed to be done. That was part of the MDUFSA legislation, and that legislation went into effect as of August of this year. So, in terms of what was done, I can tell you that we did, in fact, that those requirements did go into effect. In terms of the outcome, what effect, and how successful that will be in terms of alleviating some of the concerns that you have heard, I think we will have to just wait and see what happens.

Mrs. SCHMIDT. A followup, sir; what kind of label? What does this label look like that is one of these devices now?

Dr. SCHULTZ. It really depends on the device itself. This is a problem with labeling in general. Some devices can have relatively large, prominent labels if they are large devices. Some devices, the labeling is, by definition, based on the size of the device, fairly small. In those cases, there are exceptions where the label can actually be an attachment to the device as opposed to actually being imbedded in the device itself.

So, again, I think what we are trying to do is take sort of a common sense approach to this to make sure that the labeling actually is legible and is of a size that people can actually see it and understand who the device manufacturer is for that particular device.

Mrs. SCHMIDT. One final question, if I may; you said in your testimony that there is a savings aspect to this. Can you give me an indication of what the cost savings to reuse the device per procedure?

Dr. SCHULTZ. I think what I said was that in our talking to the user hospitals, that they expressed a benefit in terms of cost savings. We, at FDA, do not look at cost as one of our criteria regarding whether we clear or don't clear devices for market. We simply look at whether the device meets the criteria for safety and effectiveness.

Mrs. SCHMIDT. Thank you, sir.

Chairman TOM DAVIS. Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman, and thank you for holding this hearing.

Dr. Schultz, do you think that the patient has the right to know that this is being reused or that they have the right to refuse the treatment with the reprocessed if they know it? What is your position on that?

Dr. SCHULTZ. Well, in terms of our authority, we clear devices based on the data that is provided to us, and once a device is clear for marketing, it is designated as a legally marketed product. So we don't discriminate between devices that are reprocessed versus those that are not reprocessed, just as if we don't discriminate between various models and various different product types.

So I guess I am not trying to avoid your question. I think it is a good question.

Mr. TOWNS. You are not answering it; you know that.

Dr. SCHULTZ. Well, I guess what I am saying is that my best understanding, is that our authority does not extend to deciding whether or not patients should be informed about reprocessing or lack of reprocessing. Our authority is to make sure that the devices, in fact, are as safe and effective as the original devices.

Mr. TOWNS. The testimony here is very conflicting, of course. Do you feel that maybe an independent group should analyze and evaluate this because when you listen or read the testimony here, one person is saying it is great, it is no problem, and another is saying it is not. Do you think that maybe we should have some independent person to evaluate all of this?

Dr. SCHULTZ. Congressman, if I may, I would like to believe that we do, in fact, function as that independent person because frankly whether or not a device is reprocessed or whether it is an original device, I and my staff have one concern and one concern only, which is will that device perform as intended and will it provide a benefit to the patient in whom it is being used. So I can't speak to whether there ought to be another independent body looking at these questions, but I can tell you that is how we look at that.

Mr. TOWNS. The question is: Do all hospitals report to you and indicate to you that there is a problem, if there is one, all hospitals?

Dr. SCHULTZ. All hospitals are required to report problems, and that, as I mentioned, that is under the passive reporting system that we have, the so-called MDR system. In addition to that, I mentioned that we actually, on our own initiative, instituted a survey of some of our MedSun facilities to try to get a better handle on just the kind of question that you are asking. Are there concerns? What are the concerns? Do people think that this is a good process, a bad process?

Again, the responses were mixed. The responses, basically, people said no matter what the evidence shows or doesn't show, they do not believe that they should be using reprocessed devices. Even within hospitals, what we found was that there were some doctors, some parts of the hospitals, some, whether it is G.I. or cardiac may decide we will or won't allow the use of reprocessed devices. So there was a fair amount of variability.

What, again, was a clear message to us was we had a responsibility to clearly identify those devices that have gone through our review process and let the hospitals know which ones have gone through the review process, which ones haven't, and inform them so that they can make up their own minds.

Mr. TOWNS. Let me ask were you able to identify which types of hospitals traditionally use the reprocessed? Is it rural hospitals, inner city hospitals? Were you able to establish a pattern as to who would use this the most?

Dr. SCHULTZ. To the best of my knowledge, we haven't done that kind of analysis. My impression was, in participating in some of those focus group discussions, that they were hospitals of various sizes and various locations and, in fact, the MedSun program is designed specifically to include different size and different locality types of facilities. But I don't have a specific answer to your question.

Mr. TOWNS. Let me just raise, Mr. Chairman, one more question.

Chairman TOM DAVIS. Sure.

Mr. TOWNS. I think it was raised earlier on the other end.

Do you think it is appropriate for the FDA to approve a device as a single-use device and then turn around and approve the same device after reprocessing? Should new standards or regulations be put into place to set a standard for what is labeled as approved for a single use?

In other words, I just sort of have a little problem with that. If you approve it as a single-use and then you come back, don't you feel uncomfortable with that process?

Dr. SCHULTZ. I feel that we need to look at these devices individually. As I said before, some of these devices, in fact, are labeled for single-use and cannot and should not be reprocessed. Others that have gone through our full evaluation process, and if you are interested, I can provide you some examples of what that evaluation is actually like because that may be sort of helpful in terms of understanding the kind of rigor that goes into those evaluations. I have confidence based on what I know our reviewers are doing and what kind of requirements they are setting up, that those devices that go through our full review process and full inspectional process are, in fact, going to perform as intended.

Mr. TOWNS. With permission of the chairman, I would appreciate it if he would submit that.

Chairman TOM DAVIS. OK; if you could try to get that to us, that would be helpful.

Dr. SCHULTZ. The specific example; sure.

Mr. TOWNS. OK; thank you very much.

Chairman TOM DAVIS. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Dr. Schultz, thank you for your testimony. It has been very enlightening.

I just want to go back. Who usually makes the application, a reprocessing company?

Dr. SCHULTZ. Yes, yes.

Mr. CUMMINGS. Basically, other than a hospital perhaps reporting something to you, that is how these things come to issue, is that right? In other words, is there any other way?

The reprocessing company says we think this is something that can be reprocessed. You hear about a problem from a medical establishment.

Dr. SCHULTZ. Correct.

Mr. CUMMINGS. Is there any other way that it would come to your attention?

Dr. SCHULTZ. We hear about problems from the reprocessors who get reported back to them, from other parties who get reports submitted to them, and from individual hospitals and practitioners.

Mr. CUMMINGS. Let us rewind.

Dr. SCHULTZ. Yes.

Mr. CUMMINGS. So, in other words, you may approve a device for reprocessing.

Dr. SCHULTZ. Correct.

Mr. CUMMINGS. The reprocessor then discovers that someone is having a problem with the device.

Dr. SCHULTZ. Correct.

Mr. CUMMINGS. The reprocessor then has a duty to notify you.

Dr. SCHULTZ. That is correct.

Mr. CUMMINGS. When the reprocessor notifies you, what happens then?

Dr. SCHULTZ. We look at those reports, decide if there is a pattern, like we do with other adverse event reports, and then take appropriate action if, in fact, we see a pattern where a particular type of device is causing a particular type of problem.

Mr. CUMMINGS. Have we seen that happen?

Dr. SCHULTZ. We haven't.

Mr. CUMMINGS. We have not yet.

Dr. SCHULTZ. That is, part of the dilemma is that, again, we see a lot of reports. I mentioned we have seen over 400 reports of reprocessed devices. We see about 200,000 reports of all devices. And thus far, thus far—and we continue to look—thus far, we have not seen a specific pattern that would require us to take a certain action.

Mr. CUMMINGS. Now, let me ask you this. You said something that I found very, very enlightening and interesting. You said one of the things that you are most concerned about is making sure that the reprocessed device—I am not trying to put words in your mouth, so correct me—is just as good as or just as safe as the original, is that correct?

Dr. SCHULTZ. That is correct.

Mr. CUMMINGS. Now, it is my understanding that you had 6,500 deaths associated with not reprocessed but original devices, is that correct, over the last few years?

Dr. SCHULTZ. That is the number that I heard quoted. I would have to go back and confirm that, but that is the number that I heard quoted.

Mr. CUMMINGS. Well, would you say there are thousands?

Dr. SCHULTZ. Again, you know, one of the things when we talk about deaths associated with devices, I think we have to be extremely careful, just as when we talk about deaths and adverse events associated with reprocessed devices. I think the same holds true, in general, about looking at those reports critically to see whether or not the incident in which a device was used was actu-

ally, the problem was actually caused by the device or not caused by the device. Again, I don't mean to sort of over-complicate this, but I——

Mr. CUMMINGS. Doctor, you are not over-complicating. I understand it. I used to practice medical malpractice, so I understand.

Dr. SCHULTZ. OK.

Mr. CUMMINGS. There are all kinds of reasons.

Dr. SCHULTZ. Correct.

Mr. CUMMINGS. When you are talking about the human body, this very strong but very delicate machine, almost anything can happen. So it is hard sometimes—I understand what you are saying—to actually pinpoint something to the machine, I mean to the device.

Dr. SCHULTZ. That is correct.

Mr. CUMMINGS. All right.

Let us go back very quickly and just talk about the criteria. Once you get that application, what is the criteria? Is it strength?

I know you talked about the different parts of the body that it might touch. Tell me about how that—I see my time is running out—or which part of the body it touches. I want you to talk about strength of the instrument or whatever. I want you to talk about exactly what goes into the process.

And one last thing, is there a situation where something may be approved to, say, use it three times? Then the reprocessor says, look, I can do something to this, and you will be able to use it 10 times.

Can you just incorporate that all in your answer, please?

Dr. SCHULTZ. Let me try to work backward so that I try to cover all those. In terms of the number of times, again, the reprocessor has the option of defining how many times they believe the device can be safely reprocessed. When we do our review, we look at that number that they are proposing, and we ask a very simple question. Do you have the data to support the claim that you are making in terms of how many times that device can be used?

That means that during the review process, we require that testing be done to show that the device can be used, cleaned, sterilized if necessary, and that appropriate functional testing—strength testing, bend testing, whatever type of mechanical testing our engineers tell us is appropriate for that particular use—that testing, in fact, either confirmed or didn't confirm that number of uses is appropriate. Then we will go back to the manufacturer and say, you have shown us or you haven't shown us that, in fact, that device can be used that many times.

Your other question, I think was describe sort of how the review process is done. That would take a little bit longer, but let me say that, in general, we use the same set of criteria that we use for any other device, which is that we focus on those aspects of the device that relate to the way in which the device is being used. So if we are talking about a biopsy forceps, we will be looking very, very carefully at how the jaws open and close. Is it still able to capture the amount of tissue that is necessary to make a diagnosis? Is it able to bend around whatever curves it needs to bend around to get to the location that it needs to get to in order to perform optimally?

Those would be the kinds of questions in addition to: Can it be cleaned, can it be disinfected in order to be able to be used safely?

I don't know if that answers your question.

Mr. CUMMINGS. Thank you very much.

Chairman TOM DAVIS. Thank you.

Has FDA ever been able to establish a clear causal link between reprocessed devices and subsequent adverse health effects?

Dr. SCHULTZ. In general terms?

Chairman TOM DAVIS. In general.

Dr. SCHULTZ. No.

Chairman TOM DAVIS. MedWatch is the adverse event monitoring system, do you think it works well or do you think it is too passive or insensitive to capture the subtle trends?

Dr. SCHULTZ. I think it is. I think the short answer to your question, Mr. Chairman, is that we are looking very hard at the MedWatch system right now for reprocessing in particular as well as in general to see what MedWatch does well and what it doesn't do well. And I will tell you that MedWatch has been extremely useful in terms of allowing us to pick up signals. It has not been that useful in terms of helping us to analyze those signals and actually come to answer the kind of question you are asking, which is why.

You gave us the MedSun program in 1995, I believe, in FDAMA, that allowed us to have a more active system where we can actually go out and ask questions and try to get specific data from various hospitals.

I think that the MedWatch system, it needs to be improved. We need to do some updating in terms of getting electronic reports is one thing that I think would be extremely helpful, which would hopefully make the reports a little more consistent and also allow us to input those reports more quickly. But I think that we need to be realistic in terms of what a passive surveillance system can provide and what needs to be provided through a more active surveillance system or through ongoing studies.

Chairman TOM DAVIS. In its written testimony, AdvaMed describes two adverse events reports that relate to FDA in 2004. These reports involve malfunction of a reprocessed heart positioner and a reprocessed endoscopic vein harvester. Did the FDA act on these reports?

Dr. SCHULTZ. The heart positioner, that question came up as to whether or not that particular type of device should fall under the unexempt provision and whether we should be regulating those. Subsequent to that, we did, in fact, include that type of device as part of the review process which, again, required the additional validation data.

I can't give you a specific answer for the other one, but I certainly will go back and look at it.

Chairman TOM DAVIS. If you can go back and check.

Dr. SCHULTZ. Yes, sir.

Chairman TOM DAVIS. FDA, were they able to establish a causal link between the reprocessing and the adverse health effect in that?

Dr. SCHULTZ. I don't; again, the information that I got was from the MDR reports and is what I gave you.

Chairman TOM DAVIS. Well, let me ask you this. Does FDA require tracking procedures or are the reprocessing companies required to develop those procedures as part of its validation of data requirements?

Dr. SCHULTZ. Could you be more specific when you talk about tracking?

Chairman TOM DAVIS. You track the device. You track individual devices.

Dr. SCHULTZ. These; my best understanding, and I am going to go back and confirm this, is these do not fall under what we normally consider to be tracked devices which are usually things like pacemakers and other sort of immediately lifesaving, sustaining devices.

Chairman TOM DAVIS. Well, then what happens when a device is recalled by an original device manufacturer? Does the FDA ensure that reprocessed devices are withdrawn from the market, or is it hard to track?

Dr. SCHULTZ. Yes, I mean these devices are considered individually.

Chairman TOM DAVIS. Some are and some aren't is basically the answer. I guess that is where the debate lies.

Dr. SCHULTZ. I am sorry?

Chairman TOM DAVIS. I guess that is where the debate is, reuse, where it can be dangerous and where it can't, and what should be tracked and what shouldn't and how we get into this.

Thank you very much.

I think we will take a 2-minute recess while we move our next panel up.

Doctor, thank you. You owe us a couple answers, but I appreciate your patience.

Dr. SCHULTZ. Thank you very much.

[Recess.]

Chairman TOM DAVIS. The hearing will reconvene.

We are going to now move to our second panel. We have Mr. Don Selvey, the senior vice president of Ascent Healthcare Solutions; Dennis Toussaint, the director of regulatory affairs, SterilMed; and Stephen Ubl, the president and CEO of Advanced Medical Technology Association.

It is our policy that we swear you in.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you.

Please be seated. I think you know the rules.

Mr. Selvey, we will start with you, and we will move straight on down and then try to get to questions. Again, your entire statement is in the record. With most of your statements, we think we know where we want to go on this, so you can keep it within 5. If you really want or if you need extra time, take it, but I would like to keep them within 5 minutes, if we can, and then we will move on to questions. Thanks for being with us.

STATEMENTS OF DON SELVEY, SENIOR VICE PRESIDENT, REGULATORY AFFAIRS AND QUALITY ASSURANCE, ASCENT HEALTHCARE SOLUTIONS, INC.; DENNIS J. TOUSSAINT, DIRECTOR, REGULATORY AFFAIRS, STERILMED, INC.; AND STEPHEN J. UBL, PRESIDENT AND CEO, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

STATEMENT OF DON SELVEY

Mr. SELVEY. Thank you, Mr. Chairman, members of the committee.

I am Don Selvey, the senior vice president for regulatory affairs and quality assurance at Ascent Healthcare Solutions, the Nation's largest reprocessor of single-use medical devices. Although I have more than 16 years experience in the medical device industry, I am an epidemiologist by training. Prior to my service in the medical device industry, I spent over a decade as a public health professional in Arizona, originally as a registered sanitarian and then as head of Infectious Disease/Epidemiology and later as Head of the Environmental Epidemiology program.

Ascent Healthcare Soultions, headquartered in Phoenix, AZ, employs 800 persons throughout the country. Our customer base consists of approximately 1,600 hospital and surgery centers in the United States, including most of those facilities annually recognized by the U.S. News and World Report as the top hospitals in America.

We only reprocess low or moderate risk medical devices such as compression sleeves, electrophysiology catheters, and orthopedic tools. We do not reprocess high risk medical devices such as implantables or devices which come into contact with the central nervous system or the brain. In fact, we estimate that we are able to reprocess only 1 to 2 percent of devices labeled for single use.

The emergence of reprocessing in the United States is rooted in the meaning of the single-use label itself. Contrary to what one might think, the single-use label is not an FDA requirement. In fact, FDA does not require any device to carry a single-use label. Instead, single-use is a designation the original equipment manufacturer [OEM], chooses, and that choice is sometimes made in an effort to sell more devices, not for patient safety reasons. The truth is that a manufacturer could label an operating table as being for single use if the OEM believed it could persuade a hospital to throw the table out after one use.

To show you some of these single-use devices, I brought along some external fixation devices and some surgical tools. This, for example, is a clamp. This is a clamp. We are happy to pass those around, if you like. Here is a surgical saw blade made of stainless steel. These are the types of single-use devices we are talking about.

Chairman TOM DAVIS. I am going to let somebody bring these up, and we will pass them around.

Mr. SELVEY. About two decades ago, some OEMs began to change the label on certain medical devices from reusable to single-use, in some cases, without any significant structural changes in the device that would preclude safe reuse. With this change in labeling, it became evident to many hospitals that the single-use label does

not necessarily mean only single use and that certain devices designated by the original manufacturer as single-use can, in fact, be safely reprocessed. Further evidence that the single-use label does not always mean a device can only be used one time is the fact that some original manufacturers reprocess their own single-use devices. In fact, some manufacturers partner with third parties to reprocess devices that manufacturer has labeled as single-use.

Today, reprocessing of devices originally labeled for single-use is standard practice in the Nation's top hospitals. Hospitals simply cannot afford to throw out devices that can be safely reprocessed. These dollars are better spent on purchasing new medical technology and preserving nursing staff. The savings generated by reprocessing can be significant. A 2000 GAO report found that for one device alone, the electrophysiology catheter, individual hospitals are saving between $200,000 and $1 million annually as a result of reprocessing.

As the reprocessing industry has grown, so too has the strident opposition from the original manufacturers who see reprocessing as an increasing economic threat. The threat is two-fold. First, reprocessed devices are, on average, about half the cost of the original devices. Therefore, many hospitals choose to use reprocessed devices rather than purchase new ones. This means lower sales for original device manufacturers. Second, the very existence of reprocessing has resulted in a decrease in the price of certain new devices. Lower prices mean lower prices.

Ascent hopes that this hearing today will make clear that the third party reprocessing in the United States is safe and that it is highly regulated. In fact, reprocessors are more stringently regulated than the original equipment industry. Specifically, reprocessors are required to submit validation data in our pre-market submission while the manufacturers have no such requirement. Second, certain devices that require pre-market submission for the reprocess device have no requirement for the original version of that device. And third, unlike OEMs, we reprocessors are required to place an identifying mark on the device itself, not simply on the label.

Reprocessors provide a valuable service to this country's hospitals, a service that helps hospitals survive in an era of spiraling healthcare costs. Additional regulation at either the Federal or State level is not only unnecessary but also, because it would limit the ability of hospitals to use reprocessed devices, would do a disservice to America's hospitals and patients.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Selvey follows:]

**TESTIMONY OF ASCENT HEALTHCARE SOLUTIONS, INC.
BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM
SEPTEMBER 26, 2006**

I. Introduction

I am Don Selvey, the Senior Vice President for Regulatory Affairs and Quality Assurance at Ascent Healthcare Solutions ("Ascent"), the nation's largest reprocessor of "single use" medical devices. I have been employed with Ascent since September, 1999. I am responsible for all aspects of regulatory submissions, regulatory compliance, and quality assurance. For approximately four years, I was also responsible for Research and Development — that is, the development of the methods and processes used to clean, test and sterilize single use devices.

Prior to joining Ascent, then known as Alliance Medical Corporation, I worked for six years with MiniMed Inc., a manufacturer of external and implantable insulin pumps, continuous glucose monitoring systems, infusion sets and other diabetes care equipment. At MiniMed my responsibilities included domestic and international Regulatory Affairs and Clinical Research. Subsequently, MiniMed was acquired by Medtronic, Inc. and now operates as a wholly-owned subsidiary of Medtronic.

Before joining MiniMed, I was with W.L. Gore and Associates, the manufacturer of Gore-Tex® materials. I worked in the Medical Devices division, and had responsibility for certain aspects of R&D and Regulatory Affairs.

For over a decade before moving into the medical device industry, I was a public health professional in Arizona. Initially, I conducted inspections and investigations as a Registered Sanitarian, then trained through the Centers for Disease Control to become an epidemiologist. I was first an Infectious Disease Epidemiologist, then head of an Infectious Disease unit, then later headed the Environmental Epidemiology program. As an epidemiologist, I have authored or co-authored papers published in several medical journals, including the Journal of the American Medical Association and the Journal of Toxicology.

I hold undergraduate and graduate degrees in biology and physiology, respectively, from Arizona State University. I have been privileged to have received adjunct faculty appointments at Arizona State University, where I taught undergraduate and graduate courses in Public Health, and at Coconino College in Arizona, where I taught Microbiology.

Ascent Healthcare Solutions was formed in December, 2005 as the result of a merger between Alliance Medical Corporation, based in Phoenix, Arizona and Vanguard Medical Concepts, based in Lakeland, Florida.[1] The company is headquartered in

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[1] The former Alliance Medical Corporation was formed in 1998, as the result of a merger of two small, specialized medical device reprocessors -- Applied Medical Technologies, based in Utah, and Operating Room Recovery and Instrument Services (ORRIS), based in Houston, Texas. Between 1998 and 2005, Alliance acquired a

Phoenix, Arizona, although the former Vanguard facility in Lakeland remains in operation. Ascent employs approximately 800 persons throughout the country. Our customer base consists of approximately 1,600 hospitals and surgery centers in the U.S., including most of those medical facilities annually recognized by *U.S. News and World Report* as the top hospitals in America.

II. History of Reprocessing in the United States

The emergence of reprocessing in the United States is rooted in the meaning of the "single use" label itself. Contrary to what one might think, the "single use" label is not an FDA requirement. In fact, FDA does not require any device to carry a single use label. Instead, "single use" is a designation that the original equipment manufacturer (OEM) chooses, and that choice is sometimes made in an effort to sell more devices, not for patient safety reasons. The truth is that a manufacturer could label an operating table as being intended for "single use," if the OEM believed it could persuade a hospital to throw the table out after one use.

It is the fact that the OEM, rather than FDA, makes the decision about whether a device will be labeled for single use, that really accounts for the emergence of the reprocessing of devices labeled for single use. Approximately two decades ago, some OEMs began to change the label on certain medical devices from "reusable" to "single use" — in some cases without any significant structural changes in the devices that would preclude safe reuse.[2]

With this change in labeling, it became evident to many hospitals that the "single use" label does not necessarily mean "single use," and that certain devices designated by the original manufacturer as "single use" can, in fact, be safely reprocessed. Hospital skepticism of the single use label was noted in a 2000 study of reprocessing conducted by the Government Accountability Office (GAO).[3] The GAO found that health care personnel "distrust the single-use label for some devices because [among other things] . . . FDA cannot require manufacturers to support the designation of a device as single-use," and because "they perceive that manufacturers have an economic incentive to market

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succession of smaller reprocessors. Vanguard Medical Concepts was formed in 1991 to reprocess surgical kits and packs that had been opened in the Operating Room, but not used. In time, the business opportunity expanded to include a much broader array of devices. In 2002, Vanguard acquired Medical Instrument Technologies (MIT), which was based in Utah.

[2] For example, in a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products explained that, although it was changing the label on its intracardiac electrodes from "reusable" to "single use," "our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past." Letter from Product Manager, USCI Cardiology & Radiology Products (July 24, 1980).

devices as single-use that could just as well be sold as reusable."[4] Further evidence that the "single use" label does not always mean "single use" is the fact that some OEMs offer reprocessing services to hospitals for the OEM's own "single use" devices.[5] In fact, some OEMs partner with third-party reprocessors to reprocess devices that the OEM itself has labeled as "single use."[6]

The reality of the single use label has led to a predictable result. Reprocessing of devices originally labeled for single use has been standard practice in the nation's hospitals for over two decades. As a practical matter, hospitals simply cannot afford to throw out devices that can be safely reprocessed. These are dollars that are better spent on purchasing new medical technology and preserving nursing staff. The savings generated by reprocessing are significant, because a reprocessed device costs approximately one-half the price of an original device. The GAO study mentioned above found that for one device alone — a product called the electrophysiology catheter — individual hospitals are saving between $200,000 and $1 million annually as a result of reprocessing.[7]

As the reprocessing industry has grown, so, too, has the strident opposition to the practice from OEMs, who see reprocessing as an increasing economic threat. The threat is two-fold. First, reprocessed devices are, on average, half the cost of original devices. Therefore, many hospitals choose to use reprocessed devices rather than purchase new ones. This means lower sales for original device manufacturers. Second, the very

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[3] United States General Accounting Office Report entitled *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* 3 (June 2000) [hereinafter *GAO Report*].

[4] *Id.*

[5] *See* "OEM Moves Into Reprocessing," Medical Design Technology, March 1, 2006, explaining, "Orthopedic firm Synthes is offering hospitals the option to reprocess used external fixation devices as part of a new reprocessing program. The U.S. division of the Swiss firm is reprocessing over a dozen of its fixation devices, including single use devices such as its 'combination clamp' and 'tube to tube clamps,' according to a marketing document." *See also, Synthes, External Fixation Reprocessing Program*, Corporate Marketing Material, Synthes USA 2004. *See also*, FDA 510(k) clearance K033158, "Synthes (USA) Synthes Reprocessed External Fixation Devices," cleared by FDA on November 5, 2003.

[6] *See* "Nellcor and Alliance Medical Announce First-of-its-Kind Co-Marketing," Infection Control Today (April 8, 2003).

[7] GAO Report, *supra* note 3, at 19.

existence of reprocessing has resulted in a decrease in the price of certain new devices.[8] Lower prices typically mean lower profits.

Beginning in the late 1990s, therefore, certain OEMs began to put intense pressure on federal and state government to ban or restrict reprocessing. As their rationale, these OEMs have argued (contrary to all available evidence) that reprocessing puts the public health at risk. And the pressure that OEMs have placed on legislators and regulators has resulted in a period of intense scrutiny of reprocessing, which continues today. Faced with the economic threat posed by reprocessing, these OEMs have engaged in a concerted effort to achieve the enactment of legislation and regulation (on the federal and state levels) that would effectively eliminate the third-party reprocessing industry.[9] *See* Exhibit A. Although the regulatory scrutiny of the industry has, in fact, been intensified in the last six years, and regulatory requirements have grown significantly more stringent, the industry has nevertheless consistently been able to meet the new regulatory requirements and, indeed, has flourished.

Ascent hopes that its testimony today will make clear that the third-party reprocessing industry in the United States is safe, that it is highly regulated — more stringently regulated than the original equipment industry — and that it is providing a valuable service to this country's hospitals, a service that helps hospitals survive and thrive in a time of severe cost containment pressures. Additional regulation at either the federal or state level is not only unnecessary but also, to the extent it would limit the ability of hospitals to use reprocessed devices, would do a disservice to America's hospitals and patients.

III. FDA Regulation of Reprocessed Devices

In order to evaluate the adequacy of the federal regulatory scheme governing reprocessed devices, it is necessary to understand how the FDA regulatory framework governing reprocessing has evolved, and how it is that, today, reprocessors are more stringently regulated than original device manufacturers.

A. Pre-2000 Regulatory Scheme

Prior to August 2000, FDA regulated third-party reprocessors in the same way that it regulates OEMs, with the only exception being that reprocessors were not subject to premarket review requirements. As medical device "manufacturers," however, reprocessors *were* subject to FDA's establishment registration and medical device listing

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[8] In studying this issue, the GAO found that, because of the competitive alternative presented by reprocessing, manufacturers have lowered their prices in exchange for a hospital's commitment not to reprocess. *Id.*

[9] *See* Exhibit A.

requirements,[10] medical device reporting requirements,[11] the reports of corrections and removal requirements,[12] quality system regulation ("QSR") requirements,[13] and labeling requirements.[14] Reprocessing that took place inside hospitals, however, was not regulated by FDA as a device manufacturing activity.

B. August 2000 Guidance Document

On August 14, 2000, FDA issued a document entitled, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." In that document, FDA announced a significant increase in its regulatory oversight of reprocessing. First, third-party reprocessors became subject to premarket review requirements in addition to all of the other post-market manufacturer controls with which they already had to comply. As a result, today, reprocessors, like OEMs, are required to submit premarket notifications (510(k)) for the Class I and Class II devices that they reprocess, unless those devices are by regulation exempt from this requirement. The elements of a 510(k) submission for a reprocessed device include the following:

- information on the company submitting the 510(k);
- a summary of the information presented in the submission;
- a complete description of the device that is the subject of the submission;
- all pre-production validation data related to cleaning, testing, packaging, and sterilization, including mechanical testing data, electrical testing data, cleaning validation data, sterilization validations, and packaging validations;
- an analysis of the risks related to reprocessing the device (identification of the risks; determination of the likelihood of each risk occurring; and steps taken by the reprocessor to mitigate each risk);

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10 21 U.S.C. § 360; 21 C.F.R. Part 807, subpart B.

11 21 U.S.C. § 360i(a); 21 C.F.R. Part 803.

12 21 U.S.C. § 360i(f); 21 C.F.R. Part 806.

13 21 U.S.C. § 360j(f); 21 C.F.R. Part 820.

14 21 U.S.C. §352; 21 C.F.R. Part 801.

- biocompatibility analyses (laboratory-based determinations of the potential that the reprocessing method, residuals, etc. may cause a cellular reaction);
- labeling, including the product labels and instructions for use;
- a comprehensive comparison of the original and reprocessed devices; and
- a certification that all information in the submission is complete, truthful and accurate.

A 510(k) submission for a reprocessed device may contain thousands of pages of information, cost between $50,000 and $250,000 to develop, and may take more than a year to complete.

The second significant change that came about in 2000 was that FDA began to regulate hospitals that perform their own reprocessing as device manufacturers and subjected them to the full range of FDA device manufacturer requirements. Therefore, the "bottom line" was that reprocessing of single use devices — whether performed by a commercial firm or a hospital — would be viewed by FDA as a device manufacturing activity and would be subject to the same regulatory requirements as original equipment manufacturing.

The reprocessing industry did not fade away as a result of the new premarket submission requirements. Rather, the industry was able to comply with the new requirements, and many hospitals that had previously reprocessed their devices in-house began to send them to third-party reprocessors, rather than trying to comply with FDA's device manufacturing requirements.

While FDA's 2000 initiatives "leveled the playing field" by requiring reprocessors and OEMs to comply with the same regulatory requirements, subsequent legislation imposed new regulatory obligations on reprocessors. As a result, as described below, reprocessors are now more stringently regulated than OEMs.

C. The Medical Device User Fee And Modernization Act of 2002

First, in 2002, the Medical Device User Fee and Modernization Act (MDUFMA) imposed additional premarket review and labeling requirements on reprocessors.[15] MDUFMA's most significant provisions required reprocessors to submit extensive validation data as part of their premarket notification submissions for certain reprocessed devices — data that OEMs are not required to submit on a premarket basis. In addition,

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[15] Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588 (codified as amended in scattered sections of 21 U.S.C).

pursuant to MDUFMA, the premarket review requirement has been imposed on certain reprocessed devices, even though the non-reprocessed version of the device is exempt from this requirement.

The new validation requirement meant that reprocessors were obligated to submit a large amount of new data for devices that were already legally marketed, and obtain FDA clearance of these "supplemental validation data" submissions ("SVS"), or face having to remove them from the market. Ascent, and the industry, complied with the new requirement, and FDA has completed its review of most of those submissions.

D. The Medical Device User Fee Stabilization Act of 2005

In 2005, Congress included in the Medical Device User Fee Stabilization Act (MDUFSA) a provision requiring reprocessors to place an identifying mark on their devices.[16] A device marking provision had originally been enacted as part of MDUFMA, but at that time it applied to *all* devices, not just reprocessed devices. MDUFSA modified the provision to apply *only* to reprocessors. The reprocessing industry continues to believe that the provision should have been applied to *all* device manufacturers, and believes that there was no public health rationale for applying it only to reprocessors.

IV. Safety of Reprocessed Devices

The safety record for reprocessed medical devices is outstanding. Of the tens of thousands of patient adverse event reports that FDA receives through its Medical Device Reporting (MDR) program, "only a very small percentage" concern reprocessed "single use" devices,[17] and the few problems that have occurred with reprocessed "single use" devices appear to be quite similar to the types of problems associated with new devices.[18] Indeed, in a January, 2006, letter from FDA to Congressmen Tom Davis and Henry Waxman of the House Government Reform Committee, the agency wrote that 65,325 adverse event reports had been filed with the agency since October 2003 for the malfunction or injury associated with the first use of original (*i.e.,* not reprocessed) devices labeled for "single use." The same search produced only 176 cases of apparent

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[16] Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, 119. Stat. 439 (codified as amended in 21 U.S.C. § 352(u)).

[17] GAO Report, *supra* note 3, at 15.

[18] As one example, an MDR report was submitted to FDA concerning a reprocessed EP catheter whose tip had become detached. *See* MDR Report Number 1062310-1999-00001. However, the identical incident also has been reported for new EP catheters. *See* MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. *See also* GAO Report, *supra* note 3, at 16.

malfunction or injury associated with reprocessed devices. Moreover, FDA wrote, "upon analysis of these reports, FDA determined that these adverse events are not related to the reprocessing of the SUD,"[19] and stated expressly that it "did not identify any adverse events that were actually related to the reprocessing of the SUD."[20]

Further, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) medical devices since 2004. According to the same database, no deaths have been associated with the use of reprocessed "single use" medical devices.[21]

A significant body of professional and scientific literature, much of it from peer-reviewed journals, further supports the conclusion that some single use devices can safely be reprocessed.[22] As the GAO observed when it evaluated the safety of reprocessed

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[19] Letter from Patrick Ronan, Associate Commissioner for Legislation, Food and Drug Administration, to Chairman Tom Davis, Committee on Government Reform, House of Representative dated January 23, 2006 (the FDA reports were received between October 22, 2003 and December 13, 2005).

[20] *Id.*

[21] FDA's database of adverse events is available via the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>.

[22] Recent journal articles include the following: N. Ma, A. Petit, O. Huk, L. Yahia, and M.Tabrizian, "Safety Issue of Re-Sterilization of Polyurethane Electrophysiology Catheters: a Cytotoxicity Study," 14 *Journal of Biomaterials Science, Polymer Edition* 213 (2003); T.A. Ischinger, G. Neubauer, R.Ujlaky, H.Schatzl, and M.Bock, "Reuse of 'Single Use' Medical Devices After Quality Assured Reprocessing: Hygenic, Legal and Economic Aspects. Potential for Cost Savings in Interventional Cardiology," 92 *Z. Kardiol.* 889 (November, 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices — Regulatory Roles," 75 *AORN Journal* 98 (July 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices — Regulatory Roles," 75 *AORN Journal* 98 (July 2002); S. Mickelsen, BS, C. Mickelsen, BS, C.MacIndoe, BS, J. Jaramillo, S.Bass, MD, G. West, RN, and F. Kusumoto, MD, "Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States," 87 *The American Journal of Cardiology* 351 (February 1, 2001); C.M. Wilcox, "Methodology of Gastroenterology and Hepatology," 10 *Gastrointestinal Endoscopy Clin N Am* 379 (April 2000); R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., D.J.Patterson, M.D., J.J. Brandabur, M.D, "Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study," 49

devices labeled for single use, the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing can be carried out safely, and patient outcomes are not adversely affected by the use of reprocessed [single use devices].[23]

Because of reprocessing's exemplary record of safety, informed hospitals and physicians support the practice of reprocessing. The GAO interviewed hospital infection control practitioners, risk management executives, and patient safety experts and found that they all reported that careful reprocessing of the types of "single use" devices that are amenable to proper cleaning and sterilization does not pose a risk to patient health.[24]

Indeed, many of the most preeminent physicians in the country have publicly supported reprocessed devices as being safe and effective. For example, Dr. Bruce Lindsay, representing the American College of Cardiology (ACC) and the North American Society of Pacing and Electrophysiology (now the Heart Rhythm Society), testified before the House Commerce Committee that

> [t]here are studies, all of which have been published in peer-reviewed scientific medical journals, which have evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed

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Gastrointestinal Endoscopy 39 (January 1999); S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E.Sumida, Ph.D., "In Vitro Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes," 94 *The American Journal of Gastroenterology* 139 (January 1999); Blomstrom, Lundqvist, "The Safety of Reusing Ablation Catheters with Temperature Control and the Need for a Validation Protocol and Guidelines for Reprocessing," 21 *Pacing Clinical Electrophysiology (PACE)* 2558 (December, 1998); M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," 32 *Journal of the American College of Cardiology* 1384 (November 1, 1998).

[23] GAO Report, *supra* note 3, at 13 (internal citations omitted). The report went on, "For example, several studies have documented the safe reprocessing and reuse of EP [electrophysiology] catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers that reused EP catheters and centers that used each catheter only once. A later study of 69 EP catheters used in 336 procedures concluded that carefully reprocessing one model of single-use catheter up to 5 times posed no increase in health risks. Similarly, some evaluations of the reprocessing of single-use endoscopic instruments published in peer-reviewed scientific journals found that those [single use devices] could be reused at least several times without increasing patient risk."

[24] GAO Report, *supra* note 3, at 14.

> catheters is a concern or that the incidence of infection is increased.[25]

Likewise, at a Senate Hearing of the Health, Education, Labor and Pensions Committee, Dr. John Clough, representing the American Hospital Association (AHA), testified that

> [m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled "for single use." The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled "for single use."[26]

In a June 23, 1999 letter to the late Senator Paul Wellstone (D-MN), Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic, discussed the Clinic's 20-year experience with reprocessed electrophysiology catheters and said:

> Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.[27]

In 2002, the Cardiac Electrophysiology Coordinator at Johns Hopkins Hospital, Carol Tunin, Ph.D., wrote of similar experiences with reprocessed catheters. In a memorandum to Rep. John Dingell (D-MI), Dr. Tunin stated that

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[25] Testimony of Bruce Lindsay, M.D., F.A.C.C., Associate Professor of Medicine, Director, Clinical EP Laboratory at Washington University School of Medicine, St. Louis, Missouri on behalf of the ACC and the North American Society of Pacing and Electrophysiology, before the House Commerce Comm., Subcommittee on Oversight and Investigations 5 (Feb. 10, 2000).

[26] Testimony of John Clough, M.D., Chair of Health Affairs, Cleveland Clinic Foundation, Cleveland, Ohio, on behalf of the AHA to the Senate Comm. on Health, Education, Labor and Pensions 3-4 (June 27, 2000).

[27] Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999).

> [t]he *entire* clinical staff of electrophysiology physicians at Johns Hopkins prefer to resterilize catheters. Ablation catheters that deliver therapy are steerable. They can be curved into multiple angles and are used to both determine the site within the heart that is the culprit of some arrhythmias and also to deliver therapy to that location. Every catheter is a bit different no matter what the brand or lot number and consistently perform with their own "character." Some even develop a slight twist or second angle that helps steer the tip onto the muscle tissue, which gives an advantage in trying to locate the source of the arrhythmia. Before resterilization was policed so tightly and the number of reuses was pared down so low, some "misshapen" catheters became favorites in trying to get into the exact position in the heart muscle.[28]

Hospitals take great comfort in the rigorous safety standards adhered to by third-party reprocessors. Indeed, Ascent tests or inspects every reprocessed device before it is sent to a hospital, and we understand this to be the practice of the industry as a whole. This is in contrast to OEMs, who we understand typically test only a small sampling of devices. The result is that some hospitals say they prefer using reprocessed devices over original devices, because they know each reprocessed device has been individually scrutinized.

America's finest medical facilities use reprocessed medical devices, including 13 of the 14 institutions ranked by *U.S. News & World Report* in 2006 as the nation's "Honor Roll" hospitals.[29] These institutions include Massachusetts General Hospital,

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[28] Memorandum from Carol Tunin Ph.D. to Rep. John Dingell (July 12, 2002) (emphasis added). Dr. Tunin also highlighted another clinical advantage of reprocessing: because of the reduced cost of reprocessed catheters, physicians are comfortable that the cost will not be excessive if they try another tool (catheter) to see if it is more compatible with a patient's particular anatomy. Dr. Tunin noted that when pricing became a large factor at Johns Hopkins (due to restrictions on the reuse of catheters), the hospital's staff began to "limit the number of tools they will try and relentlessly persevere with one or two catheters. This often greatly extends the time on the procedure table and increases the frustration level for difficult cases."

[29] According to *U.S. News*, only the top three percent of 5,189 hospitals, 176 in all, are ranked in "one or more of the 16 specialties in this year's 'America's Best Hospitals.' And of those, just 14 qualified for the Honor Roll by ranking at or near the top in at least six specialties—a demonstration of broad expertise." The *U.S. News &World Report*'s hospital ranking can be found on the Internet at http://www.usnews.com/usnews/health/best-hospitals/tophosp.htm.

Brigham and Women's Hospital, the Mayo Clinic, the Cleveland Clinic, and Johns Hopkins University. Additionally, reprocessors serve all ten hospitals considered by *U.S. News & World Report* to be the top ten heart and heart surgery hospitals in the nation, and at least nine of the top ten orthopedic hospitals nationwide.[30]

Reprocessors also serve at least 87 percent of America's top hospitals, as listed by the 12th edition of the Solucient 100 Top Hospitals®: National Benchmarks for Success.[31] Solucient's annual list recognizes U.S. hospitals that demonstrate superior clinical, operational, and financial performance. The primary goal of the Solucient program is to use objective criteria to identify hospitals that provide the best care in the nation, and to make public the benchmark that has been set for hospital performance each year. Based on Solucient's study, reprocessors serve all of the top 25 "teaching hospitals"; at least 14 of the 15 best "major teaching hospitals"; all of the top 20 "large community hospitals"; and at least 17 of the top 20 "medium community hospitals." Overall, the major reprocessors serve 87 of Solucient's 100 Top Hospitals listed for 2004.

In short, America's finest and most respected institutions use reprocessed medical devices. It simply makes no sense to argue, as some have done and continue to do, that these institutions would put their patients at risk in order to save money. To the contrary, these facilities use reprocessed devices because they have studied the issue thoroughly and have determined that reprocessing is both safe and cost-effective.

V. Conclusion

Across the country, hospitals are facing enormous and urgent cost-containment pressures. Hospitals that cannot contain their costs are closing their doors or eliminating services, leaving too many people unserved or underserved. Reprocessing is not single-handedly going to resolve any hospital's financial pressures, but it is part of the answer. As described above, hospitals realize substantial reprocessing-related savings because the cost of a safe and effective reprocessed device is, on average, half of the cost of a new device. In addition, hospitals realize savings from reprocessing because their waste hauling and handling costs are significantly reduced. The 2000 GAO study mentioned above found that hospitals that use reprocessed devices save $200,000 to $1 million annually. To put that figure in context, for a hospital operating on a 2% profit margin, saving $200,000 is equivalent to bringing in $10 million in new revenue. The substantial savings that a hospital realizes from reprocessing can be put into hiring additional nursing staff, purchasing new capital equipment, and other patient care improvements.

Reprocessing also exerts competitive pressure on the marketplace, keeping the price of original equipment down. Biopsy forceps, for example, previously cost hospitals

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30 *Id.*

31 The Solucient study was released February 28, 2005 and is available at http://www.100tophospitals.com/.

approximately $49 per device, but after hospitals began having them reprocessed, the price of the original devices dropped to about $15. These numbers help to clarify why the makers of biopsy forceps and other "single use devices" are so eager to persuade the world that — despite all evidence to the contrary — reprocessing is not safe. The explanation lies in their bottom line: if they are successful in eliminating reprocessing, they will be able to raise the price of those forceps to pre-reprocessing levels.

As described above, reprocessing not only makes economic sense for hospitals, it is also good for the environment. The reprocessing industry helped hospitals divert over 4,000 tons of medical waste from the waste stream in 2005 alone. Reprocessing can play a significant role in meeting the goals of the U.S. Environmental Protection Agency for reducing the health care sector's total waste volume.[32]

In short, reprocessing plays a vital role in our health care system because it is one of the few ways that hospitals can achieve substantial cost savings while maintaining the absolute highest standard of patient care. Ascent respectfully urges the Congress to refrain from imposing additional regulation on this industry. Such regulation is unnecessary and would do nothing to enhance patient safety or improve patient outcomes. Moreover, to the extent it would limit the ability of hospitals to use reprocessed devices, such additional regulation would do a disservice to America's hospitals and patients.

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[32] *See* Memorandum of Understanding Between the AHA and the U.S. Environmental Protection Agency setting forth goals to reduce the impact of health care facilities on the environment.

EXHIBIT A

Examples of OEM Legislative and Regulatory Efforts Aimed at Restricting and/or Eliminating the Third-Party Reprocessing Industry

- In the late 1990's, two device manufacturer trade associations petitioned FDA to regulate reprocessing more stringently or ban it on the grounds that it posed a public health risk. FDA denied both these petitions, stating, among other things, that the agency "has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes."[1] The agency also declared that "there is no clear evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury'" and said that it "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[2]

- In March, 2001, another device manufacturer trade association filed a Citizen Petition with FDA, claiming that reprocessed medical devices are misbranded because, among other things, reprocessors do not always remove OEM trademarks from reprocessed devices.[3] The agency denied the petition in September 2001.[4]

- There has also been significant activity at the state level. In the late 1990's, anti-reprocessing legislation was introduced, but did not ultimately succeed, in Illinois, California, and Maryland.

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[1] Letter from D. Bruce Burlington, M.D., Director CDRH, FDA, to Nancy Singer, Esq., HIMA (now AdvaMed) 2 (July 15, 1998).

[2] Letter from David W. Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry R. Pilot, Esq., Counsel to Medical Device Manufacturers Association (MDMA) 1-2 (Oct. 6, 1999). On October 21, 1999, MDMA petitioned FDA for reconsideration of its decision to deny MDMA's request for a ban on the reprocessing of "single use" devices. *See* Letter from Larry R. Pilot, Esq., to FDA (Oct. 21, 1999). FDA denied MDMA's petition for reconsideration on February 9, 2001. *See* letter from David W. Feigal, Jr., M.D., M.P.H., to Larry R. Pilot, Esq. (Feb. 2, 2001).

[3] Citizen Petition from Thomas Scarlett, Hyman, Phelps and McNamara, P.C., Counsel, Association of Disposable Device Manufacturers, to FDA (March 22, 2001).

[4] Letter from Linda S. Kahan, Deputy Director, CDRH, FDA, to Thomas Scarlett, Hyman, Phelps and McNamara, Counsel to ADDM (Sept. 17, 2001).

- At the urging of OEMs, Utah enacted legislation that requires reprocessors of critical single use medical devices to assume all liability associated with the original manufacturing of the device.[5]

- Legislation similar to that proposed in Utah, but containing additional, more burdensome requirements was considered (but failed) this year in Massachusetts, Rhode Island and Virginia. OEMs are currently promoting legislation in New Jersey that would also severely burden hospital use of reprocessed devices.

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[5] Medical Device Notification and Liability, S.B. 110 (codified as amended at 78-11-28, Utah Code Annotated 1953) (2005).

Chairman TOM DAVIS. Thank you very much.

Mr. Toussaint.

STATEMENT OF DENNIS J. TOUSSAINT

Mr. TOUSSAINT. Thank you, Mr. Chairman.

My name is Dennis Toussaint, and I am the director of regulatory affairs at SterilMed. I have been in the medical device industry for approximately 18 years. Most recently, my work has been at SterilMed.

SterilMed was founded in 1997 and is a leading provider of reprocessing and repair services designed to help hospitals and other healthcare organizations generate substantial cost savings through better utilization of medical devices. As a medical device reprocessor, SterilMed cleans, tests, packages, and sterilizes previously used devices that were originally labeled for single use only. During a time of rapidly rising healthcare costs, SterilMed helps its hospital partners free up critical financial resources that can be devoted to improving their delivery of medical services while maintaining the highest possible quality of patient care at the same time.

At SterilMed, I am responsible for ensuring the company's compliance with all reprocessing-related Federal, State, and local regulations. In particular, it is my responsibility to ensure compliance with the Federal Food, Drug, and Cosmetic Act and all medical device-related regulations of the Food and Drug Administration. As my colleague, Don Selvey, has just explained, reprocessors are subject to more stringent FDA regulations than OEMs are.

SterilMed currently has more than 800 full-time and part-time employees throughout the country. We provide reprocessing services to approximately 1,400 healthcare facilities throughout the United States and Canada. We reprocess approximately 2 million devices per year. In that context, SterilMed currently saves hospitals over $40 million per year in device expenditures.

The safety record for reprocessed medical devices is nothing short of outstanding. Of the tens of thousands of patient adverse event reports that FDA receives through its medical device reporting program [MDR] program, only a very small percentage concern reprocessed single-use devices, and the few problems that have occurred with reprocessed single-use devices appear to be quite similar to the types of problems associated with new devices. Indeed, in a recent letter from FDA to Chairman Davis regarding MDR reports filed since October 2003, to December 2005, the FDA stated expressly that it did not identify any adverse events that were actually related to the reprocessing of the SUD.

A significant body of professional and scientific literature, much of it from peer review journals, further supports the conclusion that some single-use devices can safely be reprocessed. A GAO report confirms the existence of these studies. Because of the reprocessing industry's exemplary record of safety, informed hospitals and physicians support the practice of reprocessing. The GAO interviewed hospital infection control practitioners, risk management executives, and patient safety experts and found that they all reported that proper reprocessing does not pose a risk to patient health.

Hospitals demand all rigorous safety standards be adhered to by third party reprocessors. Indeed, SterilMed tests or inspects every reprocessed device before it is sent out to a hospital, and this is the practice of the industry as a whole. This is in contrast to OEMs who we understand typically test only a small sampling of devices. The result is that some hospitals say they prefer using reprocessed devices over original devices because they know that each reprocessed device has been individually scrutinized.

America's finest medical facilities use reprocessed medical devices, including 13 of the 14 institutions ranked by U.S. News and World Report in 2006 as the Nation's Honor Roll of Hospitals. These institutions include Massachusetts General, Brigham and Women's University Hospital, the Mayo Clinic, the Cleveland Clinic, and Johns Hopkins University. It simply makes no sense that these institutions would put their patients at risk in order to save money. To the contrary, these facilities use reprocessed devices because they have studied the issue thoroughly and have determined that reprocessing is both safe and cost-effective.

Mr. Chairman, that concludes my testimony. I look forward to responding to any further questions you might have regarding these issues.

[The prepared statement of Mr. Toussaint follows:]

TESTIMONY OF STERILMED, INC.
BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM
SEPTEMBER 26, 2006

I. Introduction

My name is Dennis J. Toussaint and I have been Director of Regulatory Affairs at SterilMed, Inc. (SterilMed) since November 21, 2005. Founded in 1997, SterilMed is a leading provider of reprocessing and repair services designed to help hospitals and other health care organizations generate substantial cost savings through better utilization of medical devices. As a medical device reprocessor, SterilMed cleans, tests, packages and sterilizes previously utilized devices that were originally labeled for single use only. During a time of rapidly rising health care costs, SterilMed helps its hospital partners free up critical financial resources that can then be devoted to improving their delivery of medical services, while maintaining the highest possible quality of patient care.

I have been employed in the regulatory field for approximately 18 years, working for large and small medical device manufacturers, as well as a number of start-up companies developing novel medical technologies. My educational background includes a Bachelor of Science degree in Pharmacy Practice and a Master of Science degree in Hospital Pharmacy Administration and Clinical Pharmacy Practice.

At SterilMed, I am responsible for assuring the company's compliance with all reprocessing-related federal, state and local regulations. In particular, it is my responsibility to ensure compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) and the medical device-related regulations of the Food and Drug Administration (FDA). I also assure compliance with ISO 13485, an international voluntary standard that is an FDA-recognized consensus standard for quality management systems, written to apply directly to device manufacturers.

My responsibilities include determining regulatory pathways for products that SterilMed proposes to reprocess and determining what data and information are required to be submitted to relevant regulatory authorities. I also participate in meetings of product development teams to provide input relating to compliance with federal regulations and, in particular, validation testing that must be performed to ensure a safe and effective product.

SterilMed currently has 328 full-time employees and 40 part-time employees. Our superior management team is comprised of extremely qualified and competent personnel recruited from original equipment manufacturers (OEMs), including Johnson & Johnson, US Surgical, Owens & Minor and Kimberly-Clark. SterilMed has an extensive in-house development team consisting of nurses, surgical technicians, and biomedical engineers. In addition, SterilMed employs approximately 50 surgical technicians as independent contractors and approximately 75 independent sales representatives.

SterilMed provides reprocessing services to approximately 1,400 health care facilities throughout the U.S. and Canada, including major hospital networks and group

purchasing organizations such as Amerinet, Broadlane, Consorta, Magnet, Premier, Shared Services Health care Inc., MedAssets, Ascension and Trinity.

SterilMed reprocesses approximately 2 million devices per year and has reprocessed over 7 million devices since its inception. Most of these devices are surgical and general hospital use devices. SterilMed does not reprocess devices regulated by FDA as Class III ("high risk") devices.

SterilMed currently saves hospitals over $40 million per year in device expenditures. Since inception we believe we have saved hospitals over $120 million dollars. Moreover, last year, SterilMed prevented approximately 585 tons of waste from entering landfills. Since the inception of the company, over 1,750 tons of waste have been diverted from the waste stream. SterilMed is aligned with Hospitals for a Healthy Environment, an organization that educates health care professionals and assists hospitals with their pollution prevention efforts.

II. History of Reprocessing in the United States

The emergence of reprocessing in the United States is rooted in the meaning of the "single use" label itself. Contrary to what one might think, the "single use" label is not an FDA requirement. In fact, FDA does not require any device to carry a single use label. Instead, "single use" is a designation that the OEM chooses, and that choice is sometimes made in an effort to sell more devices, not for patient safety reasons. The truth is that a manufacturer could label an operating table as being intended for "single use," if the OEM believed that it could persuade a hospital to throw the table out after one use.

It is the fact that the OEM, rather than FDA, makes the decision about whether a device will be labeled for single use, that really accounts for the emergence of the reprocessing of devices labeled for single use. Approximately two decades ago, some OEMs began to change the label on certain medical devices from "reusable" to "single use" — in some cases without any significant structural changes in the devices that would preclude safe reuse.[1]

With this change in labeling, it became evident to many hospitals that the "single use" label does not necessarily mean "single use," and that certain devices designated by the original manufacturer as "single use" can, in fact, be safely reprocessed. Hospital skepticism of the single use label was noted in a 2000 study of reprocessing conducted by

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[1] For example, in a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products explained that, although it was changing the label on its intracardiac electrodes from "reusable" to "single use," "our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past." Letter from Product Manager, USCI Cardiology & Radiology Products (July 24, 1980).

the Government Accountability Office (GAO).[2] The GAO found that health care personnel "distrust the single-use label for some devices because [among other things] . . . . FDA cannot require manufacturers to support the designation of a device as single-use," and because "they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable."[3] Further evidence that the "single use" label does not always mean "single use" is the fact that some OEMs offer reprocessing services to hospitals for the OEM's own "single use" devices.[4] In fact, some OEMs partner with third-party reprocessors to reprocess devices that the OEM itself has labeled as "single use."[5]

The reality of the single use label has led to a predictable result. Reprocessing of devices originally labeled for single use has been standard practice in the nation's hospitals for over two decades. As a practical matter, hospitals simply cannot afford to throw out devices that can be safely reprocessed. These are dollars that are better spent on purchasing new medical technology and preserving nursing staff. The savings generated by reprocessing are significant, because a reprocessed device costs approximately one-half the price of an original device. The GAO study mentioned above found that for one device alone — a product called the electrophysiology catheter — individual hospitals are saving between $200,000 and $1 million annually as a result of reprocessing.[6]

As the reprocessing industry has grown, so, too, has the strident opposition to the practice from OEMs, who see reprocessing as an increasing economic threat. The threat is two-fold. First, reprocessed devices are, on average, half the cost of original devices.

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[2] United States General Accounting Office Report entitled *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* 3 (June 2000) [hereinafter *GAO Report*].

[3] *Id.*

[4] *See* "OEM Moves Into Reprocessing," Medical Design Technology, March 1, 2006, explaining, "Orthopedic firm Synthes is offering hospitals the option to reprocess used external fixation devices as part of a new reprocessing program. The U.S. division of the Swiss firm is reprocessing over a dozen of its fixation devices, including single use devices such as its 'combination clamp' and 'tube to tube clamps,' according to a marketing document." *See also, Synthes, External Fixation Reprocessing Program*, Corporate Marketing Material, Synthes USA 2004. *See also*, FDA 510(k) clearance K033158, "Synthes (USA) Synthes Reprocessed External Fixation Devices," cleared by FDA on November 5, 2003.

[5] *See* "Nellcor and Alliance Medical Announce First-of-its-Kind Co-Marketing," Infection Control Today (April 8, 2003).

[6] GAO Report, *supra* note 2, at 19.

Therefore, many hospitals choose to use reprocessed devices rather than purchase new ones. This means lower sales for original device manufacturers. Second, the very existence of reprocessing has resulted in a decrease in the price of certain new devices.[7] Lower prices typically mean lower profits.

Beginning in the late 1990s, therefore, certain OEMs began to put intense pressure on federal and state government to ban or restrict reprocessing. As their rationale, these OEMs have argued (contrary to all available evidence) that reprocessing puts the public health at risk. And the pressure that OEMs have placed on legislators and regulators has resulted in a period of intense scrutiny of reprocessing, which continues today. Faced with the economic threat posed by reprocessing, these OEMs have engaged in a concerted effort to achieve the enactment of legislation and regulation (on the federal and state levels) that would effectively eliminate the third-party reprocessing industry.[8] *See* Exhibit A. Although the regulatory scrutiny of the industry has, in fact, been intensified in the last six years, and regulatory requirements have grown significantly more stringent, the industry has nevertheless consistently been able to meet the new regulatory requirements and, indeed, has flourished.

SterilMed hopes that its testimony today will make clear that the third-party reprocessing industry in the United States is safe, that it is highly regulated — more stringently regulated than the original equipment industry — and that it is providing a valuable service to this country's hospitals, a service that helps hospitals survive and thrive in a time of severe cost containment pressures. Additional regulation at either the federal or state level is not only unnecessary but also, to the extent it would limit the ability of hospitals to use reprocessed devices, would do a disservice to America's hospitals and patients.

III. FDA Regulation of Reprocessed Devices

In order to evaluate the adequacy of the federal regulatory scheme governing reprocessed devices, it is necessary to understand how the FDA regulatory framework governing reprocessing has evolved, and how it is that, today, reprocessors are more stringently regulated than original device manufacturers.

A. Pre-2000 Regulatory Scheme

Prior to August 2000, FDA regulated third-party reprocessors in the same way that it regulates OEMs, with the only exception being that reprocessors were not subject to premarket review requirements. As medical device "manufacturers," however,

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[7] In studying this issue, the GAO found that, because of the competitive alternative presented by reprocessing, manufacturers have lowered their prices in exchange for a hospital's commitment not to reprocess. *Id.*

[8] *See* Exhibit A.

reprocessors *were* subject to FDA's establishment registration and medical device listing requirements,[9] medical device reporting requirements,[10] reports of corrections and removal requirements,[11] quality system regulation ("QSR") requirements,[12] and labeling requirements.[13] Reprocessing that took place inside hospitals, however, was not regulated by FDA as a device manufacturing activity.

B. August 2000 Guidance Document

On August 14, 2000, FDA issued a document entitled, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." In that document, FDA announced a significant increase in its regulatory oversight of reprocessing. First, third-party reprocessors became subject to premarket review requirements in addition to all of the other post-market manufacturer controls with which they already had to comply. As a result, today, reprocessors, like OEMs, are required to submit premarket notifications (510(k)) for the Class I and Class II devices that they reprocess, unless those devices are by regulation exempt from this requirement. The elements of a 510(k) submission for a reprocessed device include the following:

- information on the company submitting the 510(k);
- a summary of the information presented in the submission;
- a complete description of the device that is the subject of the submission;
- all pre-production validation data related to cleaning, testing, packaging, and sterilization, including mechanical testing data, electrical testing data, cleaning validation data, sterilization validations, and packaging validations;
- an analysis of the risks related to reprocessing the device (identification of the risks; determination of the likelihood of each risk occurring; and steps taken by the reprocessor to mitigate each risk);

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9 21 U.S.C. § 360; 21 C.F.R. Part 807, subpart B.

10 21 U.S.C. § 360i(a); 21 C.F.R. Part 803.

11 21 U.S.C. § 360i(f); 21 C.F.R. Part 806.

12 21 U.S.C. § 360j(f); 21 C.F.R. Part 820.

13 21 U.S.C. §352; 21 C.F.R. Part 801.

- biocompatibility analyses (laboratory-based determinations of the potential that the reprocessing method, residuals, etc. may cause a cellular reaction);
- labeling, including the product labels and instructions for use;
- a comprehensive comparison of the original and reprocessed devices; and
- a certification that all information in the submission is complete, truthful and accurate.

A 510(k) submission for a reprocessed device may contain thousands of pages of information, cost between $50,000 and $250,000 to develop, and may take more than a year to complete.

The second significant change that came about in 2000 was that FDA began to regulate hospitals that perform their own reprocessing as device manufacturers and subjected them to the full range of FDA device manufacturer requirements. Therefore, the "bottom line" was that reprocessing of single use devices — whether performed by a commercial firm or a hospital — would be viewed by FDA as a device manufacturing activity and would be subject to the same regulatory requirements as original equipment manufacturing.

The reprocessing industry did not fade away as a result of the new premarket submission requirements. Rather, the industry was able to comply with the new requirements, and many hospitals that had previously reprocessed their devices in-house began to send them to third-party reprocessors, rather than trying to comply with FDA's device manufacturing requirements.

While FDA's 2000 initiatives "leveled the playing field," by requiring reprocessors and OEMs to comply with the same regulatory requirements, subsequent legislation imposed new regulatory obligations on reprocessors. As a result, as described below, reprocessors are now more stringently regulated than OEMs.

C. The Medical Device User Fee and Modernization Act of 2002

In 2002, the Medical Device User Fee and Modernization Act (MDUFMA) imposed additional premarket review and labeling requirements on reprocessors.[14] MDUFMA's most significant provisions required reprocessors to submit extensive validation data as part of their premarket notification submissions for certain reprocessed devices — data that OEMs are not required to submit on a premarket basis. In addition,

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[14] Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588 (codified as amended in scattered sections of 21 U.S.C).

pursuant to MDUFMA, the premarket review requirement has been imposed on certain reprocessed devices, even though the non-reprocessed version of the device is exempt from this requirement.

The new validation requirement meant that reprocessors were obligated to submit a large amount of new data for devices that were already legally marketed, and obtain FDA clearance of these "supplemental validation data" submissions ("SVS"), or face having to remove them from the market. SterilMed, and the industry, complied with the new requirement, and FDA has completed its review of most of those submissions.

D. The Medical Device User Fee Stabilization Act of 2005

In 2005, Congress included in the Medical Device User Fee Stabilization Act (MDUFSA) a provision requiring reprocessors to place an identifying mark on their devices.[15] A device marking provision had originally been enacted as part of MDUFMA, but at that time it applied to *all* devices, not just reprocessed devices. MDUFSA modified the provision to apply *only* to reprocessors. The reprocessing industry continues to believe that the provision should have been applied to *all* device manufacturers, and believes that there was no public health rationale for applying it only to reprocessors.

IV. Safety of Reprocessed Devices

The safety record for reprocessed medical devices is outstanding. Of the tens of thousands of patient adverse event reports that FDA receives through its Medical Device Reporting (MDR) program, "only a very small percentage" concern reprocessed "single use" devices,[16] and the few problems that have occurred with reprocessed "single use" devices appear to be quite similar to the types of problems associated with new devices.[17] Indeed, in a January, 2006, letter from FDA to Congressmen Tom Davis and Henry Waxman of the House Government Reform Committee, the agency wrote that 65,325 adverse event reports had been filed with the agency since October 2003 for the malfunction or injury associated with the first use of original (*i.e.,* not reprocessed) devices labeled for "single use." The same search produced only 176 cases of apparent

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[15] Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, 119. Stat. 439 (codified as amended in 21 U.S.C. § 352(u)).

[16] GAO Report, *supra* note 3, at 15.

[17] As one example, an MDR report was submitted to FDA concerning a reprocessed EP catheter whose tip had become detached. *See* MDR Report Number 1062310-1999-00001. However, the identical incident also has been reported for new EP catheters. *See* MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. *See also* GAO Report, *supra* note 3, at 16.

malfunction or injury associated with reprocessed devices. Moreover, FDA wrote, "upon analysis of these reports, FDA determined that these adverse events are not related to the reprocessing of the SUD,"[18] and stated expressly that it "did not identify any adverse events that were actually related to the reprocessing of the SUD."[19]

Further, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) medical devices since 2004. According to the same database, no deaths have been associated with the use of reprocessed "single use" medical devices.[20]

A significant body of professional and scientific literature, much of it from peer-reviewed journals, further supports the conclusion that some single use devices can safely be reprocessed.[21] As the GAO observed when it evaluated the safety of reprocessed devices labeled for single use,

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[18] Letter from Patrick Ronan, Associate Commissioner for Legislation, Food and Drug Administration, to Chairman Tom Davis, Committee on Government Reform, House of Representative dated January 23, 2006 (the FDA reports were received between October 22, 2003 and December 13, 2005).

[19] *Id.*

[20] FDA's database of adverse events is available via the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>.

[21] Recent journal articles include the following: N. Ma, A. Petit, O. Huk, L. Yahia, and M.Tabrizian, "Safety Issue of Re-Sterilization of Polyurethane Electrophysiology Catheters: a Cytotoxicity Study," 14 *Journal of Biomaterials Science, Polymer Edition* 213 (2003); T.A. Ischinger, G. Neubauer, R.Ujlaky, H.Schatzl, and M.Bock, "Reuse of 'Single Use' Medical Devices After Quality Assured Reprocessing: Hygenic, Legal and Economic Aspects. Potential for Cost Savings in Interventional Cardiology," 92 *Z. Kardiol.* 889 (November, 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices – Regulatory Roles," 75 *AORN Journal* 98 (July 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis," 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, "Reprocessing Single-Use Devices – Regulatory Roles," 75 *AORN Journal* 98 (July 2002); S. Mickelsen, BS, C. Mickelsen, BS, C.MacIndoe, BS, J. Jaramillo, S.Bass, MD, G. West, RN, and F. Kusumoto, MD, "Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States," 87 *The American Journal of Cardiology* 351 (February 1, 2001); C.M. Wilcox, "Methodology of Gastroenterology and Hepatology," 10 *Gastrointestinal Endoscopy Clin N Am* 379 (April 2000); R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., D.J.Patterson, M.D., J.J. Brandabur, M.D, "Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study," 49

> the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing can be carried out safely, and patient outcomes are not adversely affected by the use of reprocessed [single use devices].[22]

Because of reprocessing's exemplary record of safety, informed hospitals and physicians support the practice of reprocessing. The GAO interviewed hospital infection control practitioners, risk management executives, and patient safety experts and found that they all reported that careful reprocessing of the types of "single use" devices that are amenable to proper cleaning and sterilization does not pose a risk to patient health.[23]

Indeed, many of the most preeminent physicians in the country have publicly supported reprocessed devices as being safe and effective. For example, Dr. Bruce Lindsay, representing the American College of Cardiology (ACC) and the North American Society of Pacing and Electrophysiology (now the Heart Rhythm Society), testified before the House Commerce Committee that

> [t]here are studies, all of which have been published in peer-reviewed scientific medical journals, which have

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Gastrointestinal Endoscopy 39 (January 1999); S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E.Sumida, Ph.D., "In Vitro Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes," 94 *The American Journal of Gastroenterology* 139 (January 1999); Blomstrom, Lundqvist, "The Safety of Reusing Ablation Catheters with Temperature Control and the Need for a Validation Protocol and Guidelines for Reprocessing," 21 *Pacing Clinical Electrophysiology (PACE)* 2558 (December, 1998); M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," 32 *Journal of the American College of Cardiology* 1384 (November 1, 1998).

[22] GAO Report, *supra* note 2, at 13 (internal citations omitted). The report went on, "For example, several studies have documented the safe reprocessing and reuse of EP [electrophysiology] catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers that reused EP catheters and centers that used each catheter only once. A later study of 69 EP catheters used in 336 procedures concluded that carefully reprocessing one model of single use catheter up to 5 times posed no increase in health risks. Similarly, some evaluations of the reprocessing of single use endoscopic instruments published in peer-reviewed scientific journals found that those [single use devices] could be reused at least several times without increasing patient risk."

[23] GAO Report, *supra* note 2, at 14.

> evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased.[24]

Likewise, at a Senate Hearing of the Health, Education, Labor and Pensions Committee, Dr. John Clough, representing the American Hospital Association (AHA), testified that

> [m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled "for single use." The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled "for single use."[25]

In a June 23, 1999 letter to the late Senator Paul Wellstone (D-MN), Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic, discussed the Clinic's 20-year experience with reprocessed electrophysiology catheters and said:

> Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.[26]

In 2002, the Cardiac Electrophysiology Coordinator at Johns Hopkins Hospital, Carol Tunin, Ph.D., wrote of similar experiences with reprocessed catheters. In a memorandum to Rep. John Dingell (D-MI), Dr. Tunin stated that

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[24] Testimony of Bruce Lindsay, M.D., F.A.C.C., Associate Professor of Medicine, Director, Clinical EP Laboratory at Washington University School of Medicine, St. Louis, Missouri on behalf of the ACC and the North American Society of Pacing and Electrophysiology, before the House Commerce Comm., Subcommittee on Oversight and Investigations 5 (Feb. 10, 2000).

[25] Testimony of John Clough, M.D., Chair of Health Affairs, Cleveland Clinic Foundation, Cleveland, Ohio, on behalf of the AHA to the Senate Comm. on Health, Education, Labor and Pensions 3-4 (June 27, 2000).

[26] Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999).

> [t]he *entire* clinical staff of electrophysiology physicians at Johns Hopkins prefer to resterilize catheters. Ablation catheters that deliver therapy are steerable. They can be curved into multiple angles and are used to both determine the site within the heart that is the culprit of some arrhythmias and also to deliver therapy to that location. Every catheter is a bit different no matter what the brand or lot number and consistently perform with their own "character." Some even develop a slight twist or second angle that helps steer the tip onto the muscle tissue, which gives an advantage in trying to locate the source of the arrhythmia. Before resterilization was policed so tightly and the number of reuses was pared down so low, some "misshapen" catheters became favorites in trying to get into the exact position in the heart muscle.[27]

Hospitals take great comfort in the rigorous safety standards adhered to by third-party reprocessors. Indeed, SterilMed tests or inspects every reprocessed device before it is sent to a hospital, and we understand this to be the practice of the industry as a whole. This is in contrast to OEMs, who we understand typically test only a small sampling of devices. The result is that some hospitals say they prefer using reprocessed devices over original devices, because they know each reprocessed device has been individually scrutinized.

America's finest medical facilities use reprocessed medical devices, including 13 of the 14 institutions ranked by *U.S. News & World Report* in 2006 as the nation's "Honor Roll" hospitals.[28] These institutions include Massachusetts General Hospital,

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[27] Memorandum from Carol Tunin Ph.D. to Rep. John Dingell (July 12, 2002) (emphasis added). Dr. Tunin also highlighted another clinical advantage of reprocessing: because of the reduced cost of reprocessed catheters, physicians are comfortable that the cost will not be excessive if they try another tool (catheter) to see if it is more compatible with a patient's particular anatomy. Dr. Tunin noted that when pricing became a large factor at Johns Hopkins (due to restrictions on the reuse of catheters), the hospital's staff began to "limit the number of tools they will try and relentlessly persevere with one or two catheters. This often greatly extends the time on the procedure table and increases the frustration level for difficult cases."

[28] According to *U.S. News*, only the top three percent of 5,189 hospitals, 176 in all, are ranked in "one or more of the 16 specialties in this year's 'America's Best Hospitals.' And of those, just 14 qualified for the Honor Roll by ranking at or near the top in at least six specialties—a demonstration of broad expertise." The *U.S. News & World Report*'s hospital ranking can be found on the Internet at http://www.usnews.com/usnews/health/best-hospitals/tophosp.htm.

Brigham and Women's Hospital, the Mayo Clinic, the Cleveland Clinic, and Johns Hopkins University. Additionally, reprocessors serve all ten hospitals considered by *U.S. News & World Report* to be the top ten heart and heart surgery hospitals in the nation, and at least nine of the top ten orthopedic hospitals nationwide.[29]

Reprocessors also serve at least 87 percent of America's top hospitals, as listed by the 12th edition of the Solucient 100 Top Hospitals®: National Benchmarks for Success.[30] Solucient's annual list recognizes U.S. hospitals that demonstrate superior clinical, operational, and financial performance. The primary goal of the Solucient program is to use objective criteria to identify hospitals that provide the best care in the nation, and to make public the benchmark that has been set for hospital performance each year. Based on Solucient's study, reprocessors serve all of the top 25 "teaching hospitals"; at least 14 of the 15 best "major teaching hospitals"; all of the top 20 "large community hospitals"; and at least 17 of the top 20 "medium community hospitals." Overall, the major reprocessors serve 87 of Solucient's 100 Top Hospitals listed for 2004.

In short, America's finest and most respected institutions use reprocessed medical devices. It simply makes no sense to argue, as some have done and continue to do, that these institutions would put their patients at risk in order to save money. To the contrary, these facilities use reprocessed devices because they have studied the issue thoroughly and have determined that reprocessing is both safe and cost-effective.

V. Conclusion

Across the country, hospitals are facing enormous and urgent cost-containment pressures. Hospitals that cannot contain their costs are closing their doors or eliminating services, leaving too many people unserved or underserved. Reprocessing is not single-handedly going to resolve any hospital's financial pressures, but it is part of the answer. As described above, hospitals realize substantial reprocessing-related savings because the cost of a safe and effective reprocessed device is, on average, half of the cost of a new device. In addition, hospitals realize savings from reprocessing because their waste hauling and handling costs are significantly reduced. The 2000 GAO study mentioned above found that hospitals that use reprocessed devices save $200,000 to $1 million annually. To put that figure in context, for a hospital operating on a 2% profit margin, saving $200,000 is equivalent to bringing in $10 million in new revenue. The substantial savings that a hospital realizes from reprocessing can be put into hiring additional nursing staff, purchasing new capital equipment, and other patient care improvements.

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29 *Id.*

30 The Solucient study was released February 28, 2005 and is available at http://www.100tophospitals.com/.

Reprocessing also exerts competitive pressure on the marketplace, keeping the price of original equipment down. Biopsy forceps, for example, previously cost hospitals approximately $49 per device, but after hospitals began having them reprocessed, the price of the original devices dropped to about $15. These numbers help to clarify why the makers of biopsy forceps and other "single use devices" are so eager to persuade the world that — despite all evidence to the contrary — reprocessing is not safe. The explanation lies in their bottom line: if they are successful in eliminating reprocessing, they will be able to raise the price of those forceps to pre-reprocessing levels.

As described above, reprocessing not only makes economic sense for hospitals, it is also good for the environment. The reprocessing industry helped hospitals divert over 4,000 tons of medical waste from the waste stream in 2005 alone. Reprocessing can play a significant role in meeting the goals of the U.S. Environmental Protection Agency for reducing the health care sector's total waste volume.[31]

In short, reprocessing plays a vital role in our health care system because it is one of the few ways that hospitals can achieve substantial cost savings while maintaining the absolute highest standard of patient care. SterilMed respectfully urges the Congress to refrain from imposing additional regulation on this industry. Such regulation is unnecessary and would do nothing to enhance patient safety or improve patient outcomes. Moreover, to the extent it would limit the ability of hospitals to use reprocessed devices, such additional regulation would do a disservice to America's hospitals and patients.

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[31] *See* Memorandum of Understanding Between AHA and the U.S. Environmental Protection Agency setting forth goals to reduce the impact of health care facilities on the environment.

EXHIBIT A

Examples of OEM Legislative and Regulatory Efforts Aimed at Restricting and/or Eliminating the Third-Party Reprocessing Industry

- In the late 1990's, two device manufacturer trade associations petitioned FDA to regulate reprocessing more stringently or ban it on the grounds that it posed a public health risk. FDA denied both these petitions, stating, among other things, that the agency "has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes."[1] The agency also declared that "there is no clear evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury'" and said that it "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[2]

- In March, 2001, another device manufacturer trade association filed a Citizen Petition with FDA, claiming that reprocessed medical devices are misbranded because, among other things, reprocessors do not always remove OEM trademarks from reprocessed devices.[3] The agency denied the petition in September 2001.[4]

- There has also been significant activity at the state level. In the late 1990's, anti-reprocessing legislation was introduced, but did not ultimately succeed, in Illinois, California, and Maryland.

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[1] Letter from D. Bruce Burlington, M.D., Director CDRH, FDA, to Nancy Singer, Esq., HIMA (now AdvaMed) 2 (July 15, 1998).

[2] Letter from David W. Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry R. Pilot, Esq., Counsel to Medical Device Manufacturers Association (MDMA) 1-2 (Oct. 6, 1999). On October 21, 1999, MDMA petitioned FDA for reconsideration of its decision to deny MDMA's request for a ban on the reprocessing of "single use" devices. *See* Letter from Larry R. Pilot, Esq., to FDA (Oct. 21, 1999). FDA denied MDMA's petition for reconsideration on February 9, 2001. *See* letter from David W. Feigal, Jr., M.D., M.P.H., to Larry R. Pilot, Esq. (Feb. 2, 2001).

[3] Citizen Petition from Thomas Scarlett, Hyman, Phelps and McNamara, P.C., Counsel, Association of Disposable Device Manufacturers, to FDA (March 22, 2001).

[4] Letter from Linda S. Kahan, Deputy Director, CDRH, FDA, to Thomas Scarlett, Hyman, Phelps and McNamara, Counsel to ADDM (Sept. 17, 2001).

- At the urging of OEMs, Utah enacted legislation that requires reprocessors of critical single use medical devices to assume all liability associated with the original manufacturing of the device.[5]

- Legislation similar to that proposed in Utah, but containing additional, more burdensome requirements was considered (but failed) this year in Massachusetts, Rhode Island and Virginia. OEMs are currently promoting legislation in New Jersey that would also severely burden hospital use of reprocessed devices.

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[5] Medical Device Notification and Liability, S.B. 110 (codified as amended at 78-11-28, Utah Code Annotated 1953) (2005).

Chairman TOM DAVIS. Thank you very much.
Mr. Ubl.

STATEMENT OF STEPHEN J. UBL

Mr. UBL. Good morning, I would like to thank you, Mr. Chairman, and other members of the committee for holding this hearing today.

AdvaMed is the world's largest trade association representing medical technology manufacturers. Our member companies produce the medical devices, diagnostic products, and health information systems that are transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments.

I would like to open this morning by clarifying the basic distinction between devices sold by original equipment manufacturers, our members, and those by reprocessors. Devices that our manufacturers sell must be safe and effective. Based on their design and the data submitted, FDA clears devices designed for one-time use only as well as other devices designed for multiple use. Reprocessors, by contrast, take a device that has been cleared as safe and effective by the FDA for only one use and, after reprocessing, sell it to be used again.

There are four primary messages I would like to leave with the committee about reuse of medical devices.

First, reprocessing a medical device that is designed to be used once is inherently risky. It is difficult to clean and sterilize extremely small and structurally complex devices. Blood, mucous, and fecal material can accumulate during use in areas that are very difficult to access and clean. In addition, there can be debilitating effects from initial use, cleaning, and resterilization on the physical properties of the device. Materials can become brittle, sticky, or deformed.

Let me illustrate these points with an example, and I think somebody will bring this to the dais for the Members to review. This is one of the technologies that was mentioned in earlier testimony. It is an EP catheter, electrophysiology catheter, and this technology is threaded through the groin of a patient, up into the heart to map the heart's electrical impulses in various parts of the heart to detect abnormalities.

This device has to be rigid enough, stiff enough to actually be threaded up into the heart, yet it has to be flexible enough to make sure that it doesn't puncture the artery and it has to be flexible enough to go through the twists and turns of the artery. It also has to be sterile so as not to introduce potential infection, and it has to be sensitive enough so that when it gets to the heart, it can accurately take readings from the heart.

Every one of those properties can be negatively affected by reuse. Failure to completely clean and sterilize the device can potentially transfer blood-borne diseases from one patient to another. Cleaning and sterilization and use itself can affect the device's flexibility, durability, and sensitivity. No one should want a device used on a second, third, or fourth patient unless there is an ironclad assurance that it is literally as good as new after it is reprocessed.

That leads to me to my second point. A reprocessed device should be held to the same rigorous standard of safety and effectiveness that FDA applies to original devices.

Third, the recently enacted legislative and regulatory framework for reprocessed devices is a significant improvement. However, in our view, the public is still not adequately protected because only a limited number of reprocessed devices have been subjected to FDA review. FDA directives require that reprocessors submit validation data for only 68 or 228 device types.

Yet in 50 percent of those cases, the reprocessed device was found to be not substantially equivalent to the original device or the reprocessor voluntarily withdrew the product due to lack of adequate validation data. A 50 percent failure rate is intolerable for any industry, but it is especially intolerable when it occurs with a device designed to diagnose, treat, and cure patients. AdvaMed urges FDA to review validation data for all reprocessed single-use devices.

Fourth, we support the strengthened reporting and branding provisions in MDUFSA. However, it is still too early to draw conclusions as to whether these changes will adequately improve the identification reporting of adverse events associated with reprocessed devices. As has been mentioned earlier, the new labeling provision only went into effect in August. Prior to that date, providers had little ability to identify whether or not an adverse event was due to a device that had been reprocessed or one that was not.

In closing, if appropriate regulations means some products will continue to be reprocessed because the practice is supported by appropriate validation data, that is acceptable. If appropriate regulation of reprocessing means some of these products can no longer be reprocessed, then patient safety will benefit from that decision.

We look forward to working with the Congress and FDA to make the promise of MDUFMA a safe reality for millions of patients. Thank you for the opportunity to address the committee on this important patient safety issue. I look forward to answering any questions the committee might have.

[The prepared statement of Mr. Ubl follows:]

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HOUSE COMMITTEE ON GOVERNMENT REFORM

HEARING ON

FOOD AND DRUG ADMINISTRATION'S OVERSIGHT AND REGULATION OF THE REPROCESSED SINGLE-USE MEDICAL DEVICE INDUSTRY

SEPTEMBER 26, 2006

STEPHEN J. UBL
PRESIDENT AND CEO
THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

Good morning, Mr. Chairman and Members of the Committee. My name is Stephen J. Ubl, and I am the President and CEO of the Advanced Medical Technology Association (AdvaMed). AdvaMed is pleased to present testimony at this House Committee on Government Reform hearing on the Food and Drug Administration's (FDA) oversight and regulation of the reprocessed single-use medical device industry.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We appreciate the attention that Congress has given through legislation to the regulation of single use devices that are reprocessed for multiple uses over the last few years. We continue to monitor the steps FDA is taking to implement these provisions and provide input to the Agency, and my testimony details our comments on these efforts.

Reprocessing of Single-Use Medical Devices

The reprocessing of a single use device can present a serious risk to patients if it does not result in a product that is as safe and effective as that of the original manufacturer. Single use devices are designed and manufactured for one use only in a single patient and are intended by the original equipment manufacturer (OEM) to be disposed of permanently after use. Their use has been reported to reduce the risk of nosocomial infections.[1] Single use devices are designed for optimal performance and safety under their intended conditions of use – not ease of cleaning. They typically have characteristics that make them extremely difficult to effectively clean and resterilize, including the fact that the devices have small, difficult to access areas, such as long, narrow lumens, acute angles, crevices, coils and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, respiratory secretions and gastric mucin.

Single use devices are not designed to – and may fail to – withstand the harsh conditions (e.g., exposure to solvents and extreme temperatures) encountered during reprocessing. Reprocessing of a previously used single use device may also seriously compromise its safety and effectiveness and even destroy some single-use devices.

For these and other reasons, AdvaMed strongly supported the reprocessing provisions in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) which mandated new and

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1 For example, see the following studies: **1)** Jernigan JA, Siegman-Igra Y, Guerrant RC, Farr BM. 1998. A randomized crossover study of disposable thermometers for prevention of Clostridium difficile and other nosocomial infections. Infect Control Hosp Epidemiol. 19(7): 494-9. **2)** Nosocomial Hepatitis B virus infection associated with reusable fingerstick blood sampling devices – Ohio and New York City, 1996. MMWR Weekly, March 14, 1997/46(10): 217-221. **3)** Brooks SE, Veal RO, Kramer M, Dore L, Shupf N, Adachi M. February 1992. Reduction in the incidence of Clostridium difficile-associated diarrhea in an acute care hospital and a skilled nursing facility following replacement of electronic thermometers with single-use disposables. Infect Control Hosp Epidemiol. 13(2): 98-103.

stronger FDA regulatory requirements for reprocessed single use devices. In MDUFMA, for 510(k) devices (including exempt Class I and II 510(k) devices[2]), Congress required that reprocessors submit cleaning, sterilization and functional performance data to FDA to "demonstrate that the [reprocessed] device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification."[3] For PMA devices, Congress established a new type of application – a "premarket report" – specifically tailored to reprocessed devices, that must meet all the requirements of a premarket approval application in addition to cleaning, sterilization and functional performance validation data "that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report." [4] For PMRs, MDUFMA also provided FDA with explicit authority to require any other additional data and information needed to determine reasonable assurance of safety and effectiveness for the reprocessed device.[5]

Adverse Events Involving Reprocessed Single Use Devices

AdvaMed became aware of two adverse events involving reprocessed single use devices for which FDA had failed to require supplemental validation submissions (SVSs). We submitted these comments to FDA's reuse docket on September 30, 2004[6]. Specifically, a cardiovascular surgeon cut a patient's heart when a reprocessed heart positioner – used to manipulate the heart for access to vessels during beating heart bypass and other cardiac surgical procedures – failed to properly hold the heart during a by-pass procedure. The surgeon was forced to repair the laceration, exposing the patient to excessive bleeding and a prolonged procedure that posed additional risks to the patient (e.g., potential for compromised heart hemodynamics and infection). The foam gasket used on the suction cup to grasp the heart had decomposed due to reprocessing.

In another case, a reprocessed endoscopic vein harvesting system failed when a piece of shrink tubing broke free of the device and became lodged in a patient's leg. In this case, the surgeon was forced to 'fish' the dislodged part out of the patient's leg exposing the patient to excessive bleeding and a prolonged procedure. OEM failure analysis of the returned device found that the shrink tubing that broke free had deteriorated due to multiple sterilization cycles.

Both of these adverse events illustrate a key issue with respect to reprocessing. In many instances, surgeons are unaware that the devices they are using are reprocessed. In this case, the user or user facility returned the device to the OEM for failure analysis because they did not identify the device as one that was reprocessed.

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2 Prior to MDUFMA, FDA did not require reprocessors to submit 510(k)s for original equipment manufacturer Class I and Class II single use devices that were exempt from submitting 510(k)s.

3 Section 302(b) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002
4 Section 302(c) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002.
5 Section 302(c) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002.
6 See September 30, 2004 AdvaMed Comments to Docket No. 03N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data and Docket No. 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA)

AdvaMed was pleased when FDA announced in September 2005 that reprocessors would be required to submit supplemental validation submissions for these two specific types of reprocessed devices. AdvaMed had written to FDA in August 2003 and again in September, 2004 to urge that validation data be required for positioners. The validation submissions for endoscopic accessories and heart positioners were and are due June 29, 2006 and December 29, 2006 respectively.

On June 29, 2006, AdvaMed wrote FDA[7] to enquire about FDA's plans for notifying hospitals if the validation submissions for these products were not received by FDA's deadlines and what, if any action, FDA planned to take regarding any of these reprocessed devices still on hospital shelves on those dates. In a September 5, 2006 communication to AdvaMed, FDA indicated that notifications to reprocessors for these products would be determined on a case-by-case basis and would depend on previous correspondence to the firm and the reprocessor's inspectional history. FDA indicated it would evaluate the risk to the health for the users and patients to determine the appropriate notification to the community for product remaining on hospital shelves.

We note our disappointment regarding FDA's response to the Chairman and the Ranking Member's questions about reprocessor adverse events (AEs). First, AdvaMed specifically brought the above-referenced adverse events to FDA's attention during the same timeframe (September 30, 2004) in which FDA has said it determined there were no adverse events related to the reprocessing of a single use device (October 22, 2003 through December 13, 2005). Secondly, Secondly, FDA's response ignores the fact that the OEM devices worked the first time for their intended single use *and* that the 176 adverse events would not have occurred if the single use devices had not been reprocessed and reused.

AdvaMed Implementation Concerns Shared with FDA

AdvaMed has closely monitored and has submitted multiple comments on FDA's implementation of the MDUFMA reprocessing provisions, and some of the comments we have submitted to the FDA are detailed below.

FDA's Bundling Policy

Prior to MDUFMA, FDA allowed one reprocessor to gain clearance for over 4,000 devices on the basis of just eleven 510(k)s. Bundling – under which FDA allows reprocessors to bundle multiple single use devices from different original manufacturers into a single submission – has continued to be an issue in MDUFMA implementation. FDA reported at its November 2004 MDUFMA Stakeholder meeting that 44 reprocessor submissions accounted for 1,800 different devices.

AdvaMed has objected to reprocessor bundling for multiple OEM single use devices. Even though the single use device type is the same, each manufacturer has a unique design for their device. Manufacturers are also likely to use different materials, and different manufacturing and engineering processes. As a result, different OEM devices may react differently to cleaning and re-sterilization even though they are the same device type. These differences may also affect the

7 See June 29, 2006 AdvaMed Comments to Docket No. 2003N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data

number of times the single use device can be reused. In fact, FDA's own laboratories have previously concluded that the decision to reuse a single use medical device is not a "category" decision but rather a "model specific" decision.[8] FDA is ignoring the conclusion of its own investigation of reuse when it presumes these technological differences do not preclude bundling.

FDA's Use of Review Prioritization Scheme

MDUFMA required FDA to identify reprocessed devices types (both exempt and non-exempt) for which reprocessors would be required to submit validation data on cleaning, sterilization and functionality. To identify reprocessed devices requiring validation data, FDA relied on the Review Prioritization Scheme (RPS) – a process FDA itself had previously criticized as potentially requiring "subjective responses" and being difficult to use to make consistent determinations.[9] AdvaMed believed Congress intended the Spaulding criteria to be the primary mechanism to identify reprocessed single use devices requiring validation data. Use of the RPS resulted in only 16 device types out of 126 exempt reprocessed device types having to submit validation data and only 53 device types out of a total of 228 non-exempt devices having to submit validation data. As a result, FDA has reviewed validation data for just a small subset of all reprocessed single use devices.

FDA Significantly Extended Validation Data Submission Deadlines

In April, 2003, FDA identified reprocessed single use devices that would be required to submit validation data and indicated that reprocessed 510(k) devices would have to submit "validation data for these devices by January 30, 2004, *or marketing of these devices must cease* [emphasis added]."[10]

In mid-February 2004, AdvaMed learned that reprocessers had failed to submit validation data – information and data reprocessors claimed to have all along – for the vast majority of the reprocessed single use devices subject to the January 30, 2004 deadline. AdvaMed was concerned that the failure of reprocessors to meet the deadline suggested that reprocessors: (1) either did not have the data or (2) had determined the data was inadequate to support continued reprocessing. AdvaMed believed that continued distribution of these devices represented an unreasonable risk to patients.

It is also important to note that MDUFMA merely established the requirement for *review* of validation data – not the requirement for the *existence* of the data. The Quality System Regulation (QSR) which applies to all manufacturers requires the existence of the data. The QSR requires that all manufacturing processes be validated. Importantly, in 1998, FDA confirmed in response to a September 5, 1997 citizen petition filed by AdvaMed (then HIMA)

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8 Brown SA, Merritt K, Woods TO, Hitchins VM. 2001. The effects of use and simulated reuse on percutaneous transluminal coronary angioplasty balloons and catheters. Biomedical Instrumentation & Technology. 312-322.
9 See FDA's February 2000 draft guidance laying out the RPS scheme, entitled *"Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme."* FDA noted the scheme was subjective: "It is important to note that many of the questions asked in the flowcharts may require subjective responses." FDA also acknowledged the difficulty of using the RPS to make consistent determinations: "Despite the possibility of different interpretations, FDA has *tried* [emphasis added] to make consistent categorizations across all SUD types."

10 See April 30, 2003 *Federal Register* (FR) Notice #FR03-10413.

that reprocessors were considered manufacturers under FDA's Quality System regulation[11] thereby confirming that reprocessors were required to have such data. In 2000, Mr. Vern Feltner, representing the Association of Medical Device Reprocessors (AMDR) emphasized in verbal and written testimony before the House Commerce Subcommittee on Oversight and Investigations that "Reprocessors must comply with FDA QSRs just like manufacturers."[12]

Unexpectedly, FDA subsequently extended the validation submission deadline for reprocessors by an additional 90 days despite its statement in June 2004 in MDUFMA reprocessing implementing guidance that "we believe that manufacturers should have this validation information readily available since the reprocessed device(s) are currently being marketed and such data should have been developed and maintained as part of the Quality System requirements (21 CFR Part 820)."[13] At the time of FDA's extension, approximately 20 percent of the SVSs – for products currently on the market – had already been issued Not Substantially Equivalent (NSE) determinations by FDA.

The fact that 5½ years later reprocessors could not provide the validation data to FDA by the MDUFMA deadline suggests reprocessors did not have validation processes in place.

AdvaMed believed that FDA's decision extended the exposure of patients to products reprocessed with inadequate manufacturing controls.

Fifty Percent of Validation Submissions Contained Inadequate Data

In July 2004, AdvaMed learned that of the validation submissions received by FDA, approximately 20 percent had been deemed by FDA as non-substantially equivalent (NSE) to the original 510(k) held by the reprocessor either because the reprocessor failed to submit the required information or because the data were found to be inadequate and unable to be reviewed by FDA.

At FDA's November 2004 MDUFMA Stakeholder meeting, FDA announced that the NSE/withdrawn rate had increased to nearly 50 percent. It is important to note that this NSE/withdrawn rate is just for the small subset of reprocessed devices that were required to submit validation data.

The rate is much higher than the annual NSE rate provided in FDA's Office of Device Evaluation (ODE) and Office of *In Vitro* Diagnostics (OIVD) Annual Report of approximately 2 percent for 510(k) applications filed by original equipment manufacturers. Based on this high failure rate, AdvaMed believes it is only reasonable to conclude the failure rate for reprocessed single-use devices whose validation data FDA does not intend to review could be at least as high. We believe FDA should follow through and examine all reprocessed SUDs.

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[11] Letter to Nancy Singer, Esq., then Special Counsel to the Health Industry Manufacturers Association, July 13, 1998. Reference Docket No. 97P-0377.

[12] Hearing on Reuse of Single-Use Medical Devices, Subcommittee on Oversight and Investigations of the Committee on Commerce, February 10, 2000, Serial No. 106-89; pgs. 124 & 126.

[13] See "Guidance for Industry and FDA Staff– Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Medical Devices."

Branding and Labeling of Reprocessed Medical Devices

Prior to MDUFMA and the Medical Device User Fee Stabilization Act (MDUFSA), adverse events associated with reprocessed devices were frequently attributed to OEMs. Importantly, changes required by MDUFMA and MDUFSA should ensure that AEs associated with reprocessed single use devices will begin to be appropriately captured.

Prior to MDUFMA, FDA's MedWatch reporting form (used to report adverse events) failed to include a check box indicating that the device involved in the AE was a reprocessed single use device. Thus, prior to FDA's implementation of that provision in February 2004,[14] AEs associated with reprocessed single use devices were frequently mis-attributed to the OEM. Similarly, prior to MDUFSA, there was no requirement for reprocessors to mark or brand their devices. Since doctors and nurses are frequently unaware that the specific devices they are using have been reprocessed, those AEs are frequently attributed to OEMs.

MDUFSA requires reprocessors to brand their devices with their name, abbreviation or a unique and generally recognized symbol when the original manufacturer has prominently and conspicuously marked the single use device. The reprocessor can accomplish this by marking an attachment to the device. Where the OEM has not marked the device, MDUFSA requires reprocessors to use a detachable label identifying the reprocessor that is placed on the package containing the device and is intended to be placed in the patient's medical record. This provision only went into effect last month, August 2006. Therefore it is likely that the actual number of AEs associated with reprocessing will only begin to become accessible later this year.

With respect to FDA's response to the Chairman and the Ranking Member's questions about adverse events associated with the original use of the device, it is important to note that FDA did not implement the required addition of a check box indicating a reprocessed device was involved in the adverse event until February 17, 2004, 3½ months into the timeframe noted in the letter (November 1, 2003 through January 23, 2006). In addition, we are not aware of any significant efforts by FDA to educate users and providers about the existence of the new form. Finally, as noted above, the requirement for reprocessors to brand their devices has only been in place for one month. If users are unaware the device has been reprocessed, it is not clear how FDA could definitively eliminate reprocessed adverse events from the total number of adverse events during this period.

Reprocessor Allegations

Reprocessors make a number of allegations or statements regarding OEMs and reprocessing. Our responses to some of the most frequent are below.

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14 See February 17, 2004 Federal Register Notice (Volume 69, Number 31), Page 7490-7492, Docket No. 2003N-0016.

FDA's adverse event database (MAUDE) reveals zero patient deaths attributed to reprocessed devices.

FDA's MAUDE database reveals numerous adverse events associated with reprocessed devices. Due to the inherent limitations associated with all adverse event reporting systems it is quite challenging to prove that a reprocessed device (or any other device or drug) was the actual cause of a patient death, serious injury or other harm. Nonetheless, the association is there. The limitations associated with adverse event reporting systems are compounded when there is uncertainty regarding whether the device is an OEM (first) use device or a reprocessor device used against the original labeling. As aforementioned, until the MDUFMA MedWatch form change and MDUFSA branding change, it would have been difficult to distinguish reprocessed devices from original single use devices.

From January 1, 2004 to the present, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) devices. Because original equipment must be used if reprocessed equipment is not, it is irresponsible to report that there are alleged safety problems associated with using reprocessed equipment but fail to put this information in context by describing the safety record of original equipment.

AMDR inappropriately compares apples to oranges in an apparent attempt to overstate the safety of reprocessed devices. The correct comparison would be between single use devices and reprocessed single use devices. It is important to note that the overall number of devices used during this period alone is tremendously large. If the single use device has been reprocessed, one can only assume that the single use device was used safely in its first intended use – otherwise it would not have been placed into the reprocessing "stream" and reprocessors' validation systems should presumably have detected it. Finally, due to the relatively recent statutory changes described above, AEs associated with reprocessed single use devices may now begin to be appropriately captured.

The "single use" label is used at the OEM's discretion, often as a way to sell more devices. Indeed, "single use" does not always mean that a device is not suitable for reprocessing, as evidenced by the fact that some OEMs now reprocess their own "single use" devices, and some have changed the labels on certain "reusable" devices to "single use" without significantly changing the devices.

Single use devices are designed for optimal performance and safety under their intended conditions of use on a single patient – not ease of cleaning – and as discussed above, they typically have characteristics that make them extremely difficult to effectively clean and re-sterilize. In fact, FDA requires a single use label unless validation data demonstrates that the device can be safely cleaned, sterilized and reused. Many procedures performed today such as angioplasty or other procedures which require inserting and maneuvering devices into parts of the body that previously required open surgery cannot be done using materials that are highly durable and readily reusable. Many single use devices are manufactured of plastics, and lesser grade metals and adhesives (in order to reduce hospital purchasing costs), and the materials may not be able to be effectively cleaned and re-sterilized. Some of these materials may kink, crimp, crack or become brittle or tacky when cleaned and resterilized.

To claim that original equipment manufacturers merely re-label reusable devices as single-use in order to boost sales defies the economic basis for the single-use product market. Some commonly-used medical devices are available in both reusable and single-use configurations. This affords user institutions a logical choice based on the economics of their operation. If the institution can afford to purchase cleaning and sterilization materials and equipment and has the staff to reprocess single use devices on site (or chooses to pay an outside contractor to perform these tasks) they will purchase reusable medical devices and amortize their higher cost over a number of uses. If the user cannot afford such equipment, or does not have the staff to perform controlled cleaning and sterilization operations, they will purchase single-use devices.

However, the cost-effectiveness of this choice requires that the purchase price of the single-use device be substantially less than its reusable counterpart. Medical device manufacturers are able to meet this requirement by using lower cost materials (plastics versus metals, for example) and different designs for their single-use products. These materials and designs are nowhere near as robust or durable as those employed in reuseable devices, since they are only needed to withstand original manufacturing and a single use. Furthermore, the cost of developing a single-use device is typically lower than that for a reuseable device, since the safety and efficacy of the single use device has already been validated by the reuseable version that preceded it and the verification testing of the single use device only needs to demonstrate its ability to work once. The design of a single use device is very different from that of a reuseable device. This difference is the only way a single use device can be made available as a cost-effective option.

AdvaMed supported the MDUFMA and MDUFSA reprocessing provisions because we are interested in the appropriate regulation of these products. If appropriate regulation means some products will continue to be reprocessed because the practice is supported with appropriate validation data, then that is acceptable. If appropriate regulation of reprocessing means some of these products can no longer be reprocessed, then patient safety will benefit from that decision.

Reprocessors also routinely claim that original equipment manufacturers arbitrarily label some reusable devices as single use. This is untrue, and to date, reprocessors have failed to cite a single example of conflicting designations. Since reprocessors do not have access to the original design and material, they simply can not make this claim with any accuracy.

Obtaining informed consent from patients for the use of reprocessed "single use" devices does nothing to increase patient safety nor does it provide patients with any meaningful information about the actual risks and benefits of the medical procedures they are about to undergo. Reprocessed devices are as safe and effective as original equipment, and there is no evidence that the use of reprocessed devices increases the risks associated with a medical procedure. These are not investigational or experimental devices. It is not good or standard medical practice to obtain informed consent to use legally marketed medical devices, and there is no legal, medical or ethical basis for imposing a requirement to seek informed consent for the use of reprocessed devices but not for the use of original devices.

AdvaMed believes reprocessed single use devices may present increased risks to patients because they've been previously used in one or more patients and because single use devices typically have characteristics that make them extremely difficult to effectively clean and re-sterilize. Subsequent sterilization of previously used and cleaned single use devices may seriously

compromise their safety and performance and even destroy some single-use devices. We believe patients have the right to know and choose whether a reprocessed single use device is used in their care.

We also take issue with the reprocessors' characterization of the informed consent process. If informed consent is properly done, it does indeed provide patients with meaningful information about the actual risks and benefits of the medical procedures they may undergo.

Reprocessors are more stringently regulated than original manufacturers and as a result, reprocessed products are safer because each product is inspected before being shipped and there are no "out-of-the-box" failures.

In contrast to reprocessor assertions that they are more stringently regulated than OEMs, the MDUFMA and MDUFSA requirements simply require reprocessors to do what OEMs must already do under FDA regulations – label and brand their products as their own (something reprocessors presumably should not object to if they are confident of their products). Per MDUFMA, FDA also required a small subset of reprocessors to submit validation data demonstrating that single use devices originally intended for one use are safe and effective when reprocessed and returned to the market for additional use. As discussed above, reprocessors have previously testified to Congress that they were meeting FDA's basic regulatory requirements. However, when they were required by MDUFMA to actually demonstrate that by submitting validation data, 50% of their submissions were inadequate.

Reprocessors claim their devices are safer because each device is individually inspected. This is flawed logic because OEMs develop inspection processes that rely on the manufacturer's control of all variables (e.g., design, materials, components, and assembly). Reprocessors do not have control of all the variables that would enable them to use the statistical sampling processes used by OEMs. As a result, they must inspect each device because their history is unknown. Moreover, the final cleaned and sterilized reprocessed device cannot be individually tested without compromising the cleanliness and sterility of the product. Reprocessed devices can only be tested for functionality prior to sterilization. The integrity of the device after sterilization is therefore unknown.

Liability associated with reprocessed single use devices may be related to inherent design flaws or attributable to the OEM's own acts or omissions.

Reprocessors assume total responsibility for the single use devices they reprocess after receiving market clearance from FDA. Reprocessed devices are not the legal responsibility of OEMs. Further, if the single use device has been reprocessed, one can only assume the single use device was used safely in its first intended use – otherwise it would not have been placed into the reprocessing "stream" and reprocessor's validation systems should presumably have detected it.

Conclusion

We thank the Committee again for its interest in this important health issue. We look forward to working with Congress and the Administration on the continued implementation of the provisions in MDUFMA and MDUFSA related to the oversight of reused single-use devices.

Chairman TOM DAVIS. Thank you.

Mr. Selvey and Mr. Toussaint, let me just start.

Mr. Selvey, one of the challenges of reprocessing, it seems to me, has to be the changes to technology and designs. How do you keep up with the evolving technology and designs when you are not privy to trade secret information?

Mr. SELVEY. Mr. Chairman, if I may?

Chairman TOM DAVIS. Yes.

Mr. SELVEY. There are a couple of things that we can do to keep up with the changing in design. First off, if the design change by the original manufacturer is significant, they are required under law to notify the FDA. That becomes public information. We can monitor that and, in fact, we become aware of that.

Chairman TOM DAVIS. You can then decide if you want to buy something new at that point to make the decision?

Mr. SELVEY. Correct.

The other part would be the change that is made by the original manufacturer that is not a significant change; we would pick that up through our routine monitoring of the devices. Periodically, we will do revalidation of the process but even beyond that, we will do periodic things like materials testing, analysis of the devices, just to make sure that there hasn't been a relatively insignificant change that has not been reported to the Food and Drug Administration and therefore not made public.

Chairman TOM DAVIS. I don't know how I ask this. I guess I just ask this in a generic sense. How many times can one of the single-use devices be reprocessed before it becomes unusable? Does it just depend?

I gather you have a way to look at that and decide if it is usable or not. How do you decide?

Mr. SELVEY. Mr. Chairman, there are a couple of factors that go into it. Yes, every device does have a finite number of reprocessing cycles. Typically, for the devices that we reprocess, it is going to be somewhere between one and five cycles. The average is about three. We are going to base that on the studies that we do in order to validate our ability to clean and test and resterilize the device.

There is also a certain amount of, what I refer to as, the law of diminishing return. Typically, these devices are rejected out at about a 20 percent rate. That is, when they come into us, for whatever reason, about one in five devices is not fit to go through the process. Therefore, it is in our best interest to look very carefully at whether we are going to get more than five cycles out of the device, just based on that diminishing; typically three times, usually based, well, always based on the validation studies that we have.

Mr. UBL. Mr. Chairman, may I comment on that question?

Chairman TOM DAVIS. You may.

Mr. UBL. I think it is very, very difficult for reprocessors to keep up with those changes. Let me just give you example. This was mentioned earlier. FDA allows reprocessors to submit in bundles, sometimes covering multiple manufacturers in the same device in the hundreds. FDA would never allow original manufacturers to submit and bundle their applications in that fashion. So I think it is extremely difficult to essentially assert that these types of prod-

ucts have the same degree of sameness, if you will, and keep up with the rapid incremental changes in technology.

Chairman TOM DAVIS. Mr. Selvey asserts that the reprocessing is highly regulated and probably more stringently regulated than the original equipment industry, and you seem to contradict that.

Mr. UBL. Yes, I am absolutely baffled by that assertion. Our information suggests that, in fact, they have a much lower bar, and part of that is the bundled submission that I mentioned but, in addition, the quality systems regulation, pre-clinical testing of individual components, which they obviously can't do because they don't have the proprietary information. There is a whole range of FDA regulatory authorities that apply much more acutely to original manufacturers than they do to reprocessors.

Chairman TOM DAVIS. Why don't you guys reprocess your own stuff?

Mr. TOUSSAINT. Mr. Chairman.

Chairman TOM DAVIS. I will give you a chance to answer in a second.

Why don't your own people, your own member companies ever partner with a reprocessor to refurbish their own devices?

Mr. UBL. Why don't they? Because they don't——

Chairman TOM DAVIS. Yes; is it because you make more on selling new stuff?

Mr. UBL. Well, they fundamentally don't believe that a reprocessed device is their device. It is a different product, and they really question the premise of whether these technologies can be safely reprocessed.

I have to go back to the comment that was made that this is about money. Reprocessing single-use devices are less than 5 percent of all device sales, 5 percent. So the assertion that this all about economics is ludicrous, absolutely ludicrous.

Chairman TOM DAVIS. But obviously, if you can get this device to work well, I don't know why you wouldn't want to do something that costs less. They are getting squeezed every which way for health costs. If you can reprocess a device and use it cheaper, why wouldn't you?

Mr. UBL. Absolutely, and we do it all the time. Let me just clarify that FDA approves single-use devices and multiple use devices. Our members make both. Our members are trying to be responsive to what the patient needs are and what the hospital and provider needs are. So for example, a trocar is a technology that used to be made in stainless steel and is now made in plastic due to the customer demanding ease of use and disposability. So there is a tension in the marketplace, and we are trying to be as responsive as possible to providers.

Chairman TOM DAVIS. But you would admit that if the reprocessors and the FDA can guarantee patient safety, you don't have a problem with reprocessing.

Mr. UBL. We believe that the biggest problem is that a large number of devices don't come under the FDA purview. Dr. Schultz actually mentioned two adverse events that we reported to the FDA that were not being regulated by the FDA's reprocessing authority.

Chairman TOM DAVIS. But conceptually, if the FDA regulated them, even if they made them be single-event pieces, if they can use them and it is safe, you don't have a problem.

Mr. UBL. Conceptually, yes; I mean I think we might have some issues around bundling and some of the mechanics of how it is done.

Chairman TOM DAVIS. You are saying if they can assure the safety, you don't have a problem; OK.

Mr. Selvey, do you want to comment, or Mr. Toussaint?

Mr. TOUSSAINT. Mr. Chairman, I really need to respond to Mr. Ubl's comment about bundling. I am not sure where he is getting this, his information, but there is an FDA guidance on bundling that does apply to, not only to reprocessor but OEMs, and in that guidance document, it states specifically that it is appropriate for manufacturers to bundle devices among generic types of devices, and it defines very specifically what a generic type of device is. It is appropriate. It further states that it is appropriate to bundle devices when the differences do not reflect any changes in safety or effectiveness of the devices. So bundling is an appropriate practice.

When we do choose to bundle, we do it very carefully, and we scrutinize it very carefully. When Mr. Ubl says that hundreds of devices are not tested, that is simply not correct.

Chairman TOM DAVIS. Every time there is an adverse incident, it just hurts your industry, right?

Mr. TOUSSAINT. I am sorry, what?

Chairman TOM DAVIS. Every time there is an adverse incident with one of these devices, it just hurts your marketability and profitability, doesn't it?

Mr. TOUSSAINT. Yes, I would say.

Chairman TOM DAVIS. So, of course, OK.

Mr. TOUSSAINT. Yes. When we choose to bundle devices, however, it is not that we choose one device out of, say, 50 devices to test. Within the bundling, within bundling a family, for instance, all devices are tested, and that way, during the review process, if the FDA would choose to analyze each device separately, statistically and otherwise, they could do so.

So in effect, it would become a separate submission. So bundling is a means to increase the efficiency of FDA review, and it allows FDA to look at devices individually along with the family of devices, the generic type of family devices they belong to.

Chairman TOM DAVIS. How do you feel about the level of FDA regulation? Do you think it is about right at this point? Do you think you are under-regulated or over-regulated?

Mr. TOUSSAINT. Are you speaking to me, Mr. Chairman?

Chairman TOM DAVIS. I am. I am going to ask all three of you that.

Mr. TOUSSAINT. About the entire MDUFMA regulation, I think it is entirely over-regulated. I think many of these devices that require additional validation were previously cleared in the year 2000 or even prior to that and contain much of the data that submissions contain today, and I believe this is simply that the requirements that are required today of SVS submissions are a result of the pressure put on OEMs, so we are not allowed to process devices.

Chairman TOM DAVIS. Mr. Ubl, you don't agree with that?

Mr. UBL. I absolutely don't agree. I think the practice is underregulated. Again, FDA only regulates 68 types of technologies out of a possible 228. AdvaMed has provided to the FDA two types of technologies that have had adverse events associated with them. They, in turn, have extended their regulatory umbrella to those types of technologies. We wonder how many other technologies are out there that are at risk to patients.

I know for my family, I certainly wouldn't want to trust a reprocessor to tell me how many uses.

Chairman TOM DAVIS. Well, let me ask you another question. Do you think the OEMs are too regulated or not regulated enough?

Mr. UBL. I think there are appropriate regulations of original manufacturers.

Chairman TOM DAVIS. OK.

Mr. TOUSSAINT. Mr. Chairman, I really need to respond to one other comment from Mr. Ubl.

Chairman TOM DAVIS. Now, I am going to get to Mr. Gutknecht. Sure, we will let you respond. Let me give Mr. Gutknecht 10 minutes. Go ahead.

Mr. GUTKNECHT. Well, I just want one real quick question. If this is so dangerous, you, both Mr. Selvey and Mr. Toussaint, your product liability or your liability insurance must be just sky-high.

Mr. SELVEY. Mr. Gutknecht, that is an important distinction. We do carry liability insurance, in fact, at the same level or an even higher level than some of the original manufacturers. Although we are not trying to compete with the manufacturers, we are trying to make our hospital customers very comfortable with our level of coverage. The reality is that despite having reprocessed something on the order of 15 million devices since our inception, we have never been sued by a patient, by a hospital, claiming that we produced an adverse event in a patient. In a litigious society, I think maybe that says something.

Mr. TOUSSAINT. I don't know what our insurance rates are at SterilMed, but I can say the same thing that Mr. Selvey has said, and that is that we have never been sued by a hospital, a patient, or had any other litigious event occur against our company.

Mr. GUTKNECHT. So it is fair to say that both your insurance companies and your customers are satisfied with the quality of the products that you are putting out there.

Mr. UBL. Can I comment on that, Congressman?

In some ways, reprocessing is flying under the radar. The reason there haven't been suits by patients or by providers is because, as has been mentioned by FDA and in my testimony, there is not adequate branding so that practitioners and patients even know that a reprocessed device is being used. So, until we have well-established branding, tracking, reporting, and so forth, we are not going to know what the true impact is.

Mr. GUTKNECHT. Well, with all due respect, I have heard those siren songs before about drugs coming in from Canada, and the evidence is that a whole lot more Americans die every year from drugs that are purchased in the United States.

Mr. UBL. This is very different than a pill, Congressman. This is coming in contact with blood, tissue, and even the heart.

Mr. GUTKNECHT. I understand, and I will reclaim my time, thank you.

The point really is if this was as dangerous as some would have us believe, we would have massive lawsuits and, more importantly, the market for these devices, in my judgment, would dry up. I have talked to some of my hospital people. I have talked to some of my doctors about this very issue, and their general view is this is much ado about very little.

I yield back my time.

Chairman TOM DAVIS. Mrs. Schmidt.

Mrs. SCHMIDT. Thank you, Mr. Chairman.

I have a couple of questions for the panel. The first regards the bundling. I am very concerned about the bundling because I don't think it allows the FDA to have a clear review of each and every device. Would you be amenable? Frankly, I am not concerned about the ease of the FDA doing their job. The point is we have to have FDA doing the right job.

Would any of you be adverse to not allowing the bundling and to force the FDA to look at each and every application on its own merit without bundling these devices?

Mr. SELVEY. Mrs. Schmidt, may I take a crack at that?

Bundling is a prime example of much ado about nothing. As Mr. Toussaint has said, there is an FDA guidance on bundling for both OEMs and for reprocessors.

But there is a very practical aspect here. When we put together a 510(k) and it goes to a reviewer who is not used to seeing bundled submissions, they have not been trained in bundled submissions, honestly, the reviewer doesn't know what to do with a bundled submission. We do not put together bundled submissions. I am not sure what Mr. Ubl is complaining about, but aside from some of the very early submission that we did back in the year 2000 that caused much heartburn and grief among the reviewers at the FDA, we stopped bundling. We haven't bundled a submission in a very long time.

So to answer your question very directly, we would have no issue at all with doing away with bundling. It simply is not an issue for us in this industry.

Mrs. SCHMIDT. In the matter of time, could I have a yes or no from either one of you because I have another question?

Mr. UBL. I am delighted to hear that response. The only comment that I would make is it is important for the committee to understand we are not just talking about a family of technologies made by one manufacturer. What they are bundling is across manufacturers making a similar product which is why it is so disturbing to us.

Mr. TOUSSAINT. Mr. Chairman, why that statement is somewhat incorrect is after each family, even though we bundle across families, for each family we provide separate validation data on that family. So each family is tested independently. Whether they are bundled together in a single submission or in multiple submissions, they still undergo the same review process.

Mrs. SCHMIDT. Mr. Chairman, another question; one of my other concerns is the ability for the patient to know whether they are getting an original product or a reused product. Would any of you;

just a yes or no answer with no comment, be in agreement that in the future, if it is a reused product, the patient will know up-front that it is going to be used, yes or no?

Mr. SELVEY. No.

Mr. TOUSSAINT. No.

Mr. CUMMINGS. Yes, we would support patient informed consent.

Mrs. SCHMIDT. OK, thank you very much.

Mr. TOUSSAINT. Mr. Chairman.

Chairman TOM DAVIS. Yes, go ahead.

Mr. TOUSSAINT. I have another comment I feel I must address by Mr. Ubl, and that was his comment regarding the 50 percent rate as being totally unobjectionable as devices not being safe enough and effective. I am not sure where that rate comes from, but I believe it is a total distortion of facts. I believe that rate comes from the fact that when reprocessors originally had to submit SVSes on a number of products, we received a number of NFC determinations or requests for additional information. This in no way implied that the devices were not safe and effective.

In fact, let me read to you a quote from an FDA colleague about this matter. Larry Spears, the Deputy Director of the Office of Compliance at the FDA Center for Devices and Radiological Health stated that any reference to the specific devices that can no longer be legally marketed as being dangerous or unsafe is incorrect. Although some devices were found through review by our Office of Device Evaluation to be non-substantially equivalent to a previously marketed device, this does not mean they are unsafe or ineffective.

Mr. UBL. Mr. Chairman.

Mr. TOUSSAINT. When you receive an NFC letter, that is a request by FDA that you need to submit further information, further validation data, or other information. It does not mean that the devices at that point cannot be deemed substantially equivalent. During that period of time, many SVS submissions were submitted to FDA, and FDA was working through the process as well as the manufacturer. So it is not unexpected that we would receive NFC letters and FDA would be, would send out such letters and ask for additional information.

There are other factors that relate to that 50 percent figure. It may be simply that the manufacturer chose not, after receiving such a letter, decided, chose not to provide that additional information because it was too, not feasibly cost-effective.

Mr. UBL. I promise to be really quick, Mr. Chairman, but let us just look at FDA's testimony to this committee. They say 33 percent of the time when the reprocessor submits their application, it was not substantially equivalent. That means it is taken off the shelf. I will grant you that it seems like approval rates have improved since we have been using the 50 percent rate, but a third of the time, they are submitting applications that are not meeting the test by FDA. This, to us, tells us that not only should they be looking at the devices they are looking at now but the additional types of technologies that are currently under FDA's purview.

Chairman TOM DAVIS. All right; anything else?

Mr. TOUSSAINT. No; I would just like to respond to that comment as well.

Chairman TOM DAVIS. Go ahead and get going. Go ahead.

Mr. TOUSSAINT. Just that the 33 percent simply means that we need to provide additional validation data. It doesn't mean the devices are not substantially equivalent, nor does it mean that——

Mr. UBL. Does it mean they are off the shelf?

Chairman TOM DAVIS. Is this stuff properly categorized so you know how many times it has been used, just for the record, as you keep it, or do you just examine it and say, yes, this looks good?

Mr. TOUSSAINT. I am sorry. I didn't understand the question.

Chairman TOM DAVIS. Every time you reuse a medical device, is it logged in that this is the third time or the fourth time or the second time it has been used, or do you just kind of look at it and decide if it meets criteria or not?

Mr. TOUSSAINT. I would say we generally look at it and decide if it meets criteria.

Chairman TOM DAVIS. So it is not necessarily logged in, and you have that record of how many times it is has been used?

Mr. TOUSSAINT. Well, we certainly have. You are talking about specific devices?

Chairman TOM DAVIS. Yes.

Mr. TOUSSAINT. Certainly, we have a record of how many times a device has been used.

Chairman TOM DAVIS. Anything else?

We are going to vote, and I want to let the panel go.

This is to be continued. Obviously, we don't have a consensus here, but I appreciate everybody's testimony and being able to make the case. The committee will continue to look at this further.

Thank you.

[Whereupon, at 12:17 p.m., the committee was adjourned.]

[The prepared statement of Hon. Edolphus Towns follows:]

United States House of Representatives
Committee on Government Reform

Hearing: "Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices"
Tuesday, September 26, 2006 – 10:30 AM
2154 Rayburn House Office Building

Congressman Edolphus Towns Opening Statement

THANK YOU CHAIRMAN DAVIS FOR ORGANIZING THIS HEARING ON THIS VERY IMPORTANT ISSUE.

ACCORDING TO THE TESTIMONY, THERE ARE CONFLICTS SURROUNDING THIS ISSUE. FOR INSTANCE ORIGINAL EQUIPMENT MANUFACTURERS (OEMS) CLAIM THAT THE PRACTICE OF REPROCESSING MEDICAL DEVICES IS NOT SAFE WHILE REPROCESSORS SAY THERE IS "NO CREDIBLE EVIDENCE" THAT SUGGESTS THAT THEIR DEVICES ARE UNSAFE.

ON THE OTHER HAND, REPROCESSORS CLAIM THAT THEIR PRODUCTS ARE SAFE EVEN THOUGH THERE ARE SEVERAL NEWS REPORTS THAT HAVE IDENTIFIED CASES TO THE CONTRARY.

IN THE MIDST OF IT ALL, HOSPITALS ARE SAVING!

MY PRIMARY CONCERN IS THE SAFETY OF THE PATIENTS AND THE QUALITY OF CARE THEY RECEIVE WHEN REPROCESSED MEDICAL DEVICES ARE USED.

WE SHOULD NOT BE ARGUING THE POINT THAT THERE IS NOT ENOUGH "CREDIBLE EVIDENCE" TO SUPPORT THE THOUGHT THAT REPROCESSED MEDICAL DEVICES ARE SAFE, BUT THE QUESTION THAT SHOULD BE ASKED THIS MORNING IS WHETHER WE HAVE ENOUGH INDEPENDENT, CREDIBLE EVIDENCE THAT SUPPORTS THE STATEMENT THAT THESE DEVICES ARE JUST AS SAFE AND OF THE SAME QUALITY AS NEW DEVICES.

WE NEED TO ENSURE THAT PROFIT MARGINS ARE NOT DRIVING US TO CUT CORNERS AND PLACE PATIENTS AT RISK.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 27 2006

The Honorable Tom Davis
Chairman
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Davis:

Thank you for providing Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA or the Agency) the opportunity to speak before the Committee on Government Reform about reprocessed single-use devices (SUDs) on September 26, 2006. This letter provides the follow-up information requested by the Committee at that hearing.

Specifically, a Committee member asked FDA to provide an example that demonstrates the rigor of the Agency's pre-market review of reprocessed SUDs. Enclosed is a CD-ROM containing two CDRH Office of Device Evaluation review memos regarding pre-market submissions for reprocessed SUDs. These memos illustrate the in-depth, comprehensive testing and analyses required to validate the reprocessors' claims regarding cleaning and functional performance.

You also asked for follow-up pertaining to the second adverse event referenced in AdvaMed's testimony. AdvaMed stated that this information was provided to FDA on September 30, 2004:

> "In another case, a reprocessed endoscopic vein harvesting system failed when a piece of shrink tubing broke free of the device and became lodged in a patient's leg. In this case, the surgeon was forced to 'fish' the dislodged part out of the patient's leg exposing the patient to excessive bleeding and a prolonged procedure. OEM failure analysis of the returned device found that the shrink tubing that broke free had deteriorated due to multiple sterilization cycles."

FDA can confirm that we did receive a September 30, 2004, letter from AdvaMed which mentions the adverse event information that was mentioned in their testimony. Based on the information provided, we have searched our database and found no report of a similar incident. Please note that this information was sent to FDA by AdvaMed in their letter to the Agency as comments in response to Docket No. 03N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Pre-market Notifications; Requirement for Submission of Validation Data. If AdvaMed would like to submit additional information

or encourage the manufacturer to submit an MDR report on this event, CDRH will follow-up as appropriate.

You also asked FDA to provide information to the Committee on the tracking of SUDs that are processed multiple times. FDA's inspection process provides information to the Agency regarding the number of times a particular SUD is reprocessed. During inspections, the investigator routinely reviews the firm's reprocessing operations, from handling incoming components through packaging and distribution. The investigator also reviews the specifications and standard operating procedures for each product to ascertain the number of times it can be reprocessed. Once the investigator obtains that information, the production records are reviewed to ensure compliance. An individual device's production record is prepared or updated each time the device is reprocessed, and the reprocessed SUD is to be discarded after its final reprocessing cycle and subsequent use.

Finally, a question was raised regarding FDA documentation of enforcement actions recommended by Agency staff but ultimately not taken against medical device manufacturers. This information is protected from public disclosure by the Freedom of Information Act (Title 5, United States Code, section 552) and FDA regulations. FDA notes, however, that a recommendation for enforcement action may involve formal and informal reviews by staff and supervisors in multiple offices. Any of a number of reasons may explain a decision not to pursue a staff recommendation for enforcement action against a device firm, including an insufficiency of the evidence to support the recommended charges, a determination that an enforcement action other than the one recommended is more appropriate, or a decision that the public health would best be served by devoting limited agency resources to other actions.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

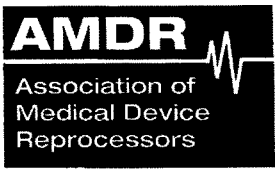
Sincerely,

Michael Nestal

for David W. Boyer
Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143



October 12, 2006

BY ELECTRONIC MAIL

The Honorable Tom Davis
Chairman
Committee on Government Reform
House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Chairman:

On behalf of the Association of Medical Device Reprocessors (AMDR), I would like to submit the following statement to the September 26, 2006 hearing record regarding "Medical Device Safety: How FDA Regulates the Reprocessing of Supposedly Single-Use Devices." AMDR is a trade association that represents the legal, legislative and regulatory interests of third-party reprocessors of medical devices labeled for "single use." AMDR's members represent approximately 95% of the third-party reprocessing industry.

Under the Food, Drug, and Cosmetic Act (FDCA), all device manufacturers must, before introducing a device to market in the United States, obtain FDA clearance of a premarket notification (510(k)), unless the device has been exempted by the agency from the 510(k) requirement. When Congress enacted the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), it mandated that manufacturers of reprocessed devices include in many of their 510(k)s certain data "that exceed[] the requirements for OEMs."[1] Specifically, MDUFMA required FDA to develop a list of reprocessed devices for which, henceforth, the 510(k) submission would be required to include data validating the cleaning and sterilization processes, and "functional performance data demonstrating that each [reprocessed device] will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed."[2]

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1 Statement Of Daniel Schultz, M.D., Director, Center For Devices And Radiological Health, Food And Drug Administration, U.S. Department Of Health And Human Services, Before The Committee On Government Reform House Of Representatives, September 26, 2006. Available at http://www.fda.gov/cdrh/reuse/testimony-092606.html.

2 *Id. see* 21 U.S.C. § 360(o).

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MDUFMA required the submission of such data not only for new 510(k)s submitted after the law's effective date, but also for devices that were already lawfully marketed pursuant to previously cleared 510(k)s. For those previously cleared devices, reprocessors were required to supplement the existing 510(k)s with the required data. The statutory deadline for making these "supplemental validation submissions" (SVSs) for devices that were already on the market was January 30, 2004. Significantly, MDUFMA did *not* specify any deadline by which FDA had to be finished reviewing those submissions and make a determination as to whether the devices would remain legally marketed. However, FDA chose to impose a deadline of November 2, 2004 for issuing or denying clearances.

FDA completed its initial review of the SVS submissions by its self-imposed deadline of November 2, 2004. At that time, the agency determined that many of the submissions warranted findings of substantial equivalence (SE) and, therefore, the devices that were the subject of those submissions could continue to be legally marketed. The agency also issued findings of "not substantially equivalent" (NSE) for a number of devices. Devices that received NSE determinations were required to be removed from the market until such time as the reprocessor submitted the additional information necessary to obtain an SE determination from the agency.

AMDR is concerned that there may be a misunderstanding about the significance of the NSE determinations that were made by FDA following the initial round of SVS submissions. As explained below, and contrary to claims of the original equipment manufacturing industry, FDA's November 2004 decision identifying selected reprocessed "single use" devices that could no longer be distributed, was not related to safety. It bears emphasizing that each of these devices, prior to MDUFMA, had been a legally marketed device for which FDA had already made a determination that the device was substantially equivalent to a predicate device. As Larry Spears, the Deputy Director of the Office of Compliance in the FDA's Center for Devices and Radiological Health, stated just after the NSE letters were issued:

> ***any reference to the specific devices that can no longer be legally marketed as being dangerous or unsafe is incorrect,***" and, although some devices "were found through a review by our Office of Device Evaluation to be not substantially equivalent (NSE) to a previously marketed device . . . ***[t]his does not mean they are unsafe or ineffective.***[3]

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[3] *Healthcare Purchasing News* (November 9, 2004) (emphasis added).

The truth about the NSE letters that were issued by FDA is as follows. Prior to the enactment of MDUFMA, there existed between OEMs and reprocessors a level playing field with respect to premarket submission requirements. Reprocessors were obligated to satisfy the same premarket regulatory criteria that OEMs were required to satisfy in order to market a particular device. In 2002, MDUFMA imposed additional submission requirements on reprocessors, but at the time that the statute was enacted, FDA itself did not know what kind of data, or how much data, the agency would need to review in order to reach an affirmative finding that the statutory requirement had been met and the device could continue to be considered "substantially equivalent" to a legally marketed predicate device. In the months leading up to the submission deadline, FDA and the industry worked together closely to determine what body of data would be needed, but in fact, after the deadline had passed and the submissions had been made, FDA, in reviewing the submissions, came to the conclusion that for some devices, additional data were needed.

This is not unusual. When FDA reviews premarket device submissions, whether for an "original" or a reprocessed device, more often than not there will be at least one round of questions from the agency followed by additional data submissions from the manufacturer. Indeed, often there is more than one round of such questions and data submissions. Typically, FDA engages in this back-and-forth dialogue with the submitter until the agency either receives all the information that it needs to clear the submission or the agency determines that the submission is not clearable.

Because of the self-imposed deadline, however, FDA, in dealing with the SVS submissions required by MDUFMA, departed from its usual practice of refraining from issuing a final SE or NSE determination until it has either received all of the needed information or has determined that the submission is not clearable. In the case of these SVS submissions, the agency issued NSE letters based only on the data in the initial submissions and what limited additional data could be compiled, submitted and reviewed prior to the deadline.

The setting of this deadline limited FDA's ability to determine and communicate what information reprocessors were required to submit and also limited the reprocessors' ability to compile, organize, format and submit the information. Because the normal back-and-forth dialogue was cut off prematurely, there were, when the deadline arrived, submissions under review for which FDA had outstanding questions that had not yet been answered. Because these submissions could not be cleared by the deadline, NSE letters were issued.

The important point is that the issuance of NSE letters was, <u>not</u> a determination by FDA that there were safety or effectiveness problems associated with the devices. Indeed, just after the NSE letters were issued, Tim Ulatowski, Director of the Office of Compliance in the FDA's Center for Devices and Radiological Health, publicly indicated that the

reprocessing companies were working with FDA to provide the additional information required to resolve any outstanding issues.[4] To date, with the exception of devices for which supplemental validation submissions were not made or were voluntarily withdrawn for business reasons (as explained below), most of the devices that were originally covered by an NSE letter have since been cleared for marketing by the agency.

The simple fact is that our members recognized during the process that the cost of putting together a supplemental validation submission (or of conducting additional testing requested by the agency) for some of these devices would exceed the revenues that the companies would earn from reprocessing them. Consequently, for these devices, the companies either did not submit SVSs or made initial submissions that were subsequently withdrawn when it became clear that meeting the agency's requests for additional data would be more costly than anticipated revenues warranted. These business decisions, however, do not constitute evidence of a regulatory or safety problem.

In short, the suggestion that the SVS process established that a significant number of reprocessed devices fail to meet regulatory requirements is simply false. The safety record of reprocessing has always been and continues to be excellent. To date, more than 40 million devices have been reprocessed and used in this country without any evidence of increased risk to patients.

Sincerely,

Pamela J. Furman, Esq.
General Counsel

PJF:la
cc: The Honorable Henry Waxman

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[4] *Id.*

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