

REUSE OF SINGLE-USE MEDICAL DEVICES

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BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
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HOUSE OF REPRESENTATIVES
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THURSDAY, FEBRUARY 10, 2000

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:21 a.m. in room 2322, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Barton, Burr, Whitfield, Ganske, Bryant, Bliley (ex officio), Waxman, Stupak, and Strickland.

Also present: Representatives Eshoo and Pickering.

Staff present: Alan Slobodin, majority counsel; Anthony Habib, legislative clerk; and John Ford, minority counsel.

Mr. UPTON. Good morning, everybody. Sorry we are a little bit tardy starting. For those not realizing what the buzzer meant, we had a vote. So we are all ready to start promptly at 10, and then we had to walk over the Capitol and come back. Before I proceed with my opening statement, I do want to ask unanimous consent that other members of the full committee, although not on this subcommittee, be allowed to sit in, provide opening statements, and also proceed with the question and answer period of both Dr. Feigal and the second panel. Without objection that will be the order of the day.

Good morning again. Today this subcommittee holds a hearing on the reuse of medical devices, labeled and approved by the Food and Drug Administration for single-use only. Within the last year there has been extensive debate, both on and off the Hill regarding the practice of reprocessing medical devices that have been designed, manufactured, and approved by the FDA for single-use only.

As many of you know, before a device may legally enter the market, original medical device manufacturers must submit product approval applications to FDA which may include extensive sterility and clinical data that demonstrate the safety and efficacy of the device. The original manufacturer must also comply with the extensive FDA regulations regarding the manufacturing of the device, as well as post-market controls that give both the FDA and the manufacturer the ability to continue to assess the safety and efficacy of the device, and ensure that patients are adequately protected.

For patients, original device manufacturers and the FDA, this system works. However, there is a significant and perhaps even a dangerous, gap in FDA's existing enforcement practices. In some

instances, hospitals, either using in-house facilities or third parties, will reprocess a disposable medical device that has been approved by FDA for use in a single patient only, and reuse the device several times on additional patients in most instances without notifying patients that the device may have already been used.

Much to my surprise I have learned that this practice includes reusing devices that have been inserted into other patients, including biopsy forceps and catheters. This practice raises two patient safety concerns. One, whether single-use devices can be adequately cleaned and sterilized for use in other patients, and two, whether attempts to clean and sterilize these devices may lead to product failures or in any way significantly affect performance and design specifications.

These concerns are not theoretical to me. I am alarmed by reports that there may be unsterile and contaminated medical devices on hospital shelves ready to be reused on patients. There is the report of a broken heart catheter in a 32 year old woman that lodged in the atrium of her heart. I am also concerned about how one knows whether the reprocessed single-use device has been used a second time, or an eighth time, or maybe even a tenth time. We need to make sure that these complex, hard to clean medical devices are really sterile and functional.

These products may look fine and dandy to the naked eye, or even one with Lasik, but under a microscope or in a patient it could be a completely different story. I am well aware that some hospitals and reprocessing companies take many precautions and work very hard to produce safe and effective reprocessed single-use medical devices. I am also aware of many studies on this issue, some showing problems with reprocessed single-use devices, and others indicating that single-use devices can be reprocessed and reused safely. But in the end, there seems to me to be too many questions about the risks to patients, the lack of informed consent, regulatory fairness, whether the newer and more complex devices really can be cleaned. That is why we need this hearing to help us understand the issues involved with reprocessing, to get some answers to some questions, and to assure ourselves that the FDA is appropriately regulating the practice of reprocessing. The FDA has acknowledged that it presently has the authority under the Federal Food, Drug and Cosmetic Act to regulate both on a pre-market and a post-market basis. To date, the Agency has chosen not to fully enforce all of the statutory and regulatory requirements over reprocessing of single-use devices that original manufacturers must comply with. Most notably, pre-market review. I look forward to hearing directly from the Agency about how it plans to address this issue, both now and in the future to ensure that American patients are not unnecessarily put at risk.

I welcome particularly Dr. David Feigal of the FDA before this subcommittee. I want to express my deep appreciation to Dr. Feigal who only a few months ago became the Director for FDA's Center for Devices and has already helped lead the FDA to a reassessment of an issue that the FDA has struggled over for many, many years. I also want to thank Chairman Bliley for his support of this hearing and the inquiry. I also want to welcome Ms. Anna Eshoo for raising attention to this issue, particularly with her legislation that

she has introduced and monitor work with her on behalf of patient safety.

We will be hearing from outstanding witnesses on both sides of this medical controversy. I thank all of our witnesses for taking the time to be here, and I also want to thank the staff which has helped us prepare, not only Mr. Alan Slobodin, but Mr. John Ford on the Democratic side as well. And with that I will yield for an opening statement to my friend from the great State—awesome State—of Michigan, Mr. Stupak.

Mr. STUPAK. Thank you Mr. Chairman, and thank you for holding these very important hearings. I appreciate the hard work that you and our colleague, Ms. Eshoo from California, have put into this issue.

Now, Americans expect when they go to the hospital that catheters and devices used in their hospital stay are safe, effective, and sterile. And Mr. Chairman, you commented a little bit, and I know you have some of these with you too, but the catheter it is basically all plastic. The little balloon on the end there. And then you have another one over here which is a little different device but it has a metal tip. And it is more than just plastic versus metal. I think what we're all looking for in these devices is to make sure that they are sterile and safe for the patient. And I know that has been the focus of your query here, but we have a number of these devices with us. I know you have them with you too, but I think it gives us a good opportunity to take a look at exactly what are we talking about.

Because Americans want to ensure that when they go to the hospital they have affordable health care at reasonable prices and really they don't care to pay retail all the time if there is a better way of doing it. Today's hearing is about striking a balance, Mr. Chairman, between patient safety and controlling costs in our health care system and all the devices that we use in modern medicine. But patient safety must be our first priority. Cost containment that puts patients at risk does not control costs at all. If a patient develops an infection or has complications due to a device malfunction, saving 50 percent on the device is no savings at all. Even if it was, I would not want to put the lives of my wife or our sons at risk to save a few dollars. Thus, I believe our guiding light should really be are we ensuring patient safety.

The FDA, the Food and Drug Administration, has up until recently, had a policy of nonenforcement with respect to the single-use requirement. In fact, medical device reprocessing has been going on for over 20 years. However, due to the ever increasing complexity of medical devices, much like I have shown us today, the FDA has decided to review its enforcement policy and increase the oversight of reprocessed devices. I know some people believe that the FDA has taken too long to act, but I applaud the FDA for beginning the process of ensuring that reprocessed devices will be safe, sterile, and effective.

I want to hear about the FDA's proposed guidance on classification and enforcement of the reprocess and reuse of single devices. I understand that some believe the guidance goes too far, and others believe the guidance does not go far enough or quick enough. I am interested in hearing all of these points of view. Mr. Chair-

man, these issues are always difficult for members up here on the dais. We are forced to choose between competing business, patient safety, and healthcare cost containment. I am hopeful that this hearing will shed some light on these issues and help provide both this committee and the FDA with input on where we go from here.

I want to once again thank you and Ms. Eshoo for your hard work on this issue and I yield back my time, Mr. Chairman.

Mr. UPTON. Thank you.

I would also make unanimous consent request that all members of this subcommittee be allowed to put their statements into the record in their entirety. Without objection, that will be the rule.

Mr. Bryant from Tennessee?

Mr. BRYANT. Thank you Mr. Chairman. I would simply echo what the two previous speakers have raised in their opening statements. And I think there are very important issues here today. I know we have some very distinguished panelists to testify.

The issue of the economy, of why this is done is important, but certainly the issue of safety, the issue of functionality of these products, all are very important and I look forward to hearing testimony on both sides of the issue.

I think my main concern in reviewing this in preparation for the hearing is with the FDA. And I am glad that, Doctor, you are here today to open the testimony. I look forward to hearing from you. I get a sense that the FDA is on the sidelines, and I want to know when the FDA is going to come in and start playing on this very important issue. And I look forward to your testimony to that effect and would yield back my time.

Mr. UPTON. Mr. Whitfield from Kentucky?

Mr. WHITFIELD. Mr. Chairman, thank you very much and I think all of us are looking forward to this hearing for a number of reasons, obviously, its impact on good quality and safe healthcare. Before a medical device can legally enter the market we know that the manufacturer must demonstrate to the Food and Drug Administration is safe and effective. And I know from discussions that I have had with other colleagues, we are disappointed by FDA's failure to enforce existing laws and apply them to reprocessed medical devices.

It is difficult to understand how an Agency which continually seeks to broaden its scope of authority can leave the impression that it is not really doing very much in this area. Yesterday we had a hearing on safety in hospitals and in healthcare, and we talked about the number of deaths because of mistakes made in the healthcare delivery system. And this is a particularly important area, and it is squarely within the jurisdiction of FDA. We all recognize the role that reprocessed medical devices play in keeping medical care accessible by containing costs, but this is not an excuse for FDA to leave the impression and to permit unsafe medical devices to be used in our hospitals.

Having said that, we are delighted that Dr. Feigal is here today to talk about this issue, to let us know what he intends to do about it, and I understand that he has been instrumental in trying to move the Agency forward in that direction. And I, for one, am disappointed, however, that we did not have an opportunity to even review your testimony because I guess we didn't receive it until

this morning. But hopefully you will do a great job of presenting that testimony and we thank you for being here this morning.

Mr. UPTON. Dr. Ganske from Iowa.

Mr. GANSKE. I Thank you Mr. Chairman. I will be brief. We want to make sure that patients are getting quality care. We have medical devices that need to be safe and clean. As a medical practitioner before coming to Congress I have used disposable equipment. I am concerned about some of the data that will be presented today. We want to make sure that it is accurate and I think the FDA has a role in the oversight of whether single-use medical devices can be reprocessed and used again.

There are some questions about health costs that are involved with this. I think it would be also useful at some time, Mr. Chairman, to have the Healthcare Financing Administration present, because I am concerned about how charges are made to our Federal system for single-use devices. For instance, does a hospital get paid the same amount of money by Medicare if they reprocess a device that then costs them half of what a new single-use device would be, and are they just pocketing the difference? I am interested in finding out how the calculations are made by HCFA for the device component of some of the services that are being billed to the Federal Government. Maybe we will get into that today. I yield back.

Mr. UPTON. It is my understanding that the answer to that question is yes. It is a very good question. Even without their presence here today, I think maybe members of this subcommittee can follow-up with HCFA in written form following the hearing. Mr. Strickland, from Ohio.

Mr. STRICKLAND. No opening statement, thank you.

Mr. UPTON. Mr. Burr from North Carolina.

Mr. BURR. No opening.

Mr. UPTON. Ms. Eshoo from California.

Ms. ESHOO. Thank you very much, Mr. Chairman, and I want to salute you for holding this very important hearing on what I think is a critical issue that is not only before the Congress, but something that the American people deal with—patients deal with really day in and day out. I know that I am a guest of this Committee of Investigations and Oversight, and I appreciate the hospitality, the legislative hospitality that you have extended to me.

For those of you in the audience, I am not a member of this subcommittee and so it's really up to the chairman to say that it is absolutely fine for me to come and testify. I was a member of this distinguished committee in my first term in serving on Commerce. I come to this issue from the perspective of both legislator and a consumer. As a legislator I have great concerns about the FDA's failure to require that reprocessed single-use medical devices meet safety and effectiveness standards. It makes no sense to me that new medical devices must meet these standards, yet the used ones do not.

As a consumer I was horrified to learn that complex delicate devices such as cardiac balloon catheters and biopsy forceps are being cleaned and used again on different patients. Now, this could happen to any one of us and there is not anything that is put before the patient to ask them whether they chose to have a reprocessed device used on them or not. So there is not any choice, there is not

any disclosure to the American patient today on this issue. I first learned of this problem last August after reading reports of an outbreak of bacterial toxins in a Colorado hospital that were traced back to reprocessed cardiac catheters. One person died from this particular outbreak, but it raises the question of how many deaths, or injuries occur from reprocessed devices that are unsterile or are made less effective due to the process that they are put through to clean them today.

FDA files on adverse outcomes from reused disposable devices tell of reprocessed electrophysiology catheters likely weakened by the harsh chemicals and intense temperatures required to sterilize them breaking inside of patients. I think we should always just keep ourselves in mind before we ever place this on a family member or anyone else. I certainly would not want that happening to me. In one case, the tip of the catheter remained lodged in the patient's heart requiring constant monitoring. In another the four inch long tip traveled from the patient's heart to his stomach. Surgeons had to open the man's stomach to remove the tip. Premature babies have suffered infections from unsterile sutures. A patient was contaminated with Hepatitis B from reused biopsy forceps.

The source of this is U.S. News and World Report in their September 20, 1999 edition. It is estimated that as many as one in every three hospitals are reusing medical devices that are designed, manufactured, and FDA approved for one use only. FDA clearly has the authority to enforce safety and effectiveness standards. Yet in my view, after reviewing the record and seeing how the policies are working, they have essentially looked the other way allowing the practice to go on, within my view, very little oversight.

In fact, in a letter dated July 9, 1999, which I will submit for the record, Mr. Chairman, with the committee's approval, the FDA admitted that reprocessed devices are subject to all safety and effectiveness standards, but said that they had chosen not to enforce these standards. This approach fails to ensure that devices designed for one use only can be sterilized and reused safely and effectively. That is why I introduced legislation on this issue. Mr. Chairman, the FDA policy permits practice of withholding information from the patient that he or she is getting a previously used device. It is also common to charge the patient and the Federal Government through Medicare for a new device when a secondhand one is actually being used. Now, when we buy a part for our car, the mechanic is required to tell us if that part is new or rebuilt and we are charged accordingly. Now, why is it that our laws are doing a better job covering car parts than they are protecting patients in our country?

I am very proud, Mr. Chairman, to have you join me in introducing the Reprocessed Single Use Medical Device Patient Safety Act of 1999. The bill is H.R. 3148. The bill would ensure the protection of patients by requiring reprocessed medical devices to meet the same standards for safety and effectiveness that new products today must meet. When the FDA approves a device for single-use only, that is exactly what it means—that the data submitted by the manufacturer has to show that this device can be safely used once.

Thus, in order to avoid injuries and infections to patients, I think that we should be requiring that those who clean devices for reuse

prove that it can be done safely and effectively. H.R. 3148 will increase awareness about reprocessed devices by requiring a patient's informed consent before that single-use medical device is used on them, and by requiring hospitals to monitor and report injuries or infections that occur as a result.

We have very little information about the scope of patient injuries that occur as a result of reused medical devices because patient consent is not required, and tracking is not required to determine if a reused device was involved in an adverse event. I am pleased that the FDA has finally developed a proposed policy with regard to reprocessing and reuse, but I am still concerned that it is an extension of their current practice of essentially looking the other way. In their proposed enforcement guidance they again state that all reprocessed single use devices are subject to the same pre-market requirements to prove safety and effectiveness, as new devices do, yet they do not or will not, as the way I read it, and maybe Dr. Feigal will point this out in his testimony, enforce these requirements unless the device is considered high risk. How will we know whether reuse of a particular device poses a high risk to patients without the data? Under FDA's proposal reproprocessors will never have to submit data to prove the risk to patients of devices that are arbitrarily determined to be moderate or low risk. Moreover, even for high risk devices, no data will be required for at least 1 year. I understand very well the fiscal restraints that our hospitals all over the country are under, what they are operating under.

I have worked closely with the hospitals before I came to the House of Representatives, and I still do today. So, I understand very well the pressures that they work under. Between managed healthcare and reduced Medicare reimbursements, hospitals indeed do feel the intense pressure to cut costs wherever possible. However, we can't put patients at risk in order to save a few dollars. I think my colleagues that have spoken before me have really stated that quite eloquently. We have to always put patients before profits. I know it is a struggle to do that, but I think the American people expect our public policy to reflect that. The Reprocessed Single-use Medical Device Patient Safety Act is about putting patients first.

I think that it is sound public policy, and I have no doubt that today's hearing is going to be very instructive to members of this very important subcommittee about this issue. So I look forward to working with you, Mr. Chairman, and the rest of the members of this very distinguished subcommittee, all of the members of the full committee, because this is the place where the legislation obviously will be heard and considered. And again I thank you for your legislative hospitality in inviting me here and being able to speak to this issue today. Thank you.

Mr. UPTON. Thank you. Mr. Pickering, do you have an opening statement that you would like to—

Mr. PICKERING. Not at this time.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Mr. Upton, thank you for this hearing. I am eager to get action and some answers for the American public about the safety of reprocessing medical devices designed, manufactured, and approved by the Food and Drug Administration for single-use only.

I am proud of this Committee's accomplishments in the last five years to make the FDA a better scientific agency, one that serves the American people, promotes innovation, and protects the public health. We have streamlined FDA procedures and cut FDA red tape. We have made the FDA more effective.

Today's hearing looks at reused single-use medical devices. I believe FDA has acted with uncertainty about its own authority. For the last several years, the FDA has sent conflicting signals about the legality and safety of reprocessing single-use devices. The result has been that patients without their knowledge have been exposed to unknown risks from devices that were used on other patients. Thus, for example, there is the possibility that tiny, hard-to-clean, disposable catheters used in patients with hepatitis are being reprocessed and reused in patients without their knowledge. That is an outrage.

But this is not all. The result of FDA uncertainty has been that the original equipment manufacturers find their good name and liability on the line because their disposable products have been reused without their knowledge or approval. The result of FDA's confused policy has helped lead to a surge of reprocessing single-use devices because hospitals and health care firms had assumed FDA's acceptance of the practice of reprocessing.

I want the inconsistencies and uncertainties to end today. We are at long last getting some answers and actions from FDA and other interested parties. FDA's leadership is late. I believe the FDA deserves credit for its hard work over the last several months. I hope FDA's new policy is reasonable and protects patients.

I commend Commissioner Jane Henney and FDA Devices Director David Feigal, both of whom came on the scene during the past year to steer FDA in a better direction on its reuse policy. I also commend Mr. Upton and Mrs. Eshoo for their leadership on this issue. I look forward to working with all concerned to give the American people the facts and swift, common-sense action.

 PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, as the author of the Safe Medical Devices Act of 1990, I am pleased that you have convened this morning's hearing.

Ten years ago, the safety of medical devices and the practices of the device industry came into serious question. Fatal product failures like the Shiley heart valve taught Congress and the public an important lesson—there is no substitute for stringent FDA enforcement of rigorous standards of safety and effectiveness.

That lesson holds true today. Due in no small part to the efforts of my friend, Senator Durbin, there is enormous interest in the regulation of reprocessed devices. Consumer, patient and health provider groups all agree that FDA must ensure such devices are safe and effective whether they are used once or reused.

Clearly, there are categories of use for which devices may be safely reprocessed. Just as clearly, there have been instances of unsafe hospital practices or inadequate safeguards on the part of reprocessors. From the written testimony submitted by both device reprocessors and the manufacturers, it appears that they agree on the need for rigorous FDA oversight and enforcement of risk-based standards. As a result, I am pleased that FDA has issued its new guidance document, which prioritizes the scrutiny of reprocessed devices.

FDA clearly lacks the resources to do all it should. Last year, Senator Durbin secured an additional \$1 million for the FDA to establish safety standards for reprocessed devices. But that is only a small step towards closing the widening gap between FDA's obligations and its resources. For years, Congress has forced FDA onto a starvation diet while we look to the agency to do more—more about tobacco, more about online drug sales, more about drug safety, and now, more about reprocessed devices.

FDA also lacks the authority to adequately answer basic questions about the products it regulates. The recent IOM report on medical errors stresses the urgency of better understanding the rates and severity of medical mistakes including medication errors. The GAO and Inspector General recently concluded that we must enhance FDA's adverse drug event reporting system and post-market surveillance authority to help eliminate the 7,000 annual deaths from medication errors.

And in the case of devices, are we certain FDA has the resources to properly analyze the 100,000 reports it receives annually? And does anyone believe those reports comprise the whole universe of device malfunctions and misadventure?

Mr. Chairman, I look forward to hearing from our witnesses. I look forward to learning more about this important issue.

Mr. UPTON. Okay. We are ready to proceed. Dr. Feigal is our first witness, the Director for the Center for Devices and Radiological Health, FDA. Dr. Feigal, we welcome you to our subcommittee. We have a long standing honored tradition of taking testimony under oath. Do you have any objection to that? Committee rules also provide that you are entitled to counsel if you would like such. Do you have any need to have counsel with you today?

Dr. FEIGAL. Not yet.

Mr. UPTON. Not yet.

If you could stand and raise your right hand.

[Witness sworn.]

Mr. UPTON. You are now under oath. Your testimony in its entirety is made part of the record. We would like to think that you would sum up your testimony in about 5 minutes or so, and the time is now yours. Welcome.

TESTIMONY OF DAVID W. FEIGAL, DIRECTOR, FOOD AND DRUG ADMINISTRATION

Mr. FEIGAL. Thank you very much. Mr. Chairman, members of the committee, and guests. I am pleased to be here today to discuss our approach to the issue of reusing medical devices labeled for single-use. I would appreciate if my entire written testimony would also be entered into the record. We value your interest and input as we study this complex issue and move forward to change our regulatory approach.

The public expects and the law requires that all devices be safe, effective, and manufactured in accordance with good manufacturing practices. As you know, FDA is currently in the process of reexamining its policy in the area of reuse of single-use devices. Our primary goal is to protect the public health by ensuring that reprocessed, single-use devices are safe, effective, and well manufactured. Let me say at the outset that I believe we have the regulatory tools to ensure that this will happen. We are crafting a regulatory approach that will apply equal treatment to the original manufacturers of devices, and those who reprocess them, including commercial reprocessing firms and hospitals. I think this approach will assure the desired public health protection.

Just this week we posted on our Web site two draft guidance documents that pertain to the reuse of single-use devices. One describes a proposed risk categorization scheme for reprocessed devices. The other describes our enforcement priorities based on that risk categorization scheme. We will publish a notice of availability of these documents in the Federal Register. I realize that since we just posted these draft guidances, they were not available for your second panel of witnesses to review before they submitted their testimony. But we hope they will be helpful in moving this debate forward.

By way of background, let me describe how reuse has grown over the years and why it poses a problem today that did not exist a few decades ago. The practice of reusing medical devices intended

only for one use began in hospitals in the late 1970's. Prior to that time most medical devices were designed to be reusable. Because most devices were made of glass, rubber, hard plastic, or metal, early reprocessing involved little more than heat sterilization, wiping, dipping, or soaking in disinfectant. Things began to change as a result of market demand for disposable equipment, the development of new plastics, the miniaturization of devices, and the advent of ethylene oxide sterilization.

These factors prompted the manufacturers to sell more and more single-use only medical devices. And as a result, hospitals began to receive products labeled single-use only that were similar to reusable devices. In fact, outside of their packaging even today some of them look identical to devices that had formerly been sold as reusable. The practice of reprocessing single-use devices expanded when an increasing number of hospitals found that reuse was a cost-saving measure and when they became concerned about the amount of medical waste generated by the use of disposable devices. The hospitals themselves began reprocessing more complex products such as balloon angioplasty and cardiac catheters.

Reprocessing of these devices required more complicated decontamination and sterilization procedures and as a result a new industry of third-party reprocessor evolved in response to the reprocessing needs of the hospitals. All of this has resulted in heightened concerns about the safety and effectiveness of reused single-use devices, and about the equitable regulation of the original equipment manufacturers and the reprocessing firms.

Where does FDA stand on this issue? We have concluded that the practice of reuse does need additional attention and controls. We have come to that conclusion even though we do not have clear evidence that the reprocessing of single-use devices changes or increases the types of risks to patients beyond those posed by the original device. We recognize that we may not have some of the evidence because our medical device reporting systems do not capture all of the information. But patient injuries are not the only reason for our taking action. Even without documented injury, the law still requires that we assure that reprocessed devices are safe, effective, and manufactured properly.

I do not want to leave you with the impression that FDA is coming anew to this issue. Although we only received research reports from the original equipment manufacturer industry within the last year, we have been actively engaged in the reuse issue for some time. In the past year, we have held numerous meetings and conferences with industry, health professionals, and consumers to determine the extent, magnitude, and changing nature of the practice. We have evaluated and conducted research to develop a scientific basis for addressing the issue. We have inspected third-party reproducers and as a result have issued ten Warning Letters for various violations. And, we have investigated reports of patient injuries.

Now, let me describe what we are proposing to do in this area. Fundamentally, our proposed strategy is based on the degree of risk posed by the device. The primary factors we will use to determine the level of risk are the risk of infection and the risk of performance deterioration if a device is reused. There are four steps

in developing this regulatory system which we proposed for comment last November. First, we identified the need to develop a list of the commonly reused single-use devices. Second, we developed a list of the factors that will determine the degree of risk or complexity associated with reprocessing. Third, we will use this information to divide the list of commonly reprocessed single-use devices into high, moderate, and low categories of risk. And fourth, we will develop priorities for enforcement of our regulatory requirement for hospitals and third-party reproducers based on this category of risk.

Since announcing this strategy in November, we have made significant progress. On February 8th, we posted on our Web site two companion draft guidance documents. One is entitled, "Reprocessing and Reuse of Single-Use Devices: A Review Prioritization Scheme". It sets forth the factors that we would consider in categorizing a reprocessed device as high, moderate, or low risk. It also includes a list of commonly reprocessed single-use devices and the degree of risk that FDA believes each type of device poses when it is reprocessed. The other draft guidance entitled, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," sets forth our priorities for enforcing various regulatory requirements, based on the level of risk associated with reusing the device.

Specifically FDA intends to begin enforcing pre-market notification and pre-market application requirements within 6 months of issuing the final guidance if the reprocessed device is categorized as high risk, within 12 months if the device is moderate risk, and with 18 months if the device is low risk. I would like to close by giving a couple examples of how this proposed risk categorization scheme and other enforcement strategies would affect the reproducers of various devices. Let's take as examples oral and nasal catheters. These are fairly simple devices. They are currently Class I and they are exempt from pre-market notification. They would be considered low risk under the risk categorization scheme just described.

Six months after a guidance became final, FDA would actively enforce all post-marketing requirements for hospitals that reprocess these oral and nasal catheters, just as we currently do for manufacturers of original equipment and third-party reproducers. These include registration, listing, manufacturer adverse event reporting, labeling, corrections and removals, and adherence to the quality system manufacturing requirements. At the other end of the spectrum let's consider the percutaneous transluminal angioplasty catheters or intra-aortal balloon catheters, which are Class III devices. Based on our own studies and other information, we have determined that cleaning and sterilizing these devices is very difficult, and so they would be considered high risk under this scheme. Hospitals and third parties that reprocess these devices would be required to submit to us pre-market approval applications to demonstrate that the reprocessing of these devices results in a product that is safe, effective, and well-manufactured.

Where do we stand right now? After the Federal Register publication of these guidances and review during the comment period, we will issue final versions. At that point, we will be ready to en-

force the regulatory scheme for third parties and hospitals that reprocess single-use devices. Mr. Chairman, let me close by saying that although we have no clear data to indicate that people are being harmed at a higher rate by the reuse of single-use devices, the results of our own research and the information provided by various stakeholders have convinced us that this growing practice needs closer scrutiny and oversight.

We are committed to addressing this in an open and cooperative fashion with the industries involved, the healthcare community, the public, and of course, Congress. We want a reasonable and fair-minded policy, but at the same time we want to ensure that when a single use device is reused it doesn't expose the patient to more risk than a new device would have. I thank you for this opportunity to be here today. I look forward to answering any questions that you may have.

[The prepared statement of David W. Feigal follows:]

PREPARED STATEMENT OF DAVID W. FEIGAL, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman, Members of the Committee, I am Dr. David Feigal, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am very pleased to have the opportunity to be here today to discuss the Agency's approach to the issue of reuse of medical devices labeled for single-use. As you know, FDA is currently in the process of reexamining its policy on the reuse of medical devices labeled for single-use. Our primary goal in doing so is to protect the public health by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe and effective and based on good science. We value your interest and input as we study this complex issue and move forward to change our regulatory approach.

The public expects and the law requires all devices to be safe, effective and manufactured in accordance with Good Manufacturing Practices (GMPs). Let me say at the outset that I believe FDA does have the tools to ensure the safety, effectiveness and manufacturing quality of reprocessed single-use devices. We have been actively engaged in reuse issues for some time and our efforts have included research, outreach, inspections and compliance investigations. We are currently in the midst of crafting a new regulatory approach that will treat Original Equipment Manufacturers (OEMs), third parties and hospitals in a similar manner to minimize risks associated with reused single-use devices.

We have held numerous meetings and conferences with industry, health professionals, and consumers over the past several years to determine the extent, magnitude and changing nature of the practice. FDA has evaluated and conducted research to begin to develop the scientific basis for addressing the issue. We have inspected third party reproducers and issued ten Warning Letters for various violations. We have evaluated and investigated reports of patient injuries.

That being said, medical progress has been accompanied by changes in technology, resulting in more devices with features that may make reprocessing difficult or impossible. At the same time, economic pressures create incentives for reuse. Despite a lack of clear data that suggests that many injuries are occurring due to reprocessing practices, FDA has concluded that the practice of reuse of SUDs needs additional attention and controls. We recognize the limitations of our medical device problem reporting systems in capturing this information. We take the reports we do get very seriously, but at the same time, even if there were no injuries, a driving question remains: Are reprocessed SUDs being manufactured properly, that is, in accordance with the Quality Systems Regulation (QSR)?

On February 8, 2000, FDA posted on its web site two draft guidance documents that pertain to the reuse of SUDs. One describes a proposed risk categorization scheme for reprocessed SUDs. The other describes the Agency's priorities for enforcing various regulatory requirements based on the risk categorization of a reprocessed SUD. We will be publishing a Notice of Availability of the documents in the Federal Register imminently and asking for public comments on these two documents.

BACKGROUND

The History of Hospital Reuse

The practice of reusing medical devices labeled, or otherwise intended, for only one use began in hospitals in the late 1970s. Prior to this time, most medical devices were considered to be “reusable.” Because most reusable devices were fabricated from glass, rubber, or metal, early reprocessing of reusable products, such as probes and surgical instruments, involved little more than hand wiping, dipping, and soaking in disinfection solutions. OEMs began to sell “single-use” medical devices as a result of market demand for disposable equipment, the development of new plastics, and the use of ethylene oxide sterilization. Hospitals began to see products labeled “single-use only” that were similar to devices that had been formerly distributed or continued to be distributed as “reusable.”

The practice of reprocessing single-use devices expanded when an increasing number of hospitals decided that reuse was a cost-saving measure and when they became concerned about the amount of medical waste generated by the use of disposable devices. Hospitals started reprocessing more complex products, such as balloon angioplasty catheters and cardiac catheters. Reprocessing of these devices required more complicated decontamination sterilization procedures. As a result, an industry of third party reproducers evolved in response to the reprocessing needs of hospitals. Expanded use of third party reproducers and an increase in the types of single-use products subjected to reprocessing heightened concerns regarding patient safety, and equitable regulation of OEMs and reprocessing firms.

The Scope of Reuse Today

The Agency has developed a list of frequently reprocessed SUDs, which includes devices that range from the technologically simple to the complex. Examples include:

- Surgical Saw Blades
- Surgical Drills
- Laparoscopy Scissors
- Orthodontic (metal) Braces
- Electrophysiology Catheters
- Electrosurgical Electrodes and Pencils
- Respiratory Therapy and Anesthesia Breathing Circuits
- Endotracheal Tubes
- Balloon Angioplasty (PTCA) Catheters
- Biopsy Forceps

The list varies greatly in type of device, material, risk of use and severity of clinical conditions of typical use. Some products have features such as long narrow lumens, fragile plastic components, and/or unsealed electronic controls that make them very difficult to clean. Other products on the list, e.g., drill bits, are technologically less complex and are relatively easy to clean.

A common type of reuse in hospitals occurs when a sterile product, such as a suture, is opened during a medical procedure but not used. Typically these are re-sterilized and re-packaged at the hospital. OEM's often provide instructions for hospitals to do so. The Agency has published applicable guidance on these products and does not consider opened-but-unused SUDs to be reused devices that are within the scope of the proposed strategy.

AGENCY INVOLVEMENT IN REUSE

Reports of Patient Injuries

There have been stories in the media which have reported catheter tip separations, faulty cataract surgical equipment, and other problems attributed to failure of a reused SUD. A recent review of Medical Device Reporting (MDR) reports received by CDRH from August 19, 1996 through December 7, 1999 revealed 464 reports (out of 300,000) of adverse events that could possibly be attributed to reuse of a SUD. The 245 reports spanned approximately 70 different types of products. From this data we can discern no pattern of failures with reused SUDs that differs from patterns observed with the initial use of SUDs.

MDR reports do not enable accurate assessment of failure rates, whatever the type of device. Detecting SUD problems is even more challenging in that they are often not labeled as SUDs (other than on the original packaging). In addition, device failures may be particularly under-reported (to manufacturers) when the hospital recognizes that the device that failed was a reused SUD. Also, infections that may have resulted from an improperly reprocessed SUD may be hard to trace back to the reused device.

Research Findings

CDRH has implemented a research program to explore safety and effectiveness issues associated with the reprocessing of single-use devices. Information on difficulty of cleaning the devices, effect of sterilization on material, efficacy of resterilization, and alteration in performance criteria are all being investigated. CDRH has had the opportunity to examine SUDs after one-time use, compare them to devices that have not been used, and do simulated reuse laboratory studies. Loss of elasticity in inflatable balloons, persistence of blood and biofilms, loss of original lubricants and the effect on catheter threading, and crystallization of liquid x-ray contrast material are just some of the factors that we have examined. This research program has expanded our ability to evaluate reports, scientific studies, and comments from the healthcare community.

Hospital infection control programs rarely identify specific incidents of patient infection caused by reuse of SUDs. Our research has shown, however, that the performance of some products is degraded by the effects of biofilms and repeated use. We have presented our laboratory findings at many scientific meetings. We continue to believe that solid research by industry, academia and FDA is the best way to understand the issues that need to be addressed and to develop consensus standards for reprocessing practices.

Outreach

The Agency has conducted numerous outreach efforts to further understanding of and participation in this issue. We have organized and participated in public meetings and conducted videoconferences. We have met with individual manufacturers and reprocessors; manufacturers' and reprocessors' trade associations; the American Hospital Association; the Joint Commission of Health Care Organizations (JCAHO); the Health Care Financing Administration (HCFA); and medical professionals and some of their associations on this issue. Two meetings with broad scope that occurred in 1999 were particularly useful in furthering our understanding of this issue.

On May 5-6, 1999, FDA and the Association for the Advancement of Medical Instrumentation (AAMI) co-sponsored a conference on the practice of reprocessing and reusing SUDs. Participants included representatives of health care facilities, firms that reprocess devices, OEMs, national oversight organizations, State governments, academia, medical ethicists, and standards organizations. This provided FDA the opportunity to hear a wide range of views and concerns from individuals and organizations involved in or affected by this practice.

FDA received divergent opinions on how reprocessing and reuse of single-use devices should be regulated. Some participants believed that reprocessors should be regulated in the same manner as OEMs and that 510(k)s or Premarket Approval applications (PMAs) demonstrating the safety and effectiveness of the reprocessed device should be required. Others believe that OEMs should be required to provide instructions on how to reprocess their devices unless they can demonstrate that the device cannot be reprocessed. Still others stated that the general controls under which reprocessing is regulated currently are sufficient to ensure protection of the public health.

Participants identified the need for additional guidance on reprocessing. Among the suggestions were: standards to assure that cleaning, disinfection, and sterilization processes are validated and that reprocessing may be performed properly; a determination of what types of devices can and cannot be reprocessed; a classification scheme establishing critical, semi-critical, and non-critical categories for reprocessed devices; and clearer definitions for the terms "reuse," "reprocessing," and "resterilization."

Participants suggested that clinical data and experience on reuse could be obtained through hospitals' existing surveillance activities; long-term clinical studies; the establishment of a clearinghouse for data; National Institutes of Health funds and studies of reprocessing; and research by professional societies with funding provided by OEMs and reprocessors.

FDA held an open meeting, on December 14, 1999, to obtain feedback from stakeholders and interested parties on its proposed strategy on reuse of SUDs. Twenty-eight public presenters voiced a variety of concerns during the first part of the meeting, and workshops in the afternoon provided attendees with an opportunity to explore particular issues in smaller groups. An Executive Summary which describes the input we received on many aspects of this complex issue is available on our web site at <http://www.fda.gov/cdrh/reuse/1214execsum.pdf>.

FDA'S CURRENT POLICY

As I noted at the outset, the American public expects, and the Federal Food, Drug, and Cosmetic (FD&C) Act requires, that devices be safe, effective, and manufactured in accordance with GMPs. When a SUD is prepared for reuse by cleaning, repairing, or refurbishing, it is being remanufactured and the FD&C Act provides controls to address these reprocessed devices, however, FDA has not regulated OEMs, third party reproducers and hospitals that reprocess devices in the same manner.

Original Equipment Manufacturers (OEMs)

OEMs are subject to all requirements of the FD&C Act including: registration and listing, premarket notification and approval requirements, submission of adverse event reports under the MDR regulation, manufacturing requirements under the QSR; Labeling requirements, Medical Device Tracking, and Medical Device Corrections and Removals. The Agency has enforced all of these requirements with respect to OEMs.

Third Party Reprocessors

Third party reproducers are subject to the same regulatory requirements as other manufacturers, including premarket requirements. As discussed previously, FDA has issued Warning Letters to third party reproducers for various violations; however, to date, FDA has not actively enforced premarket requirements against third parties. (Note that many devices that are commonly reprocessed are exempt, by regulation, from premarket requirements.)

Hospitals

According to the Agency's Compliance Policy Guide, hospitals that reprocess single-use devices assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized, and that device safety, effectiveness, and quality are maintained. The Agency currently provides no direct oversight or routine enforcement for in-hospital reprocessing. If a serious adverse event involving a reprocessed (or any other) device occurred in a hospital, however, FDA would conduct an investigation and take appropriate action, as necessary.

FDA'S PROPOSED STRATEGY

As I stated earlier, FDA is reevaluating its position on the reuse of single-use devices. In November 1999, the Agency made a document available on its web site for public review and comment which described a proposed strategy to address reuse of SUDs. One of the principal components of FDA's proposed strategy was the establishment of agency enforcement priorities concerning regulatory requirements for third party and hospital reproducers of SUDs. FDA proposed to prioritize its enforcement activities based on the degree of risk posed by the reprocessing. To accomplish this process, FDA proposed the following steps:

- (1) develop a list of commonly-reused SUDs;
- (2) develop a list of factors to determine the degree of risk associated with reprocessing devices;
- (3) use that list of factors to divide the list of commonly-reprocessed SUDs into three categories of risk—high, moderate, and low; and
- (4) develop priorities for enforcement of regulatory requirements for hospitals and third party reproducers, based on the category of risk.

Since the announcement of FDA's proposed strategy, FDA has made significant progress. On February 8, 2000, FDA posted on its web site two companion draft guidance documents. One is entitled, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme." This draft guidance set forth factors we would consider in categorizing a reprocessed device as high, moderate or low risk and includes a list of commonly-reprocessed SUDs and the degree of risk FDA believes each type of device poses when reprocessed. The other draft guidance, entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," sets forth our priorities for enforcing various regulatory requirements, based on the categorization of a device, as described in the Risk Categorization guidance.

The risk scheme guidance describes specific factors FDA would use to determine whether reprocessing posed high, medium, or low risk. This guidance has two flowcharts to help FDA and industry categorize the reprocessing risks. One flowchart addresses factors that relate to risks of infection that may accompany reprocessing. The other flowchart addresses factors that relate to risks of performance failures that may accompany reprocessing. Using these two flowcharts, FDA has categorized

all currently known reused SUDS into three categories of risk—high, medium, and low. We have clarified that the risk categorization scheme does not in any way change the classification of a device under the statute.

The enforcement priority guidance bases the Agency’s timing of enforcement of premarket requirements on the level of risk determined under the risk categorization scheme. Specifically, FDA intends to begin to enforce premarket notification and premarket application requirements within six months of issuance of a final guidance if the reprocessed device is categorized as high risk, within 12 months if the device is categorized as moderate risk, and within 18 months if the device is categorized as low risk. Although FDA has not previously enforced premarket requirements for third party reproprocessors, FDA currently enforces all other requirements applicable to manufacturers against third party reproprocessors. The issuance of this draft or any final guidance will not change the continuing obligation of third party reproprocessors to comply with those provisions of the FD&C Act. FDA would not enforce those requirements for hospitals, however, until six months from the issuance of a final guidance document.

I would like to give a couple of examples of how this proposed risk categorization scheme and our enforcement strategy would affect reproprocessors of devices of disparate complexity and risk. Oral and nasal catheters, fairly simple devices, are currently class I and exempt from premarket notification. They would be considered “low risk” under the risk categorization scheme I just described. Six months after a guidance became final, FDA would actively enforce all non-premarket requirements for hospitals that reprocess oral and nasal catheters, just as we currently do for OEMs and third party reproprocessors, including registration, listing, manufacturer adverse event reports, labeling, corrections and removals, and quality system manufacturing requirements.

Percutaneous transluminal angioplasty catheters or intra-aortal balloon catheters, class III, would be considered “high risk” under the scheme. Based on our own studies, we have determined that cleaning and sterilizing these devices are very difficult. Hospitals and third parties that reprocess these devices would be required to submit to the Agency PMAs demonstrating that their reprocessing of these devices is safe and effective, in addition to conforming to the general controls of the FD&C Act.

At this time, the Agency is limiting its focus to SUD reprocessing by third parties and hospitals. The draft SUD enforcement guidance does not apply to permanently implantable pacemakers (the reuse of which is already addressed in a Compliance Policy Guide), “opened-but-unused” SUDs, and healthcare facilities that are not hospitals.

NEXT STEPS

Issuance of Final Guidance Documents

The guidance documents I mentioned are not final, nor are they in effect at this time. These documents incorporate comments to our proposed strategy that we received at the December 14 public meeting and written submissions. We are in the process of publishing in the Federal Register of a notice of availability of these documents and are asking for comments. After reviewing the comments received, the Agency will issue final guidance documents.

Phased-In Enforcement

As I have stated earlier, FDA is planning to phase in the enforcement of regulatory requirements for third parties and hospitals that reprocess SUDs. After receiving public comment on our draft guidances, including factors used to categorize risks, and timing of our enforcement based on those risks, we will issue final guidances and begin implementation of our enforcement strategy that would regulate OEMs, and third party and hospital reproprocessors in the same manner.

Collaboration with Other Parties

The direction in which we are headed could impact significantly on the Agency’s resources, particularly for conducting inspections of hospitals that reprocess. We will be collaborating with third parties, such as JCAHO, HCFA and State agencies that currently perform oversight of the health care sector to assist us in implementing the new policy.

Outreach

We will be continuing our outreach efforts to ensure that the health care community, manufacturers, reproprocessors, patients, and the public are fully aware of the issues involving the reprocessing and reuse of SUDs. Our efforts will include talk papers, public health notifications, and lay articles on an FDA web page.

SUD Labeling

We will be considering changes to the labeling of SUDs by OEMs. One option the Agency is considering is requesting OEMs who label their devices “single-use” to provide, as part of the device’s labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs. This information would serve as a caution to users and reproducers who might attempt to reprocess these SUDs.

Institute an Expanded Research Program for Reuse

The Agency has conducted several in vitro studies on reused SUDs and is considering additional studies on the effects of reprocessing. Expansion of our research efforts may facilitate collaboration with stakeholders and interested parties to conduct more in vivo and in vitro studies.

CONCLUSION

Mr. Chairman, although we have no data to indicate that people are being injured or put at increased risk by the reuse of SUDs, the results of our own research and the information provided by various stakeholders have convinced us that this growing practice needs closer scrutiny and oversight. We are committed to addressing reuse in an open and cooperative fashion with the industries involved, the health care community, the public, and, of course, the Congress to craft a policy that is reasonable yet effective in minimizing the risks associated with this practice. Thank you for the opportunity to be here today. I am happy to answer any questions you may have.

Mr. UPTON. Thank you very much. Now we will work this clock for us. We are going to take 5 minutes each, rotating on both sides for questions. One of the items that you used last in your testimony was, in fact, this one right here, which is—I don’t know if I want to take it out because then no one would be able to use it. This is an emergency coronary artery bypass graft surgery instrument?

Mr. FEIGAL. Yes.

Mr. UPTON. And as you have indicated, it is a Class III. Okay. Currently this could be reprocessed, is that right, without the new regulations in place?

Mr. FEIGAL. That is correct. We have not been calling for pre-market applications for reproducers for such devices.

Mr. UPTON. But in fact this could be used more than once?

Mr. FEIGAL. Yes, that is correct.

Mr. UPTON. And under the regulations that you put on the Web page earlier this week, if they become final then for this to be used a second, third, or however many times, the reproducer would have to, in fact, demonstrate that it was absolutely clean and safe, and there should be no problems, and it would only be used X amount of times, is that correct? Is that basically how it is going to work?

Mr. FEIGAL. They would need to demonstrate that their cleaning process could assure that the product was clean and free from infection risk, and that the cleaning process did not degrade the performance of the item. The exact mechanism for doing that may involve testing and assessing the devices or tracking the number of times a device is used. I think there is not a single answer for all types of devices, but it would be up to the applicant to tell us that they had a way to assure that each time that device was going to be used that you could expect that it would perform as intended and be safe and effective.

Mr. UPTON. Assuming that they could show that it was safe and clean, they would have to somehow tag this so that it didn’t exceed

so many, whatever you defined as the number of uses, is that right?

Mr. FEIGAL. It has to be accurately labeled. A reused product should identify the fact that it has been reused. The hospital should know whether it is opening something that is new or opening something that is reprocessed. I think whether each device needs to be tracked each time it is used will vary with the type of device. That would be one way that someone could propose that they would control the aging of the device.

Our concern would be if someone said well, we could always use these four times so we'll count to four and throw it away, when in fact, it might show degradation after the second use. So, in fact, each time it is cleaned they need to assure that the product will perform as expected, and that may require a different approach than actually counting the number of uses to assure that it met adequate performance specifications.

Mr. UPTON. How would they determine the number of uses? Would there be a clinical trial? Would they like test it or just stand back until they figured out when it broke down?

Mr. FEIGAL. This is one of the questions that we've been trying to address with our own laboratories looking at some of the research methods. For example, a common problem with catheters. When they are first manufactured they are coated with a lubricant to facilitate threading. As you clean it the lubricant is stripped.

Mr. UPTON. That's right.

Mr. FEIGAL. And so rather than finding out in patients whether or not it is tougher to thread these things after the lubricants are stripped, we have actually done a bit of research to try and develop a mechanical way of measuring how smoothly something moves through narrow spaces. This is the kind of evidence and research we would expect the applicants to provide to address all the aspects of why products perform well and why they are failing. The issue of brittleness has been raised a number of times. That is another example of something that probably can be assessed by looking at multiple cleaning cycles and simulated use. Breakage of these fragile devices is something that even new devices are susceptible to, and I think we can learn more about product mode failure through this process.

Mr. UPTON. Now, in your deeming whether this should remain a single-use or not, would you, as part of the regulations or part of the design, would you go back to the manufacturer of this and get their comments as well?

Mr. FEIGAL. Well, what the reprocessor is doing is taking a discarded single-use device, if you will, and using that as his starting material. Obviously he can do a better job of assessing what he is up against in reprocessing if he has information from the original manufacturer. But we do not have any authority to require this. In fact, our authority and our requirements actually protect the trade secrets of the original manufacturers.

So, actually the burden on the reprocessor would be to show that he could clean it, not even knowing exactly how well it was made. We would certainly have the information in most cases ourselves as to how it had been manufactured, but we would not be allowed to share that with the reprocessor.

Mr. UPTON. Just to finish then, so it is or is not part of the process that you would have to go back to the original manufacturer to get their comments as to whether or not this should be used a second time?

Mr. FEIGAL. The application actually of the new manufacturer is a trade secret as much as the application of the OEM is a trade secret. And so that is one of the difficulties in this.

Mr. UPTON. You have got to make the judgment as to—

Mr. FEIGAL. Yes.

Mr. UPTON. [continuing] whether or not it is going to be effective as it was the first time that it was used, and therefore you would have some statistics that they, I would think they, would be willing to offer to say yes or no.

Mr. FEIGAL. Yes. Well, that is why the law gives us the ability to know all the information from both manufacturers and to consider everything we know in assessing safety and effectiveness, including all the information we have across manufacturers for multiple different types from our adverse experience reporting. There are a lot of details, I think, that you are bringing up that are important in how this will actually work. We need to do it in a way that both insures the public health, but also respects the trade secrets of the manufacturers who have applications before us.

Mr. UPTON. Okay. Mr. Stupak.

Mr. STUPAK. Thanks, Mr. Chairman. Is there reported cases of infection associated with single-use instruments?

Mr. FEIGAL. I'm sorry. Could you repeat the question?

Mr. STUPAK. Single-use instruments, first time they have been used, has there been reported cases of infection associated with them?

Mr. FEIGAL. That would be very unusual. What is more common is to have cases of infection reported to us from the lax cleaning procedures of devices designed for reuse. So, for example, bronchoscopes and endoscope, there have been reports of infections that have been spread because these devices, which are designed for reuse, were not properly cleaned by the hospitals. So, that is the more common type of infection that we have reported associated with devices.

Mr. STUPAK. Those scopes though, when they are manufactured, are they manufactured and received from the manufacturer as being a single-use item?

Mr. FEIGAL. No. They are not. They are actually marketed with detailed instructions for cleaning and disinfecting. And despite that, in hospitals, we still have infections.

Mr. STUPAK. Okay. So they are manufactured, and when they come in the package or whatever, there are instructions on how to reprocess them for reuse and how to sterilize and take care of them?

Mr. FEIGAL. Yes. And that information is provided by the manufacturer in their application to us so we can assess whether they have adequate instructions for cleaning and sterilization.

Mr. STUPAK. So the sterilization, the chemical reaction, the lubricants, that is all taken into consideration if they allow it to be a reused item?

Mr. FEIGAL. That is right. We have to consider all of that for re-used items.

Mr. STUPAK. If I am a hospital and—it may not be a fair question to you, but if I am at the hospital and I get a single-use item, am I required before I use it to go through some type of sterilization, or can I take it out of the packaging knowing I can use it immediately, or is there a requirement of the hospital to also do sterilization before they ever use a single-use item?

Dr. Feigal. Most devices that are intended for sterile use are shipped sterile in packing that can be opened. A common challenge for hospitals is that often devices are opened and made available in the operating room that are not used, and then the hospitals have to know how to repackage and re-sterilize those. The most common product for which that occurs is sutures, but it occurs for hip implants, all sorts of different things. So hospitals actually do this day in, day out and have considerable skill at doing this.

Mr. STUPAK. Okay. And Doctor, the issue of alteration of performance criteria is mentioned in your description of FDA's research on reuse issues. Could you tell us how alterations of performance criteria are handled in the draft guidance?

Mr. FEIGAL. Well, this is one of the two key factors that are identified to establish the level of risk and our level of concern about the product. The device laws are risk-based and devices are risk-stratified. We do not have the same application process for all devices. We have taken the same approach with the reusable devices in that we will start with the products that concern us the most and work our way out from there. Eventually we will cover them all. But we will start with the products of greatest concern, either because of risk of infection or difficulty in cleaning. The other factor is evidence that the material or product will not be degraded with repeated use and cleaning.

Mr. STUPAK. What are the ones that concern you the most?

Mr. FEIGAL. The products that have delicate materials or that were already Class III devices concern us the most. For us to even approve them in the first place required clinical data. Many of these devices, if you look at our prioritization scheme, are at the top of the list. The things that are low on the list are things that have large lumens or are made out of hard materials and are relatively straightforward to clean. There are many single use products. Many are not labeled as to why they are single use and many of the single-use products are labeled that way for convenience. If you look at some of the products in the low risk categories probably relatively straightforward to clean.

Mr. STUPAK. Okay. Using one or two devices as examples, could you give us a brief overview of the similarities and the differences between the quality system regulations for OEMs and repro-processors?

Mr. FEIGAL. There will be none under our proposed scheme. Whatever standard the OEM has to meet, the reprocessor has to meet. If there are differences, the differences have to do with the starting material. The OEM builds their device from scratch. The reprocessor starts with a used device. So there would be differences in the manufacturing steps, differences in some of the things that the OEM might have to do to fabricate a device. But in terms of

the nature of the law and the requirements, our proposal makes them identical. There will be a completely level playing field for OEMs and reproprocessors.

Mr. STUPAK. Okay. Well then would the guidelines then permit significant variability among reproprocessors in terms of the number of times devices are used, reused?

Mr. FEIGAL. We will ask the reproprocessors to tell us how they know that a device addresses our concern of infection and integrity of performance. If they can do that without counting the number of times it is used, for example, by testing it before re-release, that may be adequate. And I think that there will not be a single way to safely clean and reprocess all devices. We will ask for the applications and we will review them critically. There may be times when it will be appropriate to keep a detailed record, and others when it may be more important to test to see how brittle the device is, no matter how many times it has been used.

Mr. STUPAK. The reproprocessors in this case would that be like the hospitals, or could it be the manufacturer?

Mr. FEIGAL. The reproprocessor is either the hospital or a third-party commercial reproprocessor. There is, of course, some level of reprocessing that occurs, mostly in the setting of open-but-not-used devices, that is actually done cooperatively between the original equipment manufacturer and the hospital. So I think we are going to see a variety of different ways that this problem is approached, and I think some of the economic pressures will change. We may see new partnerships develop and problem solving in some of these areas. We would welcome research to develop reusable devices that can be safely manufactured, and currently are only labeled single-use for convenience or other reasons.

Mr. UPTON. We can go another round if you want?

Mr. STUPAK. Okay. Can I ask one more question? Economics I just want to ask.

Mr. UPTON. Sure. Okay.

Mr. STUPAK. One question on economics, Dr. Ganske had brought that up, and there is obviously a savings here, but is some of the pressure on reprocessing because the DRGs, I mean, you get paid a certain amount if you are doing a procedure underneath a DRG, correct? And if you can cut the cost of doing it by using a reprocess you would make cost benefit then would be—go to the hospital then because you get paid an amount whether it is reused or new, correct?

Mr. FEIGAL. This is a question outside of my authority, but it is a question I happen to know the answer to so I will be brave and answer it for HCFA. The DRG does pay a flat fee, and in fact, one of the questions about reuse is, "Are used devices billed individually in an itemized bill?" Under that system, and many other types of systems, they are not. The hospital makes its own choice in the equipment it purchases, the professional services it uses, and they provide that service for that cost. And there is no representation to the third party, where the products came from or what they were. If you want any more detail than that, I am completely out of my element so you are best to discuss this with HCFA.

Mr. STUPAK. Thank you Mr. Chairman, for allowing me that last question.

Mr. UPTON. Dr. Ganske?

Mr. GANSKE. Thanks Mr. Chairman. As a surgeon who goes overseas on surgical missions we take all of our own medical equipment provided for free, and I am always interested in the fact that for all the single-use tubing and equipment that we take over, that in this country is typically just thrown away, we will frequently see the hospital workers in these third-world countries pulling them out of the garbage, cleaning them out, sterilizing them and using them many, many times because they just simply cannot afford the equipment otherwise.

It is clear to me that there are some types of single-use items that probably can be safely cleaned, assuming that they are adequately cleaned and sterilized and reused. It also looks to me that it is possible for us to be comparing apples to oranges. There is a dispute between the medical manufacturers and the reproprocessors. It is fair to say that there are economic, big economic factors involved. Some would say that manufacturers will label a device a single-use device for their own purposes so that it should be only used once and then they have to buy another one.

There are also allegations of, and I am sure we will see some testimony today, inadequately cleaned devices. Does your organization have any information on who has done the "inadequate cleaning", for example, a lot of re-sterilization is done by individual hospitals. They are under the auspices for doing sterilization properly, of the JCAH, and they have protocols, but obviously if you are sterilizing millions and millions of pieces of equipment every day, it is dependent on how thorough those pieces of equipment are cleaned. As you pointed out in your testimony, not just for single-use items, but for permanent items.

Mr. FEIGAL. Uh-huh.

Mr. GANSKE. Like for a steel bronchoscope that is clearly meant to be used thousands and thousands of times, but if it is not cleansed properly by the technician in the hospital, then it does not matter whether it is a single-use device or a permanent device, you have the risk of contamination. And I guess my point is this—my question to you is have you looked at any of the data that the manufacturers are presenting that distinguishes between whether hospital contaminations after "reprocessing" were done by reproprocessors, commercial reproprocessors, as versus hospitals.

Mr. FEIGAL. The types of research submitted to us last February by the manufacturers came from a variety of sources. Sometimes the devices were not being sold as reprocessed devices, they were simply devices that had been used. And the purpose of the research was to identify the kind of condition that the device was in after use and how use had changed it. Other types of research has actually tried to look at devices which were purported to be cleaned, usually by third-party reproprocessors. We, ourselves, have gone into the reproprocessors and done inspections and if you look through our findings and our Warning Letters you will see the public comments that we have made about how they do their business.

Mr. GANSKE. Well, summarize that for me.

Mr. FEIGAL. That industry is not terribly different than many device manufacturers, in that if you go in and look in detail at how they follow their good manufacturing practices and their quality systems, you find areas where they need to make improvements. What we did not find were devices that were volatile and needed to be seized, or products that required public health alerts, or other types of problems.

Mr. GANSKE. When you went into those reproprocessors and looked at their results, in their reprocessed equipment sealed, ready to be sent back, did you find pieces of tissue?

Mr. FEIGAL. We did not do those types of studies. The research that we have done on devices has been done with single-use devices that have been donated to us from other Federal hospitals that were not going to reuse those devices, so we could study them. One of the issues that addresses both the reproprocessor and the hospital, to get back to one of your earlier points, is to look and see what the role of cleaning and reprocessing standards would be.

Certainly the OEMs are not calling for an application from hospitals on their cleaning procedure model by model, device by device, for their reusables. We need to look and, again, our approach is to look at the risk of the product and say which of the devices concerns us enough that we really want to see a pre-marketing application, and which are the ones for which the rigor of the quality systems regulation and adhere to certain standards can do the job.

Mr. GANSKE. Let me give you an example of this then.

Mr. FEIGAL. Okay.

Mr. GANSKE. Let's say you have a balloon angioplasty catheter that has a little, you know, latex balloon on it that you put into the coronary artery, and you blow it up, and you can crack open a narrowing of the coronary artery. Now, are those catheters, which are probably labeled single-use, are they being sterilized—cleansed and sterilized in hospitals?

Mr. FEIGAL. In some hospitals, yes.

Mr. GANSKE. Okay. Now, do those hospitals have the ability to determine whether that little latex balloon after it has been re-sterilized, has the same dimensions as it came from the manufacturer?

Mr. FEIGAL. We don't know what the practice is in the hospitals, to date, because we have not been in the hospitals. This is an issue that needs to be addressed. There are other issues that we have identified, such as persistence of crystallized dye in the catheters and in the lumens.

Mr. GANSKE. Do reproprocessors routinely check for that?

Mr. FEIGAL. Yes.

Mr. GANSKE. A commercial reproprocessors?

Mr. FEIGAL. The reason I cannot answer that is we have not yet asked them to file applications with us to show how they do these things: how they clean them, what they know. What our framework says is that they will have to tell us that in the future. That will be our approach. We will know what they are doing, what their standards are, and we will assess those to assure that a reprocessed device is safe and effective and manufactured to the kind of quality we would expect of an OEM.

Mr. GANSKE. Thank you Mr. Chairman.

Mr. UPTON. Okay. Thank you. Mr. Strickland.

Mr. STRICKLAND. Thank you Mr. Chairman. Dr. Feigal, Boston Scientific has done a study, which I am sure you are aware of, 35 reprocessed devices were pulled from hospital shelves and tested for sterility. Of the 35, 25 had been reprocessed by the hospital, and 10 by a third party. They found that 6 of the 35 were sterile. And my question has to do with FDA research and attempt to replicate this study. I understand that FDA has attempted to replicate the study and I would like to ask you what the results of that study by FDA found.

Mr. FEIGAL. When we repeated the study we did not find that the catheters would have transmitted infection. Part of the issue comes down to the definition of what the findings were, that is, whether we are talking about a clean but residual tissue or clean but residual films on the forceps. Those may be other issues that are also important to address. Where we are at this point is that we have compared notes with Boston Scientific, we have asked to see their methods so we can see if we can repeat the experiment exactly the way they did it and see if we get the results. And that is in progress. We would be happy to report back to you our findings when we complete that.

Mr. STRICKLAND. So are you telling me that there may have been residual materials found, but that they were not found to be a threat for infection?

Mr. FEIGAL. That is correct.

Mr. STRICKLAND. And I have also been told, and I would like for you to deny or confirm this, that at least in one of the studies that the devices were subject to bleach before they were examined for being sterile or being safe. Can you tell me whether or not that is a—

Mr. FEIGAL. I can answer that question, but I will have to submit it as part of the record. It depends on where we got the samples. Some of the hospitals that have been donating the equipment do soak them in bleach to disinfect them. Bleach is a good antiviral, virucidal agent. But I am not sure that is related.

Mr. STRICKLAND. But it does seem to be related to the validity of the attempt to replicate the study and that is what I am getting at.

Mr. FEIGAL. Well, that is correct. And if, in fact, we did the study in some way that clouded the issue, we are trying to do the study exactly the way they did it and see what we can find.

Mr. STRICKLAND. And are you saying to me now that based on your current knowledge you cannot say that you have done a study that, in fact, replicated the methodology of the Boston Scientific study?

Mr. FEIGAL. Not every detail, but we tried to do it according to our understanding of how they did the study and then when we got the results, we compared notes with them and said well, what might we have done different. And that is what we are trying to—

Mr. STRICKLAND. I guess an observation I would make, if you found materials on these reprocessed devices, that the materials were not considered to be a danger of infection, is it possible that

they were not a danger of infection due to the fact that they had been bleached?

Mr. FEIGAL. I take your point that it depends on how the materials were handled, and we should make sure that the two experiments were done the same way.

Mr. STRICKLAND. No more questions, Mr. Chairman.

Mr. UPTON. Thank you. Mr. Whitfield.

Mr. WHITFIELD. Thank you Mr. Chairman. I am sorry I missed the testimony after saying how much I wanted to hear it. But I was called to the House, but I will read your testimony, Dr. Feigal, and one question I had. In the European Union, do they allow reprocessed medical devices in European countries or do you know?

Mr. FEIGAL. European device laws vary considerably from country to country. Some of the device laws do not require any type of pre-market application and rely on quality system requirements, and there is some effort to harmonize those. I think if we would go country by country I think we would find countries that ignore the problem entirely and others that have some rules about it. And we could provide more detail as follow-up if you like. I don't have that information with me today.

Mr. WHITFIELD. That's okay. Now it is my understanding that on many of these devices the name or the initials of the original manufacturer are on the device, and then once it is reprocessed that would still be on there.

Mr. FEIGAL. Yes. Although we heard, actually we heard on a visit to Michigan stories of someone who was grinding off the name of the OEM and claiming that the product was just as good as the OEM's product, which was a fair statement because it was the OEM's product, just with the name ground off, but recleaned and reprocessed. That is right.

You usually can identify it, but I think one of the challenges for hospitals is, if you look at some of the catheters the members of the committee brought or that I brought today, you see there isn't very much room for very large lettering or detailed descriptions. So it usually takes someone who technically knows exactly what they are dealing with to identify the manufacturer and the model in some of these cases.

Mr. WHITFIELD. Would that subject a reprocessor to a charge of misbranding or not?

Mr. FEIGAL. I think it depends on what they claim. You need to claim accurately what you have got. If you claim you have got a reprocessed device that was originally manufactured by a specific company, then that is the truth. Now, whether you are infringing on their patents or other kinds of things, that would be Better Business Law. But I think that they need to disclose what they know about the product that is relevant for the safe and effective use of the product.

Mr. WHITFIELD. It is my understanding that in the past the FDA has claimed that they have been unable to find clear evidence of adverse patient outcomes as a result of using reprocessed devices. Is clear evidence of adverse patient outcomes the sole basis on which the FDA would determine if there is a major public health problem?

Mr. FEIGAL. No, it is not. There are times when a single serious failure of a product can result in an FDA action to correct a product. So it is not that it takes large numbers, and it is not that we do not have any reports. In fact, if you go through our MDR reporting system over a several year period, we have about 245 reports of injuries associated with reused devices. The difficulty for us is that the system does not tell us the volume of use of the product or of the different types of problems.

And so, for example, we have reports of broken catheter tips, but we also have 11 reports of catheter tips that broke in brand new devices the first time they were used. And we don't have the kind of information and the type of system to tell whether the reused device has a higher risk. Your other question is one that I think is an important one, which is that the law does not just require that the products be safe and effective. They also require that they be well manufactured, that is, manufactured under quality system regulations according to good manufacturing practices. So even if they were safe enough and usually did not cause problems, we still expect that the reproducers and the remanufacturers of these products will meet the same standards that we expect of the original equipment manufacturers.

Mr. WHITFIELD. Mr. Chairman, thank you. I just want to thank Dr. Feigal for being here, and we all recognize that you have been sort of a leader in trying to reestablish focus on this issue. And thank you very much.

Mr. UPTON. Thank you. Mr. Bryant.

Mr. BRYANT. Thank you Mr. Chairman. Dr. Feigal, let me also join with my colleague to thank you for what you have done in the short time that you have been at FDA. I think everybody from hospitals to all sides of this issue are really desirous of the FDA moving on this and issuing the instructions and advice that is necessary so that we can have clarification in this issue. And I think that is the goal of everybody. I sit here thinking what we are talking about here is reusable single-use equipment. And is that an oxymoron or what?

Mr. FEIGAL. It sounds like it, doesn't it?

Mr. BRYANT. Why did we ever go from reusable equipment to single-use equipment?

Mr. FEIGAL. There are a variety of different reasons. Sometimes there was a request for disposable equipment for convenience and it was more expensive to clean the product than it was to manufacture a disposable product. There are times when a product changes status. It has been on the market as a multiple use and the manufacturer changes it to a single-use and it is not clear always why that happens.

If someone is coming in for the first time it is a simpler application to have it be a disposable device than a device which is cleaned. If they are asserting to us that it can be cleaned, they have to include in their application the studies that show how to clean it and that those studies do not damage the device. And so there are probably some business decisions that at times they will get to market more quickly with a product if it is labeled for single-use only.

Mr. BRYANT. But originally wasn't the dominant reason had been infections and simply the safety of the product?

Mr. FEIGAL. I don't believe that there are really very many reports with medical devices that are being reused causing infections. The manufacturers are required to tell us what they know.

Mr. BRYANT. I mean originally, back in the 1950's or whenever.

Mr. FEIGAL. Well, this sort of started in the 1970's and it would be interesting to ask some of the manufacturers who have been in this business a long time the history from their individual companies. We can only speculate, but I think it is often many reasons.

And one of the things that we have asked for feedback about is whether it would be useful, if a company knows that reprocessing damages a product or that if a product is susceptible to infection if it is reused, that they should include that information in the labeling. Now there is concern by the OEMs that that is requiring them to say something about a use for the product they never intended and puts them at a marketing disadvantage. So we understand that. On the other hand, if it is a common practice and the device looks very similar to devices that once their labeling is off, their packaging is off, all look alike, then if they know their product can be damaged or made less effective that information would be useful to the medical consumer.

Mr. BRYANT. Right. And I would assume trial lawyers to know also.

Mr. FEIGAL. Uh-huh.

Mr. BRYANT. Did I understand you correctly to say that when a manufacturer comes to the FDA they have to, on a single-use product, they have to provide you with instructions on how to clean it?

Mr. FEIGAL. Only if it is a multiple use. If they have a device that is going to be reused again and again, then part of the application process is to show the performance of that device with multiple use.

Mr. BRYANT. Okay. All right. You testified that the FDA had no clear studies, and I think I wrote that down correctly. I am just wondering that maybe you have been unable to find any clear evidence of adverse patient outcomes associated with the reuse of single-use devices from any source. Is the clear evidence of adverse patient outcomes the sole basis of the FDA to determine if there is a major public health problem? And if not, what else would the FDA rely on?

Mr. FEIGAL. Certainly anything that resulted in patient injuries would be an important criterion, but when we are looking at the device we look at how complex is the cleaning process, how delicate are the materials with which it is manufactured? Is it likely that you are either not going to be able to clean it because you have got lots of crevices and narrow lumens, and areas where you are going to get residual body fluids or biofilms or even tissue?

Beyond that, even if someone can clean the device well, we look at whether or not the cleaning process itself is likely to damage the device and make it less effective. So the two primary criteria that we look at is whether you can clean it in a way that makes it safe and does not degrade the performance. So, those are the two key issues that we have said we would use to determine our level of

concern with the device and how rapidly we would move it into our priorities for taking action.

Mr. BRYANT. Given what I understand to be your testimony that the FDA believes this issue of reusable equipment ought to have more oversight and regulation, do you think it would be appropriate at this time that a patient should be informed ahead of time that reprocessed equipment might be used on them?

Mr. FEIGAL. I think this is a question about which you will hear testimony from the other panelists. When it is not in the setting of an experimental device, then we are looking at the use of informed consent and the practice of medicine. And there are many things that you do in the practice of medicine, such as agreeing to surgery or agreeing to the examination of a child, where national norms state that informed consent is appropriate in that setting. The kinds of details, the kinds of issues that are disclosed, I think, are part of that broader issue of informed consent relating to the practice of medicine. And so our position as the Agency is that that would not be something that we would consider, but it is a very important issue for the healthcare community to address and decide what is appropriate.

Mr. BRYANT. Thank you, doctor. I see my time is up and I would yield back.

Mr. UPTON. Mr. Burr.

Mr. BURR. Thank you Mr. Chairman.

Dr. Feigal, welcome. Do you regret the move from biologics to devices?

Mr. FEIGAL. Well, I came from drugs before that, so I am not yet looking for my next home.

Mr. BURR. Have you figured out which direction they are sending you yet?

Mr. FEIGAL. No. I am enjoying myself very much, thank you.

Mr. BURR. Let me take the opportunity to thank you. Since 1976, I think, that we have had in the law the responsibilities for this area, and I think since you got there you have taken this in a very serious way as a safety issue and as an equity issue within the world of OEM and reproprocessors. And I think to a large degree taking into account the need that hospitals have and for that I am very thankful. There are not too many people that would try to sort through this. And I realize that it is a process in work. But let me be real specific on some questions if I could.

Now, you said that under the scheme that FDA has designed, that reproprocessors would file a 510(k) application and they would have to prove that the device was safe, effective, and well manufactured. How could we expect a reproprocessor to prove that it was well manufactured?

Mr. FEIGAL. Let me start by saying that the reproprocessors would have to file the same kind of application that the OEM would have to file for the same device. And so in some settings that would be a PMA, in some settings it would be a 510(k), and in still other settings where the OEM is exempt from pre-market application the reproprocessor is exempt from a pre-market application. They are still required to meet all of the other standards, including our inspectional standards and their requirements for quality systems.

The cornerstone of this is that you have processes in place where you identify where the hazards are to your product, and you identify the kind of controls that are necessary in your manufacturing that can address those hazards, and you do it in a way that you can document and quantify. You do not wait for them to fail and work backwards from failure analysis, but you work forward from the start and say there has to be integrity in this system, it has to be a high quality system. Certainly as you get failures and complaints you feed those back in and you see why those were missed.

Mr. BURR. I think it is also safe to say that we would not design a system that would not work, right?

Mr. FEIGAL. That is correct.

Mr. BURR. And you mentioned earlier the proprietary information and the FDA's position on that information, and certainly this committee has learned in the past what happens when that information leaks out of the FDA, especially as it relates to laser surgery. Let me ask you, given the need to withhold so much information about the product, is it fair to believe that they can prove the well manufactured part, or is that just the wrong word?

Mr. FEIGAL. Well, withhold is probably the wrong word. We certainly don't share the companies' information with each other, but we don't withhold our concerns. And we can express our concerns and what the issues are that they need to address for a product—we learn across a whole product class what the issues are with that product.

And we lay those out for the manufacturers and now whether they are an OEM or a reprocessor, and those are the things they need to address. You have allowed us in the way that you have structured us to use all the information we have without being required to share or disclose it in order that we can meet that balance of protecting the public health but still maintaining the trade secrets that are useful in commerce. And so that is the balance that we need to do. It is a process that has to go device by device and model by model to look at how this is done.

Mr. BURR. Who determines the single-use labeling?

Mr. FEIGAL. The manufacturer.

Mr. BURR. And in the absence of any request on their application, what does the FDA put on the labeling?

Mr. FEIGAL. The manufacturer does the labeling. In fact, they have under the law the ability to actually make some changes in the label without even informing us. It has been our practice in the past if the manufacturer asked to label for single-use, to take that at face value and to evaluate how it would perform with one use.

Mr. BURR. Under your proposal, would a reprocessor be required to test every device for functionality?

Mr. FEIGAL. They have to think about the device they are dealing with and say what are the critical performance aspects of this device and how can I assure that every time I release this device it still meets those standards.

Mr. BURR. Are original equipment manufacturers, do they test every device for functionality or do they batch test, do you know?

Mr. FEIGAL. It depends on the type of testing. Some types of product testing are destructive and so you would not have any product if you tested them all. In those kinds of settings manufac-

turers typically sample. But the important thing about the way that the law and our regulations have constructed the manufacturing process for human medical products, whether it is a drug, biologic or device, is to emphasize the integrity of the manufacturing process. We emphasize the quality of the manufacturing process, rather than defect analysis at the end of the game. And we would expect that same philosophy to be adopted by re-manufacturers.

Mr. BURR. When you look at reproprocessors, and I put third party in hospitals.

Mr. FEIGAL. Yes.

Mr. BURR. Do you look at them separate? Are they different or are they one in the same as you wrote this regulation?

Mr. FEIGAL. Our proposal is to begin treating them all the same. Each one that is its own business entity will have a separate relationship with us.

Mr. BURR. How long does it take for 510(k) to get approval in the FDA on average?

Mr. FEIGAL. The average is about 180 days, I believe, but there are types of 510(k)s that are simpler and actually are approved in as short as an average of 29 days. So it varies. But you raise an issue that we thought about, which is how this is going to impact our resources since the average number of reviewer hours to assess a 510(k) is about 55. But that's for all 510(k)s and they vary widely in complexity. We imagine some of these would be simple, others would be very complex.

Mr. BURR. I found it a little odd that in this years budget there was four times as much money sought for tobacco out of FDA than the issue of reprocessing of devices. And I would ask you to share that with the Administrator when you get back that it was noticed. Let me just ask you, under FEDMA we created the ability for 510(k)s specifically to go through a third party approval process. Do you see this as an appropriate area for the trial of third party approval?

Mr. FEIGAL. The way that we constructed the third party system was to establish standards so that both the third party and the applicant would know what the review criteria were. And I think certainly that in some of the areas of very commonly used devices this could potentially work very well with third party. We are very committed to expanding that program. We have actually put specific proposals in this year's budget to expand that program and whether it is expanded in the way that is proposed in the budget or not, we are committed to seeing that program succeed. It is one of the ways in which we can expand our scope without always doing it with Federal workers.

Mr. BURR. Last question, Mr. Chairman. You have been there a limited amount of time, I realize that. But in your research of this issue, which is not new, did any point did reproprocessors come to the FDA seeking guidance or seeking the process that the FDA expected them to follow?

Mr. FEIGAL. We have met with the reproprocessors, and the reproprocessors actually have asked us for letters clarifying—

Mr. BURR. But prior to your passion for this issue, do the records show that at any point that this industry—

Mr. FEIGAL. Yes.

Mr. BURR. [continuing] be it hospitals or be it third party reproprocessors, look to the FDA for the guidance for the procedures or to set up the procedures?

Mr. FEIGAL. Yes. That did occur, and many of the efforts actually predated me. You have been kind to attribute as much progress to my getting there as you have.

Mr. BURR. I thank you for your willingness. I yield back.

Mr. UPTON. I would just like to note that we will proceed with Mr. Barton and we will take a brief recess for folks to vote. Mr. Burr is going to be asked to come back and chair while I vote and after that we will proceed with the other members that are here. Mr. Barton.

Mr. BARTON. Thank you. Mr. Chairman is this 5 minute or 2 minute questions?

Mr. UPTON. You get 5 minutes, and if you want more time we can have another round.

Mr. BARTON. No, sir, I can comply with it. I want to ask unanimous consent that my opening statement—

Mr. UPTON. It. That has already been done.

Mr. BARTON. Thank you. Doctor, we are glad to have you. I am going to be very quick because we have a vote on. The first question I have is there any reason not to treat all manufacturers and reproprocessors the same?

Mr. FEIGAL. No. And that is why the approach that we proposed just this week in our guidance really does take that philosophy.

Mr. BARTON. Okay. And on the informed consent issue, is there any reason not to require informed consent for a device that is going to be reused? Why would we not do that permanently?

Mr. FEIGAL. I think that that is a good question, but I don't think it is an FDA question in the same way that we don't specify the informed consent for putting in a hip implant or other types of things. These are the kinds of informed consent that are done in the practice of medicine and I think it is important to get some consensus on whether this is one of those things, like the examination of a child or surgery where informed consent is routinely used. But it is not something I think that is part of FDA's purview.

Mr. BARTON. If we want to give some Congressional guidance, the FDA would not object if we had some truth in advertising requirements so to speak that informed consent should be allowed? If I go buy a car I want to know if it has been pre-owned, you know, whatever I purchase I would like to know whether it is brand new or somebody else has owned it. I mean, I would think if you are going to put something in my body I have a right to know that it may have been in somebody else's body.

Mr. FEIGAL. Yes. One thing to consider is that part of our approach is to assure that the reused device will perform as well as the original device. And I think that needs to be part of the debate about the role of informed consent. And then beyond that there is the issue, if informed consent is needed, do you try and do that with labeling on the packaging or exactly what is the mechanism for that? But I think our fundamental start was we shouldn't be in a position where someone has to be informed that we are using a device on you that may not be very good.

Mr. BARTON. Right.

Mr. FEIGAL. We think the quality of the device is the fundamental issue, and then it makes the informed consent less of an issue.

Mr. BARTON. Well, I have read your testimony on page 11 as you go through the process of looking at your existing proposal. You have a list of five steps here, or four steps. The only question I have, what kind of procedure do you have in place for interested parties and stakeholders to interface with the FDA?

Mr. FEIGAL. We have a comment period open now on the two guidances that identify a list and give our proposal for risk scheme and for an enforcement time table. And those policies will not be made final until we have had that input. We also have had public meetings. There have been three or four in the last year and workshops, and there are ways to address us through our Web pages, through other types of things.

Mr. BARTON. Now, we assume that you are going to have an open process, that if you are a remanufacturer, an original equipment manufacturer, or an advocacy group or hospital group, you can have an honest dialog with the FDA and the FDA will listen?

Mr. FEIGAL. Absolutely.

Mr. BARTON. Okay. Mr. Chairman, that concludes my questions. I appreciate you holding this hearing and I will follow it very closely and work with the chairman and other interested parties on this issue.

Mr. UPTON. I know that you will. But we will take a brief adjournment. Mr. Burr will vote, come back. We will start with the members that have not asked questions and proceed from there. So it will probably be about 10 minutes.

[Brief recess.]

Mr. BURR [presiding]. If I could call the hearing back to order and ask Dr. Feigal to return to the table. I actually thought they would finish with you before that break. As is tradition here, that means that other members will have additional questions, so I can't swear to you this is the last, but the Chair would recognize Ms. Eshoo for 5 minutes of questions.

Ms. ESHOO. Thank you Mr. Chairman. I have several questions as you might guess, Dr. Feigal. What I want to do is to read the questions first. My experience is I ask the first question, most of the time is used up and then we never get to the others. So, it is going to be up to you to divide the time judicially so that you can answer them all. First of all, thank you for your testimony today. I just have a couple of observations. One, in how we use the words single-use. I think it is a real contradiction to be talking about the reuse of single-use. If we are going to be talking about the reuse of medical devices we should just say so. And we should establish a national policy that guarantees patients across the country that they are indeed safe. But to continue to use this reuse of single-use, I really do find it to be a contradiction.

Second, most of your testimony, and I think that it was excellent. You have been very direct, honest. You are a wonderful professional, and I am proud that you are in public service. Most of your testimony has really been directed toward what the FDA hopes to do—with your proposed guidelines. I want to remind members of

the committee that that is not in place. There is not the kind of system that has been eluded to or spoken to during this hearing. So here are my questions.

FDA has an approval process today for medical devices, and you know that I have a lot of experience in that, having launched from the Democratic side with Joe Barton on the Republican side the reforms that we brought about, as well as many members of the committee on this issue. So you have a process for medical devices that is in place today. The PMAs, the 510(k)s, and it goes along the lines of risk. In your proposal do you bring the same consistent policies for the reuse of medical devices? Do your proposals contain that?

Would the FDA oppose, would you come out against the issues of tracking and consent? I know that you have commented on them, but I would like to know if the FDA would oppose those—if those directives came from the Congress. Of course, those are two issues that are in the Bill that I have introduced. Is the Federal Government actually paying first rate medical device prices or reused products? Is Medicare reimbursing for that? And if so, would FDA have any voice in this or do you plan to? And can you tell us how many times a “single use” device, has actually been reused?

And what exactly is FDA’s oversight today for reused products? I am very pleased that 2 days before the hearing you have come out with your proposed policies. I would like to think that maybe my legislation has spurred FDA to really take this issue, not only seriously, but to take action on it. So, if you could address yourself to those. If you do not finish answering them, hopefully you can, you know, get the written answers back to us. And I also, Mr. Chairman, in my opening statement I made reference to a letter that the FDA wrote and asked that there be unanimous consent that that be entered into the record, and I would like that. We didn’t do that—

Mr. BURR. Without permission, of course.

Ms. ESHOO. Thank you. Okay. He doesn’t know what I asked for, does he? Okay. No, he does. I’m teasing. Thank you.

Mr. FEIGAL. Well, thank you for your questions. And we actually appreciate your interest in this area and look forward to working with you, and looking at your proposals and seeing how they fit in the area. I began my testimony by asserting that we felt we had the authority. We didn’t want any confusion out there that we needed new legislation before we acted, and that we can act within our existing authorities. And part of the reason that we are doing this with guidance rather than regulations is that we feel our regulations have the authority for us to do this. Part of the reason for a staged approach is because this process should not be brought to a screeching halt with supply problems, disruption of patterns. There are people on both sides of this issue, as you will hear today, that we wanted to engage.

One of your fundamental questions is, will we treat everybody the same? We will. That is one of the basic issues. One of the things I think underlies some of the questions is that, in the past, when we classified a device we really did not pay much attention to whether it was single-use or multiple use. One of the things we will have to address is whether single-use and multiple use of the

same device actually might in some cases even have different classifications one might be exempt but by reusing it you have changed the safety profile. And so I think there are some issues there, but our approach to that would be to say, what applies to the reprocessor applies to the OEMs. If it is an issue for the reproducers, then it is also an issue for the OEMs.

Ms. ESHOO. I didn't hear that in your discussion of the proposals, but if they are going to be equal, than I think that that's a big step.

Mr. FEIGAL. On the consent, I think we don't view that as our responsibility for this type of consent, and it probably wouldn't be most effectively implemented through a change in labeling.

Ms. ESHOO. But would you oppose it, that is what I asked.

Mr. FEIGAL. I personally would not oppose it.

Ms. ESHOO. Okay. I'm not talking about personal. This is all public.

Mr. FEIGAL. Well, when I say speak personally, I mean my part of the Agency. We could give you a more thoughtful answer about what we see are the pros and cons to this type of approach. I think the issue relates more to a device which is being cleaned and reused again and again, whether that is the element of consent. In which case it would apply more broadly than if the issue is simply that someone wanted to use a disposed of device as their starting material to craft a new device with an application for it to be used again. Your questions about payment are questions you need to ask HCFA—

Ms. ESHOO. Tracking?

Mr. FEIGAL. [continuing] ask HCFA and others.

Ms. ESHOO. Tracking?

Mr. FEIGAL. Oh, and tracking.

Ms. ESHOO. I keep track, see.

Mr. FEIGAL. Yes. You do. That is good. That is the third time. We have tracking authority in a different context for products. We do not apply it to all products. Not even all high risk products. I think again if this is an approach that would increase the safety and would be the best way to make a product safe and effective, then it would be appropriate to use it. Whether it would be the approach for all devices, I do not think would be the case. I think there are probably some disposables that would not need to be tracked, you would just need to look at what has happened to them as they were being cleaned.

Ms. ESHOO. Uh-huh.

Mr. FEIGAL. The issue about the tracking and putting information into patient's medical records, that is a practice that is commonly done with implantable devices. They are an example of a product area where it is common for manufacturers to have a peel-off label that goes on the chart. Sometimes even the patient gets a card if they are being tracked. So there is precedent for this. I think what I would do is say let us take a look at the kinds of products where this makes the most sense and where it adds something. It is more cumbersome than some of the other mechanisms. Getting hold of the right chart that has the label in it is not totally straightforward in our medical system. And so I think we need to make the solution fit the problem. But it is something that has been done. It is something that we should talk about more.

Your one last question is, do we have a Guinness Book of World Records for the single-use device that has been used the most times. And probably not. I would suspect it is probably an anesthesia circuit somewhere that has been cleaned and cleaned again. The real challenge, even for the people who clean these things, is that there is no marking on the products themselves to indicate that they were a disposable device for the vast majority of these devices. And many of them look identical to the reusable devices, and I think that is another issue that I mentioned before that we need to deal with.

Ms. ESHOO. And what exactly is FDA's oversight today? How does it work? What do you actually do?

Mr. FEIGAL. Well, I am not sure I understand the question. In terms of rolling out this framework?

Ms. ESHOO. No. I am not talking about—

Mr. FEIGAL. Or in terms of our oversight?

Ms. ESHOO. I am talking about today.

Mr. FEIGAL. Yes.

Ms. ESHOO. What is your oversight with the reuse of manufacturer's—

Mr. FEIGAL. Okay. What we have done today is that we are actively inspecting and looking at the manufacturing practices of the reproprocessors of—

Ms. ESHOO. Since the late 1970's, what has the FDA's practice been?

Mr. FEIGAL. Well, in the late 1970's FDA wrote a letter strongly discouraging the practice and telling the hospitals that they accepted complete liability if they did this. Then there was a long time period where this issue really did not get very much attention, and I think the assumption was that not very much of that was going on. It has really only been in the last year that there has been more attention to this. Some of that has been economic and there have been attempts to focus on the ethics of doing this. Some of this has been because of patient's insurance. Some of this has been because of reports of injuries. Our approach is to investigate the reports of injuries, to contact the reproprocessors. Some of them, when we first contacted them didn't think they were manufacturers. We have let them know that they are.

Ms. ESHOO. But who do you react to? Your oversight is essentially reacting or responding to something that is—

Mr. FEIGAL. Not entirely. But it is appropriate for us to be reactive when we get a report of an injury or of a problem.

Ms. ESHOO. No. I am not suggesting that it isn't.

Mr. FEIGAL. Yes.

Ms. ESHOO. But if that is your oversight—

Mr. FEIGAL. No. No. It's not.

Ms. ESHOO. [continuing] I think the committee needs to—

Mr. FEIGAL. We are also being proactive. We have sought out, for example, detailed lists of who is remanufacturing. For example, we have identified the companies who specialize in cleaning Sharps containers, which come in both single-use disposable and reusable varieties, and to inspect those and look at those patterns in a very, very narrow area. But we have not just been reactive. We have proactively sought feedback on the approach, on how to prioritize,

how we begin with this problem, and we haven't waited to go out and inspect. We have gone out and actively engaged these companies.

Ms. ESHOO. So, you only inspect those places where items are reprocessed or the devices are reprocessed? The devices themselves or?

Mr. FEIGAL. Our normal inspection process is to, in fact, regulate the manufacturer who produces it and not to inspect devices.

Ms. ESHOO. I think this is a very important distinction though to many members to hear.

Mr. FEIGAL. Well, this is also true for original equipment manufacturers. We do not inspect their devices. Now there are cases where the device fails, where we actually bring the device into our laboratories and work with it. In fact, if there had not been so many samples brought by members of the committee I would have passed out my own. And we do work with the devices themselves in a hands on sort of way. But the fundamental way that the law is written to regulate devices, as you know, is to really ensure the integrity of the manufacturing process. We go in and look at the company's quality systems and the way that they have dealt with the problems that have been reported to them. And that is our fundamental way of addressing the problem. This occurs more often where there has been a specific problem with a type of product and we have been asked to look into it.

Ms. ESHOO. Can I ask the indulgence of the chairman to ask one more question?

Mr. BURR. Okay. One more.

Ms. ESHOO. One more?

Mr. BURR. We are going to have another round, I just want to—for those members with additional questions.

Ms. ESHOO. Is there a problem inside the FDA relative to resources in order to wrap up this policy you may need more people to implement it, is there, you know, to ask this publicly may not be all that comfortable for you. But I have found with Federal agencies that at least sometimes they are reluctant to take on more responsibility, because as they carry out what they are directed to do, they know that there is going to be a strain of resources, and in my view there already is a strain at the FDA, given the very important legislation, I think needed legislation we passed relative to, you know, the reform on medical devices in another areas that you have jurisdiction over.

So have you undergone or undertaken any kind of analysis of your proposals and what that would call for monetarily inside the Agency that you can tell us about? Because I do not want one to get in front in the way of the other. I think that public policy has to take precedence here, and then it is up to the Congress to deal with what you may come forward with and say we need more to implement this. We have done it in other instances, we have risen to that occasion I think pretty fairly, and I think we have the capacity to do so again. But can you just touch on this?

Mr. FEIGAL. Sure. If you look at the current budget proposal that the President announced you will not see a specific request for reprocessing in this years budget. That is for two reasons. The most practical one is that with the long budget cycle, that budget was

prepared about 18 months ago. And the activities have significantly evolved only in the last year.

Ms. ESHOO. Well, I was calling and writing in December, in the beginning of January, so I do not necessarily agree with that, but go ahead.

Mr. FEIGAL. In our appropriation language last year there was language that we should spend at least \$1 million on the issue of reprocessing in this year. That was not difficult for us to agree with because our effort, even last year, was approximately that magnitude and this year it is somewhat larger than that. One of the things that makes it difficult for us to plan is that we do not know how many hospitals are going to decide to file pre-market applications. We do not know how many places are going to register and list and need to be inspected.

At this point because our change in the policy is so recent, there are not the kind of resources that we need. It has mostly been in the area of policy development, research, and other areas. And we have the capacity to turn and focus on an issue and not wait for a funding cycle to catch up to a public health program. One of the natures of FDA in general is that we are asked to prioritize risks and act on them. And there have been decisions that have been made in the past where this one, quite frankly, did not rise to the top of the list and other things, such as reducing backlogs to get products to market more quickly, implementing FDAMA and other things got more attention. But as the committee is aware within the last year there has been much more intense interest in this and we have turned our resources to this problem now. We do not, yet, have a proposal of where this is going. I think we need to hear more from the effected parties, what their reaction is going to be, to have an idea of the scale of what we will need. And as we need resources we will request them.

Ms. ESHOO. Thank you. Thank you Mr. Chairman.

Mr. UPTON. You are welcome.

Mr. Pickering?

Mr. PICKERING. Mr. Chairman, thank you.

Dr. Feigal, if a device is FDA approved for single-use, why is it possible to reuse these devices?

Mr. FEIGAL. Well, the simplest way to explain that is that there is nothing that is illegal about using a pre-existing device as a starting material for a new device. In fact, there is sort of a misconception that the remanufacturer is trying to restore something identical to what the original manufacturer produced. That is not the requirement. The requirement is that they produce a device that is well manufactured, safe and effective for its intended use, and that they show us that they can do that. And the difference is that they are using a used device, they are using the components of the used device as a starting material.

And if you look at refurbishers, particularly of more complex materials, that is not even the case that they use the entire device. They may just salvage part of it. And so this is something that is common, I think, throughout many industries and so long as the device is well made, safe, and effective, there is nothing in the law that precludes someone from doing that, despite the fact that the manufacturer wanted it thrown away after the first use.

Mr. PICKERING. Yes. But does the FDA need to clarify their approval description? If it is FDA approved for single-use, but you are saying that it is legitimate for multiple use, should you change your labeling?

Mr. FEIGAL. Well, the manufacturer brings the labeling to us and then we determine whether or not the product will be safe and effective as labeled. One of the complexities of the device laws is what FDA approval means. In some cases, such as a PMA, it is an evaluation of whether or not the product is safe and effective for use. But more often the standard is that the device is substantially equivalent to another device that is legally marketed. And within that framework some of those devices are exempt from pre-market applications and only are required to have registration and listing—actually I shouldn't say only.

It is actually a relatively long list of things that they are required to do. But that is one of the complexities for the public to understand. The way that the device laws have been written is that there are a variety of standards depending on the type of the device. The underlying principle that we are trying to apply to this situation is to say that there should be no distinction between the OEMs and the reproducers. If you are manufacturing a device from another device, that should have the same standards as if you are manufacturing a device from first components, you know, from scratch.

Mr. PICKERING. Now, do you give any guidelines for hospitals who may have a device that is open but unused and then they take precautionary steps to make sure that it is clean and sanitary? Are you looking at any—

Mr. FEIGAL. Those types of instructions and the testing and the adequacy, that is provided by the manufacturer. It is part of the instructions for use. We evaluate the adequacy of those instructions and that is a very common phenomenon. In fact, it lead to some of the confusion when we put together some of the initial lists, about commonly reused devices. Very many of them on the list were things that were simply being opened in the operating room and then being repackaged and sterilized for another day.

Mr. PICKERING. And you have no problem with that? You don't see a problem?

Mr. FEIGAL. It has to be done with attention to detail and that is what the manufacturers have to assert to us that they know how to do. So, for example, if you are reprocessing suture material, for example, you have to know that the way that you are going to repackage and sterilize that does not damage even the packaging which could breach the sterility of those sutures. But again, the manufacturers have worked with the hospitals because they have a need to do that. If we wanted to replace your hip today, in the operating room they would open and have available for the surgeon several different closely related sizes, because they would not be able to know in advance which one would fit you. And rather than charge you for all three sizes if they opened them up, they would use the one that fit and then they would take the others back and re-sterilize them and use them again. And we think this is a legitimate practice. It is one where the manufacturers work with the hospitals to provide instructions on how to do this. It is a different

problem, I think, than the reuse of an already used single-use device.

Mr. PICKERING. Now in that context, has FDA reviewed the cleaning processes utilized in the reprocessing of medical devices, and if you have reviewed it, are you confident that the processes used are effective and safe?

Mr. FEIGAL. Our first approach to this is to say that the cleaning and the re-sterilization and the refurbishing is device and model specific. So there is not a single standard or answer. Now, that said, there has been tremendous interest in the device manufacturing community and in the FDA to approve standards for things that are commonly done so that they do not have to be reinvented for every model and every device. And so that is one of the areas where we will be working with the people who do the cleaning to look at those standards. These are the same issues for reusable devices, and the majority of devices are reusable. And these kinds of issues are not new to us. The hospitals have been using the procedures on single-use devices that they have already found to work effectively for reusable devices.

Mr. PICKERING. And when do you plan to issue further guidelines on the cleaning process?

Mr. FEIGAL. Well, the burden is actually on the manufacturers, on the hospitals, and the refurbishers to actually show to us that they have cleaning processes that are adequate. That is their burden to demonstrate in the application process, just like it is for an OEM who claims that they have a device that can be cleaned. The OEM has to show us the evidence that validates that their process can clean.

Mr. PICKERING. So, if the burden is on them, do they have to demonstrate that before they can reuse?

Mr. FEIGAL. That is correct. As we roll out the enforcement strategy what we are saying is that these products, as we get to them in order of risk, the single-use product should no longer be cleaned until they have met the same application processes that would be required of an OEM.

Mr. PICKERING. Now, has FDA taken a position on what is the recommended life cycle for reprocessing of single-use devices?

Mr. FEIGAL. Again, there would not be a single answer to that. It would vary on the device and on the model, and that is something to be determined by empiric data. There would not be a single answer for that.

Mr. PICKERING. And what empiric data do you have?

Mr. FEIGAL. Well, the data has to come from the manufacturer. They are the ones that are claiming that they can take this single-use device and put it back into use and have it be used effectively. So, they need to develop the data in their application to us to show us that they can do that.

Mr. PICKERING. Are you telling the committee today that until that data is provided, that burden of proof is met, that the current practice of multiple use will not be allowed on a going forward basis?

Mr. FEIGAL. That is the guidance. The guidance gives the time-frame for the types of devices and when the applications would be needed for those devices. And if those devices remain on the mar-

ket, that is what our second guidance about the compliance time-frame is all about. We are asking in the simplest terms that the reprocessors provide the same kind of information that the manufacturers provide when they bring to market a multiple use device.

Mr. PICKERING. Mr. Chairman, I hope you forgive me for just a couple more questions. Now, there are three issues basically here. There is public health, public confidence, and in that confidence the right to know. Earlier this week I sent a letter to the FDA, what is the FDA's position on allowing patients to know if there is a device that is being reused, is there a simple way to provide that information to patients without some type of complex regulatory process and burden upon the providers and the doctors?

Mr. FEIGAL. The issues you bring up are intertwined. On the one hand there is safe and effective use, and there are times when for a patient to really make a choice, they need to actually know what they are getting. And so there are cases, there are products, where the information that the patient is provided is explicitly provided in the product labeling, considered inherent in the safe and effective use of the product. There are other issues about what should your doctor tell you when they do surgery.

Should they tell you the make and model of the machine? Should they tell you how long they have owned it? Should they tell you the last time it was repaired? Many of those things, I think, relate much more to what society feels is appropriate to know to be able to be medical consumers, and relate less to the product labeling responsibilities assigned to the FDA. I think where we would be enthusiastic about being involved is where the patient's consent is necessary for the safe and effective use of the product. So we would be happy to continue to participate in these discussions, but I think we would encourage you to really broaden the discussion to involve the medical practice community and others who really need to implement this. If it is something that is buried in the fine print on the product labels, which are usually attached to packaging which is thrown away when the package is opened, that is not going to do the patient much good. If it is the advice of Congress, if it is the demand of the public to know about these things, then you have to change the practice patterns of the physicians that provide informed consent for procedures.

Mr. PICKERING. Is the FDA planning to post that type of possible information as to possible risk of reuse or proper standards for reuse to create the public confidence and the public knowledge?

Mr. FEIGAL. We have a Web site that is very actively used. It is mostly used by industry. But we do have consumer parts of it and there are some consumer products that generate a lot of interest in our Web sites. We are more than happy to spell out in consumer's terms the issues of these debates and our approaches and translate some of the regulatory language of our guidance for industry so that consumers can see our vantage point on this. I think that some of the broader issues about informed consent are things that involve other professional groups, so we would not be the only source, but we are certainly welcome to be a source.

Mr. PICKERING. Mr. Chairman, just one final question.

Mr. UPTON. I've heard that today.

Mr. PICKERING. And I guess this gets down to the crux of the issue. As I talked to a friend of mine who is a cardiologist, who actually takes a persons heart into his hands and uses many of these devices, he feels confident that they are safe and feels confident in his use of them. In talking with the manufacturers concerns are raised. Is this, in your opinion, driven by true health and safety concern and risk or is this more of an economic and cost and competitive issue among manufacturers?

Mr. FEIGAL. Well, for the hospitals and the manufacturers and the physicians who are involved with this, I think the economics is a fact of life. It is actually not a factor that you have asked FDA to consider when we make approvals or take regulatory actions. And so we are bystanders on the economic issue. I think it is not an "either/or" question. It is both an economic and practice of medicine issue, and an issue that affects the safety and effectiveness of these products. You mentioned there needs to be confidence that products are well manufactured and will perform as expected, even if there is not a major safety problem. And that is actually in our minds the most common problem with reusables, the integrity of the manufacturing, not the explicit risk or safety to the patient.

Mr. PICKERING. Thank you Dr. Feigal. Thank you Mr. Chairman.

Mr. UPTON. Thank you. We are going to go to a second round. A couple of us have a couple of questions remaining. And I wanted to say to start off, too, Dr. Feigal, by thanking you for allowing a member of your staff to stay for the second panel and thus being able to address additional questions that we may have based on that panel. A couple of things. Not counting hospitals that might reprocess something on their own, do we know how many reproprocessors there are across the country?

Mr. FEIGAL. Yes. We probably do. I think we probably have identified the majority of them. We still get referrals. Sometimes if we visit one reproprocessor he will be aware that we have not visited one of their competitors and they may add to our lists sometimes. But I think we actually do have pretty good knowledge. In fact, there are even reproprocessors that have filed 510(k)s with us. So it is not that we are, you know, starting cold.

Mr. UPTON. What happens on liability on one of the devices or instruments or whatever it may be, that may fail or perhaps has been reprocessed? Historically what has been the case? Do they go after the OEM? Do they go after the reproprocessor? Do they go after both? Have there been cases that have been used?

Mr. FEIGAL. You are asking something that is really outside of FDA's expertise. We are actually only aware of a limited number of actions that relate to reuse. I think one of the difficulties for patients who think they have been injured by a device is that it is very difficult for them to identify whether the device was reused or not. Some times their physicians may not know because the devices look the same and they do not know if they are dealing with something that has been opened and re-sterilized, or if it has been reused before, or if it is brand new. So I think the whole scope of that we do not really know.

Mr. UPTON. Well, as we know in the physician data bank when there has been a judgment issued against a physician, that record

is kept and available to hospitals and other providers. Is there such a log for devices that may fail or not?

Mr. FEIGAL. Not in terms of liability. Actually our interests are broader than that. I am really out of my element talking about law, but I will try a little bit. Liability in medical malpractice relies on establishing negligence. We are interested in things that fail, whether there was negligence involved or not. So, manufacturers are required to report to us device failures that they know about. The voluntary system by health providers has tremendous under reporting. But if a manufacturer knows about something they have to tell us. When we inspect them, we look at their records. So we think that if the manufacturer knows about a device failure, whether it is going to be involved in a suit or not, we know about it. We are able to get those kinds of statistics.

Mr. UPTON. Would that same standard that is on the manufacturers then be under the regulations you have proposed be followed for the reproprocessors as well or not?

Mr. FEIGAL. Yes. The principle underlying all of this is that the same requirements would be applied.

Mr. UPTON. So, if this is reprocessed and it fails——

Mr. FEIGAL. Right.

Mr. UPTON. [continuing] the reproprocessor would have to file with you all——

Mr. FEIGAL. That is right.

Mr. UPTON. [continuing] if your regulations are made in order?

Mr. FEIGAL. That is right. Even if the reproprocessor is a hospital.

Mr. UPTON. Right.

Mr. FEIGAL. They would then have the kinds of mandatory responsibilities and if they have asserted to us, in an application that they know how to reprocess those, we would treat them like any other manufacturer.

Mr. UPTON. Good. Now, reading through your testimony that we received last night, I think that the answer to this is yes. Is the reprocessing of medical devices labeled for single-use without pre-market submissions a violation of the Food, Drug, and Cosmetic Act? It is a violation, is that not true? They just have not been enforced until these regulations are in place, is that right?

Mr. FEIGAL. It would be a violation of the Act if the labeling of the product was false and misleading, or if the manufacturer was placing into commerce a product that did not have marketing clearance or marketing approval. That is why we say we do not need new authority. We already have the authority to require these.

Mr. UPTON. Great. And last as my light is going to light now, Mr. Stupak had to testify before another subcommittee and he will be back, but he asked me to ask you for him: please discuss exempt devices and how they are dealt with under the guidance for reprocessing.

Mr. FEIGAL. Okay. Well, an exempt device is only exempt submitting a 510(k) application. They are not exempt from any of the other standards that establish the quality of devices: registration and listing, the device failure reporting, special controls, being subject to inspection. For exempt devices we have said the OEMs can manufacture and not get pre-market clearance. Our proposal says that those who remanufacture those products would also be exempt

from the pre-market clearance. But that is all that they are exempt from.

Now, someone might make the case that in fact the classification is not correct when you begin reusing certain types of devices. We have devices that are both single use and multiple use and in almost all cases they are in the same classification. In fact, I do not know of an exception. One of the things in this process of comment we will be looking at is, should that be the case, or are there cases where it is appropriate to exempt only the disposable product. If that is the case, that would apply as much to the OEMs as the re-processor because we want the same standard of quality no matter who makes it.

Mr. UPTON. Thank you. Mr. Burr.

Mr. BURR. Dr. Feigal, Med-Watch is an FDA voluntary program primarily for drugs.

Mr. FEIGAL. Yes.

Mr. BURR. It includes devices as well, doesn't it?

Mr. FEIGAL. It includes devices, yes.

Mr. BURR. Did I just hear you earlier to say voluntary programs do not work?

Mr. FEIGAL. No. They have under reporting for a variety of reasons, and it is true in almost every country that uses them. But the under reporting does not mean that we do not get signals that are very useful to us to identify the problems. What the programs that are voluntary do not do is give us good numerators and denominators. So it is very hard for us to tell—

Mr. BURR. So, are you an advocate of a continuation of Med-Watch in its current form or would you be a proponent to change to a system that was more reliable on the indicator?

Mr. FEIGAL. Well, I think Med-Watch in its current form is very useful and has identified problems with products that have resulted in actions.

Mr. BURR. Is that for devices, or devices and drugs?

Mr. FEIGAL. Devices and drugs.

Mr. BURR. Let me ask you if I could. Do you believe that the legislation that guides FDA requires FDA to make sure that proper labeling follows specific products?

Mr. FEIGAL. I'm sorry. Could you say that again?

Mr. BURR. Do you believe that the legislation that guides FDA's work in fact requires FDA to make sure that proper labeling is assigned to all products?

Mr. FEIGAL. Yes. Yes.

Mr. BURR. Give me FDA's reason for allowing single-use devices to be reused and why as you as the head of the device area would spend so much time trying to figure out a process for single-use devices to be reused, given that one of the primary roles of the FDA is to make sure that the labeling is an accurate description of the use of the product?

Mr. FEIGAL. Now, one of the fundamental questions is, if I own the device can't I do anything I want with it? That is sort of the off label drug question rephrased for devices. If I own that device I can't clean it and fix it up a little bit and use it again? I am now the owner. And our response is, the practice that has grown up in hospitals, and certainly third parties, of taking devices and trying

to refurbish them, has actually turned them into, not owners of the device, but manufacturers. And that that is the reason that they now have to describe the integrity with which the device is manufactured and develop appropriate labeling, and adhere to the same regulations as any other manufacturer. Part of the reason that this process may look so tortuous is that we are aware that this is a process that probably cannot be stopped overnight, and that is probably a comment that you will hear debated by your next panel.

Mr. BURR. But you would not consider that the labeling of a single-use device that could pass the test of reuse was mislabeled? You said in your opening statement, if I remember correctly.

Mr. FEIGAL. Yes.

Mr. BURR. Correct me if I am wrong, that many of the single-use devices today are configured in the same way with the same components as the multi use devices prior.

Mr. FEIGAL. Yes.

Mr. BURR. What, in your mind, distinguishes the difference between the multi use status that FDA agreed to and the single-use status that FDA agreed to after the application was changed?

Mr. FEIGAL. We evaluate the claims in the label from a specific manufacturer for a specific product and see if they have the evidence to support the claims. When it is re-manufactured, actually the manufacturer changes. We are no longer dealing with the OEM and his label.

Mr. BURR. Is it your interpretation then that liability would not extend back to the original equipment manufacturer, given that your—

Mr. FEIGAL. I am not the person to ask about tort issues.

Mr. BURR. But I am sure that the FDA has looked at that, haven't they?

Mr. FEIGAL. Well, and actually liability is—

Mr. BURR. I think there are some lawyers over there if I am not mistaken.

Mr. FEIGAL. There are lawyers around here, but they are not tort lawyers. They write regulations and things like that. But I think this is definitely an issue you have identified for the community that reuses devices. I do not think it is really much of a factor in consideration of our work.

Mr. BURR. What is the definition of FDA of an already used device?

Mr. FEIGAL. That is a very good question because the variations that we have discussed of open but unused and any used device—

Mr. BURR. If history is any indication there will be another director at some point in the future at FDA of the device area. What does the FDA have in place to guide them as far as this definition so that when they come in their interpretation is not an unsterile device that was in the OR in case it was needed.

Mr. FEIGAL. Right. Well, I think the first principle in FDA labeling is that you should say what you know. And the original manufacturer said that this is a single-use device. It is their responsibility to define when the device has been used so it is not used again. So does that mean, for example, in the operating room when someone may have, with their glove on, handled a couple of dif-

ferent hip pins to pick the right one out, that is now a used hip pin or is that still in the open-but-unused category which—

Mr. BURR. Would it also be the original equipment manufacturer's responsibility when they file the initial filing to tell you if this could be reprocessed it could be used this many times based upon our clinical studies?

Mr. FEIGAL. Yes. The type of use that they envision and the type of use that they are claiming is safe and effective has to be described. And actually we discuss these issues in the guidance that we have just released.

Mr. BURR. And should the original manufacturer and FDA supply guidance to the reproducers as it relates to the reprocessing of the device or sterilization?

Mr. FEIGAL. Our stance is that the reproprocessor is a new manufacturer and so there might be a business relationship between two manufacturers, but it is not required. The reproprocessor is someone who is taking a disposed of device as their starting material and saying, "I can build a safe and effective and well manufactured device out of this." And so it is not the OEM's responsibility to tell the reproprocessor how to do this. If there are things which damage these delicate devices that are commonly encountered in hospitals, it is a little bit disingenuous for the OEMs to act like these things will never happen. What if something was opened-but-unused and the product is damaged by ethylene oxide? That normally would be used in the setting of remanufacturing but, you know, we would like to have some dialog with the OEMs about when is it appropriate for them to disclose that information in their labels.

Mr. BURR. Well, I would—again, I commend you for your willingness to jump into what is a very, very difficult thing to figure out what the right balance is. I would encourage you to work with the OEM manufacturers, the reproducers, the hospitals, to work out some of the areas that you pointed out are good questions. Because clearly I think we are going to continue to think of some questions that we have not thought of and I would encourage you also to focus on the future interpretation of others by what action you take and possibly what action Congress takes, because I think it does have an effect on the quality of health and the cost of health in the future. I thank the chairman. I yield back.

Mr. UPTON. Thank you. Mr. Bryant, do you have additional questions?

Mr. BRYANT. Mr. Chairman, I really don't. I would just—it is almost entertaining to hear this discussion, not that, you know, it is humorous or anything but we are just one giant circle and some of the questions that are asked, and, you know, is it a single-use item a single-use item, and reusing a single-use item, and who decides whether it is a single-use item, and then a new manufacturer taking that item and cleaning it and saying it is now my product. I suspect in the end it would be great to have some guidance from you, but it seems to me that is one of the questions we have to decide is, and I don't know.

The FDA is probably not involved in making that decision as to whether or not this is really a single-use item. As you say, the OEM comes to you and you accept the labeling and if they say it is, it is. Question, why don't they put on there this can only be

used one time and you do it otherwise you are subject to all kinds of problems. They don't want to do that, but I suspect in the end it is going to be up to the courts of law, the trial lawyers out there, the plaintiff's lawyers, to litigate this. And it is going to take a few big cases to sort things through. But there is tremendous potential of liability here among the reprocessor, the hospitals, and maybe even reaching back to—ingenious lawyers can reach back sometimes and find those original manufacturers, too. So, it is a complicated situation and I just again urge the FDA to move as quickly as you can to give us all some guidance and assistance in this. And thank you for your testimony.

Mr. UPTON. Ms. Eshoo, did you have additional questions?

Ms. ESHOO. Yes. Thank you Mr. Chairman. I would like to go back to something, doctor, that you said just a few moments ago, and I think that you stated earlier in your responses to questions, and that is that the FDA considers reproprocessors to be manufacturers, but your policies do not reflect this. You do not treat—if, in fact, you consider them to be manufacturers how do you apply the same policies that you told me earlier are applied? I think that there is a discrepancy here. And I would also like to ask you about enforcement. What exactly are FDA's enforcement measures that are brought to bear today? I mean, we could have all kinds of policies on the books. We know if they are not enforced then they are not worth the paper they are written on, so today what are your enforcement policies and give us examples of how you have a manifestation of the enforcement.

Mr. FEIGAL. Well, one example that I mentioned earlier is that we have been inspecting reproprocessors and we have issued them Warning Letters for the kinds of manufacturing problems that an OEM—

Ms. ESHOO. Is this on the enforcement side?

Mr. FEIGAL. Yes. On the enforcement side. And we have not treated those inspections as having any different standards than we would for any other type of manufacturer. There are many different levels of enforcement. Because we have had this policy of not regulating this area in the past, there is a period of time when we are going to find people who do not believe that they are regulated by us and are putting into commerce what we consider new devices and we will—

Ms. ESHOO. And your new guidelines, does the enforcement change? Is it beefed up? Is it less? Is it—

Mr. FEIGAL. The new guideline takes the principle that the enforcement will be the same for a manufacturer, whether the manufacturer is a reprocessor or if it is an original equipment manufacturer. What the guideline does is that it gives people lead time to prepare for the change in policy, but it asks the manufacturers of high risk or high complexity devices by our definition to come into compliance more quickly. And that will mean having the same standards for applications and following all the same policies that we would expect of an original equipment manufacturer.

Ms. ESHOO. So you are maintaining that your designation of a reprocessor as a manufacturer, as well as the OEMs that the policies that you have in place now, and the enforcement policies, are

exactly the same as what your proposed guidelines are? That they are the same across the board?

Mr. FEIGAL. Once they are fully implemented, it won't matter if a device is manufactured or a new manufacturer is remanufacturing it. That the same standards will apply.

Ms. ESHOO. But see, I am confused, because I think that there is—it is very confusing to me whether you are referring to proposed guidelines and what you hope to do and what you hope to implement and/or what we have on the books today. Is it all the same? Is there enforcement across the board whether someone is an OEM or a reprocessor? Yes or no.

Mr. FEIGAL. No. It is not because the——

Ms. ESHOO. All right. Will there be consistency brought to both with the proposed guidelines?

Mr. FEIGAL. Yes.

Ms. ESHOO. As well as enforcement?

Mr. FEIGAL. Yes.

Ms. ESHOO. Across the board?

Mr. FEIGAL. Yes.

Ms. ESHOO. Not just in some areas?

Mr. FEIGAL. Across the board and it will be phased in.

Ms. ESHOO. You said earlier when I asked you about standards which is something about which I am talking about now. Today you only inspect the place where devices are processed. Is the place clean? Is the process a good one, is that correct?

Mr. FEIGAL. These are GMP inspections. When we inspect a reprocessor, we look at him in the same way that we look at an original equipment manufacturer. The reprocessor, to us, is a different manufacturer than the OEM. They just have a different starting material.

Ms. ESHOO. But you said you consider them both manufacturers.

Mr. FEIGAL. That is right.

Ms. ESHOO. So what is the difference in what you just said then or the piece that you just mentioned? How does it affect what you said previously?

Mr. FEIGAL. The starting material that the manufacturer makes his product out of is different, but we treat them both as the same kind of manufacturer with a device that is classified as the same, with a device that has the same pre-market requirements, with a device that has the same safety reporting requirements.

Ms. ESHOO. Well, the reason that I am asking these probing questions is most frankly I do not think it is the same across the board. You are saying that it might be or that it will be if you get to implement your proposed regulations. But with new devices you require that all sorts of data be accumulated before they ever get to the patients, but that is not the case with the reprocessed pieces. So I do not think that there is a consistency, with all due respect. You are getting lots of notes on this so I must have——

Mr. FEIGAL. Yes. I am.

Ms. ESHOO. You know, by reusing the three tier risk system, the practical effect will be that enforcement, I do not think, will be the same across the board. FDA, I think, is sending a message to reprocessors that you are not going to enforce the same standards on them. And that may be your direction. I do not think it is good

enough. Now, you talked about equipment that is the operating room earlier, but the equipment that you referred to is not being placed inside the patient's body. So I do think that there is a clear difference and that is why I think the standards really need to be much higher. So you may want to comment on this.

Mr. FEIGAL. Let me be clear. Right now there are differences in the way they are treated because of the policy. The guidance that we have put forward are things which we intend to do. We are asking for comments. We have given the specific time table and told you when we intend to do them. We have done what Congress has consistently asked us to do with devices, and what the public has asked us to do, which is get to the highest risk things first. Whether something is a reprocessed device or an original device, it will have the same pre-market requirements. There will not be differences in requirements. The risk staging has more to do with how we phase in the change in policy, than it has to do with where we will be in 2 years, or 3 years, or whatever it takes to get there. There will be some differences in the types of applications because the companies building the same product are taking different paths to build it. There still will be the same standards, whether it is an original equipment manufacturer or a refurbisher.

Ms. ESHOO. But reprocessors do not build products, do they?

Mr. FEIGAL. Yes, they do.

Ms. ESHOO. How?

Mr. FEIGAL. They take a product that has been disposed of and——

Ms. ESHOO. Do they reconstruct it?

Mr. FEIGAL. They do things to it——

Ms. ESHOO. They redesign it?

Mr. FEIGAL. They have to understand——

Ms. ESHOO. Or do they clean it for reuse?

Mr. FEIGAL. They may do all of those things, or it may be a simple issue of recleaning, but once they take responsibility for re-manufacturing a device, they are a manufacturer with the responsibility to explain all of those things: the design and controls, the performance standards, all of those things.

Ms. ESHOO. This is in the new policy.

Mr. FEIGAL. That is the new policy.

Ms. ESHOO. The proposed policy.

Mr. FEIGAL. The new policy is that they are no different than an OEM.

Ms. ESHOO. That is not the case today?

Mr. FEIGAL. That is not the case today, no. We have been very——

Ms. ESHOO. Thank you. Mr. Chairman, I would like to ask a unanimous consent to place into the record a series of national articles that have been carried over a good deal of last year and some from this year about this issue. Many in national publications, grey sheets, etc., and I think it is information that is important to have as part of the record on this.

Mr. UPTON. Without objection.

Ms. ESHOO. Thank you.

[The information follows:]

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August 4, 1999

The Honorable Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20857

Dear Dr. Henney:

I am greatly concerned regarding the apparent widespread practice of reusing disposable medical devices intended for one use only. Recent surveys and media reports suggest that one of every three hospitals in the United States is "reprocessing" and reusing single-use medical devices on different patients. After looking further into this issue, I'm worried that this practice is being conducted without appropriate regulatory controls and without the informed consent of patients.

I've been informed that the reuse of balloon angioplasty catheters, biopsy forceps, and other intricate and delicate medical devices has led to unnecessary patient injuries and infections. While I understand that the FDA has resource constraints, I believe the inherent dangers of this practice warrant much greater attention from your agency.

As a member of the House Committee on Commerce and its Subcommittee on Health and the Environment, I plan to pursue this issue further and to determine whether legislative oversight or action is necessary to protect the public health and patient safety. To assist me in this effort, I'd greatly appreciate your answers to the following questions:

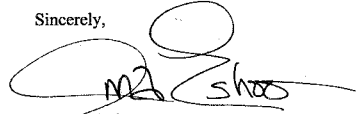
1. How many persons or entities have currently registered as reproprocessors with the FDA? Of these, how many are commercial reproprocessors, and how many are healthcare facilities?
2. Considering the FDA's limited resources for inspections, please explain how registration and compliance with good manufacturing practices alone provide the appropriate level of protection for consumers?
3. Why has the FDA chosen not to require reproprocessors, whether hospitals or other commercial entities, to file any sort of clinical or scientific data with the FDA to support premarket clearance or approval?

Jane E. Henney, M.D.
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4. How does the FDA track injuries and infections resulting from the reuse of single-use medical devices? Do you believe the FDA's current system of tracking these incidents is sufficient to identify most of the adverse events associated with this practice?
5. Does the FDA have the authority to require a manufacturer to change the labeling of a device from single use to multiple use? If so, in what situations would that authority be used?
6. What information does the FDA require from a manufacturer seeking to change the intended use of a device from single use to multiple use?
7. Does the FDA discern a trend from multiple-use to single-use labeling with certain devices? If so, to what can you attribute this trend?

I look forward to hearing from you on these issues and I thank you in advance for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read "Anna G. Eshoo", with a large, stylized flourish above it.

Anna G. Eshoo
Member of Congress

AGE:sgr

Reprocessor Vanguard Cited For Sterilizing Validation Deficiencies

Vanguard Medical Concepts inadequately validated sterilization processes in the reprocessing of biopsy forceps, according to an FDA warning letter released the week of Nov. 22.

"No information was available or submitted to demonstrate that the sterilization process has no adverse impact on the devices that are processed," the letter states. In addition, there is no assurance that the "process will consistently and effectively achieve the specified sensitivity assurance level of 10^{-6} ." The deficiencies were detected during a March 29-April 2 FDA inspection of the company's Lakeland, Florida facility. The warning letter is dated Oct. 14.

The company says it has submitted additional data to the agency to address the concerns raised in the letter, and feels confident that these will prove satisfactory. Vanguard maintains that many of FDA's concerns related to a sterilization method already being phased out at the time of the inspection because of space requirements. Previously, ethylene oxide (EtO) gas was injected into individual packages of forceps; the company now uses an industrial sterilization chamber.

FDA's warning letter comes in the wake of increasing public awareness and pressure on the agency from original equipment manufacturers (OEMs) calling for greater regulation of single-use device reprocessing. FDA has scheduled a Dec. 14 stakeholder meeting to receive feedback on its proposed reuse policy.

In Nov. 22 comments, the Association of Disposable Device Manufacturers (ADDM) reports that one OEM submitted six studies demonstrating a lack of sterility associated with used single-use biopsy forceps reprocessed by major third-party reproducers.

"Because these long, thin plastic-sheathed devices were not designed to be cleaned, the reprocessor's validated 'cleaning and sterilization' procedures include vacuum drying to remove residual water and cleaning fluids," ADDM writes. However, "once the devices are dry, and they are exposed to EtO in an attempt at sterilization...the bacterial spores on the forceps are dry and encased in a hard protective shell that forms on drying. EtO cannot penetrate this shell and destroy these spores."

Vanguard is claiming that the inspection of its facility was prompted when samples of its reprocessed devices were examined by disposable device manufacturer Boston Scientific and found to be non-sterile. A

number of devices from the same sample lot were independently tested and found to be sterile, according to Vanguard.

In the warning letter, FDA emphasized the importance of adequate validation, observing that the firm's sterilization system, according to its 510(k) labeling, was intended for an industrial setting, and not a health care setting. This does not prevent the company from using the system in this context, however, it must "demonstrate that the sterilization process can achieve the desired level of sterility assurance."

The warning letter also takes aim at the firm's validation of its cleaning process, citing a lack of recorded data on the monitoring and control of temperature, pressure and levels of chemicals and water during the process.

Records also did not reflect the monitoring and control of the air used to break the vacuum after the cleaned forceps were dried. In its April 23 response to the agency's FDA-483 inspection report, Vanguard had pledged that the validation process would be in compliance by June; in the warning letter, the agency observed that the process was still not complete.

At a Nov. 10 FDA teleconference to discuss the agency's proposed strategy for regulating reuse, Vanguard VP-Corporate Development Mark Salomon, speaking on behalf of the Association of Medical Device Reprocessors, underscored the need for developing consensus standards for cleaning and sterilization procedures ("The Gray Sheet" Nov. 15, p. 5).

Under FDA's proposed reuse policy, which would subject certain reprocessed devices to premarket requirements, reproducers of "moderate risk" devices might be able to meet those requirements by making declarations of conformity to recognized standards.

In additional comments submitted Nov. 23, ADDM also took issue with FDA's proposal that certain "low risk" Class I devices, which are exempt from premarket submission requirements, would be automatically exempted when reprocessed. The trade group argued that under such a proposal, "Class I-exempt biopsy forceps would be reprocessed without premarket submission despite the additional safety concerns introduced by the reprocessing...reuse introduces risks that were not factored into the exemption." ♦♦

U.S. Industry Lobbies For APEC Tariff Reduction At Seattle WTO Conference

The Health Industry Manufacturers Association plans to facilitate discussion on ways to promote medical technology trade and development during an interactive session at the Third Ministerial Conference of the World Trade Organization Nov. 30-Dec. 3.

Rep. Jim Ramstad (R-Minn.), chair of the House Medical Technology Caucus, will participate in the session. Participants are expected to discuss the success of certain caucus initiatives, and whether those can be extended to other countries.

Medtronic will deliver presentations to inform WTO members about the cost effectiveness and clinical success of implantable cardioverter defibrillators. France's reimbursement agency has been reluctant to provide payment for the devices, despite evidence that they are less expensive and more effective than anti-arrhythmic drugs ("The Gray Sheet" May 10, p. 17).

HIMA also plans to voice support at the Seattle meeting for WTO approval of a recently submitted Asian-Pacific Economic Cooperation "Early Voluntary Sector Liberalization" package. Passage of the measure

would eliminate tariffs throughout the APEC countries. Tariff reductions should be extended to other WTO members, such as Brazil, the association recommends.

In a Nov. 24 letter to President Clinton, HIMA joins several other industry sectors in support of the Accelerated Tariff Liberalization (ATL) initiative. Medical technology is one of eight industry sectors included in the ATL package, which is aimed at helping remove Asian and European tariff barriers to U.S. products.

The letter specifically references the effect the ATL agreement would have on China, which recently became a WTO member. "By triggering a Chinese commitment to meet the ATL end rates and dates, an ATL agreement in Seattle would mean that China would enter the WTO with a commitment to go to zero or harmonized levels on approximately 40% of tariff line items," the letter reads.

In addition to tariffs, HIMA will encourage the elimination of other technical barriers to trade among WTO countries and support greater acceptance of international standards and certifications. ♦♦

German Government Plans Separate Legislation In Lieu Of Health Reform 2000

The German government and the country's opposition party are preparing to initiate a mediation process on health reform legislation, given the likely demise of the Health Reform 2000 initiative in a Nov. 26 Bundesrat vote.

Should the legislation fail in the Bundesrat – the parliamentary house that represents the German states – members from that body would form a mediation group with representatives from the country's other legislative body, the Bundestag. The group could allow the government coalition of the Social Democratic Party (SPD)/Green Party, which has a majority of seats in the Bundestag, to forge a compromise with the Christian Democratic Union (CDU), which holds a majority in the Bundesrat.

However, such a compromise is unlikely, according to the Federal Association of the Medical Device Industry in Germany (BVMed).

Assuming that is the case, the government may opt to draft a separate legislative proposal that reportedly could be implemented by January. The measure would not address the organization of Germany's hospital

sector, however, because reforms in that area require the Länder approval through a Bundesrat vote.

With the hospital sector removed from the debate, the separate legislation could not include the "global budget" proposal, part of the government's attempt to limit national health care costs.

The government's plan to finance hospital expenses using resources from the Sickness Funds (statutory health insurance institutions) would also be off the table ("The Gray Sheet" May 31, p. 16).

The separate legislative proposal has not yet been formally issued, but the government is considering a provision to further develop a diagnosis-related group-type system for hospital billing. However, it must first consult the justice system to determine whether such a provision would need the approval of the Bundesrat, which would remove it from consideration.

It is also possible that no separate government legislation will be proposed, which likely would lead the government and opposition parties to form a new working group. The working group would design a unified reform proposal for next year. ♦♦

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This is not the face of breast cancer.

November 10, 1999

'Single Use' Medical Devices Are Often Used Several Times

Forum

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By GINA KOLATA

When patients come to the University of Virginia Health System to have an abnormal heart rhythm diagnosed or treated, they are told that doctors will be threading thin wires through their veins directly into their heart. They learn that they run a slight risk of infection, or of damage to the heart, lungs or blood vessels from the very nature of the invasive procedure.

But there is one thing they are not told: although the catheters and wires are labeled "single use only," they may have been used before. They have been cleaned and sterilized, but they have spent time in someone else's blood vessels and heart.

In hospitals and clinics around the nation, these devices and others - biopsy needles used to extract tissue, tiny scissors used to cut out tissue in patients' gastrointestinal tracts, wires or balloons that go into the coronary arteries or the heart itself - are being reused more and more often despite their labeling.

The practice of reusing devices that are approved only for one-time use is not necessarily dangerous, experts say, but it generally violates federal regulations. So far, however, the government has declined to ask the companies that reprocess the devices to submit evidence that they are safe and effective, but now, under pressure from device makers, is now reconsidering its approach.

"We have used what we call enforcement discretion not to go after them," said Dr. Larry Kessler, who is director of the office of surveillance and biometrics at the Food and Drug Administration.

One reason is that the agency has little evidence of a safety problem, Dr. Kessler said, although everyone admits that research is urgently

<http://www.nytimes.com/library/national/science/health/111099bth-medical-reuse.html>

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needed.

"There's a big yuck factor to reusing devices," Dr. Kessler said. But he added that "there are no products where we have significant evidence that there is immediate harm to public health."

Some doctors and federal officials say the issue is more about economics than safety. Device makers make less money when single-use devices are cleaned, sterilized and used again.

Hospitals and medical centers save money, in some cases tens of thousands of dollars a year, when they reuse the devices.

Doctors say that manufacturers charge so much that they often cannot afford to use devices just once; nor can they pass the cost along to patients, because in many cases the rates have been set in advance by insurance companies or Medicare. And, they say, many expensive devices that are labeled "single use only" can safely be used repeatedly.

Device makers reply that the hospitals are putting patients at grave risk to save money.

"The real issue is patient safety," said Josephine Torrente, president of the Association of Disposable Device Manufacturers. "Until you prove otherwise, these devices are safe and effective for one use. After that, they're garbage."

The F.D.A., caught in the middle, is considering regulating those who reprocess devices in the same way it regulates the original device makers. They would have to get approval -- showing the reprocessed devices were safe and effective -- before they could sell them. The only exception would be devices, like surgical saw blades, that are considered to pose a very low risk after being cleaned and sterilized. At the same time, the agency is suggesting that the device makers explain on their labels what the risks would be if the devices were processed.

The agency is posting the proposal on its Web site (www.fda.gov -- follow the links to "Medical Devices," then "Recent Federal Register Notices"). On Wednesday the agency will hold a satellite teleconference in which the device makers, the companies that reprocess devices, doctors, hospitals, and ethicists can comment. And on Dec. 14, the agency will hold a public meeting on its proposal.

From all accounts, the business of reprocessing medical devices is booming, with commercial companies springing up to clean and sterilize devices and to take on the liability if their processes fail.

Mark Salomon, the senior vice president of corporate development at Vanguard Medical Concepts, a reprocessing company in Lakeland, Fla., said that when he joined Vanguard in 1995, it had just 12 employees. Now, 220 people work there and the plant has grown to 50,000 square feet from 2,000 square feet.

Used devices are cleaned and disinfected. Then the company tests them to make sure they still function the way they are supposed to. Finally, the devices are packaged and sterilized with ethylene oxide gas, the same method that the device makers use. The question is: Are the devices really as good as new?

One way to keep track of device problems is through the F.D.A.'s device surveillance system. When medical devices fail or injure patients, manufacturers, hospitals, and doctors are supposed to notify the agency. Of the 100,000 such reports to the agency each year, virtually all are from devices that were used just once, Dr. Kessler said. Of course, if a reused device does fail, the agency may not get a report.

"Can you imagine a hospital that discovers a problem and the manufacturer had said, 'Don't reuse that device'?" Dr. Kessler said. "Do you think the hospital would want to tell anyone? They are worried that they will be in court and in serious trouble."

The Centers for Disease Control and Prevention tracks outbreaks of infections, which would occur if devices were not sterile. "To date, there is no strong evidence in this country that reprocessing medical devices leads to more adverse events than single use," said Dr. William Jarvis, who heads the infections and prevention branch in the hospital infections program at the centers.

Some ask why take a chance. Dr. Philip Grossman, a gastroenterologist in Miami who is a consultant to the device manufacturers group, says he has challenged defenders of reuse in public forums. "I said, 'You look me in the eye in front of this group and tell me you do it because you think it's better for your patients,'" he said.

But others say that the debate can best be advanced by actual data on safety. Some medical groups, as well as a device maker, have done their own studies, asking whether medical devices can be safely cleaned, sterilized, and reused.

Patricia Davis, an electrical engineer and senior patent attorney at Boston Scientific, a leading device maker, says her company has evidence that devices often are contaminated and degraded when they are re-processed.

The company takes reprocessed devices off hospital shelves and sends them to independent labs for testing, Ms. Davis said. "In all cases," she said, "at least 45 percent of the devices have come back contaminated." In one instance the F.D.A. and Vanguard said they independently tested devices from a lot that Boston Scientific had said was contaminated. But the F.D.A. and Vanguard tests found that the devices were sterile.

Larry Spears, a director of enforcement at the F.D.A., says the agency is still investigating. "We have a number of different lab results for the same product," he said. "We need to find out what

happened -- and we will."

Ms. Davis, who said the company was working on getting its studies published in the United States, also says Boston Scientific's tests indicate that reprocessed devices can have subtle changes in their functions that could be devastating to patients.

Other safety studies were published in leading medical journals. In one, Dr. Richard A. Kozarek, who is chief of gastroenterology at Virginia Mason Medical Center in Seattle, examined the reuse of an argon beam plasma coagulation probe, a \$190 device that is used to stop bleeding in the gastrointestinal tract. If used 10 times, it would cost \$24 per procedure, even with the cost of cleaning and sterilizing; if used five times, it would cost \$42. The device was first introduced in Europe and Asia, labeled for multiple use. It even came with instructions for cleaning, Dr. Kozarek said. A few years ago, it was introduced in the United States, labeled for single use only.

Dr. Kozarek and his colleagues put the device through a rigorous test, contaminating it with spores from the bacterium *Bacillus subtilis*, among the most difficult organisms to kill. "We found organisms too numerous to count throughout the device," Dr. Kozarek said. But after he cleaned it and sterilized it, they were gone. The investigators also asked if the device still functioned and found that it did.

"The long and short of it was that it was reusable for up to 10 times and we didn't test it more than 10 times," said Dr. Kozarek, who published his results in the *American Journal of Gastroenterology* in May 1998.

Dr. Kozarek also tested sphincterotomes, which are used to cut open abnormal sphincter muscles in the bile duct. His group again found that the devices could safely be cleaned, sterilized, and reused, publishing their data in *Gastrointestinal Endoscopy* in 1997.

Dr. Kozarek's group began reprocessing the devices and, among 1,000 patients treated, found two who had become infected. They checked, fearing the infections had arisen from improperly sterilized devices. But "they were brand-new devices," Dr. Kozarek said. The infections turned out to be unrelated to the devices.

Now Dr. Kozarek and his colleagues routinely reuse gastroenterology devices. "We saved this institution about \$65,000 in medical costs," he said.

Some, like Dr. James T. Frakes, a gastroenterologist in Rockford, Ill., say they do not reuse devices because of liability concerns. But Dr. Frakes says such caution has a cost. "We cannot afford to use some single-use accessories in our unit," he said.

At the University of Virginia Health System, where electrocardiologists routinely reuse devices that can cost \$1,000 or more per patient but far less if they are reused, there have been no

safety problems, said Dr. David E. Haines, a professor of internal medicine there.

Several groups have published papers reporting that it is safe to reuse the devices. And Dr. Haines says the economics of medicine leaves him little choice.

"The cost of single use is prohibitive," he said. "If we were forced to have single use on catheters we would shift from being marginally profitable to probably losing \$600,000 a year."

But Ms. Torrente said that those who reuse devices that are designed for single use are playing a risky game. "If this is so safe and so O.K., why don't we tell the patients?" Ms. Torrente asked.

Dr. Haines said there was no reason to bring it up.

"Why force the issue?" he said. "Show us the data that says this is exposing the patient to increased risk."

What if patients started insisting that Dr. Haines use new devices, fresh out of the package?

"If we found that a lot of patients were starting to demand that we use brand new equipment," Dr. Haines said, "we would probably decline to take their cases and refer them elsewhere."

This is not the face of breast cancer.

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Risk Classification Governs SUD Reprocessor Premarket Requirements – FDA

FDA's current resource levels are insufficient to carry out inspections of health care facilities that reprocess medical devices intended for single use, FDA staffers believe.

Despite its fiscal concern, the agency's "Reuse, Single Use Devices" strategy paper, released Nov. 2, leaves open the possibility that both health care facilities engaged in reprocessing and third-party reprocessors could be subject to full inspections. Such a policy would have "a significant impact on the agency's resources," the document acknowledges.

Due to the prohibitive cost, FDA "would consider collaboration with accredited third party organizations or other federal agencies to inspect these facilities," the proposal explains.

The agency has not disclosed which outside bodies it plans to approach for assistance with such inspections, although the Joint Commission for Accreditation of Health Care Organizations would appear to be a likely candidate. While FDA has presented its strategy to the Health Care Financing Administration for review and comment, that agency is not designed to perform audits in a way comparable to the FDA's original equipment manufacturer inspections, officials note.

If implemented, the revised reuse strategy would bring the regulations applied to reprocessors and health care facilities much closer to those faced by OEMs. Third-party reprocessors currently are inspected for compliance with the agency's quality system regulations, however, they are not required to submit premarket data for individual reprocessed devices. The agency also has used its discretion not to enforce premarket and QS regs on health care facilities that reprocess.

The strategy proposes to require all reprocessors to comply with registration and listing, labeling, corrections and removals, quality systems and tracking requirements. Even if inspections of health care facilities prove too costly to implement, it still is likely that FDA would ask hospitals to comply with registration and listing requirements, staffers note.

If implemented, the strategy would require reprocessors of single-use devices (SUDs) that are considered "high risk" to submit data "through the premarket approval process" within six months of the release of the agency's final policy on reuse. Devices

presenting "moderate risk" would be required to meet "applicable premarket requirements" within two years of the final policy.

SUDs that fall into the "low risk" category would not undergo premarket clearance, "provided that the reprocessors have validated reuse procedures or declare conformity to a recognized consensus standard," the proposal states.

The agency has yet to assign specific products into the three risk categories – an issue it likely will take up with stakeholders at an open public meeting scheduled for Dec. 14. The issue also may be addressed during a Nov. 10 Food & Drug Law Institute videoconference.

Possible factors that could be involved in risk classification include "the complexity of procedures associated with reprocessing the device; the actual and potential risk for infection should the reprocessed device be reused; and the quality and extent of published data on reprocessing for the specific device," the reuse strategy explains. It appears likely that devices initially requiring a premarket approval application, such as certain cardiac catheters and guidewires, sutures, and balloon angioplasty catheters, would fall into the "high risk" category.

Reprocessors of "moderate risk" products might be able to fulfill premarket requirements by making "declarations of conformity to recognized consensus standards," the agency suggests. Such submissions would be similar to "abbreviated" 510(k)s that are currently submitted by OEMs, staffers note.

Although FDA's plan to subject reprocessors to premarket requirements will benefit OEMs of disposables devices, it does not go as far as OEM associations had hoped. The Medical Device Manufacturers Association recommended a complete ban on SUD reprocessing; the Association of Disposable Device Manufacturers urged FDA to subject reprocessors to all premarket rules applicable to OEMs.

The released strategy does not confirm whether OEMs would be required to submit scientific data on reprocessing for devices labeled as single use ("The Gray Sheet" Oct. 11, p. 3). "One option the agency is considering is requesting OEMs that label their devices single use "to provide, as part of the device's labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs," the document states. ♦ ♦

Abbott's AFP, CA 125 Cancer Tests Unaffected By Consent Decree

Abbott Laboratories' AFP and CA 125 diagnostic cancer tests are among the diagnostic products deemed "medically necessary" by FDA and will continue to be made available under the company's Nov. 2 consent decree with the agency.

The consent agreement, which includes a \$100 mil. payment to FDA by Abbott, stems from repeated quality system regulation (QSR) violations at the company's diagnostic product manufacturing facility in Abbott Park, Illinois.

In a letter to the medical community explaining its action, FDA clarified that "not having several of these [medically necessary] products available could potentially cause shortages that could compromise patient care."

Other devices not affected by the decree include test kits for identifying tumors and detecting heart attacks, as well as blood screening tests for diseases such as HIV and hepatitis. However, if these products are not brought into compliance within one year, Abbott must pay 16% of gross proceeds from their sale.

To increase assurance that the kits are performing as intended, FDA will subject the blood donor tests to lot release through the Center for Biologics Evaluation and Research. Products regulated by the Center for Devices and Radiological Health are recommended to be used in conjunction with quality control materials made by other companies. Of Abbott's 300 *in vitro* diagnostic products, 286 are regulated by CDRH and 14 by CBER.

Among devices to be taken off the market by Dec. 1 are anemia tests using B12, ferritin and folate assays on the company's *AxSYM* and *IMx* automated analyzers. Also covered is the firm's *TestPack* assay line, which includes diagnostic products for pregnancy and strep A infection.

Signed by Judge Harry Leinenweber in Chicago federal court, the consent decree represents the largest civil money penalty ever levied by the agency, FDA notes in a Nov. 2 release. The action culminates six years of discussions between the two parties over good manufacturing practices and QSR violations.

During that period, FDA issued two warning letters and conducted several inspections of Abbott's diagnostics production facility. The agency maintains

that the court action was necessary because the company failed to respond adequately to numerous FDA requests to achieve regulatory compliance.

In its most recent warning letter on March 17, the agency took issue with the fact that Abbott waited three months before reporting a process validation failure of the *AxSYM* system. In general, inspectors found that Abbott's correction and prevention action system failed to correct or report manufacturing deficiencies in a timely manner.

Other products not affected by the decree include Abbott's MediSense, i-STAT, hematology and Murex products. Abbott also can continue distributing its *Spectrum*, *Aeroset* and *Aleyon* clinical chemistry products, as well as products from divisions outside diagnostics. The company has agreed to bring these products into QSR compliance according to an FDA-approved schedule. Failure to adhere to the timeframe will result in a fine of \$15,000 per manufacturing process per day.

Correction of the manufacturing deficiencies for non-medically necessary products is a prerequisite for FDA's permitting the products back on the market. Continued commercial availability thereafter would be contingent on favorable audits by independent inspectors of the firm's IVD facility at least twice a year for at least four years. Results of the inspections would be directly reported to FDA. Non-compliance could result in renewed cessation of manufacturing and distribution of those products.

Abbott says it will take a one-time, \$168 mil. pre-tax charge against fourth-quarter earnings in connection with the consent decree.

The decree is not expected to affect Abbott's plans to acquire wound closure device developer Perclose. The firm has scheduled a Nov. 19 shareholder meeting to vote on the \$680 mil. stock swap. However, certain Alza shareholders have filed suit seeking to block Abbott's planned \$7.3 bil. stock acquisition of the controlled release drug delivery firm.

Initial anxieties within the financial community were apparently allayed by the recent development. After falling as low as 36 13/16 the day after the announcement, Abbott stock rallied to close the week at almost \$40 per share, where it began the week. ♦ ♦

House Reprocessed Medical Device Bill May Have Smoother Sailing

Bipartisan support could help facilitate the progress of reprocessed single-use medical device legislation pending in the House during the next congressional session, Hill staffers predict.

Introduced Oct. 26 by Reps. Anna Eshoo (D-Calif.) and Fred Upton (R-Mich.), the "Reprocessed Single Use Medical Device Patient Safety Amendments" (HR 3148) bill is largely similar to a measure introduced in the Senate (S 1542) on Aug. 5 by Sen. Richard Durbin (D-Ill.).

Durbin has been the legislative point man on the device reuse issue; he was also responsible for an amendment to the FY 2000 agriculture appropriations bill that earmarked \$1 mil. of FDA's Center for Devices and Radiological Health budget to regulate medical device reprocessing.

Both Eshoo and Upton sit on the House Commerce Committee, to which the legislation has been referred. In Upton, the bill has a GOP champion who could help gain the necessary backing of Commerce Chairman Thomas Bliley (R-Va.).

Both are also members of Rep. Michael Bilirakis' (R-Fla.) Commerce/Health and Environment Subcommittee, through which the bill would move before consideration by the full committee. Upton also chairs the Commerce/Oversight and Investigations Subcommittee. The Senate Health, Education, Labor and Pensions Committee has yet to take any action on the Durbin bill.

Like S 1542, HR 3148 would require premarket review for any medical device intended for reuse. Eshoo staffers responsible for drafting the bill note that they conferred with Durbin aides during the development of legislative language.

Also like the Senate bill, the Eshoo/Upton measure would require hospitals to obtain informed consent from patients before using a reprocessed device in their treatment. Both hospitals and reprocessing companies would be required to monitor and report any injuries or infections that occurred as a result of reusing medical devices.

However, the informed consent provisions in the two bills differ slightly. While Durbin's is limited to reprocessed *Class II* and *Class III* devices, Eshoo/Upton adds "critical" *Class I* devices.

The legislation defines a critical *Class I* device as one that "may break the mucosal boundary, may be introduced in the bloodstream, or may be introduced into other than normally sterile areas of the body." Durbin staffers indicate that the inclusion of these devices would not represent a major problem in reconciling the two bills.

The Eshoo/Upton measure has the backing of the Medical Device Manufacturers Association, which called the bill a "comprehensive patient-centered approach" to the issue in an Oct. 27 press release.

"Hospitals and other health facilities commonly reuse these devices on multiple patients, without anyone having demonstrated that these devices have been cleaned properly or will still perform effectively," MDMA Executive Director Stephen Northrup commented.

Meanwhile, FDA has been developing its regulatory approach to device reprocessing, an area it has tended to eschew until recently. A formal policy is expected from the agency the week of Nov. 1, according to staffers.

The device center has scheduled an interactive satellite teleconference for Nov. 10 at 1:00 p.m. to discuss the policy. Panels representing FDA, industry and users will participate.

The agency will be represented by Larry Kessler from the Office of Surveillance and Biometrics, Don Marlow, Office of Science and Technology, Larry Spears, Office of Compliance, and Tim Ulatowski, Office of Device Evaluation.

On the industry side, panelists will include attorneys Pamela Furman, representing the Association of Medical Device Reprocessors, and Josephine Torrente, from the Association of Disposable Device Manufacturers. The user panel includes National Consumers League representative Linda Golodner, Philip Grossman, MD, a physician in private practice, ECRI's Christopher Lavanchy, and Gerald Naccarelli, MD, North American Society of Pacing and Electrophysiology.

Legislation banning the reuse of single-use devices is also pending in California. The Assembly's Health Committee is expected to hold a hearing before year-end ("The Gray Sheet" Aug. 30, p. 19). ♦ ♦

HIMA Device Industry Strategic Study Update Expected In January 2000

A Health Industry Manufacturers Association-sponsored study scheduled to commence sometime in January will focus on the state of the medical device sector and the impact of Medicare regulations on patient access to medical devices since 1995.

HIMA President Pamela Bailey described the industry white paper at an Oct. 28 press briefing as "a major report in terms of identifying issues that will be part of the [national health care] debate over the next year."

The January initiative, which will update the status of the medical technology sector since 1995, comes almost five years after a similar undertaking by the association, which was conducted by the New York City-based Wilkerson Group health consulting firm.

Broadly, the update will hit on three principal areas, according to an independent consultant to HIMA also serving as director of the strategic study project. A vendor to conduct the study will be selected by mid-November.

First, the report will examine changes in both the market environment since the Wilkerson report was published and the impact FDA and the Health Care Financing Administration regulations are having on the industry. Second, it will address how today's demand for increasing amounts of evidence, particularly in terms of reimbursement, has an effect on the time it takes for products to get to the market and the costs associated with product development.

Finally, the study will look at the changing dynamics in industry and its technological advances over the past five years since the last report was issued. Topics likely to be addressed are continued consolidation of the industry and the migration of venture capital resources from the medical device industry to Internet start-ups.

The Wilkerson report helped focus the attention of Congress on the threat to the U.S. medical device industry posed by FDA regulations on manufacturers. In particular, it cited a growing trend by companies "to relocate technological capacity overseas" in order to gain product approval under more favorable European regulations ("The Gray Sheet" June 12, 1995, p. 3).

Over 60% of device manufacturer respondents indicated that they had marketed or planned to market products overseas before launching them in the U.S. Of those firms, 93% (98% of start-ups) cited U.S. premarket requirements as a reason for doing so. The

1995 study also provided a list of 100 products that were approved overseas at the time of release but not yet approved in the U.S.

Other factors that the report cited as reshaping the device industry included cost-containment pressures in the health care industry; product liability; Medicare nonpayment for use of investigational devices; unmet clinical needs for continued advances in device innovation; decreasing venture capital investments in the devices industry; and a diminishing infrastructure.

As part its lobbying effort for FDA reform, HIMA unveiled the Wilkerson report before Congress, where it played a role in the drafting of the 1997 FDA Modernization Act, according to one former Capitol Hill staffer who contributed significantly to the development and ultimate passage of the bill.

Bailey maintained at the Oct. 28 briefing that Medicare reform proposals likely would take center stage in the second session of the 106th Congress (*see related story, p. 3*).

The upcoming report's focus on Medicare reform proposals likely will be on the perceived burden that HCFA regulation places on device manufacturers and how that prevents industry from bringing products to market in a timely fashion.

HCFA's only reference in the 1995 report centered on Medicare coverage for investigational devices. Following its June 1995 release, the agency published a final rule in September establishing its category B IDE exemption policy, which allows for reimbursement of certain investigational technologies. In that reg. FDA and HCFA agreed to separate approved IDEs into high risk and low-risk categories ("The Gray Sheet" Sept. 18, 1995, p. 2).

The 250-page Wilkerson Group report was based on a survey of nearly 1,600 device industry executives, out of which the consulting firm received 526 responses. Managing Director Stephen Shapiro said that survey respondents comprised a "very good representation" of the device industry.

In addition, over 150 face-to-face interviews were conducted with industry executives and analysts. Trade and scientific journals, government data and publications, and company annual reports were also reviewed. The methodology for the upcoming report has yet to be determined. ♦♦

FDA Reuse Policy Demands Data From Both OEMs And Reprocessors

FDA's revised policy on reprocessing of disposable medical devices would require manufacturers seeking to label a product as single-use only to submit data demonstrating that it cannot adequately be reprocessed, FDA staffers report.

If a manufacturer collected data showing that current reprocessing techniques could not restore a device to its original specifications for safety and efficacy, labeling for that product would prohibit any reprocessing of the device, staffers explain.

At the same time, the policy would no longer allow manufacturers to automatically label a device as "single-use only" if reprocessing data had not been submitted, agency officials note. Instead, the policy likely will encourage manufacturers to disclose to users as much information as possible about the various methods for reprocessing.

Details of the policy have not yet been finalized, but they are expected to be released in the near future. FDA announced at a reuse conference sponsored by the Association of Advanced Medical Instrumentation in April that it would release a revised policy by October of this year ("The Gray Sheet" May 10, p. 18).

Manufacturers assert that FDA's current review practices require labeling to state clearly whether a product is reusable or single-use only. In order to obtain labeling as a "reusable" device, manufacturers must submit data and follow FDA's guidance entitled "Deciding When To Submit A 510(k) for a Change to an Existing Device." Devices for which no such data are submitted currently receive the "single-use only" label, according to industry reps.

FDA's new policy would change this practice, eliminating gratuitous labeling of any device as single-use only and instead instituting more detailed labeling based on data that have been submitted. However, it appears unlikely that FDA would apply the new policy when dealing with devices for which reuse was not a relevant concern.

Larger disposable manufacturers, such as Tyco's U.S. Surgical subsidiary, Johnson & Johnson's Ethicon, Mallinckrodt and Boston Scientific, appear well positioned to provide FDA with the necessary data to obtain single-use only labeling under the new policy. In one study submitted earlier this year by the Association of Disposable Device Manufacturers,

Boston Scientific showed that out of a sample 20 reprocessed *Microvasive* forceps retrieved from hospitals, 85% were found to be non-sterile.

Similarly, Ethicon has evaluated product integrity and specification data in a study of nine of its disposable products that had been reprocessed by hospitals ("The Gray Sheet" May 17, p. 21). U.S. Surgical also has completed in-house studies in which samples of nine instrument types were contaminated and then evaluated for sterility and functional performance.

Manufacturers would likely have to conduct in-house studies similar to U.S. Surgical's to obtain single-use only labeling. Firms also can look to a reprocessing study completed by FDA's Office of Science and Technology for guidance. After performing cleaning and sterilization procedures on various angioplasty balloons and catheters, OST staffers concluded that each model of a particular product line requires separate testing in order to evaluate whether reprocessing is appropriate and safe.

FDA's revised policy not only will take a new approach to OEM labeling but also requires data submissions from reprocessors, FDA officials add. Although the nature of the submissions has not been fully determined, staffers expect reprocessors will need to generate substantial amounts of non-clinical data — such as sterilization, cleaning and simulated performance testing — for specific products or product lines.

While FDA's current compliance policy guide on reuse of disposable devices (CPG 7124.16) acknowledges that reprocessing "could affect both the safety and effectiveness of the device," the agency has used its regulatory discretion not to apply premarket requirements on third-party reprocessors to date. Reprocessors are inspected for their compliance with good manufacturing practice regulations, but hospitals conducting in-house reprocessing are not.

In a recent response to a citizen's petition submitted by Washington, D.C. law firm McKenna & Cuneo on behalf of the Medical Device Manufacturers Association, FDA maintains its current position that "there is no clear evidence that reprocessing presents an unreasonable and substantial risk of illness or injury."

The letter denies MDMA's request that reprocessing be banned, explaining that it "does not believe that

banning is the appropriate action to address the many and varied issues tied to this practice." However, the response acknowledges that "a significant re-evaluation of FDA's position with regard to reuse of single use devices is in order."

In addition to addressing third-party reproprocessors, the new policy also will be directed at hospitals that perform in-house reprocessing, staffers note. The agency has always maintained that reprocessing conducted by hospitals falls within its jurisdiction, even if the hospital is also the end-user of the device.

If the agency strictly enforces its revised policy on hospitals, there could be a significant impact on the existing relationship between OEMs and their customer base, potentially expanding the demand for reusable versions of disposable products.

While representatives from the reprocessing industry claim that OEMs label devices as "single-use only" merely to drive revenues, manufacturers of disposables contend that the devices are not capable of being reprocessed and that there is little demand for reusable versions.

Reusable models of devices likely would require more expensive materials, presenting a cost that would not

save money for hospitals, OEMs note. Rather than demand that reusable models be developed, hospitals have chosen to reuse the disposable devices.

Under the new policy, hospitals reprocessing devices that are designated as single-use only (based on OEM data submissions) might be subject to FDA enforcement action. While the single-use labeling could be viewed by OEMs as an advantage, some hospitals may choose to use devices that are not indicated for single-use only, leaving the door open for a reprocessing submission to be made.

The timing of submissions by reproprocessors and OEMs and the agency's approach to existing labeling of "single-use" devices are two of the many logistical questions that FDA likely will address at its planned Dec. 14 stakeholders meeting on the issue. The agency may decide to give companies a window of time to collect data and update labeling.

The agency currently plans to implement its policy using a risk-based, tiered approach. High-risk products that the agency would address first likely include electrophysiology catheters and angioplasty catheters and balloons. *Class II* products that may present lesser risks, such as general surgical instruments, would be evaluated subsequently. ♦♦

FDA To Issue Remarketer Labeling Regs, Monitor Registration System

Device remarketers that label serviced devices as "ready for clinical use" under a recently proposed voluntary registration system will be subject to FDA enforcement action if the devices do not meet performance specifications, according to FDA staffers.

Remarketed products that are labeled as "ready for clinical use" but do not safely and effectively function as intended would be considered misbranded as defined by section 502(a) of the FD&C Act, explain agency officials.

FDA enforcement of the truthfulness of labeling could have a significant impact on the success or failure of the voluntary registration system crafted by a task force comprised of industry trade groups and recently submitted to FDA ("The Gray Sheet" Sept. 27, p. 23).

The voluntary system is solely aimed at remarketing firms, which process and resell devices designated as "reusable," as well as servicing firms, which clean and repair devices and return them to the original user. The system would not apply to firms that reprocess devices

intended for single use only, which will be subject to a forthcoming FDA policy (*see related story, p. 3*).

Members of the task force include the Association for the Advancement of Medical Instrumentation, the International Association of Medical Equipment Remarketers, the Service Industry Association, the Health Industry Manufacturers Association, the Medical Device Manufacturers Association and the National Electrical Manufacturers Association.

Participants in the system would be required to register with a third party and would need to label their remarketed devices as either DC 1 (device must be checked for proper performance and safety) or DC 2 (device is performing properly and safely and is ready for clinical use). Labeling under the voluntary system also would be required to include the name of the remarketer and the date of the work performed.

FDA still must give the proposed system its blessing via publication in the *Federal Register*, which is expected to take place shortly, agency staffers say.

'Secondhand' Medical Devices

Manufacturers of medical devices are sounding an alarm that some hospitals are harming patients by reusing "single-use" medical devices like biopsy needles and cardiac catheters. They cite incidents in which improperly "reprocessed" devices have infected patients with bacteria and harmed them during surgical procedures.

The troubling accounts point to a solution sought by the manufacturers, calling on the Food and Drug Administration to flatly ban the reuse of all single-use devices.

But problems outlined by Times reporter Sylvia Pagan Westphal suggest that a solution is not so clear-cut.

The dangers posed by reused medical devices are uncertain because the current system for evaluating their safety is woefully inadequate. Independent, peer-reviewed studies of reused disposable devices are few, and those that have been done, experts agree, are not sufficient to conclude that reprocessing disposable devices is either safe or unsafe.

The manufacturers' argument is grounded more in self-interest than in science. The U.S.-dominated medical device industry has become hugely profitable, with global sales in 1996 of \$130 billion. The industry fears its profits will decline if the FDA continues to allow hospitals to save up to half of their medical device costs by reusing devices rather than buying new ones.

Solving the problem will require innovative thinking. The FDA lacks the resources to oversee medical device reuse. Its funding has already been stretched thin by the surging burden of monitoring prescription drugs and dietary supplements. Medical device manufacturers, in turn, have so far shown little interest in funding studies that would undermine their business.

The FDA should explore requiring both reprocessors and device manufacturers to contribute annually to a fund for independent safety studies. It should also work with the Joint Commission for the Accreditation of Health Care Organizations to require hospitals to abide by national protocols or contract out reprocessing work to the four private companies that successfully overhaul tens of millions of medical devices each year.

Congress had a hand in creating the present crisis. It passed laws in 1992 and 1996 that weakened medical device oversight. It could have a hand in resolving the problem by passing a bill by Sen. Richard Durbin (D-Ill.) that would require hospitals reporting malfunctions of medical devices to specify to the FDA whether those devices were new or reused.

The United States leads the world in innovating medical devices but lags in regulating them. Government and industry need to begin working together to eliminate this conflict.

HEALTH

News You Can Use

Risky recycling

That "disposable" catheter may have been used before

BY DANA HAWKINS

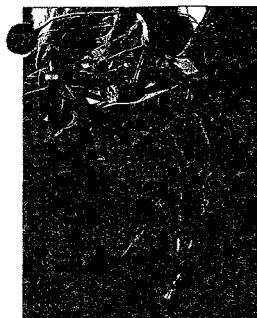
It was a bit complex as such procedures go, but cardiologist Peter Karpawich had done it hundreds of times before. Hunched over an operating table at Children's Hospital of Michigan, he delicately snaked a catheter through the artery of a young patient's groin, up inside his body, and into his heart. All seemed to go well. It was only after Karpawich removed the catheter that he noticed the final segment of the instrument had pulled apart from the main shaft, exposing sharp, thin electrode wires that threatened to rip a gushing, potentially fatal hole in his patient's heart.

Remarkably in this case, the patient appeared uninjured. But others in similar circumstances may not have been so lucky, because of a growing practice that is threatening untold numbers of patients in U.S. hospitals. The danger comes from medical instruments that are intended to be used once and thrown away but that, instead, are repackaged and used over and over again. In the case of the unnamed patient at Children's Hospital, the plastic-wrapped catheter was clearly marked "Single Use Only." In fact, according to a report filed with the federal Food and Drug Administration, it had been used at least once before.

Cutting costs. It is medicine's dirty little secret. Under pressure from HMOs, Medicare, and insurance companies to cut costs, thousands of U.S. hospitals are quietly recycling millions of disposable sawblades, biopsy forceps, and catheters for

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SURGERY

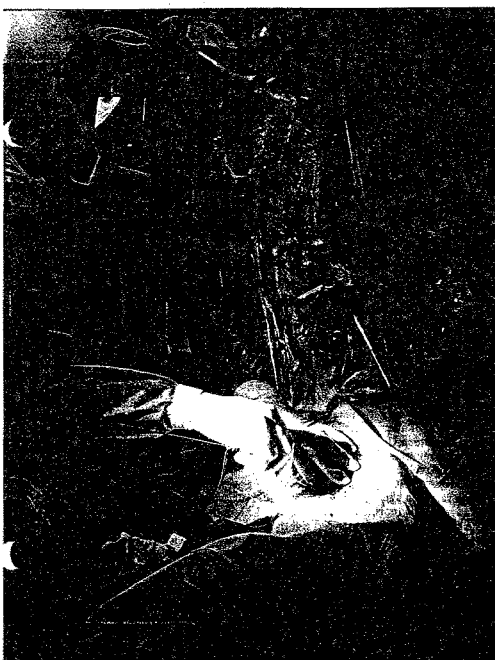
PHOTOGRAPHY BY
JEFFREY MACMILLAN FOR USN&WR



use in procedures from cardiac angioplasties to orthopedic surgery, putting unwitting patients at risk for injury, infection, and worse. Proponents say the practice is safe and saves millions of dollars. But John Fielder, a bioethicist and expert on reuse at Villanova University, calls it "medical experimentation without patient benefit, written consent—or even patient knowledge."

The full consequences of instrument recycling are impossible to determine, since direct cause and effect is difficult to prove and since patients are almost never told about reuse in the first place. But documents from the FDA, obtained by *U.S. News*, reveal numerous incidents of pa-

MEDICAL WASTE. A container overflows with disposable devices at Baltimore's Johns Hopkins Medical Center, where angioplasty balloons are not recycled.



tients put at risk from what appear to be recycled disposable instruments that were contaminated or defective. The reports, submitted by hospitals, outline cases of premature babies stitched with unsterile sutures; a crumpled tube lodging in the pulmonary artery of an elderly woman; a fractured catheter becoming stuck in a patient's facial artery; a biopsy patient possibly being contaminated with hepatitis B; and two catheters breaking during the brain scan of a 50-year-old woman, requiring surgery.

New technology. Before disposable devices became commonplace in the 1980s, most medical instruments were made of glass, rubber, or metal and were meant to be reused. They were easy to clean and sterilize, but they limited the doctor's ability to perform delicate procedures. As plastics technology improved, devices became smaller, more flexible, and more intricate. Doctors could now treat patients less invasively; cardiologists, for instance, could repair blood vessels without the risks of open-heart surgery. But manufacturers said these new instruments, with their multiple internal passageways, tiny crevices, and coils, were impossible to clean—a problem made more threatening with the discovery of AIDS—so they made them disposable.

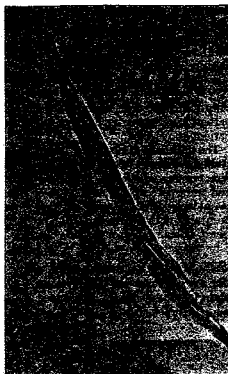
With the arrival of managed care, however, hospitals had to cut costs, and the medical-device budget, typically one of a hospital's largest, was an obvious target. The \$20 million-a-year reprocessing industry was born. While many hospitals clean and sterilize their disposables in-house, others contract with these reprocessing companies, hoping to improve quality and reduce costs further. Pamela Furman, executive director of the Association of Medical Device Reprocessors, says that if hospitals took full advantage of the practice, they could save \$700 million a year.

Critics say the risk is not worth the savings. To be sure, reprocessing companies use sophisticated methods for cleaning and sterilizing disposable devices, and in many cases, the practice is safe. The large plastic compression cuffs used to keep blood clots from forming in the arms and legs during surgery, for instance, are easily recycled. The practice also cuts down on medical waste. But complex instruments are more problematic. Catheters break, recycled plastic staplers wear out, and orthopedic sawblades can be over-sharpened, shattering kneecaps. Refurbished biopsy jaws—passed through one patient's rectum and later down another's esophagus—can accumulate traces of blood, mucus, and feces that reprocessors

HEALTH



CARDIAC CATHETER. At left is the electro-physiology catheter that pulled apart at Children's Hospital. At right, a new one.



ANGIOPLASTY BALLOON. Tiny cravices are filled with blood after balloons are deflated and removed, making them hard to clean.



BIOPSY FORCEPS. A standard forceps (left) is covered with a sheath. At right, sheath is removed to show the intricate interior.

may not completely remove. The crannies of multichanneled instruments, such as spaghetti-thin catheters for clearing coronary blockages, are especially difficult to clean, and the plastics, adhesives, and slippery coatings used in many disposable devices can't always stand up to the harsh chemicals and high temperatures used in sterilization.

S. Noel Irwin has worked as a sterilization technician for nearly 30 years in major hospitals in California, Arizona, and Washington, and what he has seen has converted him into a "tosser." Whenever he sees a disposable device he thinks should not be reprocessed, he simply tosses it into the incinerator. He says he has made hundreds of items "disappear" this way, including skin staplers that shed dry blood flakes, tubes clogged with feeding material, bloody angioplasty balloons, and a large biopsy needle containing pinkish fluid and a piece of skin.

A former sales representative for a major reprocessing company says he was so concerned about the dangers of recycling that he quit his job. He says his supervisor told him several times to return to hospitals and take back defective devices the company had reprocessed but not to file any paperwork. Among the hundreds of items he says he retrieved were disposable balloon inflation devices that leaked "putrid blue fluid" and batches of dispos-

able biopsy forceps from hospital stockrooms. "That told me they knew damn well they had faulty products out there," he says. Similar concerns prompted Ellen Berthelsen, a longtime nurse, to speak out. She says she learned that a hospital where she once worked was reprocessing disposable instruments after a patient apparently suffered a serious internal burn during gallbladder surgery. Berthelsen says the protective rubber insulation around a laproscopic cautery instrument had sheared from reuse. "We raised a stink and were told to shut up, that the hospital insurance would cover us if a patient ever sued," says Berthelsen. But she and her co-workers continued to protest until the hospital stopped the practice.

Growing trend. Yet, clearly, reprocessing has taken hold elsewhere. Furman says the members of her association have recycled over 9 million instruments to date, including many open, yet unused, devices. The manager of a large cardiac catheter lab in the eastern United States reports that he has reused some instruments on as many as 50 surgical patients. And a 1997 study of reuse by ECRI, a nonprofit health services research agency, found that one third of hospitals reprocessed devices.

The trend, which has expanded significantly in the past couple of years, has caught the attention of the FDA, and the agency is expected to announce a some-

what tougher position on reprocessing soon. Although the FDA oversees the use of medical devices, so far it hasn't required hospitals or reprocessors to prove that recycled disposable devices are safe and effective. But neither has the FDA seen proof that they are unsafe, officials say. "We haven't seen adverse patient outcomes directly attributed to reprocessing," says Larry Spears, the director of medical device enforcement at the agency.

But critics say the government shouldn't wait for a tragedy before acting. "The FDA was created to prevent dead bodies," says Robert O'Holla, vice president of regulatory affairs at Johnson & Johnson, one of many device manufacturers that are losing sales to the reprocessors. He points to incidents such as one that occurred last January at Wesley Medical Center in Wichita, Kan. During a cardiac procedure on a 32-year-old woman, a chunk of an electrode from a disposable catheter—which had been used in five previous patients—broke off and lodged in the patient's right atrium. The doctor was unable to remove it. Officials at Wesley, when contacted about an FDA report describing the incident, would not say whether the patient knows that she is walking around with a piece of platinum in her heart. However, they insist she is in no pain or danger.

Stephen Hammill, director of the electrophysiology lab at the Mayo Clinic in

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Rochester, Minn., makes no apologies for reprocessing. He says his lab has reused some 50,000 catheters without a single problem. He doesn't tell patients whether they are getting a fresh catheter, but he says Mayo carefully tracks each device and reprocesses only the less complex ones, as advised by the American College of Cardiology. The group says that, without recycling, many financially strapped labs could be forced to close. Indeed, because the devices cost from \$200 to \$900 each, Hamill estimates that his lab alone has saved some \$9 million over the past 20 years.

Other physicians, however, are considerably more wary. Jon Resar, director of the catheterization lab at Johns Hopkins Medical Center in Baltimore, said a major reprocessor told him it could recycle 80 percent of Hopkins's angioplasty balloon catheters. But Resar, who has performed over 700 coronary procedures in the past year, turned the company away. His experience performing surgery in India, he says, convinced him that reuse was dangerous. "Balloons were unable to cross the blockages," he says. "The procedures took longer, became riskier, and sometimes weren't possible at all with reprocessed devices."

Resar bolstered his point during an especially complicated case last month at Johns Hopkins. After completing several procedures on a 67-year-old man, he inserted a new single-use balloon catheter and blew open three separate heart blockages. When he later pulled out the device, it was a bloody, crinkled mess. "If this could have been done with reprocessed devices, we would have saved about \$500," said Resar, pointing to a hazardous waste drum overflowing with medical refuse. "But that's not enough to compensate for how unsafe it is."

Likewise, Resar and others contend that it is unethical to charge patients for a new device, as some hospitals do, when they are actually getting a secondhand one. Some institutions argue that they prorate the charge, so all patients share equally in the price break (although there is no evidence that reuse actually results in lower

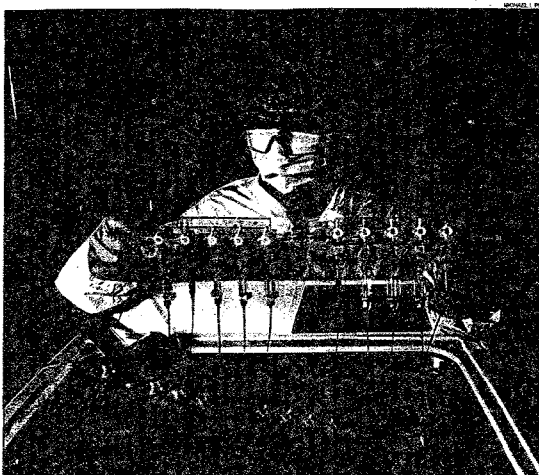
patient bills). Further, reproprocessors insist that manufacturers are less concerned with protecting patients than with maintaining their multibillion-dollar business. "It's easy to say: 'Ooh, this is kind of risky in concept,'" says Elizabeth Stoneman, executive vice president of Paragon Healthcare Corp., a reprocessor. "But it's clearly a niche the market has created. Manufacturers haven't come out with more reusable options." Stoneman adds that reproprocessors have forced manufacturers to lower their prices to compete, resulting in additional cost savings for hospitals.

Washing bedpans. Mark Salomon, senior vice president for marketing at reprocessing giant Vanguard Medical Concepts, contends that manufacturers sometimes designate a device as single use simply to sell more products. For instance, he says manufacturers have arbitrarily changed the labeling on certain types of sutures and orthopedic bits, burs, and blades from reusable to single use. Says Kristen Morris of the American Hospital Association: "We've washed and reused [disposable] bedpans for years, and so far nobody has died from them." Manufacturers agree that

some low-end disposable items might be safely reused. But they say the issue is a red herring. Says Josephine Torrente, president of the Association of Disposable Device Manufacturers: "I don't know who'd make money reprocessing bedpans."

The crux of the issue, Torrente insists, is that reproprocessors and manufacturers are not subject to the same FDA regulations for labeling a device as reusable. If a manufacturer wants to change a single-use item into a recyclable one, it must first prove to the agency that the device will suffer no loss in function and that it can be adequately cleaned and sterilized. Yet hospitals that reprocess in house avoid all FDA regulation, and third-party reproprocessors are required only to register with the agency, follow production guidelines, and undergo spot inspections. However, FDA officials say many of the 23 reproprocessors they have identified are not registered.

Registered reproprocessors insist that the current level of FDA regulation is sufficient. As evidence of safety, they say every device is inspected before it leaves the plant, and they point to an analysis by Vanguard, which showed that catheters they re-



CLEAN ENOUGH? A worker at Vanguard Medical Concepts reprocesses instruments. Critics say such companies cannot guarantee safety. Reprocessors say the practice is safe and saves millions of dollars.

HEALTH

processed were sterile and effective. Yet an FDA study on balloon catheters showed that upon reuse, several of the models tested did not reinflate to the original size. "If the balloon overexpands, it could rupture a vessel and require emergency open-heart surgery to repair it," says FDA biomedical engineer Stanley Brown. And if a balloon underexpands, he explains, the doctor would have to pull it out and use another one, increasing the risk of damage to blood vessels.

Spreading infection? Some experts blame reprocessing for a rise in the rate of infections and diseases contracted in hospitals. But poor patient tracking makes the connection impossible to prove. "Hospitals that only track 24 to 48 hours are kidding themselves," says Patricia Davis, an expert on reuse at Boston Scientific Corp., a device manufacturer. "Hepatitis takes three to six weeks to incubate, tuberculosis takes over three months, and HIV also takes months to develop." A survey by Hershough Associates, a market research firm specializing in medical products, showed that only a small minority of electrophysiology labs noted which patients had reprocessed catheters used in their care. In fact, most of the physicians surveyed said they didn't always know whether a patient had an infectious disease.

Faced with concerns like these, Congress has ordered the U.S. General Accounting Office to determine the extent of reuse and how it affects patient care. AIDS Action, whose immune-depressed constituents are especially vulnerable to infection, has called on the FDA to crack down on reuse. And manufacturers have discussed suing the agency to force it to develop efficacy and safety standards for reprocessing and to require hospitals to obtain consent from patients. A strong sign that the FDA is listening is a letter it fired off in July to the Association of Medical Device Reprocessors, challenging what it called "false and/or misleading statements" in which reprocessors claim recycling is FDA safety-approved. In the letter, agency officials say they consider reuse "unlawful" unless a reprocessor provides documented proof that its devices are safe and effective. Yet officials admit they are not enforcing the policy.

For now, patients like Bill Donnelly, who underwent the angioplasty with Resar at Johns Hopkins, are pleased to know that recycled instruments were not used on them. His son, Joe, acknowledges the safety claims of reprocessors and the reported savings of \$500. Still, he says, "I don't think anyone would want to sacrifice the health and well-being of a loved one to save a couple hundred bucks."

PATIENTS' RIGHTS

If you don't ask, they won't tell

Would you want recycled disposable instruments used on your loved ones? For the majority of doctors, nurses, and other medical professionals *U.S. News* asked, the answer was clearly "No." Some professionals said they would even smuggle in new devices to prevent a family member from getting a used one.

But what can you do if you don't have keys to the hospital supply room? You could ask your doctor not to use such items in your care. Better yet—you could get it in writing. Ex-

dark when it comes to reprocessing. Indeed, Nazari testified in a hearing before the Illinois Department of Public Health last year that his hospital's patient consent policy on recycling was "something similar to the military's: 'Don't ask, don't tell.'"

Check the package. If you are a knowledgeable patient and are alert just before your surgery, there are other precautions that you can take or that a family member can take on your behalf. You can ask the nurses to wait until you're in the procedure



DELICATE WORK. Disposable catheters ready for use in an angioplasty procedure

perts advise adding the following line to the traditional patient consent form: "Do not reuse single-use devices without my written permission." Betty Napier, a former nurse in Fort Pierce, Fla., did just that when she had a cardiac catheter procedure. "It sends up a red flag," says Napier. "The physician will know that you're aware of reuse and won't risk having anything go wrong."

The tactic, although rarely used, appears to work. Jose Nazari, an electrophysiologist at several Chicago-area hospitals, has reused 1,500 cardiac catheters over the past four years. He says he knows of only one time when a patient requested a fresh catheter. The hospital complied.

But what about patients who didn't know to ask? Critics claim that hospitals purposefully keep patients in the

room before unwrapping the instruments. That way, you can inspect the labeling to see if the devices were reprocessed. Once they are unpacked, it can be very difficult to tell the difference between new and reused devices. If the instruments are already unwrapped when you arrive, you can ask to see the packaging in the waste bin. But remember: Doctors and nurses don't always know when a device has been reprocessed. And if it was recycled in house, the package may not be properly labeled.

Finally, infection-control professionals agree that it is best to schedule any procedure for the early morning. That way, you're more likely to get a new, or at least a properly sterilized, device instead of one that has been hastily cleaned for use later that day. —D.H.

Recycling List — Paper, Bottles, Aluminum C

Toolmakers ask FDA to rethink rules allowing hospitals to reuse items

Catheters are marvels of modern medicine, spaghetti-thin devices that doctors thread through blood vessels to open clogged arteries or to perform other repairs without surgery.

Unbeknownst to patients, however, many hospitals send such instruments out to be reprocessed and reused — even though the labels on the instruments say they're for a single use.

In recent months, medical device manufacturers have waged a

savvy campaign to publicize this practice and pressure the Food and Drug Administration into reconsidering current policies that allow hospitals to reprocess a broad range of single-use devices.

"They're taking medical waste out of the trash can and trying to reuse it," says Washington, D.C., attorney Josephine Torrente, who represents the large device-makers behind the campaign.

Now all the industry stakeholders — device-makers, hospitals and reprocessing firms — are awaiting an FDA decision due this month. Indications are that despite the obvious yuck factor, the agency will not issue a blanket ban on reuse.



BIOSCOPE

Tom Abate

"Why not just declare the practice illegal and arrest half the hospitals in the country?" an FDA official close to the process asked

rhetorically.

The answer, the officials say, is that device-makers have a wide range of instruments and uses. Sometimes the design seems to make sense. In the catheters, the delicate instrument indeed could lose their elasticity and effectiveness when reused.

But some manufacturers have labeled durable items, such as saw blades for sin-

gular use, suggesting that they have something other than patient protection in mind.

Roger Richter, a spokesman for the 600 hospitals in the California Healthcare Association, says devices are sterilized carefully.

... Medical Devices

that they won't transmit infections. Richter says that if the FDA is going to review its policy on reuse, it also should review its guidelines for single-use labels so manufacturers will not use this as a marketing technique.

This seems like an issue where each side has its points. If I were lying on the surgical table, I might not insist on a virgin scalpel. But it might be nice to know whether the four-foot-long catheter making its way to my heart already had traveled through somebody else's aorta.

LIFELINE Patients who've exhausted all conventional remedies often

seek to enroll in clinical trials of experimental drugs or medical devices. People with AIDS, for instance, can consult a database that points them to experimental therapies.

But people with other diseases haven't had any way to learn about experimental therapies. Nearly two years ago, Congress ordered the National Institutes of Health to create a single database where patients could find information about clinical trials on all life-threatening conditions.

The good news, according to Deborah Katz with the National Library of Medicine, is that by year

► **BIOSCOPE**: Page E12 Col. 1

Database for Clinical Trials

► BIOSCOPE

From Page E1

end, the first installment of the database will go online. It will be searchable by disease and will contain information about more than 4,000 clinical trials being conducted by NIH scientists.

"You might not have food, clothing or shelter," Katz said, joking about the Year 2000 problem, "but you'll have a database on clinical trials."

But it's not yet clear when drug and biotech firms will join the online repository, and exactly what types of clinical trials they will publicize. Drugs go through three phases of tests. The first two phases test whether new drugs are safe, and set the dose levels. Only in the third phase do companies enroll large numbers of patients to test whether the drugs work.

The Pharmaceutical Research and Manufacturers Association (PhRMA) would like to exclude Phase I and Phase II tests from the database, out of concern that early disclosure of clinical trials will give competitors too much information about drugs in development.

PhRMA spokesman Jeff Trewitt said disclosure of Phase I and Phase II data also would be of little use to patients because 80 percent of the drugs that go into early stage tests fail before they get to Phase III.

FDA Associate Commissioner Terry Toigo will make a recommendation on this issue in January. But it will be several months after that be-

fore final rules are posted and before commercial firms are required to post clinical trials on the public database.

Meanwhile, the FDA must wrestle with another issue: whether to include clinical trials of new medical devices in the public database. On this issue, Congress waffled. Lawmakers pretty much ordered drug and biotech firms to join the database. But they merely requested that NIH and FDA "determine the feasibility" of including devices in the clinical trial repository.

TECHNOLOGY

Stephen Northrup, executive director of the Medical Device Manufacturers Association in Washington, D.C., said his members oppose the notion of being forced to publicize their trials.

Northrup explained that, unlike drugs, devices undergo two test phases, a pilot project and a full-blown test, that can be done relatively quickly.

The FDA has some time yet before it has to report on whether device tests can be added to the public database.

While the bureaucracy churns, several Web sites already list many clinical trials. Start with the NIH's

partial registry at www.nih.gov/health/trials/index.htm. Two commercial sites, CenterWatch (www.centerwatch.com) and Med-Trial (www.medtrial.com), also contain some trial information.

COSMIC RELIEF: Ever since she capitalized on the notion of asking medicine men to help her scour the rain forest for potential drugs, Lisa Conte of Shaman Pharmaceuticals has shown a flair for publicity.

Remember Shaman? The company was plunged into crisis in February when the FDA rejected its bid to sell a diarrhea drug. Its shares sank; it was delisted from the Nasdaq. After spending more than \$90 million

in 10 years, Shaman had to quit the drug business.

Undeterred, Conte said she would remake Shaman into a vendor of herbal remedies — potions that can be sold without the costly, bothersome process of winning the FDA's seal of approval.

Conte, who recently raised \$10.7 million in a stock sale, last week put out a press release that got biotech insiders chuckling.

"ShamanBotanicals.com... announced today its rebirth in a ritualistic web blessing from multiple indigenous groups around the world."

What an image! Visualized natives in feathered headdresses danc-

ing around a Webcam link to a drumbeat heard throughout the global village.

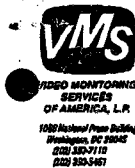
"Actually, they e-mailed us their good wishes," Conte said.

But she promised to reread the blessing next weekend, when the born-again company launches its botanical version of the poop pill at an alpaca ranch in Woodside "that has a very spiritual feel."

Ah, now I can hear the pan pipes.

Look for BioScope every Monday in the Business section. Send your biofeedback to Tom Abate by e-mail, abate@siggate.com; fax, (415) 543-2482; or phone, (415) 777-6213.

MONDAY, OCTOBER 4, 1999



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A BUREAU OF AMERICA

Transcript

DATE September 22, 1999
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Diane Rehm, host:

Hospitals all across the country regularly sterilize and reuse medical devices in one patient that have already been used in another. Sterilization techniques make this a safe procedure for devices designed to be used more than once. But today, clinics and hospitals also clean and reuse devices that are labeled single use only. Joining me to talk about how medical devices are manufactured and used, Pam Furman (sp) of the Association of Medical Device Reprocessors; Josephine Torrente of the Association of Disposable Device Manufacturers. Joining us by phone, Dr. Jose Nazare (sp), a Chicago-area cardiologist; and from Miami, Dr. Phil Grossman, a Miami gastroenterologist.

We'll take your calls throughout the hour, 1-800-433-8850.

Good morning to you, Ms. Furman.

Pam Furman (Association of Medical Device Reprocessors): Good morning.

Rehm: And Ms. Torrente.

Josephine Torrente (Association of Disposable Device Manufacturers): Good morning, Diane.

Rehm: And Dr. Nazare, are you with us?

Dr. Jose Nazare (Cardiologist): Yes, I'm with you. Good morning, Diane.

Rehm: Good morning, sir. And Dr. Grossman, are you there.

Dr. Phil Grossman (Gastroenterologist): I am, in sunny Miami. Good morning.

Rehm: I'm glad it's sunny.

Let me start with you, Dr. Grossman. Doctors have been

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sterilizing and reusing medical instruments for decades. How safe do you believe this procedure to be?

Grossman: Well, I think the most important distinction is the difference between sterilizing and reusing instruments that were originally invented, designed, created, and made of materials to be reused, compared to those instruments that were originally designed, created, and built with materials that were not meant to be reused. Certainly, the act of reprocessing something like a surgical clamp made out of stainless steel--no hidden crevices, throw it into an autoclave--has been safe for decades. But in contrast to a thin catheter with a very narrow lumen, biopsy forceps with a sharp point, intricate wires where debris can get caught, physical material like plastics and polymers, which can't be subjected to autoclaving, then it's a very unsafe practice.

Rehm: Ms. Furman, how do you see this situation?

Furman: Yeah, I'd like to comment on that. I think Dr. Grossman's comments really highlight one of the big misconceptions that we see about this whole debate, and that is what does the single-use label really mean? Does it mean that these devices are designed and intended and can only be used once? And what we see is that in fact that's not the case. Simply because a device is labeled as single-use does not necessarily mean that it needs to be discarded after one use.

Rehm: Why not?

Furman: Well, the main reason for that is that it's the manufacturer that's choosing to put the single-use label on the device. It's not an FDA requirement. And there's really a clear economic incentive for the manufacturer to label a device as single-use.

Rehm: Ms. Torrente.

Torrente: Yeah, that's actually a good bit misleading when you think it's true that there's no FDA regulation that says this must be single-use, this must be multiple-use. But if I, as a manufacturer, were to go in with a device and only have data to prove it can be used once--I can't prove that it could be cleaned and still be functional for use in a second or third or tenth patient--FDA will mandate that I label that device single-use only. They won't let me sell it for use in a third or tenth patient because it could injure that patient. We don't know that it's safe.

Rehm: Dr. Nazare.

Nazare: While I think all the points mentioned are important and good points, there is historical data on

which to fall back on, on how the single-use came about. Now, I will particularly be talking to you about what I have expertise in, which is cardioelectrophysiology catheters. That is because I'm a sub-subspecialist in cardiology who does nothing but cardioelectrophysiology, and that's what I have knowledge of.

Historically, catheters were reused routinely through the 1970s, when we were, oh, a group of doctors hidden in an obscure lab in a corner of the hospital somewhere doing basically research procedures and procedures which had a small impact of clinical importance by the numbers. Later on, we came to the forefront when radio-frequency ablation, which you may have heard of, which is a procedure, one of a few procedures in medicine which results in a cure from the disease--something we wish we had more of in medicine. When that came about, electrophysiology came to the forefront. And with that backdrop on the electrophysiology per se, historically catheter reuse was--or catheter labeling as single-use did not come about in EP until the early 1980s. Prior to that, the identical catheters were labeled for multiple use.

And the reuse issue came about after accommodation of the FDA, when they thought that pyrogens, which are substances which can create a fever--not necessarily infections, but can raise a patient--the patient's temperature--could be caught in catheters that were defined for angiographic procedures--that's catheters that have a lumen or a light or have a hole through them. No distinction was made for electrophysiology catheters, which are solid and which do not have a lumen; which are designed to measure electrical properties. And no data existed to support a policy for or against the reuse of these catheters.

Rehm: Dr. Jose Nazare. He's a Chicago-area cardiologist. We're talking about the use and reuse of certain medical devices. If you'd like to join us, call us on 1-800-433-8850. I recognize that, to a great many of you, this may seem like an obscure subject, but it has come to the fore because there has been a great deal of news coverage on the issue of whether reuse of certain medical devices is in fact safe or whether the enforcement of disposing of what many believe may be perfectly safe reusable devices is coming about because of a push from manufacturers. 1-800-433-8850.

I want you to know that we received some information from the FDA this morning on a proposed strategy on reuse of single-use devices. They plan to issue an FDA position paper in October that's going to describe that strategy, that will summarize some of the suggestions the FDA received during a May conference on the issue. And the FDA's proposed regulatory strategy is based on what they say are the known and potential public health risks to

patients and users from the processing procedures and the reuse of previously used single-use devices. So, do join us. 1-800-433-8850.

According to U.S. News & World Report, hospitals are cleaning and reusing these disposable devices. Now, why should that be, Ms. Torrente?

Torrente: Well, actually, Diane, you mentioned the May FDA conference, and I think FDA's probably the best body to give us an opinion on this because they are an independent third party with no economic or other interests. The catheters Dr. Nazare was talking about--the electrophysiology catheters--you might have heard of this procedure, where they essentially make an incision in your leg and snake a catheter all the way up into the heart.

Rehm: Right.

Torrente: Those are the kind of things that we're talking about, so you understand that and your listeners understand that these are really invasive, delicate devices. FDA showed data at that meeting they developed themselves that all the little electrodes on the tips of those catheters are popping off after they try to clean them. They're being removed. And there's big gaps exposing the internal wires. So this is independent FDA data of a study that FDA conducted. We're very hopeful that, based on this data and other similar data, FDA will do the right thing when it comes out with its position in October and appropriately regulate reprocessing.

Rehm: All right, so let me understand. If in fact these catheters are somehow being affected--I won't use the word damaged--but being affected, you're saying that despite that, they are then reused.

Torrente: Absolutely. These catheters and other devices we've seen to have bacteria still on them. We've tested reprocessed devices to see if they meet their functional specifications. So the things the FDA has said these devices are approved for--here are the specifications, a good eighty percent do not meet those specifications any longer.

Rehm: What about that Pam Furman?

Furman: Yeah, let me make a comment on that. I think, you know, in this debate, we have on the opposite polar sides the manufacturers and the reproprocessors, both who have an economic stake--an opposite economic stake.

Rehm: Indeed.

Furman: And I think our view is that who should--whom

should we really listen to? It's the health care providers, it's the doctors. And what we have seen again and again is it's the doctors who have come out in support of reprocessing. And I'll be specific here because we're talking about the electrophysiology catheters.

Let me read a quote from the North American Society of Pacing and Electrophysiology, which is the association for the electrophysiology doctors. They say, "After studying thousands of patients who have undergone cardiology procedures with resterilized catheters, findings indicate there is no increased risk of infection for patients. Resterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years, with no known patient adverse outcomes."

Rehm: Dr. Grossman, if I am a patient going in for a catheterization procedure, do I have any way of knowing whether that device has been used, reused, or whether it's a brand-new device?

Grossman: In the overwhelming majority, you do not. And that's a major point of contention on my part. The French government just this week, in a lawsuit, issued a ruling saying that using--reuse of single-use devices was, and I quote, a deceit to the patient. One of my recommendations at the FDA meeting in May was that patients get an informed consent, and the consent should say something like, we are going to use a device in your procedure which has been used in another patient, sent out and been reprocessed. That device may have been used in a patient who has had AIDS, tuberculosis, or hepatitis C; and that there are sterile first-time-use devices available as an alternative.

Now, that statement is completely true. And it's my contention that the public is entitled to have that as part of their consent because then, as you said in your question, they have the right to say, hey, look, I'm satisfied, go ahead and use it; or to say, wait a second, if you tell me that there's one available that's not been used in somebody that I don't know what they had, I want the new one.

Rehm: What about that, Dr. Nazare? What do you think?

Nazare: Well, the issue of informed consent is something we have battled with in multiple committees at multiple hospitals where reuse has been established. The committees have included ethicists, hospital quality-assurance and quality-control, infection-control committees, and committees made of people from the community in community health.

Rehm: And what did they say?

Nazare: Well, what it boils down to is that the reuse of a particular device or product, if it represents an increased risk of injury above and beyond that inherent to the initial use of that device, it should be specified to the patient and brought to the patient. But if it does not...

Rehm: All right. Dr. Nazare, excuse me. We've got to take a short break. More on this issue and your calls-- 1-800-433-8850. Stay with us.

(Commercial break)

Rehm: If you've just joined us, we're talking about the use and reuse of certain medical devices. Some are, across this country, used and reused; others are disposed of. The issue becomes, number one, safety of using those devices labeled for single use--and apparently that is happening across the country, that some of those devices are being sterilized and reused. And the other question becomes patient consent, patient awareness, whether you, as you go into the hospital, have even a sense that the device that's being used, say, to perform a catheterization has been used before, whether it's in perfect condition, or whether it's not.

Now, the FDA has indicated that such devices may not necessarily be amenable to resterilization and/or reuse. But the FDA is not aware of any data that would establish conditions for the safe and effective cleaning and subsequent resterilization and/or reuse of any disposable medical devices.

We've got a real dilemma here, it seems to me, Ms. Torrente, because, number one, people don't know about this, and number two, the whole processing question comes into play.

Torrente: It certainly does, Diane. And, you know, when you're a patient going into a hospital to have a procedure done, you've got a lot to worry about. The last thing you need on your mind is a concern that the medical devices that are going to be used in your procedure have been used with another patient with a communicable disease, and they haven't been cleaned properly. You also don't need to worry that the device isn't going to function properly because it's been handled in an improper way. The FDA should take that worry away from you. And for new devices, they do take that worry away because they approve the device as safe and effective for that first use.

Rehm: Pam Furman, Dr. Grossman mentioned hepatitis, he mentioned AIDS. What's your reaction to that in terms of reprocessing these devices?

Furman: Well, I think there are really two issues that

we're talking about here. The first is the informed consent one, and I'll address that for a moment, if I may...

Rehm: All right.

Furman: ...because I think that's a critical issue.

Rehm: Yes.

Furman: In our view, the issue of informed consent always must be a decision between the patient and the doctor. And if the doctor feels that a procedure or a product used in the procedure will increase the patient's risk, then absolutely, the doctor should disclose it. But what we have here are properly reprocessed devices that are as safe and effective as new devices.

Rehm: But what about Ms. Torrente's statement earlier that in reprocessing, sometimes filaments break off, something happens?

Furman: And I think what I would say there is to direct us back to one of the quotes that was in the U.S. News article, which was the FDA saying that they have not seen evidence of patient adverse events directly attributed to reprocessing.

Rehm: But that doesn't say that the portions are not breaking off.

Furman: What it does say is that we don't have a safety problem here, that proper reprocessing is safe. But let me follow that up with the question of FDA--what should FDA be doing here? As an association, we are very much in favor of a strong FDA role here. We think FDA should be regulating reprocessing and that it's critical to the safety and effectiveness of reprocessed devices that FDA play a role here. And in fact, FDA has in place a strong regulatory regime for reprocessing.

Rehm: Is it strong enough, Dr. Grossman?

Grossman: No, it's not. And if you go to a January report of a woman who had a cardiac procedure done on a device that was meant to be used once, had been reprocessed six times, and the metal tip broke off, traveled through her circulation and is now lodged in her heart like a spear, I think that woman would clearly believe there is a potential safety problem. I think she clearly would indicate that informed consent certainly had a role and there is a problem. It's just like a set of tires. If it was meant to go ten miles, you run a risk when you arbitrarily take it a thousand miles.

Rehm: Now, to what extent do you believe the FDA is going to take up the issue of informed consent? Or do you believe that the FDA is going to concentrate on processing and reprocessing, Dr. Grossman?

Grossman: Well, I think--and I can't speak for the FDA; sometimes I'm not even sure they can speak for themselves.

Rehm: Well, and they were invited to participate this morning and chose not to.

Grossman: I think where I hear them potentially going is to assemble a couple of pieces together. One is to say when people reprocess a device that was originally intended for single use, the FDA considers them to be a manufacturer. Take a second piece, where the FDA says to an original manufacturer, if you want to do something different than you've originally submitted data for, you need to give us the scientific validation before you go out and give it to the public. Where I think they may head is to say to reproducers, we're simply going to hold you to the same standard. If you want to go ahead and use things differently than they were approved or intended, then you do exactly what the original manufacturer did--send us data, show us that it's been tested, show us there's process, and show us that it's safe.

Rehm: Dr. Nazare, where do you come down on this?

Nazare: Well, I think that to analyze this carefully, we have to be careful to not concentrate on a single anecdote or single anecdotes of patients. There's ample scientific studies conducted in the EP literature specifically, which is what I'm familiar with, in which catheters have been reused and analyzed carefully, including a specific paper by one of the electrophysiologists here in Chicago, outside my hospital, who is also an engineer who designs catheters. His studies have proven that in patients who are unselected, when we take a group of patients and analyze the data scientifically, it is safe to reuse these catheters. Based on these studies, the electrophysiology community, including our association, the NASPE--or the National--North American Society of Pacing and Electrophysiology--came up on the side of reusing catheters. When we look at other products, we may need to look at them specifically. It may be that...

Rehm: So you're saying you have to, perhaps, look at these devices one by one rather than granting an overall umbrella statement.

Nazare: Absolutely. Absolutely. If we lump them together, we're going to come up with a mishmash of issues which are incompatible.

Rehm: What do you think about that, Ms. Torrente?

Torrente: Well, thanks for the opportunity to respond, Diane. I, too, am a biomedical engineer by training, before I was an attorney. And so looking at these studies that Dr. Nazare talks about and looking at other studies, it's clear that the studies aren't always conducted in the best way. Patients aren't followed up for long enough to see if HIV is a problem, to see if tuberculosis comes around. So--and also, many times the device...

Rehm: It could take as many as ten years.

Torrente: Oh, two, six months typically. And typically patients are followed for a couple of weeks, if that.

So that's really one issue. But Dr. Nazare is right that one-by-one device evaluation is key here, and that's exactly what we have asked FDA to do. We've asked FDA to tell the reproducers, for every single device you want to reprocess, prove to us that that device is safe. We can't have standards that cover across-the-board different types of devices.

Rehm: Josephine Torrente of the Association of Disposable Device Manufacturers.

Let's open the phones now, 1-800-433-8850. And we'll take your calls between now and the top of the hour. First, to Rochester, New York. Fritz, you're on the air.

Fritz (Caller): Yes, hello, Diane.

Rehm: Good morning, sir.

Fritz: Good morning. Thank you very much. I'm a professor of packaging at RIT. And before that--I came out, I was a senior development engineer at Baxter Labs in Chicago, and I did a lot of work with devices and the effects of sterilization on materials. And what your panelists have said seems to hold true. The different materials respond differently to different types of sterilization. Glass and metal seem to sterilize very well. But when we talk about polymeric materials, the effects of radiation are cumulative, and you can get--the materials will embrittle, they'll degrade, and you get a very--a big change in the quality of the materials if you try to resterilize disposable devices.

You were talking about the increased risk of process problems. I remember back in the '60s, in literature, talking about the improved health care because with disposables you weren't getting cross-contamination from reesterilized products in the hospital. I mean, the hospital personnel is--are health care professionals.

They're not trained to run sterilizers. And to expect them to do a number of different tasks like that encour-- you know, you've run the risk of potential error.

Rehm: What about that, Ms. Furman, the fact that hospital personnel are not necessarily trained to do this correctly?

Furman: Well, I think if we look at the safety record of reprocessing in general, and--what we have to understand is that reprocessing has been standard practice in America's finest hospitals for over twenty years. It was originally done primarily in hospitals and in-hospital reprocessing centers. And there's still quite a bit of reprocessing that is done in hospitals. It's been in the last ten years or so that the third-party reprocessors have emerged, and really, as an extension of the hospital.

So the question what about the hospital's ability itself to do reprocessing, what we see more and more is the hospitals looking to the third-party reprocessors--for whom this is their own business, their specialty, and there's FDA regulation--as perhaps a safer way to do reprocessing.

Rehm: Dr. Grossman, in the last ten years, twenty years, we've seen an increase in iatrogenic infection. And that is, when individuals go into hospitals, they find themselves getting infections that they didn't have before they went in. To what extent do you think that this issue of reprocessing devices may be playing a role?

Grossman: Well, that's a good point because if you go back historically, that's how this country went to the development of single-use devices. It was thrust by both technologic advance as well as the desire to avoid those. And I think one of the biggest issues that has been overlooked is when Dr. Nazara and others say there's years of safety and no adverse patient effects, people aren't looking. And if you're not looking and counting, you don't find. There has never been a study, there has never been anybody who has said to me we have tested all of the patients before we used a reprocessed device, we have then tracked the device and then brought the patients back at three months, six months, nine months, twelve months and retested them. So I believe we are creating a subset of silent victims who are being contaminated and who don't know it because they show up somewhere else six months later, and so the obvious link to that device is there.

Rehm: Dr. Phil Grossman. He's a Miami gastroenterologist. And we're talking about the use and reuse of medical devices. At twenty-five minutes before the hour, you're listening to "The Diane Rehm Show."

And another caller, this one here in Washington, D.C. Good morning, Karen.

Karen (Caller): Good morning.

Rehm: Go right ahead, please.

Karen: Yes. I had a question for Dr. Grossman.

Rehm: Fine.

Karen: I read in the paper reports about, you know, problems with the recalls of new devices. And I was just kind of curious with regard to his position on informed consent and whether a patient has the right to know when a particular type of device has been recalled in the past.

Rehm: Yes. Dr. Grossman.

Grossman: If a device has been recalled in the past and is now again on the market with FDA approval, with resolution of whatever the problem is, then I don't think that there's a need for some separate statement. If, on the other hand, a patient has recently been treated with a device where there has been a recall, where the patient is at risk, then by all means the patient needs to be notified. Or if there is a belief of an ongoing risk, the patient should be notified.

Bear in mind, when we do a semi-invasive procedure--or any procedure, informed consent does not mean--contrary to what was said earlier in the show--telling a patient that there's increased risk. Informed consent means telling the patient what the risks are and what the alternatives are so that the patient can say, I understand the choices, I understand the risks and benefits, and I agree with this plan of action.

Rehm: Do all of you come to that same conclusion as far as notification of the patient of the possible risks involved, the devices used, whether they've been reprocessed, whether there has been a problem, and getting informed consent?
Dr. Nazare.

Nazare: Absolutely. But imagine if every time we gave a patient informed consent we had to tell him--imagine if the surgeons had to tell the patients, in addition to what's involved in their surgery, that they're going to reuse devices that are designed for reuse.

Rehm: OK.

Nazare: It's similar to what happens with these devices which have been labeled as single-use without any, really, underlying reason that can be identified in the literature. There is no scientific reason to label them so. The manufacturers...

Rehm: But on the--but at the same time, we have seen some indications of some problems showing up, have we not?

Torrente: We have, Diane. In fact, there's quite a few. Dr. Nazare said we shouldn't be anecdotal, but the bottom line is that there haven't been diligent studies done. And so we need to be anecdotal. In terms of the informed consent, though...

Nazare: Actually--actually, we don't.

Torrente: In terms of the informed consent, I think there's an easy solution to the problem. The reason a doctor doesn't tell you about all the devices that are going to be used in your procedure...

Rehm: Sure.

Torrente: ...is because FDA has said those are safe, those are effective. And we as a public put trust in FDA that they can make those decisions. If FDA would look at the reprocessed devices and tell us which ones are safe and effective, then we wouldn't need informed consent because we would have that same federal government assurance that the devices are safe and effective, and as patients we could go into the hospital comfortable.

Rehm: I think I would still, frankly, as an individual patient, like to have that knowledge so if there is a choice to be made, I can make that choice.

Furman: Diane, I think to your sort of blanket question here--are we all on-board with the concept that if you're going to do something that is going to introduce a risk to a patient, should you disclose it--absolutely, that's the answer. But I think the caller really raised a bigger issue here and it exposes, I think, what is at the heart of the debate, and it's economics. And what we see, I think, on the part of the manufacturers with the clamoring for informed consent for reprocessed devices and a focus on reprocessed devices, as opposed to risks introduced by all devices, is really what this debate is about. For the manufacturers, the reprocessing is posing an economic threat. And clamoring for informed consent for patients, with a focus on reprocessed devices, is a way to basically get rid of reprocessing.

Rehm: Pam Furman of the Association of Medical Device Reprocessors. We will continue our discussion and take your questions, comments. Call us on 1-800-433-8850. I'm Diane Rehm. Stay with us.

(Commercial break)

Rehm: And welcome back to our discussion of the use and reuse of medical devices, things used in the hospital routinely. Some are labeled for single use only and yet are reused--sterilized, of course--reused. The question becomes should patients be informed? The question also becomes should these single-use devices be allowed to be reprocessed and reused?

We've got lots of callers. I'll go back to the phones now, to Sean in Jackson, Michigan. You're on the air.

Sean (Caller): Morning, Diane.

Rehm: Morning, sir.

Sean: There's two issues that I'd like to address.

Rehm: Sure.

Sean: The first one is, as a medical product designer, when a product is reused, as one of the commentators had mentioned, we do indeed lose money because the device is not repurchased. The question that I would have about that is whether those cost savings are somehow passed on to the patient, and I would willing to--be willing to bet that they're probably not. The other issue that I'd like to address here is that when we have to make a very conscientious effort to design our devices so that they can't be reprocessed, because there is no conceivable way in the world that I can assure you that that device is going to do exactly what I guarantee it to do the first time.

Rehm: So then who's liable if it's...

Sean: That's exactly it.

Rehm: Yeah.

Sean: You're opening me up to liability because you're using something for a reason other than what it was intended.

Rehm: What about that, Pam Furman?

Furman: Well, I--there are two questions here. The first is, I think, a really good one, and that is are the cost savings from reprocessing passed on to the patient, because we hear again and again that this is purely a cost-saving mechanism with no benefit to the patient. And the fact of the matter is that the patient is benefitting from proper reprocessing because hospitals are saving millions of dollars each year through reprocessing. And those dollars are being directed towards preserving nursing staff, towards preserving procedures that would go away

without reprocessing. This is not sort of a pipe dream. This is what the hospitals tell us; this is why they're reprocessing. So there's absolutely a benefit in terms of patient access and medical care to repro--for proper reprocessing.

Rehm: Ms. Torrente.

Torrente: Diane, I'm not sure that we have any documented evidence that the patients benefit. And I think we do all know that the patient's bill certainly doesn't go down. So in that way, they don't benefit. The issue is, though, even if we could save two nurses, if we kill one person with HIV, is that worth it? I don't think it is.

Rehm: The other question that Sean is raising is if he designs a medical device for a single purpose and that device cannot be reprocessed and used exactly as designed and intended, what happens, who's liable? Dr. Grossman.

Grossman: Well, I think in the litigious society in which we live--and I guess it's easy for me as a non-attorney to say that--I don't know who would ultimately be liable, but I could assure you that everybody's going to be held accountable. The physician, who is the last bastion of protection for the patient, is certainly on the hook for knowingly using this on the patient. I think the hospital that makes this choice. And, from what I've been told, even the original manufacturer may bear some responsibility even though their label says don't to this.

Rehm: Interesting. All right, thanks for your call, Sean. Let's go to Indianapolis. Brad, thanks for being with us.

Brad (Caller): Hi.

Rehm: Hi, there.

Brad: Well, thank you. Yes, I'd like to say that I think it's an economic issue more than anything else. I mean, if somebody wasn't losing money on this, it never would have been brought up. I had an exterior device, and I know that my insurance company paid the full price for that. And that was reused. My surgeon kind of blurted that out. So I don't think that the patients are saving any money. I think the hospitals are making money by reselling these devices. And besides that, I mean, I wouldn't want a device that would only be able to be used once.

Rehm: What do you think, Ms. Torrente?

Torrente: Well, Diane, he's absolutely right. I don't think the patients are saving money. And more importantly, more important than the economics, it is a patient-safety issue. Even though the device used on Brad was an exterior

device, we have reports where devices that are supposed to be covered in a foam padding and put on the feet of neonates, the padding is worn off by washing and reprocessing and the baby's foot, this premature baby's foot is exposed to an aluminum shield and burned. That's the problem. It's not economics, it's patient safety.

Rehm: So if I'm a patient, can I walk into a hospital if I'm about to undergo some invasive procedure, or even an external procedure--should I be asking whether this is a device that's already been used on someone else? Should I--if I ask, will I be given an honest answer?
Dr. Grossman.

Grossman: The answer is a resounding, absolutely you should be asked. The value of shows like yours is to get the public to ask those questions. That's where the solution comes from. If you don't get an honest answer, I would suggest you high-tail it to another health care facility.

Rehm: But how do you know you're getting an honest answer?

Grossman: Well, that's a--that's a good question. You don't. But I can tell you from personal experience that when I see physicians as patients and their families, they make sure to ask and they make sure to pick places for themselves and their loved ones where they are going to get a single-use device that was used the first time.

Rehm: Pam Furman, do the hospitals and clinics themselves have ways of tracking just how many times a device has been used?

Furman: Yes, they do. Our reprocessors in our trade associations provide to the hospitals, for example, a peel-off label with the reprocessed device that can be put in the patient's chart so it can be noted that a reprocessed device was used. If a problem should occur, that notation will be traced back to the reprocessor and we can know the whole reprocessing profile of the device. So, absolutely, we provide hospitals with ways to trace the devices. Our companies track the devices. The products are labeled as reprocessed. There are several mechanisms in place if, God forbid, something should happen.

Rehm: Ms. Torrente, I understand Senator Dick Durbin of Illinois has proposed two measures to address some of these issues. What would these initiatives do?

Torrente: Well, the most important, Diana, is an amendment to an appropriations bill, which is a bill that provides FDA with funding. FDA has noted that this is an issue. They've stopped saying it's not a patient safety issue and FDA said that they haven't currently taken action because

they don't have the funds to do so. What Senator Durbin has done in the name of patient safety is propose that Congress allot one million dollars to FDA so that FDA can assure that reprocessed devices go through a pre-market review. Before they get used in any patient, FDA would look at them and say this is safe, this is effective or it's not and it can't be used.

Rehm: Considering the number of devices out there, a million dollars doesn't sound like a great deal of money.

Torrente: Well, you know, you're right. It doesn't sound like a great deal of money, but when you think of all the devices, I think there are a great many for which FDA will never even get a chance to review them, because nobody could possibly develop the data to show that they're safe and effective in reuse.

In order to submit data to the FDA, the data has to be available and if you can't clean and reprocess these devices, FDA won't see a download of many outpatients. They may see a handful or two and I think those will trickle in over time and if Congress deems appropriate, they can up the appropriation in another year. But they could...

Rehm: What about this Dr. Grossman? What do you think of possible Senate action in this direction?

Grossman: I think it's an excellent step because the very action will almost have a self-fulfilling prophecy of weeding out the problems because, as people are obligated to provide data, if they can't generate data to show it's safe, there's nothing to send to the FDA. So I, for one, don't think the FDA is going to be overwhelmed. I think what's going to happen instead is the FDA is going to get applications for things that can legitimately be done, for which there is scientific data and everybody would support. And the ones that can't will fall by the wayside.

Rehm: Pam Furman.

Furman: To reiterate, we are absolutely in support of FDA regulation here and, to that end, we have supported Senator Durbin's one-million-dollar set-aside for FDA oversight of reprocessing activities, because we think it's very important that FDA play a role. What we're not in favor of, Diane, is a level of regulation that would put reprocessing out of business because, really, the only beneficiary there are the manufacturers. The health care industry suffers, the hospitals suffer, the patients suffer, and our business goes out of business.

Rehm: So, to what extent would the elimination of reprocessing up costs for patients hospital sell off?

Furman: It would be a significant effect in that there are a number of reasons why. The first, obviously, is every time a hospital safely reuses a device, that's a lost sale for a manufacturer because the hospital's not purchasing a new device. So that's an added cost. If a hospital couldn't reprocess a device, they'd have to buy a new one.

But there's actually even a grander dynamic that's occurring here. What we've seen as a result of reprocessing is a downward effect on the cost of medical devices. Manufacturers say to a hospital, if you don't reprocess, we'll cut the price of your device. And we've seen a downward spiral of device costs.

Rehm: And at seven minutes before the hour, you're listening to "The Diane Rehm Show."

Ms. Torrente, what do you think about the cost factor?

Torrente: Diane, you know, it's interesting, but I think again, we've been a little bit misled here. I don't think anybody would go out of business by appropriate FDA regulation to protect patient safety. There's a whole class of devices we really haven't talked about. Those are the things that the hospitals do carefully inside the hospital and that Ms. Furman's members do. These are devices that have never touched a patient--things that, say, the nurse has opened onto the sterile field, but then the doctor didn't need during the procedure. FDA and Senator Durbin are putting those devices aside. Those could still be reprocessed and that is a large bulk. We're only talking about the ones that have come in contact with a patient that could be infected and could be functionally inappropriate.

Rehm: All right. Let's take a caller from St. Louis, Missouri. Good morning, Greg.

Greg (Caller): Good morning, Diane.

Rehm: Hi, there.

Greg: How are you?

Rehm: Good, thank you.

Greg: Two years ago, Diane, I was in a office of a urologist and a cystoscopy was performed on me with a reusable fiberoptic scope. Twenty-four hours later, I developed a raging infection and a case of pyelonephritis due to a defective scope. Ironically, that scope was at the manufacturer for repair just weeks before and was given a clean bill of health, if you will. So I was the fifth

person that was scoped that day--the last one of the day. And I was so sick I thought I was going to die. But I guess my point in this is that even the reprocessing of reusable devices is not an infallible process and there are problems with those situations.

Rehm: How easy is it, Pam Furman, to absolutely be sure that in the reprocessing that that instrument is absolutely pure and clean?

Furman: I think that's an excellent question and it really goes to what FDA regulation is there in place right now. And what our reproprocessors have to do is, we operate under the Quality System Regulation. The most important aspect of that is what's called the validation requirement. That means that our reproprocessors have to document in their files that their cleaning and sterilization methods will, on a consistent basis, not just once or twice, but consistently yield a safe and effective device.

Rehm: Ms. Torrente.

Torrente: Diane, I'd like to go back to what Greg said, because he brought up such an excellent point. Imagine, if hospitals and clinics are having trouble cleaning devices that were designed to be reused? Imagine the problems with these intricate complex devices labeled for one use. If we can't even get the reusables right on occasion, how can we possibly try to clean complex, single-use devices?

Rehm: Dr. Nazare.

Nazare: Well, there's--again, there's ample data for devices that are simple, in which the infection rates are identical with new and reused devices, and they're extraordinarily small. By the way, one of the diseases people are naturally scared of is HIV, the AIDS virus, which is a notoriously weak virus outside the body. It is one of the easiest viruses to destroy...

Rehm: All right.

Nazare: ...and almost anything will.

Rehm: I want to leave just a few seconds for Dr. Grossman to make a last comment on Greg's call.

Grossman: I think Greg's point is, again, back to this fundamental issue. This is a patient-safety issue. There's a real live patient who was affected by it. And what his experience tells us is that when there's a break in the appropriate deliberate process...

Rehm: All right.

Grossman: ...adverse events occur.

Rehm: Dr. Grossman, Dr. Nazare, Ms. Torrente and Pam Furman, thank you all so much for a fascinating discussion.

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Monday, August 2, 1999

Risky Reuse of Medical Equipment Is on Rise

Health care: U.S. officials say the largely unregulated practice has resulted in catheter tips breaking off in hearts, caused infections and created other problems. FDA action is imminent.

By SYLVIA PAGAN WESTPHAL, Times Staff Writer

ADVERTISEMENT

Millions of medical devices that come in contact with blood or other body fluids and are supposed to be discarded after one use are instead being reprocessed and reused, putting other patients at risk without their knowledge, some experts fear.

The U.S. Food and Drug Administration is poised to crack down on the largely unregulated practice, which is escalating because managed care reimbursements are not sufficient to cover the costs of new devices. About 1 million disposable devices are reprocessed every year in the United States. Reports stored in government files document malfunctions related to reprocessed disposable devices, such as cases of cardiac catheters with tips that have broken off inside a patient's heart. Other incidents include infections caused by presumably non-sterile devices, as well as adverse patient reactions to bacterial toxins left after devices are cleaned. The situation is most critical at hospitals, which often lack guidelines on how to reprocess a device. About one-third of all hospitals use reprocessed disposable devices, according to a recent survey.

"It's a pretty grim scene, as far as I'm concerned, with what's going on in the hospitals," said Anne Cofield at a recent meeting co-sponsored by the FDA and the Assn. for the Advancement of Medical Instrumentation. Cofield represents workers at hospital sterilization facilities.

"I can tell you, just in general, there's lots of reuse going on with no protocols, no standards, no nothing," added Patty Stein of Advanced Sterilization Products.

The FDA historically has not considered reprocessing illegal, openly exercising regulatory discretion with those who reprocess **single-use** medical devices. That includes hospital in-house reprocessing facilities, as well as a rapidly growing group of "third-party" reprocessors.

At present, the agency does not require reprocessors to demonstrate that a device is safe after it has been reprocessed. But that might not last long. In a recent letter to the Assn. of Medical Device Reprocessors, the FDA stated that "third-party reprocessing of devices labeled for **single use** is unlawful" unless reprocessors provide documentation that a device is safe.

Manufacturers also are urging the agency to take a stand on the issue of reprocessing. In May, the Medical Device Manufacturers Assn. requested a ban on use of reprocessed

single-use devices. And recently Sen. Richard Durbin (D-Ill.), who is proposing legislation to force stricter regulations on reprocessors, asked the U.S. General Accounting Office to investigate the practice of reprocessing.

Caught in the middle of the controversy is the patient. Doctors are not required to inform patients that a reprocessed **single-use** device will be used on them. Also, the patient is usually billed the same amount, regardless of whether a device was new or reused.

"It is only a matter of time until the public becomes aware in large measure of the reuse situation," said Lynn Schulster of the U.S. Centers for Disease Control and Prevention at the conference in May. "Will they tolerate this practice? This remains to be seen, but for now, reuse is largely unadvertised." The situation sets manufacturers, who want to sell as many new devices as possible, against the rapidly growing industry of third-party reprocessors, who cater to hospitals striving to save health care dollars.

According to the manufacturers, reusable devices are made of durable materials, shaped so they are easy to clean, and tested for multiple use. In contrast, says the association, **single-use** devices are engineered for only one use.

"These devices are intricate, they have sharp points or tightly coiled wires, and they're often made of materials not used to withstanding mechanical or biochemical aspects of reprocessing," said Philip Grossman, a Miami gastroenterologist who is a consultant for manufacturers. Widely reprocessed devices include electrophysiology catheters--long wires guided through a blood vessel into the heart that are used for measuring the organ's electrical activity. Also on the list are angioplasty balloons--thin inflatable devices that unclog arteries--and biopsy needles, used to take small tissue samples.

Rising Costs Drive the Practice

Even as the controversy unfolds, economic pressures are forcing hospitals to consider reuse of disposable devices more than ever.

For example, the cost of two new cardiac catheters during a typical electrophysiology procedure can amount to about \$2,000, said Mark Salomon of Vanguard Corp., one of the biggest third-party reprocessors. This is about 60% to 80% of the reimbursement for the entire procedure, including personnel and surgical costs.

Third-party reprocessors can save the hospital from 30% to 50% of the cost of the devices.

If reprocessing were to be restricted, health care costs for hospitals would escalate, many argue. According to the American Hospital Assn., restrictions on reprocessing could "seriously affect both the quantity and the quality of health care we offer our patients."

Roger Richter, a spokesman for the California Healthcare Assn., said he doubts that a ban on reprocessing will lead to higher reimbursements for procedures.

Reprocessors agree that not all **single-use** devices are reusable. In fact, Salomon said that out of the thousands of **single-use** devices, his company reprocesses only 15 types.

Salomon said Vanguard will reprocess only those devices that

can be successfully cleaned and sterilized. Reprocessing, when done well, does not pose a threat to patients' health, reprocessors say.

But FDA files on adverse outcomes from reused disposable devices in the last few years would seem to argue the contrary. Some involve malfunctioning devices, such as three cases of electrophysiology catheters that broke during surgery.

In one case, the tip of the catheter remains lodged in the patient's atrium. In another, the 4-inch-long tip traveled from the patient's heart to his stomach, leading to additional surgery in which doctors opened the man's stomach in an attempt to remove the tip. The device's manufacturers say they are unaware of any cases in which such a catheter broke during its first use.

Also, cardiac catheters became contaminated with high levels of bacterial toxins in a Colorado hospital.

"One death occurred from this particular outbreak, and these were definitely reprocessed catheters," said Trish Perl, an infection control practitioner at Baltimore's Johns Hopkins Hospital.

But as emotionally charged as those incidents are, FDA officials stress that they are isolated, considering that tens of millions of devices have been reprocessed over the years. And even then, they say, it is hard to prove that a device malfunctioned or spread an infection because it had been reprocessed.

In fact, the FDA has many reports of new devices failing during their first use. And a number of tuberculosis and hepatitis C outbreaks have been linked to devices that were approved to be reused.

"The problem all along, and the reason why we have not exercised any regulatory discretion, is because we have not had really good data with which to project that a certain amount of harm was occurring to the public," said Larry Spears, director of the division of enforcement at the FDA's center for devices and radiological health.

The lack of adverse reports is not hard to envision in a system where tracking of reprocessed devices is poor, manufacturers say. Product failures are often registered as a problem with the device itself, without mentioning that the device was reprocessed.

Health professionals know that using a reprocessed **single-use** device can bring liability, a clear disincentive to report an adverse outcome.

And there is no proper follow-up on patients on whom reprocessed devices have been used. Many participants at the recent conference agreed there is no good tracking, by either hospitals or doctors, of which patients have been operated on with reused devices.

"So we don't really know what's happening to all of these patients. Sometimes complications that can occur look like the complications [that] occur from other things," Grossman said at the conference.

Few Safety Studies Have Been Undertaken

Independent, peer-reviewed studies of reused disposable devices are scarce. The few studies that have been done, experts agree, are not substantial enough to conclude that

reprocessing disposable devices is either safe or unsafe. Other analyses abound that tend to incriminate or absolve the practice of reprocessing--but these are mostly sponsored by manufacturers or reproprocessors, and the results tend to support the sponsor's point of view.

Manufacturers say all they ask of the FDA is a level playing field. Health care in the United States is based on the premise that devices and drugs need to be proven safe before they even go to the market. If it is not known whether reprocessing is safe, manufacturers argue, those devices should not be allowed near patients until their safety is proven beyond doubt.

Right now, if a manufacturer wants to change the label of a device from "single use" to "reusable," the FDA requires it to submit documentation, called pre-market notification, showing that the change in use is safe.

But the FDA does not require third-party reproprocessors to submit similar documentation, even though reprocessing essentially changes the classification of a device from single-use to reusable.

In fact, manufacturers argue that many third-party reproprocessors are not even registered with the FDA. Of an estimated 23 such companies, only seven are registered with the agency.

The FDA is considering several options. One is to force reproprocessors to submit documentation that reprocessed devices are safe. The agency also could request manufacturers to prove that labeling a device as "single use" really means that it can't withstand reprocessing.

"Absolutely, some simpler-looking devices labeled as single-use can maybe be reused. But the burden will be on the person [who wants to find out]," said Josephine Torrente, president of the Assn. of Disposable Device Manufacturers.

In fact, some of the instruments being reprocessed, Vanguard's Salomon said, used to be marketed by manufacturers as reusable before the labels were changed to "single-use."

Others claim that in the past, manufacturers knew that hospitals were reprocessing their single-use devices, and it did not seem to be causing much concern.

"So it appears to many of us that as long as it was just hospitals reprocessing any device, that was not a problem. But as soon as the reproprocessors stepped on the playing field and took too much of the piece of the pie, then there was cause for a concerted alarm," said Kay Watson, who manages sterilization for the Texas Heart Institute.

FDA officials said the agency hopes to have an official position on reprocessing of single-use devices by October.

* * *

Most Frequently Reused

Disposable Medical Devices

1. Anesthesia breathing circuits
2. Electrosurgical devices
3. Respiratory therapy breathing circuits
4. Biopsy needles
5. Electrophysiology catheters
6. Hemodialyzers
7. Cardiac catheters
8. Angioplasty balloons

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HEADLINE: Hospitals Weigh Cost vs. Risk of Infection

BYLINE: By Stuart Drown

BODY:

The battle against germs never ends. It only escalates.

A century ago, a patient entering the hospital for surgery had a better-than-even chance of picking up an infection. Now, only 5 per cent of surgery patients get a new infection as part of their stay.

Still, the Center for Disease Control estimates such infections cost \$ 4.5 billion in 1995 and contributed to more than 88,000 deaths.

And measured by the days patients spend in the hospital, infections have increased more than a third from 1975 to 1995.

Although concerns remain, hospitals are proud of their progress. But the added safety has come at considerable cost. And cost now looms large for hospital administrators who face increased pressure on revenues as Medicare and Medicaid pare their reimbursements.

Nearly a century after hospitals started superheating equipment to kill infectious disease, a debate is raging in hospital operating and board rooms and within government regulatory agencies pitting concerns about the spread of germs against rising costs.

Many hospitals are reusing supplies marked for one-time use, such as \$ 800 heart catheters. In most cases, patients aren't told.

"It's a very volatile subject," said Eleanor Reilly, director of processing services at the Cleveland Clinic. "And it's going to get worse."

The reason: More insurers are turning to capitation, the method for reimbursement where insurers pay a flat rate for a patient or a medical procedure, despite the actual cost to the hospital.

Critics of reusing single-use supplies base their opposition on legal, moral and health grounds.

Complex medical devices can be hard to clean, especially if they are designed to be thrown away. They can harbor new strains of infectious microorganisms that resist antibiotics.

And despite increasingly stringent precautions, hospitals remain concerned about the threat of infection from the human immunodeficiency virus, which can lead to AIDS.

For its part, the nation's \$ 58 billion medical supply industry, which saw its fortunes soar with the advent of single-use products during the 1970s, sees the potential for being sued if a recycled product isn't cleaned properly or falls apart and hurts a patient. Left mostly unsaid: widespread recycling also could cut into sales.

Hospitals have struggled with sterilization policies since doctors and nurses began a systematic effort to stop the spread of germs at the turn of the century.

But each advance of technology and health practices soon was matched by a new, often stronger, infectious microorganism.

"The world of microbes is not getting simpler," William Sanford, chairman of the Steris Corp. of Mentor. Steris makes equipment that sterilizes medical equipment, such as \$ 50,000 endoscope sets, that are designed to be used again.

"You've got global travel exposing more people to more germs and viruses, things like Ebola, (an African-based virus that causes massive internal bleeding and is fatal 80 percent of the time) and an older, more immune-challenged population," Sanford said.

Hospital Peer Review, a professional journal, reported that hospitals routinely resterilize disposable or single-use equipment. Not all hospitals do, however. Both Akron General Medical Center and Summa Health System, which owns Akron City and St. Thomas hospitals, said they do not reprocess single-use supplies.

Recycling doesn't make sense for tongue depressors or rubber gloves, which cost pennies apiece, but for more sophisticated supplies, such as the equipment used in microsurgery, the numbers become more compelling.

In some heart procedures, the amount the insurer pays can quickly be eaten up by the cost of supplies, particularly if a routine operation suddenly turns complicated, the Cleveland Clinic's Reilly said.

If the cost exceeds the payment, "the hospital eats the difference," Reilly said.

Recycling equipment after sterilizing can help offset the loss, some hospitals reason.

The problem is that many devices labeled "single-use-only" really are designed to be used just once. Some cannot be properly cleaned; others break with repeated use.

Josephine Torrente, president of the Association of Disposable Device Manufacturers, points to the plastic staplers used for abdominal surgery as one example.

Reusable steel models are available. But some hospitals clean and reuse the cheaper plastic models that are engineered to be used only once. With repeated use, the plastic stapler's parts, such as the anvil that bends the staple, can become deformed, reducing the tool's effectiveness.

"If the staple is too tight, it kills the tissue. If it isn't tight enough, then the tissue doesn't close and can leak," said Torrente, a food and drug lawyer.

Official statistics on problems caused by reusing one-time supplies don't exist. Some health officials say that means there is no problem. Most cases settled

Torrente said the lack of data should be no surprise. When a reused device breaks inside a patient, or a patient gets infected, hospitals aren't quick to report the news, Torrente said. Most cases are settled out of court and the records sealed, she said.

The Ohio Hospital Association, in a letter to the State Medical Board, said the "single use" label on supplies alone shouldn't deter mine whether the equipment can be safely recycled. While patient safety should be top priority, some devices labeled single use can be resterilized without compromising patient health, the OHA concluded.

"A manufacturer has much to gain and little to lose by labeling as single use' a medical device," the OHA said. The label both limits liability and increases sales, the OHA said.

The Health Industry Manufacturers Association, which represents more than 700 makers of health care devices and supplies, disagrees. It opposes reusing devices labeled for single use as well as efforts by the Food and Drug Administration to require manufacturers of single-use devices to test or label them for multiple use.

The Washington-based trade group also wants the FDA to take a harder line with a new industry that has sprung up to resterilize medical equipment.

In an effort to determine guide lines for what single-use equipment can be reused, the Cleveland Clinic and Steris have spent the last four years testing supplies the clinic uses in heart surgery. Researchers started with simple items such as the tubes used to connect heart patients to heart-lung machines.

The laboratory study was prompted by the high cost of balloon catheters the clinic used in angioplasty, the procedure to flat ten plaque deposits in clogged arteries, said Dr. Fred Cornhill, the clinic's chairman of biomedical engineering.

In their initial study, the clinic and Steris concluded that many single-use devices can be sterilized and used again safely. A follow-up study on more complex devices, such as the balloon catheters, reached a similar conclusion. But in the newer study, which hasn't been published yet, the researchers also conclude that even the most responsible reprocessing program isn't worth the effort because of political, legal and regulatory obstacles.

Sending equipment out to be sterilized isn't the answer either, said Steris chairman Sanford.

"From a practical standpoint, this is going to have to wait until there's more support from the manufacturers," Sanford said.

Sanford believes the situation will become more complicated as more microsurgery is done in out

patient clinics.

Hospitals as a rule are reasonably well-controlled environments, he said. But it will become difficult to maintain the same level of control in the outpatient facilities, he said.

"The challenge will become greater because the cleaning of new equipment with sophisticated requirements then is being done by people who aren't necessarily trained to do sterilization," San ford said. "Our challenge will be to develop sterilization that is easier to use -- foolproof."

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Ms. ESHOO. Thank you Doctor.

Mr. BURR. Mr. Chairman, could I ask unanimous consent for one additional question?

Mr. UPTON. Yes, you may.

Mr. BURR. I just want to clarify one thing. If a hospital unpackages but does not use a sterilized device, is it your position that they are, in fact, a manufacturer when they re-sterilize it for additional use?

Mr. FEIGAL. It depends on how it is labeled. If the original equipment manufacturer provided instructions on how to re-sterilize, then they are using the device in one of the ways that it was intended to be used, which is to have it open and available but be able to close it back up and sterilize it. If the hospital is doing this for other types of products for which there are no instructions on how to sterilize, then we are back in the area of manufacturing. In general though, this is a practice that hospitals know very well how to do and it is part of routine practice, and this is one of the lower priorities on the risk scale for us to address this particular practice of repackaging products which have been opened.

Mr. UPTON. If the gentleman will yield just 1 second, I note on this particular device which I did not open, but somebody did maybe. I do see a warning. This device is intended for one time use only. Do not re-sterilize and/or reuse it as this can potentially result in a compromised device performance and the increased risk of inappropriate sterilization and cross contamination. But if that happened, they open this up and it goes in the trash if they do not use it.

Mr. BURR. I guess my question would go a little deeper, given that the hospital did not repurchase it or resell it.

Mr. FEIGAL. Right. No, that is right.

Mr. BURR. The commerce question comes in and the question of your jurisdiction as well.

Mr. FEIGAL. Yes, that is right.

Ms. BURR. So, can you sort that out for me?

Mr. FEIGAL. Well, that does get back to the issue of where do we get the definition of placing a device into trade. One of the factors that we have thought about is if the hospital is charging for it more than once, they are putting it back into trade, whether they are using something that they own or not. But it is a complex issue. The hospital oftentimes is acting as a third party for the physicians that practice there. And so they, in that sense, are much more like the third party reprocessor than they are the physician who owes the device who wants to modify it in some way and use it in his own practice.

Ms. BURR. But clearly based upon what you have told me, there could be a situation where a device was never used, but it was unpacked, it needed to be re-sterilized, the manufacturer did not have re-sterilization instructions with it, no commerce took place, but they would still be considered a manufacturer when they repackaged it and reused it?

Mr. FEIGAL. If this was something that was a very common practice, it would be a practice that we would say needs to come under some control, because in fact they do not know if they are damaging that product by trying to re-sterilize it. In most cases OEMs

will work with hospitals to provide instructions when a product can be re-sterilized. And if they said it cannot be, I think that the hospitals are taking on the responsibilities of a manufacturer.

Ms. BURR. The FDA does not currently ask for reporting of re-sterilized devices, do they?

Mr. FEIGAL. No.

Ms. BURR. Okay. Thank you Mr. Chairman.

Mr. UPTON. Thank you. Well, as you can tell Dr. Feigal, I was thinking maybe we ought to have a 2-day hearing. We appreciate your expertise and help certainly with our subcommittee. It has been a very good process for all of us. We look forward to seeing the regulations made permanent so that, in fact, we do have some enforceability that is out there. We appreciate your dialog with us, and we look forward to working with you in the future. Again we appreciate having a member of your staff remain to listen to the testimony from the next panel and to be able to respond to questions that may arise. You are formally excused. Thank you.

Mr. FEIGAL. Thank you.

Mr. UPTON. Thank you.

Okay. The second panel includes these individuals, Laurene West, R.N., Dr. Robert O'Holla, Vice President of Regulatory Affairs from Johnson & Johnson, Dr. Philip Grossman, Dr. John Fielder, Professor of Philosophy, Ethics, at Villanova University, Mr. Vern Feltner, President of Alliance Medical Corporation, Dr. Bruce Lindsay, Associate Professor of Medicine at the Washington University School of Medicine, Dr. Walter Maurer from the Cleveland Clinic on behalf of American Hospital Association, and Dr. Griffin Trotter, Center for Healthcare Ethics at Saint Louis University.

I appreciate all of you being here this afternoon. As you may understand all of us are on multiple subcommittees. It seems like they are all meeting today. In addition to votes on the floor, and because this hearing has gone much longer than anticipated when we started, members scheduled are being telescoped so we will see a number of members coming in and out. We have a general rule that we would like you to limit your remarks to 5 minutes. As I am not real careful with the gavel, I will try to be a little more attentive to that clock. As you understood, I think, your testimony in its complete form is made already part of the record as earlier made under unanimous consent. As you may have also heard, it is our committee practice always to take testimony under oath. Do any of you have any objection to that? Seeing none, we also allow under committee rules the possibility of you being represented by counsel. Do any of you need counsel to represent you at your own expense? And last then, if you would rise and raise your right hand.

[Witnesses sworn.]

Mr. UPTON. Okay. You are now under oath and we will start with Ms. West, if that is okay. Also for those behind you, particularly if you would make sure that you bring that microphone close to you, it would be helpful for all in the room. With the clock, a little warning light will go on with a minute to go, if that is okay. I can change that if you do not like that, but that is the way it will be. Ms. West, we recognize you.

Ms. WEST. Thank you.

Mr. UPTON. Go ahead.

STATEMENTS OF LAURENE WEST; ROBERT H. O'HOLLA, VICE PRESIDENT REGULATORY AFFAIRS, JOHNSON & JOHNSON; PHILIP GROSSMAN; JOHN H. FIELDER, PROFESSOR OF PHILOSOPHY, ETHICS CONSULTANT, VILLANOVA UNIVERSITY; WALTER G. MAURER, CLEVELAND CLINIC FOUNDATION, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION; VERN FELTNER, PRESIDENT, ALLIANCE MEDICAL CORPORATION; C. GRIFFIN TROTTER, CENTER FOR HEALTHCARE ETHICS; AND BRUCE D. LINDSAY, ASSOCIATE PROFESSOR OF MEDICINE, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Ms. WEST. Mr. Chairman, members of the committee, I appreciate the opportunity of expressing my concerns this morning, actually this afternoon, sorry. I am here today not as a spokesperson, not as a lobbyist for any group that is paying me, but as a classic example of a patient who has suffered from the reuse of a single-use device. My perspective on this pandemic healthcare issue comes from not just being a patient, but also having been a registered nurse with a critical care certification and current licensure for 25 years.

There are actually two ways that a single-use device can be used twice. One is if you have an incompetent staff member who does not follow sterile procedure and is using the device for the second time. And then second, as we have just talked about, the sterilization of a device, excuse me, autoclaving a device, perhaps, to make that single-use device into a multi use device. My personal example falls into category one which comes from an incompetent staff member not following sterile procedure. Just a little bit of history so that you will understand why I was in this position. In 1983 I was diagnosed with a tumor in the center of my brain and, in order to remove that tumor, I went through a procedure which is called a transsphenoidal hypophysectomy.

I can describe that for you, but there are some people that perhaps would prefer not the clinical aspect of that. In order to get to that part of the brain the surgeons need to go through the bottom of the brain. So they went through my sphenoid sinus in order to do that. And while I was having that surgery there was a break in sterile technique. I was exposed to and infected by the bacteria known as staphylococcus aureus commonly known as staph. And because that infection was acquired during a hospital stay it is referred to as a nosocomial staph infection. And I have actually battled that infection for 17 years. As the purpose of this hearing is to describe the reuse of single-use devices, I am going to concentrate my testimony on an incident that occurred when I was ill in 1988.

I had had two surgeries that year to remove infected bone from both my head and my facial structure in an effort to try to prevent Meningitis. Meningitis is where the infection is collected on the outside of your brain. The cultures that were taken of the bacteria in my head indicated that the bacteria had mutated to the point that I was no longer sensitive to any antibiotic other than one called Vancomycin which needs to be administered intravenously.

So, I was admitted to the hospital and what is referred to as a central line was inserted. That goes into your antecubital vein, it is threaded up into your arm, and up into the superior venacava of my heart.

For the first day I had a phenomenal nurse who followed sterile procedures. She changed the needles, she changed the tubing each time she hung the doses of Vancomycin. However, the next day I did not have such luck. The nurse who took care of me, as she took the needle out to end the dose, she put the needle on the table. My thought was well, you know, that is the end of the dose. The sterile procedure is that you would then hang a new bag, put new tubing, put a new needle on there. She did not do either, and before I realized what she had done she had picked the needle up off the bedside table, without any cover, not even wiping it off with an alcohol swab and then put that back into my central line which flowed directly back into my heart. Actually I would have been much better off had I just taken care of myself at home.

My physician ordered blood cultures because we needed to know what additional bacteria that I was now exposed to. It is flashing red. Have I already gone 5 minutes?

Mr. UPTON. You have.

Ms. WEST. Okay. I will make this very, very quick. In order to save my life, I went on a regime of three IV antibiotics. I have continued to suffer from that process of having had that device reused. I will skip over just very quickly that the reuse of a vital medical device can be a result of a bad habit, a result of not having appropriate quality assurance within a facility. However, every organization has a responsibility of maintaining a patient relationship that allows for a sterile procedure. As we are mutating bacteria year by year, the essentiality of sterilization is more, and more, and more important. As patient we deserve the right to be given treatment by trusted, trained professionals.

Very quickly I will explain that. The implementation of the 1996 Health Insurance Portability and Accountability Act known as HIPAA-96, that was intended to standardize and simplify administrative procedures for nurses, who are currently spending 50 percent of their time taking care of paperwork. So if there is proper implementation of the HIPAA legislation, then we then have nurses back on the floor who can monitor, and train, and certify and make sure that devices are not reused. Since I am over my time, I would be happy to answer any questions that you have. I appreciate the opportunity of sharing with you part of my story and hope that we can find a way so that all patients have access to quality care.

[The prepared statement of Laurene West follows:]

PREPARED STATEMENT OF LAURENE WEST

Mr. Chairman, members of the committee, my name is Laurene West. I would like to ask that my full statement be inserted into the record of this hearing.

I am here today not as the spokesperson or lobbyist for any organization, nor for any group that is paying me to testify—but as a classic example of a patient suffering from the results of a re-used, single use biomedical device. My perspective on this pandemic healthcare issue is derived from being both a patient and a Registered Nurse with Critical Care Certification and Licensure for 25 years.

There are two ways in which single-use devices can be re-used; 1) staff incompetence or failure to follow sterile procedures and perhaps inadequate training 2)

cost containment but high risk procedures of autoclaving single-use devices to become multi-use devices.

My personal example falls into category 1—*staff incompetence or failure to follow sterile procedures and equally likely, inadequate training.*

In 1983 I was diagnosed with a tumor in the center of my brain. The tumor was surgically removed by a procedure called a Transsphenoidal Hypophysectomy. During my surgery there was a break in sterile technique and my brain was exposed to and infected by the bacteria staphylococcus aureus, or more commonly known as staph. Because this infection was acquired while in the hospital, it is referred to as a nosocomial staph infection.

As the purpose of this hearing is to describe incidents directly related to the re-use of single use devices, my testimony will concentrate on an incident in 1988 where this common, hospital wide, cost saving practice nearly took my life.

1988 was a rough year. I had two surgeries within three months trying to prevent meningitis—which is where the lining of the brain becomes infected. The infection in my head had traveled to my frontal sinus and the cultures revealed that the staph had mutated so that it was no longer sensitive to any antibiotic except Vancomycin, which must be administered intravenously.

I was admitted to the Hospital, a central line was inserted via my antecubital vein into the superior vena cava of my heart. For my first day, I had a wonderful nurse who followed sterile procedure correctly, used only new IV tubing and needles as appropriate—and my temperature of 104 degrees began to decline. However, my next nurse, a foreign national, barely able to speak English, did not follow sterile procedure. When the current dose of Vancomycin had been infused, she took the needle out of the mainline and laid it on the bedside table. I assumed this was her way of reminding herself that she needed additional tubing and a new needle for the next dose. The correct procedure for administering the next dose would have been to hang the Vancomycin with new tubing and a new needle. However, she did neither. Before I realized what she was doing, she re-inserted the old needle with the old tubing into the mainline for that dose of the antibiotic. *The damage was done—I had now been contaminated with additional bacteria from the table.* Within 12 hours my temperature had spiked to 108 degrees and I developed septicemia, meaning that the infection in my head had traveled to my blood system as well.

I would have been better off taking care of myself at home.

My physician, ordered blood cultures drawn so that he could determine if there were additional bacteria causing the increased temperature. However, my rapidly deteriorating condition caused my doctor to immediately start a regime of three IV antibiotics, each with exhaustive lists of negative side effects, to save my life.

I was *very lucky* and after weeks of therapy, recovered from the sepsis and returned to my normal battle with just the routine staph infection.

My case is only one of a *vast undocumented number of similar if not worse life-threatening stories.* Most patients entering the hospital or clinic do not understand what is happening to them and without a clinical background they do not know they need to be cautious. They go into a facility, *trusting that they will receive the best possible care from trained and responsible professionals.* They don't know the difference between a single-use or multi-use device.

Earlier in my testimony I referred to two ways single use devices can be reused. I suffered from professional incompetence and the failure of an allegedly trained professional to follow appropriate procedures.

The reuse of a biomedical device could simply be the result of bad habits not recognized during training and quality assurance review. A health care organization has constant follow-up and training responsibilities in every single patient relationship. With infection rates growing and bacteria being mutated to new forms that are no longer sensitive to existing antibiotics, the essentiality of sterilization is of the utmost importance for patient safety.

The implementation of the 1996 Health Insurance Portability and Accountability Act, known as HIPAA 96', is intended to standardize and simplify administrative procedures, known as paperwork. Currently nurses are spending 50 percent of their shift time on these administrative procedures. Appropriate implementation of HIPAA 96' would allow for greater time spent in training, practice certification and supervision of licensed caregivers. Put nurses back on the floor taking care of patients rather than doing paperwork.

Category 2, reuse of biomedical devices as a cost containment effort, is either sanctioned or not sanctioned by the health care organization. If the organization chooses to reuse these devices firmly labeled as single use, they are violating the implied sterilization warranty and putting patients at high risk of infection. This ultimately increases patients morbidity and mortality rates.

This silent epidemic radiates throughout healthcare, from large acute care facilities to home health agencies and nursing homes—regardless of the owner organization. I have shared with you my own story but can give you example after example of things that I have seen and heard from other healthcare professionals and from the 55 million patients I represented last year on the Year 2000 Project as the National Patient Advocate.

- Autoclaving IV tubing for second and third patient use.
- Autoclaving Pacemaker wires for use on additional patients
- Saving neonatal ambu-bags and pulse oximeters without being autoclaved, to be given to 3rd world countries.
- Subclavian guidewires autoclaved to be used on additional patients
- Suction catheters being used by multiple patients without any cleansing process in-between patient contact.

Most caregivers are not able to document cases of increased infection, morbidity or mortality from the re-use of single use devices as doing so would cause them to lose their jobs.

Ladies and Gentlemen, healthcare must be driven by quality, compassion, honesty, and with respect for the rights and wishes of the individual. It must be provided by trained and competent staff.

I offer my assistance in any way possible to this committee or any organization to help further awareness of this issue, to help better train hospital staff and make patients more enlightened consumers.

I want to thank the members of the Committee for allowing me to testify today and will be happy to answer any questions you may have.

Mr. UPTON. Thank you very much.

Mr. O'Holla?

TESTIMONY OF ROBERT H. O'HOLLA

Mr. O'HOLLA. Good afternoon, Mr. Chairman. Thank you. Members of the committee, my name is Robert O'Holla, I am Vice President of Regulatory Affairs for the Medical and Diagnostic Group at Johnson & Johnson. I am also Chairman of the Association of Disposable Device Manufacturers, you have come to know as ADAM. Mr. Chairman, I would like to thank you and Mr. Bliley for raising the visibility of this important issue through this hearing and also by introducing a bill along with Congresswoman Eshoo on this issue.

I am going to do my best to control my passion for the issue this afternoon. I have worked for approximately 30 years in the medical device industry, and I am seriously concerned that anyone would attempt to clean and reuse a medical device that was designed for use in a single patient and approved by FDA for only one use. Just as concerning, and I share the concern raised by this committee all morning, was the apparent disinterest on the part of FDA until very recently in this threat to the health and safety of U.S. patients. I have submitted my written testimony, but because my time is limited, today I would like to concentrate on just one aspect: The threat that reprocessed single-use devices present to quality healthcare for patients. The evidence for action is clear to me. There are reports of two patients who have been blinded in one eye, a premature baby whose foot was burned, increased pneumonia rates in children, and a 32 year old woman who we heard about earlier this morning who has a piece of metal lodged in her heart.

In addition, ADAM members have retrieved approximately 1,000 reprocessed devices from hospitals where they were awaiting use in patients. The results of the tests are chilling. Approximately 75 percent of the samples collected failed either due to the presence

of blood and/or proteinaceous matter, bacterial contamination, functional failures, or defective packaging leading to non-sterile devices. And I brought some pictures along so you can have some appreciation for what we found. I would like to note that these are not unique pictures. These are representative of what we found. The first photograph shows a piece of proteinaceous material that was ejected from a reprocessed surgical clip applier when we fired it in the laboratory. This is a device that is used to close bleeding blood vessels. That piece of material is not actual size by the way. That is about a quarter inch to an eighth inch piece of material that would have been injected into the next patient. The interesting thing about this is that as we tried to fire the device further, there was so much tissue in the mechanism of this device that the device clogged and became nonfunctional.

The second picture is in the anvil of a surgical stapler contaminated again with similar material. The next set of pictures we see a reused electrophysiology catheter that pulled apart while inserted in a second patient's heart making it difficult for the doctor to remove. Last is a photograph of another electrophysiology catheter. What we see is contamination with tissue residue. We found that this residue was indeed one that caused a marked increase in blood clot formation. In addition to all of this, FDA's own data indicate problems with the reuse of angioplasty catheters, electrophysiology catheters, and biopsy forceps. One FDA study revealed that the tiny tubes inside reprocessed angioplasty catheters were often kinked and clogged with blood and cleaning chemicals. Most disturbingly, some reprocessed balloons ended up being at least one size larger than they were supposed to be.

Now, the proponents of reprocessing have said that they do not put patients at risk and they have no evidence that the practice is unsafe. Yet, by simple random sampling and without any trouble we found reused products that clearly increased the risk to patient's health and safety. A large portion of the devices we found were non-sterile. How many infections and more serious diseases such as Hepatitis-C and perhaps even HIV, have been spread to unknowing patients as a result of this practice? The sad answer to that question is, we do not know because nobody has been looking. There is a clear increased risk of disease transmission and functional failures. Is this an acceptable standard for medical device performance, or are we just inviting an increase in medical errors? It certainly is not the standard that FDA has applied to new medical devices for the last 24 years, and should not be the standard applied to reprocessed devices. It is time that FDA enforced the full requirements of the law so that the second, third, or sixth patient has the exact same level of FDA protection FDA oversight provides to devices used on the first patient. No other standard is acceptable. Thank you.

[The prepared statement of Robert H. O'Holla follows:]

PREPARED STATEMENT OF ROBERT H. O'HOLLA, VICE PRESIDENT OF REGULATORY AFFAIRS, JOHNSON & JOHNSON

Good morning, Mr. Chairman and members of the Subcommittee. My name is Robert O'Holla and I am Vice President of Regulatory Affairs for the Medical Devices & Diagnostics Group at Johnson & Johnson. I am also Chairman of the Association of Disposable Device Manufacturers, a trade association of single use medical

device manufacturers. Thank you for the opportunity to address this important patient health and safety issue. I have worked for 30 years in product development, quality assurance, microbiology and regulatory affairs. As a long time professional in this area, I cannot understand why anyone would believe it is acceptable to clean and reuse a delicate, complex medical device that was designed for use in a single patient and approved by FDA for only one use. Just as concerning is the apparent disinterest on the part of FDA until very recently in this threat to the health and safety of patients.

FDA has said that it is now going to regulate the practice of reprocessing. I hope that means that FDA is now going to apply all of the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). No evidence of harm is needed before FDA can and should apply the law. The FDCA and its implementing regulations establish a presumption that all medical devices are unsafe, and require that the safety and effectiveness of new or substantially modified devices be affirmatively demonstrated prior to their introduction into interstate commerce. Claiming that a single use device may be reused causes the device to be treated as a new device under FDA's regulatory scheme. Yet, for years FDA has chosen to ignore this clearly stated Congressional intent by allowing reprocessed single use devices to be used on patients without requiring or reviewing the necessary data to establish their safety and effectiveness.

Risk to Patients

FDA is aware of reports of two patients who have been blinded in one eye, a premature baby whose foot was burned, a thirty-two year old woman with a piece of metal lodged in her heart, and increased rates of pneumonia in children.

Nevertheless, FDA's first step in regulating reused devices was to improperly shift the burden by refusing to require that reproducers demonstrate safety and effectiveness of their products, and suggesting instead that OEMs provide data regarding the risks associated with reprocessing. Despite this improper move, the original equipment manufacturer (OEM) industry expended substantial effort to test reprocessed single use devices. The data from that testing, all of which has been submitted to FDA, overwhelmingly demonstrates serious safety issues. Moreover, FDA's Office of Science and Technology (OST) simultaneously generated its own independent data confirming the risks of reusing certain single use devices.

At least nineteen scientific studies involving approximately 1000 individual devices have been submitted to FDA on this topic. These studies have been conducted by independent scientists, hospitals, OEMs and, as mentioned above, FDA's own laboratory personnel. Many of the devices used in these studies were obtained directly from hospital shelves where they were "ready for use" in seriously ill patients—patients suffering from cancer or heart disease, and requiring major abdominal, cardiovascular or thoracic surgery.

Devices studied included biopsy forceps, angioplasty balloon catheters, electrophysiology catheters, surgical trocars, staplers, papillotomes, and other general surgical instruments. Approximately 75% of the samples studied failed, either due to the presence of blood and/or proteinaceous matter, bacterial contamination, non-functionality, or defective packaging. In each of seven studies of reprocessed biopsy forceps, a lack of sterility assurance was reported in over 45% of the samples tested. This particular failure was not unexpected. As recently as last October, FDA issued a warning letter to one of the largest commercial third-party reproducers specifically citing the reproducer's failure to adequately validate the sterilization process. These studies also found devices with mismatched parts, a scalpel blade designed to be blunt that was, instead, sharpened, a surgical stapler contaminated by a large piece of proteinaceous matter, and devices lacking warnings about latex content. These nineteen separate studies clearly demonstrate that reusing a single use device may seriously compromise the integrity and subsequent safety and efficacy of that device.

To date, FDA has failed to make public any study reports summarizing OST's data. Nonetheless, public presentations by OST scientists clearly indicate that these findings include safety and effectiveness concerns with percutaneous transluminal coronary angioplasty (PTCA) catheters, electrophysiology catheters, and biopsy forceps. One presentation revealed PTCA catheters with non-patent lumens, crimped guidewire lumens, and plugged balloons or balloon channels. In some instances, cleaning chemicals and blood could not be removed from the device lumens. Some reprocessed PTCA balloons varied in size by more than 10% of the approved specifications. As a result, a cardiologist has no assurance he or she will get the particular balloon size intended for the patient.

FDA has failed to acknowledge the demonstrated patient safety risks associated with reprocessing single use devices despite volumes of data to the contrary. Reproc-

essing amounts to a misuse of medical devices that can only add to the nation's preventable medical error rate. The agency's Congressional mandate to protect the public health will not be served by reversing the burden of proof and awaiting a proven public health disaster before taking action.

Requirements of the FDC Act

The FDC Act requires that, prior to their introduction into interstate commerce, all new medical devices must be FDA-cleared or approved through the premarket notification (510(k)) or premarket approval (PMA) process. This process requires submission of data by the party that intends to market the device. For a single use device, the OEM demonstrates that the device is safe and effective for use on a single patient in a single procedure, and the device is then cleared/approved for only that use. Under FDA's own rules, reprocessing significantly modifies a single use device by changing its intended use to multiple use, creating, in effect, a "reusable" device. FDA requires manufacturers of single use devices that wish to market those devices as reusable to submit a new 510(k) or PMA, including data to support the safety and effectiveness of the device for multiple use, prior to marketing the device for that new use.

FDA agrees that reproprocessors of single use devices are manufacturers under the FDC Act and its implementing regulations, and, as such, reproprocessors are subject to the provisions of the FDC Act that require manufacturers to obtain clearance of a 510(k) or approval of a PMA. Despite this recognition, the agency clearly announced its intention to permit reprocessed single use devices to be marketed without its prior clearance/approval, and, to date, has subjected them only to some degree of post-market regulation. In a letter dated July 9, 1999, FDA stated that, "third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements." However, the agency then reversed itself by announcing in the same letter that "FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements." This unjustifiable use of enforcement discretion is perpetuated for many reprocessed single use devices under FDA's recently issued strategy for regulation of single use device reprocessing.

The FDC Act requires pre-clearance of reprocessed single use devices by all device manufacturers, whether they are OEMs or reproprocessors. The Medical Device Amendments of 1976 (MDA) were enacted for the purpose of implementing pre-market review of devices because Congress was concerned that post-marketing regulation of medical devices was inadequate to protect the public health. The design of the MDA is consistent with Congress' belief that post-market controls are insufficient to regulate medical devices. In today's world of increasingly complex medical devices and heightened concern over disease transmission, the regulatory discretion FDA has proposed to use under its new strategy, is inconsistent with Congress' intent. In enacting the MDA, Congress' goal was to protect patients from unsafe and ineffective devices, regardless of the identity of the device's manufacturer. As such, there is no justification for a patient to receive less protection from FDA merely because the device used for the patient's treatment is a reprocessed single use device rather than an FDA-cleared reusable device. FDA is, in effect, creating a *de facto* exemption from the premarket review requirements for most reprocessed single use devices "and in doing so, is violating its Congressional mandate.

FDA's Disparate Treatment of OEMs and Reprocessors is Illogical

FDA acknowledges that it has not regulated OEMs, third-party reproprocessors, and health care facilities in the same manner with respect to single use devices. For example, in order to market a single use surgical stapler for use in multiple patients, an OEM must first obtain clearance of a 510(k) from FDA. A reproprocessor that wishes to market that same stapler for use in multiple patients is currently free to do so without a 510(k). Not only is this dichotomy arbitrary, it is also illogical since only the OEM has full knowledge of the design criteria and performance specifications of the device and thus is in a far better position than the reproprocessor to determine whether the device can be reused.

In the FDA's November strategy, the agency lists the seven requirements of the FDC Act to which OEMs must adhere: 1) registration and listing; 2) premarket notification and approval requirements; 3) submission of adverse event reports under the Medical Device Reporting regulation; 4) manufacturing requirements under the Quality Systems Regulation; 5) labeling requirements; 6) Medical Device Tracking; and 7) Medical Device Corrections and Removals. Of these requirements, FDA acknowledges that reproprocessors have only been subject to four "registration and list-

ing, QSR, labeling requirements, and MDR reporting requirements. This unequal treatment has no justification in law.

Moreover, this unequal treatment also seriously compromises public safety. Devices are being marketed that have not been demonstrated safe and effective as required by law. FDA is effecting a double standard that lowers the burden for reproducers as compared to OEMs. The protection of U.S. patients requires that FDA regulate all manufacturers in the same manner, regardless of whether those manufacturers are deemed OEMs or reproducers.

Conclusion

FDA must quickly establish timelines for enforcement of the 510(k) and PMA requirements on all reprocessed single use devices. The FDC Act requires FDA to protect U.S. patients from unsafe and ineffective medical devices before they cause patient injury. Such injury has already been attributed to reprocessed single use medical devices. Proper regulation of these devices, including enforcement of the pre-market submission requirements, will prevent further injury and protect patients.

Mr. UPTON. Thank you very much.

Dr. Grossman?

TESTIMONY OF PHILIP GROSSMAN

Mr. GROSSMAN. Mr. Chairman, honorable committee members, and guests, good morning. My name is doctor——

Mr. UPTON. Good afternoon.

Mr. GROSSMAN. You are right. Good evening, actually. My name is Dr. Grossman. I am a practicing gastroenterologist in Miami, Florida, a Clinical Associate Professor of Gastroenterology, but I have spent my entire adult life as a patient advocate. I want to thank both Chairman Bliley and Upton for holding these hearings and for inviting me to participate. Like many of you I am somewhat heartened by the recent iteration of the FDA proposals because they address many of our prior concerns, but they certainly do not go far enough and in my opinion certainly do not get us there fast enough, and I think the time is clearly now to act. I find myself shaking my head in disbelief every day that this continues.

In simple terms let me explain to you what this is about. Medicine has gone through an evolution to less invasive procedures. There have been devices that have been designed, created, and built to foster that improved healthcare and perform a specific task. They were not built to achieve the ability to reuse. They were built to achieve the ability to take better care of patients. What are the implications? They allow us to repair blocked coronary arteries without open heart surgery. They allow us to remove benign and malignant polyps without a laparotomy, and for the first time in our country they allow for a national initiative to prevent colon cancer using safe and effective techniques. But to achieve this ability their very construction is somewhat unique. They have sharp points, they have tightly coiled wires, and they have very, very narrow lumen to permit the flexibility and mobility required in many of these areas. This allows them to do the job, but does not necessarily allow them to be cleaned.

Imagine being at home trying to clean the inside of a swizzle stick and then using it again. What are the consequences or the potential consequences of reuse? Infection, major concern. Lost function. If I take one of these devices in my hand to care for a patient and it fails in the middle of the procedure, it is not a question of dollars and give me another one. It may fail in a time and place that causes great harm to that patient. There is risk from chemical

toxic injury from the reprocessing solution and finally, there is even a risk of misdiagnosis. There is a case I am familiar with where a patient underwent esophageal surgery for a diagnosis of esophageal cancer, but at surgery there was no cancer. It was believed that the tissue from which the diagnosis was made was residual tissue left inside the tiny cup in the biopsy forceps, and perhaps somebody could put a picture of the biopsy forceps up.

In essence, if we permit what amounts to the recycling of medical waste, these consequences will confront us day in and day out. I implore you, do not be misled by the proponents of reuse who tell you there are no complications, there are no problems, and there are no dead bodies. The reason is that nobody is counting, and if you do not go looking and if you do not count, you do not find it. There has never been a prospective study investigating patients before procedures, looking at their HIV status, their hepatitis status, and then bringing them back every month for a year to determine if, in fact, they have suffered a consequence. It is easy to say that it is not there. We are creating a potential generation with infectious time bombs. The incubation period for Hepatitis-C alone is over 6 months. These patients are not followed during that time. If you look at the biopsy forceps that is up there, you can start to see why these problems occur. I agree with the FDA that this is a high-risk device. My concern that the loop hole for exemption may allow it to escape and go beyond the protection that the law intended.

I would like to comment on informed consent for a moment, and that is until the FDA actually embarks on device by device review and approval, there will be two standards of care in this country. I believe patients have a right to know. And if the people who think that this is so safe really believe it, I see no reason why they should not be bragging about it. In the last group, your healthcare workers, the unsung heroes who are being exposed to unnecessary risk by handling these contaminated devices. My conclusion would be and my hope for this committee, the final answers may not be in, but if reasonable doubt exists and reasonable doubt does exist, we must err on the side of patient safety and patient well-being. I thank you for your attention and particularly thank you for your leadership.

[The prepared statement of Philip Grossman follows:]

PREPARED STATEMENT OF PHILIP GROSSMAN

INTRODUCTION:

My name is Philip Grossman, MD., F.A.C.P., F.A.C.G., I am a practicing Gastroenterologist in Miami, Florida, and Clinical Associate Professor of Medicine and Gastroenterology at the University of Miami School of Medicine. I am submitting this written testimony to address the following subject not because of any titles, but primarily as a family man and a concerned citizen. I feel very strongly about this issue and have traveled from Florida to provide both written and oral testimony. I applaud your efforts to protect United States citizens.

THE PROBLEM:

The problem we are facing is the reuse of medical devices that were designed, manufactured, tested, packaged, and labeled for the sole purpose of a single use in a single patient. These are devices for which the very approval from the FDA is contingent upon information submitted, including the fact that these devices are to be disposed of after a single use. Reprocessing refers to the cleaning, packaging, and

attempt at resterilization of a single-use medical device which was used on a patient for its intended purpose and which will then be used again on another patient.

Some single-use medical devices, for example, biopsy forceps, are critical devices, which, according to the Spaulding Classification, are those which routinely break the mucus membrane, thereby coming into contact with sterile tissue or the vascular system. Critical devices carry a much higher level of risk when reused than do non-critical or semi-critical devices, which would include endoscopes—devices which in themselves have been associated with disease transmission even in the absence of sharp points and coiled wires. The core of this matter is not the paperwork, labeling, or the official box these devices fit into, although these factors are important as well. Rather, the core issue is the actual reuse of single-use devices in real, live people—husbands and wives, parents and children, brothers and sister.

The scope of this problem is broad. It encompasses a wide range of devices in multiple specialties and includes biopsy devices, cardiac catheters, and various access-related devices used in gastroenterology, urology, and cardiology, as well as other specialties. This issue has become increasingly controversial as more healthcare facilities consider reuse of single-use devices as an attempted means of cost containment. According to a survey published in 1997 by ECRI, a non-profit health service research firm, approximately one-third of healthcare facilities reused medical devices labeled for single use, and 25% more were considering the practice (Costerton).

I must be clear though that I am discussing used single use devices not single use devices that were opened prior to a procedure and then not used. An unused single use device presents less risk to the next patient. In a recent issue of OR Manager, 250 hospitals were surveyed on this topic. Of the devices that were being reprocessed, 80% of them were open but unused devices. Hospitals must look to the manufacturer's instructions to determine if these devices can be resterilized. These are not the devices that are being discussed here. I will focus my comments on the reuse of used single use devices.

OVERVIEW:

Devices are designed for single use only

No matter what the specialty—gastroenterology, cardiology, or urology—single-use devices are specifically designed from inception for safety and performance. Therefore, the very design structure did not take into account the need to access all the nooks and crannies in order to clean them. The research, development, and design of the structure focused on a safe, effective product to be used once. An analogy to this situation might be as follows: You are asked to design a car to take a family of two adults three blocks from their home. However, it is only later that you find out that this car needs to transport eight schoolchildren fifteen miles away. But the car is six seat belts short. As with the design of the car, the design and all of the safety features of a single-use device make it totally suitable for the purpose for which it was created but do not automatically apply when the rules are changed. That's what this problem is about.

Proponents of reprocessing may maintain that reuse is safe and vital as a measure to reduce healthcare costs; however, a preliminary FDA study uncovered dozens of reports of infection, chemical injuries, and mechanical failures associated with reusing equipment designed to work just once. Although reprocessing single-use devices had been widespread abroad; France has prohibited such reuse, and other countries are looking at the issue.

Design features make cleaning/reprocessing a problem

Single-use devices have a number of common features:

1. They tend to be very small and intricate.
2. They typically have complex wiring systems, such as diagnostic wiring that carries an electronic signal for measurement, or mechanical wiring that operates the working portion of the device much like a remote control tweezer or remote control cane.
3. Because many of these devices are used for the purpose of removing pieces of tissue or altering tissue during a procedure, they typically have sharp points and sharp edges.

The problem is that the very structure just described that makes the device work so safely and effectively in its intended use is the same design that precludes the ability to access its nooks and crannies and that encourages human debris to get caught in tightly woven wires or on sharp points. In essence, the success of these devices is what makes them such a risk in terms of the inability to clean them for reuse. The basic tenet in the world of microbiology is: "If you can't clean it, you can't sterilize it!!!"

Devices designed to be reusable differ from reprocessed single-use devices

Manufacturers are required to conduct additional testing for devices that are intended to be reusable. They must meet FDA criteria to validate that a device can be cleaned and resterilized multiple times. Data supporting reuse must be submitted to the FDA through the premarket notification process. FDA is not enforcing these same regulations against reproducers of used single use devices.

Many devices, whether labeled as single-use or reusable, may appear identical. However, the devices may not include the same materials or internal components. For a number of reasons, manufacturers may change the materials used in production. Changes in materials may not be obvious on visual inspection, but unless the device is specifically labeled “reusable,” the new materials may not be able to withstand the heat or chemicals required for resterilization, particularly on a repetitive basis.

Fallacies of cost savings with reprocessing

In an effort to control costs, some hospitals have taken the position: “If a device costs \$50 and it is used just once, it costs the full \$50. If a device costs \$50 and is used ten times, it costs only \$5 per use.” The two fallacies of this position are:

1. It reduces human risk solely into dollars per session; and
2. There are very real costs associated with processing a device for a second or subsequent use. Devices are either reprocessed in-house (at the hospital) or are outsourced to the new industry of device reproducers. Device reproducers take the devices from the hospital (much like dry cleaning) and later return them, typically charging approximately 50% of the cost of a new device. So, it’s not an issue of \$50 vs. \$0. When you factor in the cost of the reproducer, as well as the hospital’s cost of labor in preliminary cleaning, nursing time, as well as plastic bags, labeling, etc., the actual costs of reprocessing increase significantly.

Devices being reused that are not intended for that function are in fact being reused at risk to the patient—as a cost saving measure. Because of the very nature of these devices, well meaning people wanting to do a good job may still not be able to adequately make single-use devices safe and appropriate for the next person.

Cost of failure

In addition to the issue of patient risk, there is a genuine cost, both medical and economic, to a device which now performs at less than the standard for which it was built. It may result in a delayed procedure, damage to other medical devices, for example, endoscopes, higher complications, and/or greater risk to the patient as well as the medical personnel. In fact, the entire economic issue may become lopsided beyond recognition when one actually weighs the economic cost of an injured patient whether due to infection or device failure, against the acquisition cost of single-use devices. It may take decades to break even following such an adverse event.

DISEASE TRANSMISSION:

Reports document disease transmission

Extremely well documented reports and additional medical literature confirm that diseases that have been transmitted from patient to patient have been tied to improperly reprocessed medical scopes and devices. Two reports documented the transmission of tuberculosis and the transmission of hepatitis. Both of these studies were documented with DNA fingerprinting—that is, researchers were able to actually demonstrate that the exact DNA of the organism identified from patient #1 was also found in patient #2—on whom the same scope had been used. Scopes were implicated in these reports, and scopes *do not* have sharp points. If you take a tweezer-like device with a tiny spike in it and stab it into tissue, then reprocess the device and stab it into someone else’s tissue, it does not take a leap of the imagination to understand why disease transmission is of great concern.

A fallacy: cleaned and sterilized equals safe

Some argue that because a device is cleaned and sterilized, it is therefore safe. This view is faulty for the following reason: some devices are constructed in a way that make it literally impossible to properly clean. In order to clean in between wire segments, you would have to literally unravel the device. An analogy would be: If in order to get a pair of stretch pants properly cleaned, you have to remove the elastic before taking them to the cleaners, thus rendering them useless in the future.

When devices are reprocessed, whether in a hospital or by outside contractors, there is a human chain of activity—that is, a series of human events where people perform a variety of tasks. Even with well meaning and competent people doing this task over and over, there is still a possibility for human error, which magnifies as

the number of steps and number of people increase. When the task involved in the process is repetitive, tedious and arduous, the likelihood of human error along the way is further multiplied. Everyone agrees that any human error, whether from inadequate cleaning, scrubbing, or delay, makes it impossible to properly reprocess a device and may be the cause of disease transmission. Compare that to the patient lucky enough to be the recipient of a first-use device—where the device comes out of a manufacturing plant which is inspected and whose processes are regulated and monitored by the FDA, has an established Quality Assurance process, and complies with stringent published standards for microbiological testing. There is essentially no concern about the possibility of error association with a repetitive human chain because, compared to the alternative, the device comes out assuredly sterile.

Devices may be pooled in reprocessing

If a hospital farms out its devices, hospital personnel are supposed to do a preliminary cleaning. The devices are then placed in a bag, picked up by the reprocessor, taken offsite for reprocessing, and returned. It is not uncommon for reproprocessors to return a similar but not identical device. For example: You're a reprocessor. I give you Catheter A from my hospital, and some time later you give me back a ready-to-use Catheter A that came from a general pool of Catheter As from various facilities. My staff, over whom I have control, may have done a great job with the preliminary cleaning of our Catheter A devices, but we got back someone else's catheters. Therefore our staff's diligence might not be benefiting our patients.

Bacteria can become trapped

When human organic material—blood, stool, tissue, saliva—is allowed to stand and crust, it forms a type of biofilm. The problem is that, in many cases, devices sit for a period of time, waiting to be picked up. A hospital being busy or any number of factors can result in an initial delay in cleaning. This delay, as well as the possibility of inadequate cleaning, enables the debris to form a resin that literally seals in and therefore insulates the bacterial. (Picture the bacteria going into a "bomb shelter" and reemerging when "the coast is clear.") When the reprocessed device is returned to the hospital it has allegedly been sterilized by the reprocessor. However, the bacteria are not effected by the sterilization process because they've been ensconced in this insulating shell. The problem gets worse. When the reprocessed device is put into a patient, the shell, at body temperature, and in the presence of body fluids, starts to degrade, thereby releasing the bacteria into an innocent victim.

Devices are often used in contaminated areas of the body

In addition, the actual nature of reprocessed single-use devices lends itself to disease transmission because: (a) the majority of devices are used in the vascular system or in a contaminated area such as the urological or gastrointestinal tract, and (b) most devices have sharp points. All of the above factors contribute to disease transmission in reprocessed devices and enormously raise the likelihood that this is not a safe device when used under these circumstances.

PUBLIC AWARENESS

The reason the public is not up-in-arms about the use of reprocessed devices is that people don't know enough about this issue, which is why this hearing is so important. Reprocessing is not an issue of greedy manufacturers; it is an issue that the public, when informed, decries. The following data illustrate the issue of public awareness—or lack thereof—and people's responses when they become aware.

1. In a study called The Medical Device Reuse Awareness Study for Halsted Communications, conducted in October 1997, the following question was posed to 501 participants from Los Angeles, New York, Chicago, and Atlanta: How would you feel if a device that by law was designed to be used once, was reused on you or on someone you love? People responded as follows: 84% stated they would be angry; 76% would demand an explanation; 69% would be frightened; and 59% would ask for a guarantee that the person that the device was used on before was healthy. Nineteen percent of the respondents from Los Angeles stated that they would sue if they found out this happened.
2. Recently in Japan, a clinic initiated a policy in which patients were told that there were two kinds of accessories they could use in a procedure: single use or reprocessed. If they chose the single-use device, however, they would have to pay an out-of-pocket premium. Everyone chose to pay the premium.
3. Some time ago the television show "Dateline" did a piece on the practice of reusing some dental material—braces in particular. Following this program,

- there was a huge outcry. Again, it was a case of the public initially not knowing, but voicing their displeasure when they found out.
4. Many studies, commissioned by original manufacturers, have been conducted by independent sterility testing labs. In these studies, researchers took random samples of reprocessed medical devices sitting on shelves in hospitals—ready for use in patients. The reprocessed devices were then sent to the independent lab for testing. In all the studies, a large number of devices were found to be contaminated with blood, body fluids, tissue, cleaning chemicals and bacteria. These studies represented real situations, not just a theoretical concept. It was not a case of “What do you *think* would be used?” Rather it was a case of what *would* have been used, since these devices were right there on the shelf awaiting the next patient.
 5. At a symposium during a meeting of the Society for Gastrointestinal Nurses and Associates, Inc. (SGNA) held in 1998, nurses were asked the following question: “If you were a patient, what would you want used on you: single-use or reprocessed devices?” Unanimously, they did not want reprocessed devices. Since then, the SGNA as an organization has published a position paper speaking out against the practice of reprocessing. It states, “In the absence of clear regulatory guidelines for reuse of single-use devices, based on current scientifically based literature, and taking into consideration concerns for patient safety and ethical practice, the Society of Gastroenterology Nurses and Associates, Inc. supports the position that critical medical devices labeled for single-use should not be reused.”

INFORMED CONSENT AND LIABILITY:

The outgrowth of the practice of reprocessing single-use devices raises the issues of informed consent and liability. I believe that:

1. Ultimately the physician or physicians using the devices bear a significant liability. They are the guardian of the patient. If physicians have knowledge that the device handed to them in any way might cause harm, they have accepted some responsibility.
2. If a hospital makes a choice to take a legally labeled single-use device and use it contrary to the manufacturer's instructions, the hospital also bears responsibility.

The patient's right to know

This also raises a question as to what the patient has the right to know and do. Based on the above, it is my belief that, in addition to telling the patient of the risks and benefits, potential complications, and the names(s) of the physician(s), there should also be informed consent. It would state: “Devices that we use have been previously used in other patients. Those patients may have had infectious diseases, including AIDS and hepatitis. These devices are used contrary to manufacturer's instruction.” The patient would then have the opportunity to say, “Yes, I understand; go ahead and use the reprocessed device.” This, however, is obviously not being done. I believe the practice of reprocessing of single-use devices is a significant enough deviation that does warrant *truly* informed consent.

Why is information withheld?

Before conducting a procedure, I don't hesitate to tell my patients that they have a one in “x” risk of perforation, the possibility of hemorrhage, or even death. Clearly, it is not atypical to advise patients of potentially serious or even possibly fatal events associated with procedures. So why is it that we hide information about the risks of reprocessed devices? The answer is that physicians and hospitals are comfortable saying, “The procedure we're doing is the best available for your condition, while recognizing that no procedure is perfect. Here is the scientific information to show why, given the risk/benefit ratio, it is in your best interest.” That is different from trying to hide the fact that “We paid \$50 for a single-use, disposable device, but by reusing it over and over, we will save the hospital money.”

It is as though physicians and hospitals are not informing people about using reprocessed devices and are not asking for consent because they don't want people to know. If they are unwilling to ask for informed consent, does that not tell the whole story?

Do patients get equal treatment?

A patient might rightfully question, “Why do I go through life living so carefully and avoiding risky behavior, then you expose me to the risky behavior of someone else without telling me that the motivation is to save money for the institution?” Or, “Why does patient #1 get the benefit of a sterile, first-use device with no risk

of disease transmission while I, patient #2, get a reprocessed device?" There would be no justifiable answer.

IN CONCLUSION:

I have never in my own profession or in related specialties heard a physician or hospital say, "I think reprocessed single-use devices are better." The only justification is that "it helps control costs and I think it's OK." Ardent supporters may say that they have conducted many procedures safely with reprocessed single-use devices without hearing about resulting deaths or diseases. But, you can't take a device apart to ensure that it's sterile, and therefore, one doesn't really know. We need to be open enough to state that we have seen tremendous microbiological studies, including DNA fingerprinting, that confirm that reprocessed devices can transmit disease. If we err on this position, we should do so on the side of **public protection**. I don't think the public is best served by waiting to form public policy until enough victims are amassed.

You will hear from many people who will offer their legal, microbiological, and engineering perspectives. The real message you need to take away from me in my professional, life-long role as a patient advocate is that, while not dismissing the hospital or its association's role as the patient advocate, it is perhaps the physician who has the major advocacy role and who ultimately drives the decision.

I understand cost containment, I am not a naive physician saying that cost doesn't matter. In today's healthcare climate, we all must be mindful of cost in order to be able to continue to deliver healthcare to the populace. In fact, I currently sit on the board of directors of a hospital and constantly deal with cost containment. However, understanding the need to control health care costs and making decisions for which current information tells us that our decisions may be injurious to the patient, are hopefully—and should be—mutually exclusive.

In closing, I'd like you to ask yourselves this question: Would you want your loved ones who had the misfortune of being ill to be in the care of a doctor or a hospital where you sat in the waiting room and not only needed to worry about the disease that has afflicted them, but also had to worry about the safety of the very device used to try to bring about their wellness?

Mr. UPTON. Thank you for your final answer.
Dr. Fielder?

TESTIMONY OF JOHN H. FIELDER

Mr. FIELDER. Mr. Chairman, I am John Fielder. I am a professor of Philosophy at Villanova University and I am here not representing any group.

Risk is the probability of harm times the severity of harm. We know that the severity of harm, potential harm is very great. Hepatitis C, tuberculosis, and other diseases. What we do not know is how large the probability of that harm is, however, even if you have a low probability of harm, if the severity of harm is high, you have a significant risk. Now, the ethics of risk are clear and they are well established, both in ethics and law. It is the patient's right to be informed of the risk, informed of the benefits, the alternatives to treatment, and to give consent. These principles are based on the fundamental idea that persons are in charge of their lives and it is the job of healthcare professionals to guide them in making those decisions. Most patients are not informed that they are being treated with devices that pose additional risk to them over a single-use device.

Last fall I prudently got a flu shot, went down to the infirmary at Villanova and they shot me, but I had to sign a consent form first that told me the dangers, the benefits, and the alternatives. So I signed it and I got my shot. And I was thinking as I was walking back that if it is appropriate for me to sign a consent form to get a flu shot like millions of other Americans, I would sure like to sign a consent form if somebody was going to put one of these

things that had been in somebody else into my body and to bite off a piece of me to bring back for a sample. It is enlightening and constructive to try to construct a consent form for a patient who is going to be treated with a reused device. First the risk. Okay. We have talked about the risks, we know that there is a potential of transmission of disease, of functional degradation, and so forth.

But what exactly are the benefits here to the patient? See, this is where we hit the ethical brick wall. The patient is getting no benefit by being treated with a reprocessed device. They are getting additional risk, but they are not getting any additional benefit. Now, you will be told that the savings from these reprocessed device will be put back into patient services and life will be better for patients and hospitals. This may be true. But it is also true that money might go into the pockets of investors or for-profit hospitals as well. Also, it seems to me if this is a great benefit, put it down, let patients decide if they want that benefit based on the risk that the device poses.

I think the use of reprocessed devices in a present form is really a kind of vast medical experiment that we are doing. We do not really know the outcomes of using these extensively, we do not really know how much disease is being transmitted, and we are doing it without people's knowledge and consent. And that is wrong. We should not be doing that. A couple of other items. Fairness. I am pleased that the FDA is moving in the direction to make the regulatory burden for the original equipment manufacturers and the reproprocessors more or less equal. That seems to be appropriate. It is simply unfair to ask one group to go through a complicated song and dance to get their device approved and not the others. Another item I am concerned about is labeling. Many times physicians do not know that they are using a reprocessed device. They do not open it in the operating room. Somebody else does and hands it to them. So when they get the device, it says Cortis, or Boston Scientific, or whatever, and they will think they are using an original device. I think that is unfair to the original equipment manufacturers because that is no longer their device once it is reprocessed. And I would urge FDA and perhaps this committee if it is appropriate, to make sure that this information about the device is on the device so that people who are using it can tell, and so that patients who may be damaged can use that if they want to sue for damages.

Finally, as in all things, money is a big issue here. I know that hospitals are under tremendous financial pressure. Some of it from the Government, from HCFA and Medicare, some of it from insurers. One of the reasons this kind of problem pops up was that it is very hard to treat people in hospitals and make money and to stay afloat. I am very concerned that we create a system where hospitals start looking for places that are ethically questionable to save money. I would much rather have a system where they could do their work and have adequate resources to do it, and not have to consider this kind of practice. Thank you Mr. Chairman, I appreciate your holding hearings on this important topic.

[The prepared statement of John H. Fielder follows:]

Introduction

The patient is the ethical center of health care. All who participate in patient care, directly or indirectly, are ethically obligated to provide adequate and appropriate care to patients and to safeguard their right to make informed health care decisions. Patients are ill, vulnerable, dependent, and usually ignorant of the nature of their illnesses, their treatment options, and what they mean for them. As a result, they require a greater degree of help and protection than persons who are not ill.

Almost all health care procedures involve some risk to the patient. It is a long-standing tradition in ethics and law that patients have the right to decide what risks to take, and health care professionals have the obligation to inform them of the risks and benefits of alternative treatments, including nontreatment.¹ Patients are in charge of their lives, not doctors. The greater the risk, the greater the patient protection that is needed. Formal biomedical research must meet extensive requirements concerning maximizing benefits while minimizing risks, independent review, and informed consent.² The concept of informed consent embodies the ethical principles of patient autonomy and provider beneficence.

Risk

From the patients' point of view, the primary question concerns the risks posed by the reuse of medical devices approved by FDA only for a single use. The devices in question are those that pose the greatest risk to patients. No one worries about the reuse of single-use compression sleeves or bedpans. It is the complex devices like cardiac catheters, biopsy forceps, and similar devices that raise the most serious questions of risk. These devices enter the patient's blood stream, intestines, and major organs where disease organisms reside. They also have tiny passages for guide wires which may be difficult to clean and resterilize.

It is important to distinguish the two factors that are used to determine risk. Risk is the product of the probability of harm and the severity of harm. Thus, high risk could result from the high probability of moderate harm as well as the low probability of very serious harm. In assessing risk we must look at both the seriousness of the potential harms as well as the likelihood of their occurrence.

In addition, we need to distinguish two kinds of harms that may result from treatment with a reused single-use device. First, diseases may be transmitted from previous patients to the patient being treated through inadequate cleaning and resterilization. Second, devices may have their functional characteristics changed as a result of cleaning, so that patients may be injured or be given less than optimal treatment. Thus we need to look at the probability and severity of harm regarding both functional changes and disease transmission.

From my study of reuse of single-use devices, the following facts emerge:

- We know that studies of reprocessed single-use devices by FDA and others show that some devices have debris left in them and are contaminated with fungi, bacteria, or viruses. A study of Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheters found that some clean easily while others seemed to regularly get clogged. About half the samples grew organisms in the middle sections.³ Other studies report residual organic debris that cannot be adequately eliminated.⁴ Company-sponsored studies, some by independent laboratories, confirm these results.⁵
- We know that reprocessing devices can result in functional changes. Another FDA study of PTCA balloon catheters found that there were changes of up to 10% in balloon diameter after reprocessing. Reprocessed balloons were also stickier

¹ Beauchamp, Tom, and Childress, James, *Principles of Biomedical Ethics*, Fourth Edition (1994), Oxford University Press, New York.

² Faden, Ruth, and Beauchamp, Tom, *A History and Theory of Informed Consent* (1986), Oxford University Press, New York.

³ Merritt, Katherine, Hitchins, Vicki, Woods, Terry, and Brown, Stanley, "Re-Use of Devices: Cleaning Issues," presentation at the Association for Medical Instrumentation/FDA Conference, *The Reuse of Single-Use Devices: Practice, Patient Safety, and Regulation*, Crystal City, VA, May 6, 1999. This information was taken from a public presentation; FDA has not made a report of this study publicly available.

⁴ Yang M, Deng X, Zhang Z, Julien M, Pelletier F, Desaulniers D, Cossette R, Teixeira FJ, Laroche G, Guidoin R, "Are intraaortic balloons suitable for Reuse? A survey of 112 used intraaortic balloons." 1997 *Artificial Organs* 21(2) 121-130.

⁵ Two of the most extensive were conducted by Ethicon Endo-Surgery, a Johnson and Johnson Company, "Evaluation of Reprocessed Ethicon Endo-Surgery, Inc. Single-Use Medical Devices," (1998) Ethicon Endo-Surgery, Cincinnati, OH, and Muradali, Kumaree, "Report on Re-furnished Single Use Devices," Cordis, a Johnson and Johnson Company, Miami Lakes, FL.

that new ones. The effects of cleaning agents on the various plastics used in devices is materials-specific.⁶ The company-sponsored study (see note 5) also found function changes in the devices they studied.

- We know that devices approved for reprocessing have been responsible for the transmission of TB and hepatitis C during bronchoscopy and colonoscopy because of improper cleaning and sterilization.⁷
- We know that reprocessed devices can also transmit diseases. Sixty percent of pediatric patients treated with reused tracheostomy tubes contracted pneumonia compared to 25% treated with new ones.⁸ We do not know if other diseases, particularly hepatitis C, are being transmitted because no studies have screened patients before treatment and tested them later. A report by a well-regarded independent organization concluded that “there is no clear evidence that reuse of single-use medical devices is either safe or unsafe for patients.”⁹
- We know that reprocessed devices have failed and injured patients. A patient undergoing cardiac catheterization for coronary angiography reported a sudden loss of vision in his right eye. The procedure was stopped and an examination of the eye revealed a green crystalline foreign body within the central retinal artery on the optic nerve head. The catheter, approved only for a single use, was reautoclaved, making it more friable. A fragment had broken off and traveled to the central retinal artery, occluding blood flow. Treatment of the injury was unsuccessful and the patient was left with only light perception in his right eye.¹⁰ In another case the tip of a reused cardiac catheter broke off and lodged in a patient’s atrium.¹¹
- We know that a few studies in peer-reviewed journals show that single-use and reprocessed devices have similar rates of in-hospital adverse events. One study in this literature is a double-blind, randomized control trial of 1,033 procedures, of which 753 were reused PTCA balloon catheters. They found slight differences in serious adverse complication rates, urgent coronary artery bypass surgery, and abrupt vessel closure.¹²

Several conclusions can be drawn from these facts.

Changes in Functional Characteristics

Severity of Harm: Reprocessed devices can fail and cause serious injuries. Other changes in functional characteristics can result in difficulties in treatment that may result in injuries or additional exposure to risk.

Probability of Harm: There are only a few reports in the literature of patients being harmed by failure of these devices, but it is likely that device failures are underreported. Also, physicians may not recognize problems caused by reprocessing. The probability of in-hospital adverse events does not appear to be high, but more studies need to be done to confirm this.

This analysis suggests that the probability of harm from functional failure is likely to be low, although more good scientific evidence is needed to establish this with reasonable certainty. I conclude that patients who are treated with reprocessed single-use devices are being subjected to a low risk of failure to function adequately.

⁶Brown, Stanley, Merritt, Katherine, Hitchins, Vicki, and Woods, Terry, “Effect of Use and Simulated Reuse on Materials and PTCA Balloons and Catheters,” presentation at the Association for Medical Instrumentation/FDA Conference, *The Reuse of Single-Use Devices: Practice, Patient Safety, and Regulation*, Crystal City, VA, May 6, 1999. This information was taken from a public presentation; FDA has not made a report of this study publicly available.

⁷Bronowicki JP, Venard V, Botte C, Monhoven N, Gatin I, Chone L, Hudziak H, Rhin B, Delanoe C, LeFaou A, Bigard MA, and Gaucher P, “Patient-to-Patient transmission of Hepatitis C Virus During Colonoscopy,” *New England Journal of Medicine* (1997) July 24; 337(4): 237-40. Michele TM, Cronin WA, Graham NM, Dwyer DM, Pope DS, Harrington S, Chaisson RE, Bishai WR, “Transmission of Mycobacterium Tuberculosis by a Fiberoptic Bronchoscope. Identification by DNA Fingerprinting,” *Journal of the American Medical Association* (1997) Oct. 1; 278(13):1093-5.

⁸Bahng, Susanna, VanHahn, Sonja, Nelson, Virginia, Hurvits, Edward, Roloff, Dietrich, Grady, Elizabeth, Lewis, Cathy, “Parental Report of Pediatric Tracheostomy Care,” *Archives of Physical Medicine and Rehabilitation*, (1998) Vol. 79; 1367-9.

⁹ECRI Special Report, *Reuse of Single-Use Devices: Making Informed Decisions* (1996). ECRI, Plymouth Meeting, PA., p. 1.

¹⁰Hallermann D, Singh G. “Iatrogenic central retinal artery embolization: a complication of cardiac catheterization,” *Annals of Ophthalmology* 1984; 16:1025-27.

¹¹MedWatch report, 3/18/99. MedWatch is a voluntary reporting system of FDA.

¹²Mak, Koon-Hou, Eisenberg, Mark, Plante, Sylvain, Strauss, Bradley, Arheart, Kristopher, and Topol, Eric, “Absence of Increased In-Hospital Complications with Reused Balloon Catheters,” *The American Journal of Cardiology* (1996) Vol. 78; 717-9.

Transmission of Disease

Severity of Harm: Reprocessed devices have the potential to transmit deadly diseases; thus the severity of harm is high.

Probability of Harm: The probability of transmission of disease is unknown but is certainly greater than zero. It also varies with the type, brand, and model of device.

The real risk is not in functional failure but in the transmission of disease. The severity of harm is great from TB and hepatitis C, and we simply do not know much about the probability of this happening with reprocessed single-use devices. We do know that improper cleaning and resterilizing of used devices can transmit these diseases, and we know that there is no manufacturer-developed and FDA-approved protocol for cleaning them. Even if this is a low probability of harm, the severity of the consequences creates a significant risk for patients.

Informed Consent

In cases where patients are exposed to a significant risk, ethics requires that they be informed of the benefits of treatment, the risks, and the alternatives. This is true even for common, low risk procedures. Last October I got a flu shot at the Villanova University Health Center. Vaccines have a small probability of triggering an immune reaction that can cause serious illness or death. Because of this I was asked to read and sign a consent form that informed me of the benefits of the injection, the risks, and alternatives. The form is appended to this document.

Since patients treated with reprocessed single use devices are also exposed to a significant risk, it is enlightening to construct a consent form for this procedure. Imagine that you are being asked to consent to the use of a reprocessed device in your treatment instead of an otherwise identical new, single-use device.

The form would have to state that the potential harms include the possibility of transmission of TB and hepatitis C, very serious diseases, and possible functional changes or failures. While some studies suggest that the probability of these events occurring is low, we do not really know how likely they are.

What are the benefits? None to you, the patient, only to the hospital's finances. Note that the consent form may also have to include the fact that the hospital has a significant financial interest in treating patients with reprocessed devices.¹³

What are the alternatives? Besides nontreatment and any other less invasive procedures, you could be treated with a new device at no extra cost to you and avoid these potential complications. In effect, you are being asked to take significant risks in your treatment for no corresponding benefit to you but to contribute to the financial health of the hospital.

To see how this works in practice, consider two patients, in 403A and 403B, both scheduled for cardiac catheterization. The patient in 403A will be treated with a new, single-use device and will have no risk of the infection being transmitted by the catheter, nor will that patient or the physician have to worry about any functional changes from previous uses. In contrast, the patient in 403B is put at risk, without any corresponding therapeutic benefit, and without the patient's knowledge or consent. This is simply ethically unacceptable. You cannot put people at risk without their informed consent.

Patient Benefit

Proponents of reuse sometimes argue that savings will be passed on to patients in the form of more and better services, but this is a weak argument. First, in for-profit hospitals those savings will, in part, be returned to investors as dividends. Second, it is not guaranteed that any savings will directly affect the patients taking the risk, because savings may well be applied to other hospital service areas. Third, patients being treated with a reprocessed device may get some indirect benefit from previous savings generated by reuse, but none from their treatment with a reprocessed device. Fourth, if these are patients' benefits, no matter how remote, shouldn't they have the right to decide where they should be spent? The fact of the matter is that it is the hospitals who benefit, and that benefit may have some indirect beneficial impact on patient care. But this does not alter the fact that any beneficial impact that accrues to a particular patient is greatly out of proportion to the risks being taken.

Medical Experimentation

There are further ethical anomalies in the reuse of single-use devices. When you take your flu shot, the probability of harm is reasonably well established. When you are treated with a reprocessed device, there are substantial unknowns, especially

¹³ *Moore v. Regents of the University of California*, 51 Cal. 3d 120 (1990)

concerning disease transmission. Consequently, the use of reprocessed devices is a form of experimental treatment, providing an even stronger claim for the traditional ethical protections, particularly informed consent.

The adequacy of consent to a pure experiment or to experimental treatment raises more issues than consent to an established therapy simply because less is known about the risks involved in an experimental procedure... Therefore a prospective subject must be aware that little is known about the possible risks and consequences...¹⁴

In the absence of adequate scientific evidence to establish the probability of harm, particularly the transmission of disease, and in the absence of FDA-approved, device-specific protocols for cleaning, resterilizing and number of permitted uses, the continued use of reprocessed medical devices is a large, ongoing medical experiment, but one that lacks even the rudimentary protections to patients, particularly the requirements that risk be proportional to patient benefit and informed consent.

This raises further questions about the ethical responsibilities of all who participate in this practice—hospitals, health care professionals, and reproprocessors. Because the use of reprocessed medical devices is an unethical form of medical experimentation, then the hospitals, physicians, and other health care professionals who take part in it are also not meeting their obligations to put patient interests first and to uphold their right to informed consent.

Other Ethical Issues

Regulatory Fairness: Risk and patient protection are the primary ethical issues, but there are others that need to be mentioned. Original equipment manufacturers (OEM's) who wish to market a reusable device must submit a validated protocol to FDA for approval. The protocol must include scientific evidence to show that it can be properly cleaned and resterilized, the effect of cleaning and resterilization on the materials, functionality, and safety of the device, and the number of times it can be reprocessed without loss of safety and effectiveness. No such regulatory burden falls on the reproprocessor, who must, at most, meet good manufacturing and quality control standards. This is an unequal burden for which there is no adequate justification. Thus the present arrangements are unfair to OEM's. However, FDA has recently taken significant steps to bring reprocessed devices under greater regulatory scrutiny.

Labeling: Reprocessed devices still bear the name of the OEM on the device, but in a real sense it is no longer theirs, since they can no longer vouch for their safety and effectiveness. Unless there is clear information in the labeling of the reprocessed device, there is the misleading suggestion that the device has the assurance of quality, safety, and effectiveness associated with the OEM, or that any failure is to be attributed to the OEM.

OEM's and Reprocessors: Are OEM's unethical for failing to produce reusable catheters? Critics have charged that what were once reusable devices were simply relabeled for single use. Is this practice wrong? The FDA does not have the authority to determine what products companies may develop or what they charge for them. It is a basic principle of our economic system that producers have a right to decide what products they wish to market as long as they meet all legal and regulatory requirements. Unless there is some strong reason to think otherwise, OEM's and reproprocessors are not ethically obligated to make or withhold particular products.

Conclusion

Hospitals are under severe financial pressure from payers, including Medicare and HCFA. They are, understandably, looking for ways to cut costs and using reprocessed devices is one of them. However, this practice is, at present, ethically unacceptable because of the severity of potential harm to patients, the lack of knowledge about the probability of disease transmission, and the absence of device-specific FDA standards for cleaning and resterilizing. It amounts to an extensive medical experiment without patient benefit, knowledge, or consent.

It may be useful to end with the observation that it is the problem of costs that is driving the issue of reuse of single-use medical devices. The present arrangements encourage ethically questionable arrangements because of the pressure to cut costs of services.

Mr. UPTON. Thank you very much.
Dr. Maurer, welcome.

¹⁴ Woltjen, Maria "Regulation of Informed Consent to Human Experimentation," *Loyola University of Chicago Law Journal*, Vol. 17 (1986), p. 313.

TESTIMONY OF WALTER G. MAURER

Mr. MAURER. Thank you. Mr. Chairman, members of the committee, I am Dr. Walter Maurer, Director of Quality Management at the Cleveland Clinic Foundation in Cleveland, Ohio. I am here today on behalf of the American hospital Association. In addition to being Board Certified and practicing in both the areas of internal medicine and anesthesiology, I serve as Medical Director of the Office of Quality Management. With approximately 50,000 surgeries and more than 1.5 million outpatient visits yearly, it is my responsibility to guide and direct our quality management team in ensuring the highest level of patient care is provided. I also chair the Quality Council, the Safety Coordinating Committee, and the Joint Commission Preparation Team.

The term reuse and reprocess can encompass numerous scenarios and they take place in multiple locations: In hospitals, ambulatory surgical centers, and physician offices. Some hospitals utilize the services of third party reproprocessors while others reprocess within their own facilities. In some cases, the device never touches a patient. For example, almost every day at the Cleveland Clinic we have a surgery cancelled or postponed, sometimes after the operating room has been prepped for the procedure. That preparation may include assembling customized procedure trays that contain many open single-use devices, such as needles, scalpels, and syringes. I have with me here today what we term our total hip pack. This total hip pack costs us \$236. I just spent \$236. This is medical trash. Right now this is all thrown away. This is gone.

Another common scenario is the use of a low risk device, one that does not penetrate a sterile tissue plane or mucus membrane during use, but may simply contact the patient's skin. For instance, the device put on a patient's leg to promote circulation comprised largely of plastic and fitting like a sleeve over a patient's leg. Hospitals routinely clean, sterilize, inspect, and repack these types of devices. Ironically the most controversial reprocessing practice is probably the least common for hospitals, that of cleaning, sterilizing, and repackaging a single-use, critical device after it has been used on a patient. With constrained healthcare resources and a heightened commitment to the environment, reprocessing does make sense.

I need only reiterate the slogans we now teach our children, the three Rs of reduce, reuse, and recycle. AHA members are committed to being better stewards of the environment by pledging to reduce, not increase waste. The AHA strongly supports the FDA's plan to develop a research program to help bridge the data gap between the perceived and actual safety risks associated with the reuse of single-use devices. We must move away from anecdotal reports although they are important to look at. Research should be directed at more complex or high-risk devices and be peer reviewed and published for credibility. This will provide device specific scientific evidence regarding patient safety. We applaud the FDA's plan to develop consensus standards for the reprocessing of single-use devices. The FDA should include all stakeholders, manufacturers, third party reproprocessors, healthcare facilities, physicians, and members of the public in developing the consensus standards.

At the Cleveland Clinic, for example, our cardiology electrophysiology laboratory reprocesses diagnostic heart catheters. These are solid tubes without hollow lumens. Each catheter is limited to five uses. First it is thoroughly cleaned by professionals in sterile processing. It is then tested after each and every use for electrical and mechanical safety and function and only then re-sterilized. Each year standard operating procedures are reviewed and patient outcomes are assessed. The sterilization practices are regularly reviewed and staff competency assessed. Since 1993 our lab has had a continuous quality improvement project on any infections caused by any procedures done in that lab. Infection cases are then reviewed with the Infectious Disease Department.

Additional oversight is provided through existing Federal and State agencies charged with ensuring safe quality patient care. We must restore the meaning to the term single-use. Original equipment manufacturers have little to no incentive to label their devices as reusable, and, in fact, have financial incentives to self-designate devices as single-use. In the last 2 years we have observed products that have been historically labeled as reusable arriving with the single-use label with no observable change in the product. These are orthopedic saw blades. Stainless steel. There are no small lumens in these. This is reusable. This is not. The ones that we have started to use reproprocessors of, I found out, are marked when they come back. So we know which ones are reusable and how many times they have been reused.

The FDA should begin to regulate the use of single-use only labels and require manufacturers to both justify labeling a device as single-use and provide scientific data specifying any re-sterilization or reprocessing techniques that may compromise the integrity of the device. In conclusion, Mr. Chairman, patient safety is the first and foremost concern of all hospitals and health systems. The AHA believes that the FDA's proposed strategy on the reuse of single-use devices represents a thoughtful approach to a complex issue. And we are pleased that the FDA has been consulting with front-line caregivers and other experts in its effort to make the standards even more meaningful. We further believe that the additional legislation is unnecessary at this time and would only undermine the progress that the FDA has already made. We welcome the opportunity to work with the FDA to ensure the best practices are universally used. Thank you.

[The prepared statement of Walter G. Maurer follows:]

PREPARED STATEMENT OF WALTER MAURER, CLEVELAND CLINIC FOUNDATION, ON
BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. Chairman, I am Walter Maurer, M.D., director of quality management at the Cleveland Clinic Foundation in Cleveland, Ohio. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network, and other health care provider members. We are pleased to have the opportunity to testify on the long-standing practice of reprocessing medical devices.

The Cleveland Clinic Foundation, founded in 1921, integrates clinical and hospital care with research and education in a private, non-profit group practice. Last year at the Cleveland Clinic and Cleveland Clinic Florida, more than 850 physicians representing 100 medical specialties and subspecialties provided care for more than 1 million outpatient visits and close to 50,000 hospital admissions.

I have spent most of my career as a private practice internal medicine specialist and anesthesiologist at the Cleveland Clinic with a focus on outpatient, pediatric, and ear, nose and throat anesthesia. I also have been involved in resident education,

quality assurance and preoperative testing. Currently, I serve as the medical director of the Office of Quality Management. The role encompasses the hospital, its ambulatory settings including community health centers, and a long-term care facility. With approximately 50,000 surgeries and more than 1.5 million outpatient visits yearly, it is my responsibility to guide and direct our quality management team in ensuring the highest level of patient care is provided. I also chair the Quality Council, the Safety Coordinating Committee and the Joint Commission Preparation Team.

BACKGROUND

The term “reuse” and “reprocess” can encompass numerous scenarios, and they take place in multiple locations, in hospitals, ambulatory surgical centers and physician offices. Some hospitals utilize the services of third-party reproducers while others reprocess within their own facilities. In some cases, the device never touches a patient. For example, almost every day at the Cleveland Clinic we have a surgery cancelled or postponed, sometimes after the operating room has been prepped for the procedure. That preparation may include assembling customized procedure trays that contain many open single-use devices (SUDs), such as needles, scalpels, sponges and syringes. What becomes of these devices when the surgery is cancelled? Most of it would be unfortunately wasted as “medical trash”, but because of increased environmental concerns and cost reduction initiatives, we have found that we can safely sterilize, inspect and repackage many devices for later use.

In another scenario, often a manufacturer will ship SUDs to hospitals with separate sterilization instructions, if the manufacturer is experiencing a period of high demand and has not had time to sterilize the SUDs prior to shipment. Hospitals sterilize, inspect and repackage these devices too.

Another common scenario is the reuse of a non-critical device—one that does not penetrate a sterile tissue plane or mucus membrane during use, but may contact the patient’s skin. For instance, a sequential compression device, which is used on the patient’s leg to promote circulation and avoid deep vein thrombosis, is comprised largely of plastics and fits like a sleeve over a patient’s leg. Hospitals routinely sterilize, inspect and repackage these types of devices.

Ironically, the most discussed reprocessing practice is probably the least common for hospitals: that of cleaning, sterilizing and repackaging a single-use, critical device after it has been used on a patient so it can be used again on another patient.

REPROCESSING MAKES SENSE

Many medical products can be safely reused. The AHA is unaware of any evidence to demonstrate a problem with reprocessed SUDs. With constrained health care resources and a heightened commitment to the environment, reprocessing makes sense. I need only reiterated the slogans we now teach our children—that’s the three R’s—reduce, reuse, and recycle. AHA members are committed to being better stewards of the environment by pledging to reduce, not increase waste. In 1998, the AHA and the Environmental Protection Agency initiated a joint-partnership to reduce hospitals’ total waste volume by 50 percent by 2010. Responsible waste management and recent cost reduction initiatives have resulted in the discovery that hospitals can safely sterilize, inspect, and repackage many devices for later use.

The AHA is encouraged by the Food and Drug Administration’s (FDA) decision to provide guidance in this area to ensure and enhance patient safety, which is the first and foremost concern of AHA members. AHA members have a great deal of experience with reprocessed medical devices and have been working closely with the FDA as it refines its strategy. We believe that the agency’s Proposed Strategy represents a thoughtful approach to a complex issue; it both echoes and furthers the goals of patient safety, which we share.

The potential for device malfunctions, patient injuries, or infections related to the reprocessing and reuse of single-use devices is a matter of great concern to hospitals and health systems. The AHA strongly supports the FDA’s plan to develop a research program to help bridge the data gap between the perceived and actual safety risks associated with reuse of SUDs. Such research should be directed at the more complex or high-risk devices and be peer reviewed and published for credibility. This will provide device-specific scientific evidence regarding patient safety.

The AHA also is encouraged by the FDA’s proposal to categorize SUDs into risk categories, and we agree that the level of regulation for a device correspond to the level of risk to a patient.

Furthermore, the AHA applauds the FDA’s plan to develop consensus standards for the reprocessing of SUDs. These kinds of standards would go a long way toward addressing the safety, and effectiveness of reprocessing. The FDA should use a

“community best practices” approach for low-risk devices and a more formal FDA interdisciplinary advisory panel for high-risk devices. The FDA should include all stakeholders—manufacturers, third-party reproducers, health care facilities, physicians and members of the public—in developing the consensus standards.

OVERSIGHT OF REPROCESSING

Hospitals are subject to significant regulatory and accreditation oversight by entities such as the Health Care Financing Administration, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), state licensing authorities, and other county and city agencies, particularly with respect to patient safety and quality of care. By contrast, only one outside source—the FDA, regulates manufacturers and third-party reproducers.

Hospital reprocessing activities are marked by a high degree of physician involvement, supervision and control. In many cases, a multi-disciplinary committee, such as the infection control committee, consisting of clinical staff (physicians and nurses) and operational staff (sterile processing, risk management, and materials management) oversees the reprocessing activities of health care facilities. This committee monitors reprocessing quality assurance and improvement activities, recommends strategies for improving performance, and reports such findings and recommendations to the facility’s performance improvement oversight committee, medical staff and governing body.

Through its membership, activities and reporting structure, this type of multi-disciplinary committee meets the requirements of numerous JCAHO standards, including those for surveillance, prevention and control of infection, etc. Naturally, medical professionals and the health care facilities in which they practice have as their primary mission quality patient care, and have in place standards, policies and procedures for reprocessing.

At the Cleveland Clinic, for example, our cardiology electrophysiology laboratory reprocesses both non-lumen diagnostic electrophysiology catheters and non-lumen radiofrequency ablation catheters. Each catheter is used five times or less. It is tested after each use for electrical and mechanical safety and function, and then resterilized. Each year, standard operating procedures are reviewed and patient outcomes are assessed. The sterilization practices are regularly reviewed and staff competency assessed. Since 1993 our lab has had a continuous quality improvement project on any infections caused by any procedures done in the lab. Infection cases are then reviewed with the Infectious Disease Department.

Reprocessing standards, policies and procedures, in conjunction with the quality improvement program, are designed specifically to protect the well-being of hospital patients. Existing nonFDA regulatory oversight, which the AHA believes includes the components necessary to address and satisfy the FDA’s concerns in this area, has resulted in the development of these processes.

For instance, JCAHO, during its announced and unannounced surveys, focuses heavily on patient safety. In addition to visiting patient care and reprocessing areas to observe infection control practices, JCAHO reviews the minutes of the infection control committee, the medical staff executive committee, the performance improvement oversight committee and the governing body. The inspectors look for evidence of sufficient reporting of performance improvement information and for action on performance improvement recommendations. Failure to adequately demonstrate compliance in these areas would result in substantial findings of noncompliance for the facility.

RESTORE MEANING TO THE TERM “SINGLE USE”

Original equipment manufacturers have little incentive to label devices as reusable, and, in fact, have financial incentives to self-designate devices as “single use.” Manufacturers appear to use the term “single use only” as part of their labeling without justifying whether, in fact, the device can be safely reprocessed for subsequent use. In the last two years, we have observed products that have been historically labeled as reusable, arriving with the “single use only” label with no observable change in the product.

We must ensure that the label “single use only” is meaningful and not simply an attempt to increase device sales. Currently, device manufacturers determine whether a device is labeled “single use.” However, the FDA should begin to regulate the use of the “single use only” label and require manufacturers to both justify labeling a device as “single use” and provide scientific data specifying any resterilization or reprocessing techniques that compromise the integrity of the device. Manufacturers are the repository for data on the functional specifications of their devices and know the most about the ability of their devices to hold up to repeated cleanings and steri-

lizations. They should share that information with those of us who use the devices, and be actively involved in developing consensus standards.

OPENED BUT UNUSED DEVICES DESERVE SPECIAL TREATMENT

As discussed earlier, it is common practice for hospitals to reprocess open, but unused, SUDs. Many SUDs are routinely opened prior to use and are assembled as part of customized procedure trays that contain several devices. Sterile processing professionals assemble, wrap and sterilize these trays, which may consist of single-use and disposable items. It is essential that hospitals be permitted to open single-use devices, combine them with other devices as needed for each medical procedure, and resterilize the entire tray. The creation of these trays in advance of surgeries and other procedures is designed to avoid delays in the surgical suite, create efficiencies, and prevent subsequent infection during the procedure. Treating this process as a "reprocessing" activity impedes these efforts.

As I stated earlier, any regulation should reflect the relative risk of the device involved. Reprocessed devices that have been opened, but not used on a patient, do not need to be part of the FDA's guidance. Resterilization and repackaging of such devices pose virtually no risk for patients.

There are three general areas of risk associated with reprocessing: 1. contamination of the device, if it is not properly cleaned and sterilized, could lead to infection; 2. the cleaning and/or sterilization process could harm the integrity of the device; and 3. the repeated use of the device in subsequent procedures could harm the integrity of the device.

With respect to unused devices, the third risk is eliminated entirely. A major component of the first risk, patient crosscontamination, is also eliminated. The only possible risks, therefore, are whether the device can be adequately resterilized and if the process of resterilization somehow harms the device. Hospitals have a great deal of experience in sterilization of medical devices as sterilization is routinely performed on many types of devices. In fact, as mentioned earlier, it is not uncommon for manufacturers to ship SUDs to hospitals with separate sterilization instructions. Therefore, many providers suspect that the "single use only" label and "do not resterilize" instructions are not based on reliable scientific evidence.

CONCLUSION

Mr. Chairman, as we have already noted, patient safety is the first and foremost concern of all hospitals and health systems. The AHA believes that the FDA's proposed strategy on the reuse of SUDs represents a thoughtful approach to a complex issue, and we are pleased that the FDA has been consulting with front-line caregivers and other experts in its effort to make the standards even more meaningful. This is an important step towards the goal of assuring patient safety. For the sake of all concerned, we commend the FDA's efforts to move forward, with all deliberate speed, to finalize its strategy. We further believe that additional legislation is unnecessary at this time and would only undermine the progress that FDA has already made towards developing a balanced and reasonable regulatory structure. We welcome the opportunity to work with the FDA to ensure best practices are universally used.

Mr. UPTON. Thank you very much.
Mr. Feltner?

TESTIMONY OF VERN FELTNER

Mr. FELTNER. Good afternoon. The Association of Medical Device Reprocessors appreciates the opportunity to present testimony regarding the reprocessing of medical devices labeled as single-use. My name is Vern Feltner. I am President of Alliance Medical Corporation. We are a member of AMDR. AMDR is a trade association representing the legal and regulatory interests of third party reprocessors of medical devices labeled as single-use. It is estimated that AMDR members perform approximately 80 percent of the third party reprocessing done in the United States. AMDR is not here today seeking exemption from regulation and oversight. In fact, just to the contrary. AMDR believes that a strong, rational, FDA regulatory regime is critical to ensuring the safety of repro-

essed devices. FDA currently imposes a number of regulatory controls on third-party reproprocessors, and membership in AMDR requires compliance with all applicable FDA requirements. In AMDR's view, protecting the patient must be of the highest priority, and accordingly FDA regulation of reprocessing must be based on demonstrated patient safety risk and not on hypothetical risk designed to provoke public alarm.

Unfortunately much of the opposition of reprocessing comes from original device manufacturers who view reprocessing as an economic threat, and who stand to reap enormous financial gains by eliminating reprocessing as an option for hospitals. Their strategy has been to portray reprocessing as unsafe, but the facts simply do not support their claim. The truth is that the safety record of reprocessing is excellent. As you will hear, reprocessing enjoys the support of major hospital and physician groups, and the safety of reprocessing has been demonstrated in numerous peer review studies and scientific studies. AMDR companies, themselves, have reprocessed over 9 million devices with very few problems. In order to ensure the safety of their devices, AMDR members adhere to several important safety principles, including testing every single device before it is returned to the hospital that requested that reprocess.

The reality is that proper reprocessing of certain medical devices labeled for single-use is absolutely safe. Manufacturers label devices as single-use, not because FDA requires a single-use designation, but because the manufacturer chooses that label. And what we have seen again and again is a single-use label being used for economic reasons as a way to sell more devices, and not out of a concern for patient safety. Hospitals that discard devices that could easily be reprocessed, are wasting resources that could be directed toward improvement in patient access and medical technology.

Mr. Chairman, as I listened to the testimony being given I would like to take the rest of my short period of time and set the record straight on a couple issues that I believe are very important. First, there seems to be a gross impression that the industry is not regulated. Nothing could be farther from the truth. Reprocessors must comply with FDA QSRs just like manufacturers. The fact is that FDA does not regulate all medical companies in exactly the same way. There is a whole industry known as device servicers and refurbishers. FDA considers these companies to be manufacturers, but pre-market review and compliance with QSRs are not required. Second, an issue I believe that is most important and certainly of highest concern to everyone here and that is patient safety.

This is a hard one to say, but there have been documents distributed, even to members of this committee that at best are misleading and disingenuous. At worst blatant untruths. There have been articles commissioned and published insinuating that multitudes of patient injuries due to the use of reprocessed devices are labeled as single-use, and that patient safety lies in using only the new devices. Facts are stubborn things, and the facts expose the disingenuous nature of these accusations. Public records solidly promote the efficacy and safety of commercially reprocessed devices. As a matter of comparison between AMDR companies and just four device manufacturers, the four that happen to be so

strongly fighting our industry, the facts state this. In the reporting period from January 1997 to March 1999, 27 months, there were three medical device reports filed concerning devices reprocessed by AMDR companies. In the same reporting period for just these four device manufacturers, there were in excess of 16,000 medical device reports filed, 11,827 product malfunctions reported, 2,508 patient injuries recorded, and a very unfortunate number of 163 deaths associated with the new products. Now, everyone knows that the delivery of healthcare is not risk free. Not for one moment am I suggesting that any of these companies market inherently unsafe products. These are good companies, good histories, made up on the most part of good and caring people. But the facts remain that in the 12 year history of the reprocessing industry, there shows an excellent record, whether you judge it on its own or whether you compare it to the OEM industry segment. I thank you for your time.

[The prepared statement of Vern Feltner follows:]

PREPARED STATEMENT OF THE ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

The Association of Medical Device Reprocessors (AMDR) appreciates the opportunity to present testimony regarding the reprocessing of medical devices labeled for single-use. My name is Vern Feltner, and I am President of Alliance Medical Corporation. AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for single-use. It is estimated that AMDR members perform approximately 80 percent of the third-party reprocessing done in the United States. Members of AMDR serve a nationwide customer base of hospitals and outpatient surgery centers, and reprocess a limited set of devices in several clinical areas, including perioperative, cardiology, orthopedics, patient floor, and respiratory therapy. AMDR companies contract with hospitals in all 50 states, and reprocessing takes place in many of the elite hospitals of our nation.¹ AMDR companies very likely work with hospitals in the districts of many Subcommittee members.

AMDR is not here today seeking exemption from regulation and oversight. To the contrary, AMDR and the reprocessing industry can only survive in a clear, rational regulatory scheme. It is important, however, that any regulatory scheme be based on demonstrated public safety risks and not on hypothetical risks designed to provoke public alarm. This industry is made up of people who are doctors, nurses, parents, husbands, and wives. Our families are the very ones on whom reprocessed devices will be used. If there was truly a question of increased risk to patients and, therefore, to our families, we would not be in this business. The hospitals we serve are populated by doctors who live and work under the Hypocratic Oath, which is based upon the premise that patient safety must come first. In fact, the reprocessing industry came to be as a direct result of doctors who saw the need for reprocessing. Yes, we are a business, and yes, hospitals have bottom-lines, but that does not mean that our motives are suspect or that reprocessed devices are inherently unsafe. All businesses have bottom lines. AMDR members stand committed to complying with all Food and Drug Administration (FDA) requirements applicable to third-party reprocessing. It is in AMDR's best interest to ensure that reprocessing is a safe, rationally regulated practice that hospitals can utilize to conserve health care resources without compromising patient care.

I. HISTORY AND BACKGROUND

Over Two Decades of Successful Reprocessing. From the recent press and congressional interest, one might believe that reprocessing of medical devices labeled for single-use is new, uncharted territory. One might also assume that reprocessing is a haphazard practice applied indiscriminately to a garden variety of medical devices. In fact, these assumptions are entirely false. The reprocessing of certain medical devices labeled for single-use has taken place for over two decades. The American Hospital Association (AHA) calls reprocessing of "single-use" devices "a safe and standard medical practice" that hospitals have used "for years with excellent

¹ See "America's Best Hospitals," *U.S. News & World Report*, July 19, 1999, at 61.

success.” The American College of Cardiology wrote to Congress that “there are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broke[n] or caused infection.” And the Mayo Clinic states that “for more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection.”²

Hospitals originally began to reprocess for two reasons: 1) certain devices initially labeled “reusable” were switched to “single-use” without any structural change in the device; and 2) doctors and nurses recognized the inherent waste in discarding certain devices after one use. The single-use designation is not based on a determination by FDA. To the contrary, the single-use label is *chosen* by the original equipment manufacturers (OEMs), and, for many devices, the single-use designation is a marketing decision, not a safety decision. AMDR believes that much of the attack on the reprocessing industry is also based on marketing concerns, not true safety concerns. The math is easy—the more devices that are reprocessed, the fewer brand-new devices are purchased, and that much less money is made by manufacturers.

Making the Decision to Reprocess. Hospitals do not reach the decision to reprocess lightly. Rather, they rely on committees made up of physicians, nurses, sterile processing professionals, infection control specialists, risk managers, and hospital lawyers to determine whether a specific device can and should be reprocessed. At each AMDR company, the specific devices are carefully scrutinized in order to determine whether they can be safely and effectively reprocessed. Because of this rigorous selection process utilized by hospitals and third-party reproducers, only a small percentage of the thousands of medical devices used by hospitals are actually reprocessed.

II. THIRD-PARTY REPROCESSING IS AN FDA-REGULATED INDUSTRY

In the past, manufacturers have claimed that third-party reprocessing is an “unregulated” industry. The fact is that third-party reproducers are currently required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation. The Quality System Regulation is an extensive set of quality assurance provisions governing every aspect of a reproducer’s operations, including production and process controls, process validation, control of non-conforming product, and finished device acceptance. Pursuant to these Quality System Regulation requirements, third-party reproducers must: (1) control and monitor production processes to ensure that a device conforms to its specifications; (2) validate with a high degree of assurance that their reprocessing processes ensure that specified requirements are met; and (3) establish and maintain procedures for reprocessed device acceptance to ensure that each production run, lot, or batch meets acceptance criteria. *See* 21 C.F.R. Part 820. In other words, reproducers must document that they have developed comprehensive systems to assure that a reprocessed device is clean, sterile, and able to perform its originally intended clinical function. The functional testing step of reprocessing differs significantly from the testing performed by device manufacturers: AMDR companies functionally test *every single* reprocessed device before sending it back to a hospital, whereas device manufacturers test only a small sampling of their finished devices.

Third-party reproducers must make all required Quality System Regulation information and data available for FDA inspection³, and firms that fail to comply with these requirements are subject to agency enforcement action. In addition to complying with Quality System Regulation requirements, third-party reproducers also are required to: (1) register with the agency; (2) comply with FDA labeling controls; (3) and adhere to Medical Device Reporting (MDR) regulation requirements. Pursuant to MDR requirements, third-party reproducers must report to FDA certain device malfunctions and device-related patient adverse events.

AMDR members reprocess three broad categories of medical devices labeled for single-use: 1) opened devices that have never been used; 2) unopened devices whose expiration date has passed; and 3) previously utilized devices. All three of these categories are reprocessed in compliance with the rigorous quality assurance requirements contained in FDA’s Quality System Regulation.

² See Attachment A for these letters.

³ All AMDR companies have been inspected by FDA in the last 12 months.

III. THE MANUFACTURERS' ALLEGATIONS ARE BASED ON ONE OVERRIDING CONCERN: ECONOMICS

Manufacturers Want to Erect Economic and Regulatory Barriers to Market Competition. In AMDR's view, there exists little, if any, factual basis for the vast majority of objections to third-party reprocessing. The major medical device manufacturers have embarked on a crusade at the federal and state level to eliminate third-party reprocessing. This is not a surprise. Hospitals are fully aware that the "single-use" label on a medical device does not necessarily mean that it should be discarded after one use. As the AHA noted, "In our view, the real issue is not whether reuse is appropriate, but whether the single-use label is a complete and accurate representation of the device."⁴ For hospitals, proper reprocessing offers a way to maintain the highest quality patient care, while also achieving significant cost savings.

Reprocessed Devices are More Affordable, and Market Competition Exerts Downward Pressure on the Price of New Devices. It is clear that third-party reprocessing represents a potentially formidable economic threat to manufacturers. A future where hospitals no longer needlessly discard certain devices labeled for single-use could, ultimately, mean a future of lower profits for manufacturers. The fact is that reprocessing has already had a substantial impact on the sales and profits of device manufacturers. Indeed, every time a hospital chooses to reprocess a device rather than purchase a new device, that means a lost sale for manufacturers. In addition, in an effort to persuade their customers not to reprocess, manufacturers have lowered the price of their devices. Lower prices generally mean lower profits.

The experience of one hospital that utilizes third-party reprocessing services is particularly telling. EP Technologies, Inc., a division of Boston Scientific Corporation, informed the hospital that it

would be willing to supply [the hospital] with new catheters at the price of each returned catheter, if I (the hospital's Chief of Infection Control Service) would stop reprocessing... Being dumbfounded with this offer for cutting the price in half for each new catheter, I immediately asked her (the E.P. Technologies representative) where her integrity was with keeping the price so high all this time? She had no answers.⁵

Not surprisingly, the device manufacturers fail to acknowledge that their opposition to third-party reprocessing is rooted in economics. Rather, they repeatedly assert that their primary motivation is patient safety. While emotionally appealing, the manufacturers' professed interest in patient safety is disingenuous at best, misleading at worst. As set out below, third-party reprocessing is a safe, federally-regulated industry. When performed properly, third-party reprocessing poses no threat to patient safety.

A. Manufacturers Frequently Designate a Device As "Single-Use" For Economic Reasons, Rather Than Out Of Concern For Patient Safety

FDA does not require manufacturers to designate certain devices as "single-use" only. There are no FDA regulations or formal standards distinguishing the quality or functionality of reusable devices from single-use devices. The discretion to label a device as single-use lies solely with the device manufacturer.

The "Single-Use" Label Provides Little Indication of the Product's Useful Life. The device manufacturers have repeatedly contended that devices labeled for single-use must be discarded after one use because they are manufactured in such a way that makes reuse prohibitive. As a practical matter, however, it is nearly impossible to manufacture a medical device for "one use and only one use." For example, a surgical instrument labeled for single-use does not "wear out" simply because it was used in a surgical case that took three hours rather than two hours. Likewise, it is absurd to suggest that if a scissor labeled for single-use is utilized to snip only once in a surgical case, then its entire useful life has been exhausted. In reality, a manufacturer's "single-use" designation on a medical device provides little indication of the product's useful life. The "single-use" designation more often than not reflects a manufacturer's decision to market a product that will lead to a needless waste of scarce health care resources. The key issue should be the device's functionality. If a device labeled for single-use can be properly cleaned, packaged, and sterilized without negatively affecting its functionality, it can, and *should*, be used again.

⁴See Attachment A.

⁵Letter from Dana Gruber, Chief, Infection Control Service, Brooke Army Medical Center, to William B. Stoermer, Jr., Executive Vice President, Alliance Medical Corporation (December 29, 1999). See Attachment B.

Evidence that manufacturers often designate devices as single-use for economic reasons, rather than out of a concern for patient safety, is abundant. For example, the December 11, 1998, episode of NBC's "Dateline" exposed Johnson & Johnson's practice of labeling as "single-use" contact lenses⁶ that were virtually identical to the lenses that the company had been marketing as reusable. Thus, consumers were needlessly discarding lenses after one use. When asked why it had designated the lenses as single-use, Johnson & Johnson stated: "If we had changed the label and marketed for general use, then we couldn't advertise and create this single-use, daily disposable category. *We made that decision because we felt it was a good business decision to do it that way.*"⁷

Another example is a letter written by USCI Cardiology & Radiology Products (USCI) to a hospital explaining that, although USCI had decided to change the label on a particular device from reusable to single-use, it had made no structural changes to the device. Specifically, USCI stated: "[O]ur manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner they have been in the past."⁸ In another example, Microvasive, a division of Boston Scientific Corporation, advised hospitals that, although Microvasive's hemostatic probes are labeled for single-use only, they may be reused under certain circumstances. Specifically, the Microvasive notice states: "BICAP® Hemostatic Probes are recommended for single-use only. However, this recommendation does not prohibit reuse under certain specific conditions..."⁹

In light of the above evidence, the manufacturers' protestations that the single-use designation on a device is never arbitrary, and that "economics must be subordinate to this concern for proper health"¹⁰ ring hollow. The reality is that some devices that carry a single-use label are suitable for reprocessing, and many are not. Every product—whether it is labeled "single-use" or "reusable"—must be assessed individually to determine whether it can be cleaned, packaged, and sterilized without impairing functionality. Hospitals, and their doctors and nurses, should not be forced to needlessly discard devices labeled for single-use that could be safely reprocessed. Hospitals should be free to redirect their limited resources where they are truly needed—toward improvements in patient access and medical care.

B. When Done Properly, Third-Party Reprocessing Is Safe

The most frequently levied allegation in the manufacturers' arsenal of scare tactics is that third-party reprocessing is unsafe. There simply is no factual basis for this claim. The manufacturers cling desperately to this argument as a way to disguise what is, for them, an economic issue. The facts are as follows: *AMDR member companies have collectively reprocessed over 9 million devices labeled for single-use with very few problems.*

Indeed, FDA itself recently stated 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."¹¹ Similarly, a physician with the Centers for Disease Control and Prevention remarked that he "would just be absolutely amazed if [reprocessing] is a major health problem and the [leading hospitals] have failed to realize it."¹²

1. The Safety Record Of Reprocessed Devices Is Excellent—As Demonstrated By The Handful Of MDRs And As Compared To The OEM Record

Based on FDA's own database of device-related patient adverse events, the safety record of reprocessing is excellent. Pursuant to the agency's MDR regulation, hospitals must notify FDA when they learn that a device may have caused or contributed to a patient death or serious injury. 21 C.F.R. §803.30. Every year, FDA receives over 100,000 MDR reports. Significantly, there have been only a handful of MDR reports associated with reprocessed devices. Indeed, FDA itself recently remarked that the number of MDR reports involving reprocessed devices is "tiny" compared with other problems.¹³ Furthermore, the incidents reported in the few MDRs involving reprocessed devices are identical to problems that have occurred in

⁶AMDR members do not reprocess contact lenses.

⁷Transcript of December 11, 1998, *Dateline* episode at 5 (emphasis added).

⁸See Attachment C.

⁹See Attachment D.

¹⁰Josephine Torrente, President, Association of Disposable Device Manufacturers, testimony to Illinois State Board of Health Board Meeting and Public Hearing Regarding the Reprocessing of Medical Devices Labeled for Single-Use, December 10, 1998.

¹¹Letter from David W. Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, McKenna & Cuneo. See Attachment E.

¹²Lauran Neergaard, *Debate on Reuse of Medical Devices*, Associated Press, August 13, 1999.

¹³Device & Diagnostics Letter, Vol. 26, No. 48 (Dec. 17, 1999) at 1.

new devices. Thus, it is not at all clear that these incidents were caused by reprocessing.¹⁴

There are Thousands of MDR Reports on Brand New Devices Each Year. The OEMs have made much noise about the handful of MDRs on reprocessed devices. Attached to my testimony is a chart of some of the MDRs for the few companies leading the attack on reprocessing. From January 1997 to March 1999, a 27-month period, Boston Scientific companies had a total of 2,396 MDRs. This number includes 874 injuries and 50 deaths. Johnson & Johnson companies had 11,327 MDRs, including 1,239 injuries and 58 deaths. Mallinckrodt companies had 1,755 MDRs, including 90 injuries and 47 deaths. Tyco companies had 552 MDRs, including 305 injuries and 8 deaths.¹⁵

As you can see, there are numerous examples of medical devices causing patient injury during their *first* use. For example, a 1994 outbreak of post-surgical infections has been attributed to bacteria-contaminated sutures manufactured by Ethicon, Inc. (Ethicon), a division of Johnson & Johnson. The contamination allegedly resulted from a malfunction in Ethicon's sterilization system.¹⁶ Ethicon ultimately recalled 3.6 million packages of sutures.¹⁷ As another example, FDA recently found that an improperly functioning coronary stent system manufactured by Boston Scientific Corporation had caused 26 patient injuries, and may have been a factor in the death of one individual. Boston Scientific Corporation is engaged in a recall of the defective stents.¹⁸ We cite these examples to show that the use of medical devices is not and will likely never be 100% problem-free. That said, the reprocessing industry believes that having one injury is still one injury too many, and we will continue to strive to make our services as safe as possible.

2. *The Warning Letters Received By Certain Third-Party Reprocessors Do Not Constitute Evidence That Third-Party Reprocessing Is Unsafe*

The device manufacturers also cite FDA Warning Letters received by certain third-party reprocessors as evidence that third-party reprocessing is unsafe. Once again, the manufacturers are not applying their own logic to themselves. While it is true that some third-party reprocessors have been issued FDA Warning Letters, most, if not all manufacturers have also received FDA Warning Letters. Indeed, FDA often issues Warning Letters to device manufacturers.¹⁹

By way of background, a Warning Letter is based upon an FDA inspector's inspectional observations and is not independently verifiable by a court or other impartial finder of fact. A Warning Letter is informal and advisory, and constitutes only an FDA communication that the Agency *considers* a violation to exist.²⁰ Typically, the company in question addresses the concerns raised in the Warning Letter, and FDA re-inspects the facility to ensure that any necessary changes have been made.²¹

By failing to frame FDA Warning Letters in their proper perspective, and by choosing not to disclose that manufacturers themselves often receive Warning Letters, the manufacturers clearly hope to create the impression that FDA has singled out third-party reprocessors for some sort of special scrutiny. This is not the case. Actually, a discussion of our receipt of Warning Letters helps prove our case—that reprocessors are subject to FDA oversight, that oversight is active even as we sit here. Also, what is important is that the Warning Letter recipient take the appro-

¹⁴ As one example, an MDR report was submitted to FDA concerning a reprocessed electrophysiology (EP) catheter whose tip became detached. MDR Report Number 1062310-1999-00001. See Attachment F. However, the identical incident has been reported for new EP catheters. MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. See Attachment G.

¹⁵ See Attachment H.

¹⁶ See, e.g., Lance Williams, "Common thread in illnesses: sutures lawsuits blame postsurgical infections on a single source," *San Francisco Examiner* (Feb. 21, 1999); Lance Williams, "Patients wounded by infections across the country, lives have been torn by post-op complications," *San Francisco Examiner* (Feb. 21, 1999); Lance Williams, "How suture maker kept lid on infection suits despite recall, Ethicon said product was harmless," *San Francisco Examiner* (Feb. 22, 1999); Lance Williams, "Patients who suffered," *San Francisco Examiner* (Feb. 22, 1999).

¹⁷ See, e.g., FDA Enforcement Reports 94-43 & 95-08.

¹⁸ See, e.g., Ronald Rosenberg, "Boston Scientific, FDA spar over stent," *The Boston Globe* (October 10, 1998).

¹⁹ FDA's Center for Devices and Radiological Health issued 303 Warning Letters in 1999. See www.fda.gov/foi/warning.htm and Thompson.com, an FDA Warning Letter Monitor.

²⁰ See Regulatory Procedures Manual at Ch. 4; FDA Office of Regulatory Affairs Warning Letter Reference Guide (October 4, 1994) at p.14.

²¹ As an example, we are including an FDA letter issued to an AMDR member company indicating that, in FDA's view, the concerns raised in the Agency's Warning Letter had been adequately addressed. See Attachment I.

appropriate steps to address the agency's concerns. While AMDR members have full confidence in the safety and efficacy of their operations, they recognize that there is always room for improvement, and they welcome FDA's input in this regard. But, if the suggestion that receipt of Warning Letters means that reprocessed devices are inherently unsafe, then brand new devices should also be considered inherently unsafe. We do not believe this line of thinking is logical and urge the manufacturers to be consistent in their application of the facts.

3. A Substantial Body Of Peer-Reviewed Scientific Literature Demonstrates The Safety Of Reprocessing

Physician and hospital groups have articulated strong support for reprocessing. There is also a significant body of independent, peer-reviewed scientific literature confirming the medical community's confidence in the safety of reprocessing devices labeled as single-use. Indeed, studies demonstrating the safety and efficacy of reprocessing have been published in a number of highly esteemed medical journals, including *Gastrointestinal Endoscopy*, *The American Journal of Gastroenterology*, *Journal of the American College of Cardiology*, *Journal of Thoracic Cardiovascular Surgery*, *Pacing and Clinical Electrophysiology (PACE)*, *American Journal of Cardiology*, *Medical Journal of Australia*, *Canadian Journal of Surgery*, and *Canadian Journal of Cardiology*.²²

As one example, Dr. Richard Kozarek, Chief of Gastroenterology at the Virginia Mason Medical Center in Seattle, Washington, and former President of the American Society for Gastrointestinal Endoscopy, has conducted a number of independent studies demonstrating the reusability of certain endoscopic accessories. In the area of sphincterotomes labeled as single-use, for instance, Dr. Kozarek found that "[d]ouble channel sphincterotomes marketed as one-time-use items can be reused safely when properly cleaned."²³ Likewise, with respect to argon beam plasma coagulation (APC) probes labeled for single-use, Dr. Kozarek concluded:

The combination of manual cleaning and ETO sterilization consistently cleaned APC probes. Ninety percent of the probes showed no sign of physical deterioration and 100% maintained their electrical activity after 10 uses. APC probes can potentially be safely and effectively reused up to 10 times, and a significant procedural savings is possible with reuse."²⁴

As another example, Dr. Edward V. Platia, a nationally recognized electrophysiologist at the Washington Hospital Center in Washington, D.C., conducted an extensive multi-center study of the reuse of electrophysiology (EP) catheters, involving 14,640 EP cases and 48,075 catheter uses. Dr. Platia concluded that:

the sterilization and reuse of non-lumen, woven Dacron pacing catheters is safe, and does not appear to result in any increase in the risk of infection. The catheters are sufficiently durable to allow them to be reused well in excess of five times. One-time use of such catheters appears to be an unnecessary and expensive policy."²⁵

What is, perhaps, most striking about the rigorous body of scientific evidence supporting the safety and efficacy of reprocessed devices is its dramatically superior quality, as compared to the "studies" offered by the OEMs that oppose reprocessing. Indeed, most of the "scientific evidence" submitted by the opponents of reprocessing should be disregarded, as: (i) much of it was conducted by the OEMs themselves, rather than independent entities, and, as such, is tainted by the OEMs' clear economic incentive to portray reprocessing in a negative light; and (ii) much of it is plagued by fundamental scientific deficiencies, such as lack of an adequate sample size, and, as a result, cannot serve as a basis for any conclusions about the safety of reprocessed devices.

4. Tracking And Tracing Systems For Reprocessed Devices Help Ensure Accountability And Safety

Third-party reprocessing is not conducted in a black hole where no one is accountable. There are several steps taken to ensure appropriate tracking and tracing of each device. Once a hospital makes a determination that a specific type of device can be reprocessed, AMDR members pick up a batch of the devices from the hos-

²²See Attachment J for a bibliography and summary of these studies.

²³R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., J.J. Brandabur, M.D., "Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP: a one-year prospective study," *Gastrointestinal Endoscopy*, Vol. 49 (1999) at 39.

²⁴S.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," *The American Journal of Gastroenterology*, Vol. 94 (1999) at 139.

²⁵E.V. Platia, M.D., S. O'Donoghue, "Reuse of Pacing Catheters: a Survey of Safety and Efficacy," *PACE*, Vol. 11 (Sept. 1988) at 1280.

pital, reprocess those devices, and return the same devices to the hospital. AMDR members also ensure that there are numerous ways to determine whether a device was reprocessed and to identify who the reprocessor was. For example, some reproprocessors employ bar code tracking systems, which allow devices to be tracked back to the reprocessor. Likewise, some reproprocessors provide hospitals with “peel-off” labels, which can be placed in a patient’s record to identify where the device was reprocessed. Therefore, it is quite easy for a doctor and a hospital to know if a reprocessed device was used and to identify who the third-party reprocessor was.

5. *Proper Reprocessing Does Not Require Access To The Manufacturer’s Specifications*

One the most misleading arguments made by the manufacturers is that third-party reproprocessors are incapable of safely reprocessing devices labeled for single-use because they lack access to the original manufacturer’s specifications. The assertion that the manufacturer’s specifications are required to reprocess most devices is misleading.

Access to manufacturers’ specifications is unnecessary because third-party reproprocessors employ a variety of techniques to equip themselves with intimate knowledge about the workings of every device they reprocess. For example, in addition to utilizing every publicly available source of product-related information, *e.g.*, product labeling, marketing materials, AMDR members also use independent laboratories to “reverse engineer” certain devices. In addition, AMDR member companies are engaged in an ongoing dialogue with the clinical users themselves, *i.e.*, the hospitals and physicians, in order to understand the performance requirements for each device they reprocess.

More importantly, AMDR member companies have developed validated protocols to ensure that every device they reprocess is safe and effective for its intended use. If an AMDR member lacks sufficient information about a device in order to safely reprocess it, then that device will not be reprocessed. Furthermore, as described above, AMDR members—unlike manufacturers—perform functionality testing on *every single device* that they reprocess. Thus, the manufacturers’ argument that access to the original specifications is necessary to safely reprocess devices labeled for single-use is without merit. Indeed, if the manufacturers were correct in this claim—and they are not—it certainly is difficult to understand why so many hospitals and doctors’ groups have endorsed the use of reprocessing.

IV. THE MANUFACTURERS’ CALL FOR “INFORMED CONSENT” IS SIMPLY ANOTHER PRONG OF THEIR ECONOMIC ARGUMENT

As part of their campaign to create an “aura” of suspicion around third-party reprocessing, the manufacturers argue that the very doctors committed to treating and curing the sick are keeping patients “in the dark” about the alleged hazards of third-party reprocessing. Indeed, the manufacturers advocate vociferously for mandatory “informed consent” regarding the use of reprocessed devices.

Although dressed up in the garb of patient safety, the manufacturers’ informed consent argument is merely another prong of their economic agenda. Medical ethicists state that the objective of informed consent is to arm patients with sufficient information to make a prudent judgment about their medical care. If a physician believes that the use of a certain device or procedure will increase a patient’s risk, then the physician should disclose this to the patient. Properly done, third-party reprocessing presents no additional risk to patients. Because properly reprocessed devices are as safe and effective as new devices, there is no ethical basis for requiring informed consent before the use of reprocessed devices.

Should There be Informed Consent for New Devices? It is striking that, although they push vigorously for informed consent with respect to the reprocessing of devices labeled for single-use, the manufacturers conspicuously avoid the obvious implications of their own argument. According to the manufacturers’ thinking, a physician should tell a patient before using any device that has been the subject of an MDR report, Warning Letter, or recall. Similarly, it seems only logical that the manufacturers would demand informed consent with respect to the “second use” of devices that are labeled *reusable*. The manufacturers do not make these arguments because they realize that informed consent regarding MDR reports, Warning Letters, and recalls would be detrimental to their own economic interests.

V. CONCLUSION

As we have demonstrated, when performed properly third-party reprocessing is safe. Third-party reproprocessors are required to comply with a host of FDA requirements. Hospitals that take advantage of the benefits of third-party reprocessing can

maintain the highest quality patient care, while also achieving significant cost savings. Resources saved through third-party reprocessing can be redirected toward improvements in patient access and medical technology. We believe that patient safety is of utmost concern, but health care cost containment is also of extreme importance. In this age of rising health care costs, reprocessing is one of the few technologies that offers a solution.

June 23, 1999

ATTACHMENT A

The Honorable Thad Cochran
United States Senate
326 Russell Senate Office Building
Washington, DC 20510



Dear Chairman Cochran:

The American Hospital Association (AHA), which represents nearly 5,000 hospitals, health care systems, networks, and other providers of care, wants to raise our serious concerns about an amendment that Senator Richard Durbin (D-IL) is preparing to offer to the Agriculture Appropriations bill when it comes to the Senate floor this week. The amendment would restrict reprocessing of medical devices, and could seriously affect both the quantity and quality of health care we offer our patients.

The clinical use of reprocessed medical devices is safe, effective, and efficient. Hospitals have reprocessed devices labeled "single use" or "disposable" for years with excellent success. In our view, the real issue is not whether reuse is appropriate, but whether the single use label is a complete and accurate representation of the device. With this in mind, it is the general practice for hospitals to rely on physicians, nurses, sterile processing professionals and infection control specialists to deliberate carefully before deciding to reprocess any device and ensure that proper safeguards exist in the reprocessing procedure. In-hospital reprocessing is also subject to Joint Commission on Accreditation of Healthcare Organizations oversight.

For hospitals, proper reprocessing is a safe and effective way to deliver the highest quality patient care. There is an extensive body of research demonstrating that reprocessing of certain medical devices is appropriate and poses no significant risk to patients. If the Durbin amendment is adopted, it would result in devices being disposed of after only one use, even if the device could still be used safely and effectively, contributing unnecessarily to the waste streams generated by health care facilities.

Finally, the Food and Drug Administration (FDA), whose jurisdiction includes oversight of reprocessed devices, has indicated that it shares some of our concerns regarding Sen. Durbin's amendment. The FDA agrees that more research needs to be done to determine the prevalence of reprocessing and the ability of reprocessors to maintain quality.

There is no quick and easy solution to this issue. The Durbin amendment is at best premature and at worst would have a far-reaching negative impact on what is a safe and standard medical practice. The whole issue deserves a much more thoughtful review before legislation is enacted. We respectfully ask that this amendment not be included in the Agriculture Appropriations bill when it comes to the Senate floor.

Thank you for your attention to this matter.

Sincerely,

Rick Pollack
Rick Pollack
Executive Vice President

AMERICAN COLLEGE of CARDIOLOGY

Heart House
9111 Old Georgetown Road
Bethesda, MD 20814-1597
USA

202-897-5600
800-525-4626
Fax 202-897-5745
<http://www.acc.org>

June 25, 1999

The Honorable
Richard Durbin
364 Russell Senate Office Building
Washington, D.C. 20510

Dear Sen. Durbin:

It has come to the attention of the American College of Cardiology (ACC) that you are considering offering an amendment to the Agriculture, Rural Development, and Related Agencies Appropriations bill that would severely restrict the use of reprocessed medical devices. On behalf of more than 24,000 cardiovascular specialists, I wish to express the ACC's deep opposition to your amendment.

When it comes to treating patients, our number one concern is safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective. In particular, the ACC is concerned about the effect your amendment will have on the use of reprocessed catheters, such as those used in electrophysiology. Solid, rigid catheters are used by cardiovascular specialists in electrophysiology for the placement and removal of pacemakers and implantable defibrillators. Generally, between two and six catheters are used during a single procedure, but it is not uncommon for as many as eight to be used. Now, these catheters cost between \$150 and \$1000 each. Reprocessed catheters are not only safe and effective, they are also cost efficient.

The catheters used in electrophysiology can be used safely, following sterilization, as many as five times, thereby greatly reducing costs. Concerns that reprocessed catheters could cause serious injury to patients are completely unfounded. There are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broke or caused infection. Simply stated, your amendment will unnecessarily increase health care costs and could potentially result in the closing of electrophysiology labs.

Generally speaking, your concern for patient safety is appreciated. The ACC simply questions the claims that reprocessed medical devices, particularly those used in cardiovascular medicine pose a danger to patients. Therefore, the ACC must oppose your amendment, as it will unjustifiably increase costs, and urges you not to seek its passage until a more detailed discussion about the issue can occur.

Sincerely,



Arthur Garson, Jr., M.D., F.A.C.C.
President

cc: Sen. Edward Kennedy
Sen. William Frist
Sen. Jim M. Jeffords

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Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-255-2311

Stephen C. Hammill, M.D.
Cardiovascular Diseases
& Internal Medicine

June 23, 1999

The Honorable Paul Wellstone
United States Senate
Washington DC 20510

Dear Senator Wellstone:

As Professor of Medicine and Director of Electrophysiology at Saint Marys Hospital and Mayo Clinic, I am writing to express my concern about reports that Senator Richard Durbin may propose legislation to restrict the reprocessing of medical devices labeled for single use. Such legislation would have a seriously negative economic impact on our Electrophysiology Program at Saint Marys Hospital.

The Electrophysiology Program at Mayo has sought to provide the highest quality care while maintaining a cost-efficient approach. For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures. During electrophysiologic testing, we use between two and eight catheters per study with total catheter costs approaching \$300-\$4000. 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.

I am greatly concerned that any legislation to add new and unnecessary regulatory requirements for the reprocessing of medical devices would add tremendous costs to the electrophysiology study and achieve no benefit for patients. I would appreciate you not supporting this type of legislation, and I would be happy to provide any additional information you might desire.

Sincerely,

Stephen C. Hammill, M.D.
Professor of Medicine
Director, Electrophysiology
and Electrophysiology Laboratories

SCH:mp

NASPE[®] North American Society of Pacing and Electrophysiology



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NASPE's Mission Statement

The mission of the North American Society of Pacing and Electrophysiology is to improve the care of patients by promoting research, education and training and promoting legislation that optimizes healthcare policies and standards.

Executive Director

Carol J. McGivern

June 22, 1999

The Honorable Richard J. Durbin
Senate Russell Building
Room 364
Washington, DC 20510

Dear Senator Durbin:

The North American Society of Pacing and Electrophysiology (NASPE) is very concerned with your proposed amendment to Senate Bill 1233, titled "Reprocessed Medical Devices". This amendment would restrict the re-processing of medical devices labeled for single-use. The current medical practice of re-sterilizing medical devices, such as cardiac catheters, is not only common, but has been proven safe and effective in the care and treatment of patients with cardiac rhythm problems, also known as arrhythmias.

NASPE is an organization of physicians, scientists and allied health professionals dedicated to the study and management of cardiac arrhythmias and to improving the care of patients by promoting research, education and training. NASPE members diagnose and treat patients with cardiac rhythm problems.

There has been considerable peer-reviewed published research into the effect on patient care using re-sterilized cardiac catheters. A brief list of references is attached. After studying thousands of patients who have undergone cardiology procedures with re-sterilized catheters, findings indicate there is no increased risk of infection for patients. Re-sterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years with no known adverse patient outcomes. In addition, the Food and Drug Administration permits re-sterilization of catheters provided that a meticulous quality assurance program documents the structural integrity of the catheters, and that sterility and chemical residuals are monitored.

NASPE members foremost priority is to provide quality medical care to patients. Appropriate medical device re-processing is a safe and effective way to achieve health care cost savings without compromising patient care. These savings can be directed towards improving patient access and medical care.

Legislation, which would add new and unnecessary regulatory requirements for the reprocessing of medical devices, would hinder the practice of cardiac electrophysiology in this country. NASPE encourages you to research this topic further before passing a legislative mandate that would, in essence, ban a medically acceptable and safe practice. Hearings on this topic could include

experts in the field of medical device reprocessing, representatives of the Food and Drug Administration, physicians, as well as patient representatives.

NASPE would be pleased to provide you with additional information on this critical issue. Please feel free to call me at the Hershey Medical Center at 717-531-3907 or Amy Meinick, Director, Government Relations at NASPE. Thank you for your attention.

Sincerely,



Gerald Naccarelli, MD
President
North American Society of Pacing and Electrophysiology

References:

- 1) O'Donoghue S, Platia EV. Reuse of Pacing Catheters: A Survey of Safety and Efficacy. PACE 1988;11:1279-1280.
- 2) Dunnigan A, Roberts C, McNamara M, Benson DW, Benditt DG. Success of Re-Use of Cardiac Electrode Catheters. American Journal of Cardiology 1987;60:807-810.
- 3) Avitall B, Khan, Krum D, Jazayeri M, Hare H. Repeated Use of Ablation Catheters: A Prospective Study. American Journal of Cardiology 1993;22:1367-1372.
- 4) Aton EA, Murray P, Frase V, Conaway L, Cain ME. Safety of Reusing Cardiac Electrophysiology Catheters. American Journal of Cardiology 1994;74: 1173-1175.

ATTACHMENT B



DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234-6200

REPLY TO
ATTENTION OF

Mr. William B. Stoermer, Jr.
Executive Vice President
Alliance Medical Corporation
P.O. Box 8469
Asheville, NC 28814-8469

29 December 1999

Dear Mr. Stoermer:

This letter is a follow up to our recent telephone conversation. While I was investigating the current practices and SOPs in the Cardiac Cath Lab at Brooke Army Medical Center, I was presented by the EP Technologies, Inc. representative a letter telling me reprocessing of single use items was "unlawful". Moreover, she emphasized because it was unlawful, Wilford Hall Medical Center, San Antonio, Texas, just stopped reprocessing all items.

Because (1) BAMC has done this reprocessing solely through the Alliance Co, and (2) has incurred no problems with the returned items, (3) all the physicians were very satisfied with the returned items, and (4) Alliance has comprehensive records of the entire QA program IAW the FDA Quality Systems Regulations, and (5) provides liability coverage for each item, I told her I was not going to stop they way we were reprocessing EP catheters.

She then said that EP Technologies, Inc. would be willing to supply BAMC with new catheters at the price of each returned reprocessed catheter, if I would stop reprocessing and using Alliance. Being dumbfounded with this offer of cutting the price in half for each new catheter, I immediately asked her where her integrity was with keeping the price so high all this time? She had no answers.

Clearly, the reprocessing of EP catheters does not cause a safety problem for the patient when done according to FDA QSR guidelines. I continue to be amazed at the reactions of the manufacturer, who definitely is out to kill the commercial reprocessing industry, even at the expense of reducing their own revenues. I believe that EP Technologies, Inc. must be overcharging all the Federal Government today. In the light of tight operating budgets and continued shortages of operating funds throughout the military, I would appreciate any help you can provide in bringing this information to the attention of anyone who might have an interest in reducing healthcare costs throughout the military and VA healthcare system.

Thank you,

A handwritten signature in black ink, appearing to read "Dana Gruber", is written over the typed name.

DANA GRUBER
LTJG, AN
Chief, Infection Control Service

ATTACHMENT C



USCI CARDIOLOGY & RADIOLOGY PRODUCTS

July 24, 1980

Dear Dr.

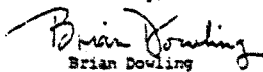
I am writing this letter, as per your request, to substantiate that our manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past.

USCI has been manufacturing intracardiac electrodes since the early 1960's. Throughout this time, USCI electrodes have been held as standards of the industry. We are proud of our heritage, but now find that current hospital and government practices makes traditional methods, such as reuse, difficult to justify and increasingly untenable for the manufacturer. USCI does not control the "reuse decision" that is yours to make, however, we do believe it is in the best interest of all concerned that a new electrode instrument be used on each case. USCI has changed its labeling and instructions to reflect this position.

To insure that our customers receive the safest product possible, and a product which is guaranteed to be within accepted specifications, all USCI Woven Dacron Electrodes have been shipped in double sterile packages as of March 1980. This new package includes two major modifications: the elimination of cleaning instructions, and a label which indicates that the product is intended for one time use. With these changes, USCI now offers a product which conforms with accepted standard for the marketplace in which we sell.

I am fully aware that these changes may impinge on certain budget restraints which you are faced with. I would be more than happy to review with you scheduled orders and quantity discounts which may be applicable. Please call me if I can be of any further assistance. I hope this information prove useful to you.

Sincerely,


Brian Dowling
Product Manager

BD/jab

Enclosures: (1) HEW Position, (2) HEW Position, (3) VA Circular, (4) HEW Position
(5) Morbidity and Mortality Weekly Report, (6) VA Circular

DIVISION OF C.R. BARD, INC., BOX 566, 129 CONCORD ROAD, BILLERICA, MA., 01821, USA.
TEL. 617-667-2311

ATTACHMENT D

May 1, 1987

Dear

As you know BICAP Probes are labeled for single use only. Reusing a probe can put a hospital and physician in an extremely precarious position legally if there would be a complication due to the probe.

Considering the price of each probe, \$165, we at Microvasive realize it is very difficult for a hospital to dispose of a probe after each use.

Enclosed you will find a letter legally allowing the reuse of Microvasive BICAP Probes. In essence, if you follow our cleaning instruction and always have an unused probe as a back up, we will legally back the reuse of our probes.

Please keep this enclosure as a document for your records and it does only apply to Microvasive BICAP Probes.

Our Probe catalog numbers are:

#4007	7 fr Probe	\$165.00
#4010	10 fr Probe	165.00
#4050	5 fr Probe	225.00 (for the Bronchoscope)

Our probes will fit the ACMI as well as Microvasive BICAP's. After all, they are the same unit.

Please call if you have any questions, 800-225-3226 or 612-936-9166.

Respectfully,



Geoffrey M. Allen

GMA/jr

Enclosure

cc: Stewart Gonn

BICAP® HEMOSTATIC PROBES - SINGLE USE OR REUSE

BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions and with full knowledge of the potential consequences.

The single use recommendation is based upon the fact that each activation of any therapeutic probe induces stresses in that probe and consumes some portion of its useful life. There are no readily available means for assessing the magnitude of the induced stresses or the remaining useful life.

The useful life of the BICAP® Therapeutic Probe is strictly a function of the clinical therapeutic procedure for which no standards have been developed. Therefore, any life tests tend to report average life which is meaningless in a specific clinical application. It has been reported to us that the useful life has varied from a fraction of one complex procedure to eight simple procedures.

In order to assist physicians in making the single use or reuse decision, MICROVASIVE makes the following recommendations:

1. If the clinical indications are such that you expect a longer than average therapeutic procedure, start the procedure with a new BICAP® Hemostatic Probe.
2. Reuse a BICAP® Hemostatic Probe only after you:
 - a. Assure that the probe has been carefully cleaned.
 - b. Assure that the probe has been inspected and is acceptable.
 - c. Assure that the probe has not been subjected to disinfection/sterilization environments more severe than those stated in the Operating and Maintenance Manual.
 - d. Assure that an alternate new probe is readily available.
 - e. Accept the potential adverse consequences in the particular therapeutic procedure should the probe reach the end of its useful life before the procedure is completed.

MICROVASIVE will continue to recommend that prudent practice dictates single use of the BICAP® Hemostatic Probe rather than to start a procedure with a probe whose condition is unknown. However, we also recognize and understand the cost concerns in the clinical environment which frequently cause devices intended for single use to be reused without the benefit of a consistent criteria. Our recommendations are intended to reduce the risk of this practice.

ATTACHMENT E

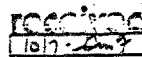


DEPARTMENT OF HEALTH & HUMAN SERVICES,

PUBLIC HEALTH SERVICE

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1999



Larry R. Pilot, Esq.
McKenna & Cuneo, L.L.P.
Counsel to Petitioner
Medical Device Manufacturers Association
1900 K Street, N.W.
Washington, D.C. 20006

Re: Docket No.. 99P-1516/CP 1

Dear Mr. Pilot:

This letter is in response to your citizen petition on behalf of the Medical Device Manufacturers Association (MDMA), dated May 20, 1999, requesting that the Food and Drug Administration (FDA) issue a proposed regulation identifying reprocessed single use devices as banned devices and that such proposed regulation be made effective upon its publication in the Federal Register. As stated, the petition applies to practitioners, institutions, and reproducers. Thank you for the detailed petition and the issues you raised. We regret the delay in responding.

The petition requests that FDA issue a proposed regulation to ban the practice of reprocessing single use devices and to make the ban effective on the date of publication of the proposed regulation in the Federal Register. The stated grounds for the petition included a statement that the "complexity of these devices for their intended use severely constricts any possibility of cleaning and sterilizing the device in order to restore it to its original unused condition." Your letter also stated that manufacturers are required to obtain PMA approval or 510(k) clearance for their devices and that "FDA required labeling" for such devices must state that they are for single use and are not to be reused. You stated that this requirement must be met in the absence of information provided to FDA demonstrating that reprocessing will not adversely affect product safety or effectiveness.

FDA has carefully reviewed your petition to ban the reprocessing of single use devices, and we are denying it. The Agency does not believe that banning is the appropriate action to address the many and varied issues tied to this practice. Our reasoning follows.

There is no clear evidence that reprocessing presents "an unreasonable and substantial risk of illness or injury," which is one of the criteria for banning a medical device. FDA

Page 2 of 2 - Larry R. Pilot, Esq.

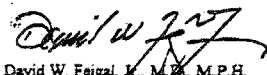
has received adverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported. In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source. Therefore, the "unreasonable and substantial risk" criterion has not been met.

According to the banning provision of the Federal Food, Drug and Cosmetic Act, Section 516, another criterion that can be used for taking such an action is substantial deception. As your petition suggests, it would be difficult to establish whether deception with respect to reprocessed devices has occurred and who was the target of that deception. Even if we did establish a basis to claim substantial deception, the statutory option of banning does not seem to be an appropriate response. There is no evidence to date supporting any such danger to individual health from the reuse of products that have been labeled for only a single use. This burden has not been met.

While FDA will not support a banning action, we believe that a significant re-evaluation of FDA's position with regard to the reuse of single use devices is in order. During the May 1999 AAMI/FDA Reuse Conference, FDA committed to provide a formal response to the conference in a Federal Register notice by October 1999. We plan to honor that commitment. Our Federal Register statement will address the direction of FDA's thinking with regard to key issues and concerns raised at the May conference, such as data generation, premarket submissions, and labeling. We encourage you and your client, MDMA, to be active participants in reviewing and responding to the upcoming Federal Register notice and any other document that FDA may issue on this subject.

If you have any questions, please contact Larry Spears at 301-594-4646, Ext. 151.

Sincerely yours,



David W. Feigal, M.D., M.P.H.
Director
Center for Devices and
Radiological Health

ATTACHMENT F

MAUDE

DR KON-MDE

http://www.fda.gov/scripts/cdrh/cfmaudetail.cfm?MASTER_ID=1212-2

MAUDE Search

BRAND NAME	DEFLECTABLE ORTHOGONAL CATHETER
TYPE OF DEVICE	SEE ABOVE
MANUFACTURER	PARAGON HEALTHCARE CORP. 107 CORPORATE DR. SPARTANBURG, SC 29303 US
DEVICE EVENT KEY	209533
MDR REPORT KEY	216005
EVENT KEY	202692
→ REPORT NUMBER	1062310-1999-00001
PRODUCT CODE	DQO
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	11-MAR-1999
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	ELECTRODE DETACHED & LODGED IN PATIENT
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE MODEL NUMBER	7FR D-TYPE
DEVICE CATALOGUE NUMBER	0D7-8XCD-005-FS
DEVICE LOT NUMBER	ORIGINAL LOT 708492-599
OTHER DEVICE ID NUMBER	PARAGON LOT 9900008
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
CONCOMITANT MEDICAL PRODUCTS	1. ABLATION CATHETER, 2. HEXAPOLAR CATHETER
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
TYPE OF REPORT	FOLLOWUP
REPORT DATE	10-Mar-1999
WAS THE REPORT SENT TO FDA?	NO
INITIAL REPORT SOURCE	USER FACILITY
DATE MANUFACTURER RECEIVED	28-JAN-1999
MANUFACTURER REPORT NO	1062310-1999-00001
EVENT REPORT TYPE	OTHER

WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	11/20/99
LABELED FOR SINGLE USE?	NO
REMEDIAL ACTION	OTHER
TYPE OF DEVICE USAGE	REUSE
BASLINE BRAND NAME	DEFLECTABLE ORTHOGONAL CATHETER
BASLINE GENERIC NAME	SEE ABOVE
BASLINE CATALOGUE NUMBER	OD7-8XLD-001-FS
BASLINE MODEL NUMBER	7FR D-TYPE
OTHER BASELINE ID NUMBER	PARAGON LOT 9900008

EVENT DESCRIPTION

PER PHONE COMMUNICATION FROM HOSP. A CORDIS WEBSTER ORTHOGONAL ELECTROPHYSIOLOGY CATHETER WAS USED IN AN ELECTROPHYSIOLOGY STUDY THAT PROGRESSED WITHOUT DIFFICULTY UNTIL THE PHYSICIAN REMOVED THE CATHETER FROM THE CORONARY SINUS. THE PHYSICIAN REPORTED RESISTANCE UPON REMOVAL FROM CORONARY SINUS. PT WAS NONSYMPTOMATIC THROUGHOUT PROCEDURE. A CHEST FILM CONFIRMED THAT A SMALL FRAGMENT WAS IMBEDDED IN THE RIGHT ATRIAL WALL. SURGICAL CONSULT REVEALED THAT REMOVAL OF FRAGMENT WAS NOT INDICATED. PT REMAINS SYMPTOM FREE PER HOSP REPORT. FRAGMENT PRESUMABLY IS A SINGLE PLATINUM ELECTRODE FROM CATHETER. ONE OF THE SURFACE MOUNTED ELECTRODES MAY HAVE BEEN COMPROMISED BY THE EXTERIOR RIM OF A TUBE USED TO PACKAGE THE CATHETER INSIDE THE MYLAR TYVEK POUCH.

ADDITIONAL MANUFACTURER NARRATIVE

ON MARCH 8, 1999, PARAGON REC'D A COPY OF A MDR FILED BY WESLEY MED CTR IN WICHITA, KANSAS. THE MDR REPORTED THE PERFORMANCE OF THE DEVICE DURING A PERCUTANEOUS INTERVENTIONAL ELECTROPHYSIOLOGY STUDY. THE USER FACILITY INFORMED PARAGON THAT THE ELECTROPHYSIOLOGY STUDY PROCEEDED WITHOUT DIFFICULTY UNTIL THE PHYSICIAN INITIATED THE REMOVAL OF THE CATHETER FROM THE PT'S CORONARY SINUS. THE PT WAS DESCRIBED BY A CLINICIAN TO BE ASYMPTOMATIC DURING AND POST ELECTROPHYSIOLOGY PROCEDURE. A CHEST FILM ORDERED BY THE ELECTROPHYSIOLOGIST CONFIRMED THE LOCATION OF A METAL FRAGMENT IN THE RIGHT ATRIAL WALL. CONSULTATION WITH A CARDIO-THORACIC SURGEON REPORTEDLY DETERMINED THAT NO INTERVENTION WAS INDICATED. PARAGON IS UNAWARE OF ANY ADVERSE EFFECTS TO THE PT OR THAT ANY FURTHER CORRECTIVE PROCEDURE WAS RECOMMENDED. NO OTHER ADVERSE EVENTS HAVE BEEN REPORTED TO PARAGON. THE CO'S INVESTIGATIVE ANALYSIS HAS DEMONSTRATED THAT ANY POSSIBLE RECURRENCE OF THIS INCIDENT WOULD BE LIMITED TO THIS TYPE OF CATHETER. THE PRODUCT CONTAINED SURFACE-MOUNTED PLATINUM ELECTRODES. THEY MAY HAVE COME IN CONTACT WITH THE EXTERIOR RIM OF THE TUBING WHILE BEING INSERTED. THIS MANEUVER MAY HAVE COMPROMISED THE STABILITY OF THE CATHETER ELECTRODES IN ISOLATED CASES. IF ALL ELECTRODES ARE FOUND TO BE PROPERLY INTACT FOLLOWING INSPECTION, THEY WILL BE REPACKAGED INTO MYLAR TYVEK POUCHES WITHOUT TUBES AND RETURNED TO THEIR OWNERS. COMPROMISED, OR QUESTIONABLE, UNITS WILL BE DESTROYED AND REPLACED WITH NEW EQUIPMENT. RECORDS OF THESE INSPECTIONS WILL BE ADDED TO DETAILED REPROCESSING HISTORIES ON FILE AT PARAGON.

ATTACHMENT G

MAUDE

Page 1 of 2

BRAND NAME	MAP
MANUFACTURER	EPT. A DIV. OF BSC <i>But Scientific</i>
	2710 ORCHARD PARKWAY
	SAN JOSE, CA
	95134-2012
	US
DEVICE EVENT KEY	163382
MDR REPORT KEY	167912
EVENT KEY	157793
→ REPORT NUMBER	6000087-1998-00002
PRODUCT CODE	DRF
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	15-MAY-1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
OUTCOME OF EVENT	MALFUNCTION
DEVICE EXPIRATION DATE	UNK
DEVICE MODEL NUMBER	1675P
DEVICE LOT NUMBER	7B296
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
CONCOMITANT MEDICAL PRODUCTS	UNK
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
TYPE OF REPORT	INITIAL
REPORT DATE	17-Apr-1998
WAS THE REPORT SENT TO FDA?	NO
DATE REPORT SENT TO FDA	UNK
EVENT LOCATION	HOSPITAL
DATE REPORT TO MANUFACTURER	UNK
INITIAL REPORT SOURCE	HEALTH PROFESSIONAL
DATE MANUFACTURER RECEIVED	UNK
MANUFACTURER REPORT NO	6000087-1998-00002
EVENT REPORT TYPE	MALFUNCTION
WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	01-FEB-1997
LABELED FOR SINGLE USE?	NO
REMEDIAL ACTION	OTHER
TYPE OF DEVICE USAGE	INITIAL
BASELINE BRAND NAME	MAP
BASELINE GENERIC NAME	.

LAUDE

Page 2 of 2

BASELINE CATALOGUE NUMBER *
BASELINE MODEL NUMBER 1675P
OTHER BASELINE ID NUMBER *

EVENT DESCRIPTION

SMALL SECTION OF DISTAL TIP IN PROXIMITY TO ELECTRODE SIDE OF CATHETER
BROKE AWAY. UNABLE TO LOCATE FRAGMENT.

ADDITIONAL MANUFACTURER NARRATIVE

THIS MEDICAL DEVICE REPORT IS NOT AN ADMISSION BY EPT, A DIV. OF BSC, THAT ANY PRODUCT DESIGN MFG OR SOLD BY SAID COMPANY, CAUSED OR CONTRIBUTED TO ANY OF THE EVENTS DESCRIBED IN THIS REPORT, NOR THAT EPT, A DIV. OF BSC HAS LEGAL LIABILITY OR RESPONSIBILITY WITH RESPECT TO SUCH EVENTS OR OCCURRENCES OR THAT INFO CONTAINED IN THIS REPORT IS REQUIRED TO BE REPORTED UNDER MDR REGULATIONS. F-1 THROUGH F.14: THIS INFO WAS NOT PROVIDED BY THE HOSPITAL REFERENCED IN F.3. IT WAS COMPLETED BY BSC SAN JOSE COMPLAINT COORDINATOR TO THE BEST OF HER KNOWLEDGE BASED ON INFO PROVIDED BY SALES REP.

[\[Return to Search\]](#)[\[CDRH HomePage\]](#)[\[FDA HomePage\]](#)[\[Comments\]](#)

(Database Updated July 6, 1999)

MALDE

BRAND NAME	DEFLECTIBLE D-CURVE ABLATION
TYPE OF DEVICE	CATHETER
MANUFACTURER	CATHETER CORDIS WEBSTER, INC. 4750 LITTLEJOHN ST BALDWIN PARK, CA 91706 US
DEVICE EVENT KEY	30352
MDR REPORT KEY	29314
EVENT KEY	27472
REPORT NUMBER	4501350000-1995-0088
PRODUCT CODE	LPB
REPORT SOURCE	USER FACILITY
WAS MANUFACTURER REPORT SUBMITTED?	NO
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	04-DEC-1995
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	HOSPITALIZATION
DATE OF REPORT	04-Dec-1995
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	01-DEC-1997
DEVICE LOT NUMBER	411044
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	22-NOV-1995
TYPE OF REPORT	INITIAL
WAS THE REPORT SENT TO FDA?	YES
DATE REPORT SENT TO FDA	04-DEC-1995
EVENT LOCATION	HOSPITAL
DATE REPORT TO MANUFACTURER	04-DEC-1995
EVENT DESCRIPTION	

PT IN CARDIAC CATH LAB FOR ABLATION. CATHETER PRESENT IN RIGHT ATRIUM. WHILE PHYSICIAN WAS REPOSITIONING THE CATHETER UNDER FLUOROSCOPY, CATHETER TIP WAS NOTED TO BE DETACHED FROM CATHETER. PHYSICIAN ATTEMPTED RETRIEVAL; UNABLE TO RETRIEVE. PHYSICIAN CONTACTED MFR WHO STATED THAT PREVIOUS EXPERIENCE INDICATED CATHETER TIP COULD SAFELY BE LEFT IN CURRENT POSITION (WEDGED INTO CORONARY SINUS). PT KEPT OVERNIGHT FOR OBSERVATION; DISCHARGED HOME FOLLOWING DAY. CATHETER TIP AND APPROXIMATELY 2 MM OF CATHETER TUBING LEFT IN PT. (LABEL)

[\[Return to Search\]](#)
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(Database Updated July 6, 1999)

ATTACHMENT H

	A	B	C	D	E	F	G	H
1	Medical Device Reports (MDR)							
2	Reported Jan 1997 - Mar 1999 (27 Months)							
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ATTACHMENT I

FROM: VANGUARD MEDICAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

1996-08-01

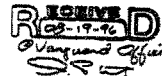
Public Health Service



August 12, 1996

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

Charles Masek, President
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33801



Dear Mr. Masek:

This responds to your firm's response dated May 6, 1996, signed by Douglas Stante, vice president, concerning validation of your sterilization process.

We find that your response appears adequate. Further verification of the methodology and success of the validation runs will be covered during the next inspection of your facility.

If there are any questions, please contact the undersigned at the Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32819, or call (407) 648-6823, ext. #264.

Sincerely,

Timothy S. Cousins
Compliance Officer
Florida District

ATTACHMENT J

Bibliography and Summaries of Articles Addressing Reprocessing Of Medical Devices Labeled for Single-Use

1999

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," *Gastrointestinal Endoscopy*, January 1999, Vol. 49, No. 1, p.p. 39-42

Study to evaluate if disposable double-channel sphincterotomes can be sterilized and reused an average of 3.4 times. Easily detected broken or stiff cutting wires were the cause for discard. The reuse of the sphincterotomes had a total savings of \$66,000. Study concluded that double-channel sphincterotomes can be reused safely when properly cleaned and the cost benefit of doing so was substantial.

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," *The American Journal of Gastroenterology*, January 1999, Vol. 94, No. 1, p.p. 139-143

Study of argon plasma coagulation (APC) probes to determine if they could be re-sterilized and still maintain their electrical integrity. All ten of the ten probes tested completed the study in good condition. 90% of the probes showed no signs of deterioration and 100% maintained their electrical integrity. Concluded that APC probes can be safely and effectively reused ten times with significant cost savings.

Hensley, Scott, "More hospitals buy into device recycling: The practice of reprocessing disposable products is moving into the mainstream," *Modern Healthcare*, February 22, 1999

Hensley's article focuses on the decisions of hospital purchasing groups to contract out for reprocessing services to third-party reprocessors. The writer states that the trend means third-party reprocessing is gaining mainstream acceptance. The article found that hospitals that were originally using third-party reprocessors only to re-sterilize open and unused devices are now including previously utilized medical devices in their reprocessing service contracts. Such hospitals have confidence in their third-party reprocessors and are achieving significant cost savings.

1998

R. Kleinbeck, et. al., "Reprocessing and Reusing Surgical Products Labeled for Single-Use, A Survey of Current Practices," *Surgical Services Management*, January 1998, Vol. IV, No. 1

Kleinbeck found that third-party reprocessors have validated methods and protocols to address sterility and functionality testing issues. The article concluded that third-party reprocessing is a safer alternative than some in-hospital reprocessing programs.

M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," *Journal of the American College of Cardiology*, November 1, 1998, Vol. 32, No. 5, p.p. 1384-1388

Study to evaluate technique for sterilizing nonlumen electrophysiology catheters. Found that there was no loss of electrical integrity or mechanical integrity during the study. With the new catheter costing \$200 to \$800 and Hydrogen peroxide gas plasma sterilization costing \$10, Bathina determined that the savings were \$2,000 per catheter, or \$9,000 for five ablation procedures. Concluded that hydrogen peroxide gas

plasma sterilization was cost-effective and safe as long as it is accompanied by visual inspection of the catheters.

1997

R.A. Kozarek, M.D., S.E. Sumida, Ph.D., S.L. Raltz, R.N., M.S.N., L.D. Merriam, D.C. Irizarry. "In vitro Evaluation of Wire Integrity and Ability to Reprocess Single-Use Sphincterotomes." *Gastrointestinal Endoscopy*, February 1997, Vol. 45, No. 2, p.p. 117-121

Study to evaluate sphincterotomes' ability to be safely reprocessed without loss of form or function. Seven of ten sphincterotomes completed the study in good condition with no detected problems. Concluded that single-use sphincterotomes have the potential for safe reuse.

"What Does 'Single-Use Only' Mean to You? Reprocessing Road Map: Policies for the Reuse of Disposables." *Materials Management*, May 1997, p.p. 44-46

The article discusses suggested guidelines for hospitals to use in evaluating their needs and ability to safely reprocess single-use devices. If hospitals lack the facilities for reprocessing, the article suggests that third-party reprocessing is a good option.

"What Does 'Single-Use Only' Mean to You? The Third Degree: Ask Tough Questions Before Going Outside." *Materials Management*, May 1997, p.p. 48-50

Article describes what hospitals should look for when researching third-party reprocessing and the companies that provide the service.

R. Sites. *OHA News*, "Reuse of Certain Medical Devices Encouraged," May 16, 1997

Discusses OHA's request to the Ohio Administrative Code medical board to revise their policy on reuse of single-use devices. Author states that the single-use label is an economic issue for the manufacturer. With the single-use label, manufacturers have been able to reduce their liability risks, sell more devices and eliminate the expense of testing a device to market it as reusable. The article concludes that reprocessing certain devices can save funds, ultimately benefiting the consumer with lower health care charges, lower health insurance costs, and improved access to care.

D.F. Bloom, et. al., "Technical and Economic Feasibility of Reusing Disposable Perfusion Cannulas," *Journal of Thoracic Cardiovascular Surgery*, September 1997, Vol. 114, No. 3, p.p. 448-460

Study to evaluate reusability of disposable single and dual-stage venous and arterial perfusion cannulas. Found that all devices were able to be successfully sterilized with no functionality changes detected by experienced cardiac surgeons in selective evaluation. A 64% cost savings was achieved.

Stewart, "'Single use only' labeling of medical devices: always essential or sometimes spurious?" *Medical Journal of Australia*, November 17, 1997, Vol. 167, p.p. 538-539

Article discussing the "single-use only" label wherein the author could find neither anecdotal nor factual evidence of any transmission of viral disease attributable to the reuse of cardiac electrode catheters.

Author calls the evidence supporting the single-use status of "high risk" cardiac catheters "unconvincing." Goes on to list various items that are needlessly labeled single-use, such as: disposable PVC oxygen masks, disposable pressure infuser, disposable nasal oxygen prongs, single-patient-use oxygen transducers, pill cups, kidney trays, suction tubing, sequential calf compression cuffs and arm splints for intravenous lines. States that the financial and environmental cost of disposal for hospitals is increasing and should be calculated into the true cost of "single-use only" devices.

R. M. Whitby. "Single use only: obfuscation or the necessary attainment of zero risk?" *Medical Journal of Australia*, November 17, 1997, Vol. 167, p.p. 519-520

Discusses the benefits and risks associated with reprocessing devices. States that if high risk items are deemed as unfit for reprocessing because they are used in invasive procedures then, "... logic demands that restaurants provide 'single-use only' crockery and cutlery to each patron - as these items enter body cavities and are regularly contaminated with body fluids, they induce as much, if not more, risk of transmitting infection." Finds that it is important to determine what motivates the manufacturers to label a device "single-use only."

1996

"Reuse of Single-Use Items." *Infection Control & Sterilization Technology*, May 1996, p.p. 78-80

A published survey of hospitals with regard to their reuse and reprocessing policies. Found that the majority of hospitals did not have set guidelines for reprocessing. Only one hospital, Kaiser Permanente in Bellflower, CA, was able to supply a written policy on reuse and reprocessing. Found that many respondents wrote that they thought visual inspection of a device after resterilization was sufficient. The article made a strong argument to send devices to a knowledgeable third-party reprocessor.

Turi. "Reuse of Disposables: Let's Not Embrace Waste." *Catheterization and Cardiovascular Diagnosis*, June 1996, Vol. 38, No. 2, p.p. 133-343.

Article addressing the cost burden of single-use items, especially on developing nations. Author finds reuse possible and necessary.

English, et. al., "Reprocessing Disposables: One Strategy to Balance Cost Reduction and Quality Patient Care," *Today's Surgical Nurse*, July/August 1996, p.p. 23-26

States that health care organizations must now respond to the demands to reduce costs as well as new regulations to reduce the amount of waste disposed of in landfills. Finds that many disposable devices are made from durable materials and that in Canada and Europe manufacturers have sold as "reusable" the same devices that are labeled as single-use in the United States. The author finds that the protocols required of a hospital to establish a safe and viable reprocessing center require that hospitals make a substantial investment in reprocessing. Therefore, the article recommends outsourcing to third-party reproprocessors. Also states reprocessing has a positive environmental impact, finding that disposing of hospital waste costs from 1.5 to 30 cents per pound. Reprocessing allows for less waste and reduced disposal costs.

1995

J. McCormack. "Put Those Nagging Sterilization Worries to Rest, Once and For All." **Materials Management**, September 1995, p.p. 50-51

Addresses three worries associated with sterilization: first, determining if the label chosen by a manufacturer is accurate in stating that the device is reusable or disposable, as the single-use only label may be motivated by economic or liability concerns. Second, because validated cleaning standards do not exist for items such as endoscopes, it is important for a hospital to establish cleaning methods wherein the benefits greatly outweigh the risks. The third concern is to make sure sterility monitoring devices are being used properly.

G. E. Becker. "Reposables - A Matter of Financial Survival," **Infection Control & Sterilization Technology**, October 1995, p.p. 38-40

Becker addresses central processing professionals' need to reevaluate their policies on single-use items. "Can we safely throw out items that could safely be reprocessed at least a few times?" he asks. Becker states that, "disposing of items that still have useful life is a wasteful practice that can no longer be tolerated in our financial environment." He noted that, in one case, a prominent ophthalmologist found he could successfully reuse a phaco tip for a total of six uses, saving \$90,000 per year. One supplier of these "single-use" tips began to market reusable tips as a result of the ophthalmologist's practice. The other example Becker cites involves keratome knife blades manufactured by OASIS. OASIS helped Southern California Kaiser Hospitals develop reprocessing protocols for their keratome knife blades, which OASIS said could safely be reused up to 20 times. Following their testing, Kaiser decided to reuse the blades ten times as a cost savings of approximately \$80,000 per year.

J.G. DesCôteaux, M.D., et. al., "Reuse of Disposable Laparoscopic Instruments: A Study of Related Surgical Complications," **Canadian Journal of Surgery**, December 1995, Vol. 38, No. 6, p.p. 497-500

Study of surgical complications due to reuse of disposable laparoscopic instruments. Concluded that the instruments may be safely reused under "carefully monitored conditions with strict guidelines."

1994

"The Re-Use of Single use Cardiac Catheters: Safety, Economical, Ethical, and Legal Issues," **Canadian Journal of Cardiology**, May 1994, Vol. 10, No. 4, p.p. 413-421

Study of diagnostic and angioplasty catheter reuse. Concluded that catheters can be reused without posing a significant threat to patients or staff when cleaning, sterilizing and quality control procedures are followed. Found savings of \$5,000 (Canadian) for each diagnostic catheter reused five times and \$100,000 (Canadian) for each angioplasty catheter that was reused three times.

M.G. Bourassa, M.D., "Is Reuse of Coronary Angioplasty Catheters Safe and Effective?" **Journal of the American College of Cardiology**, November 15, 1994, Vol. 24, No. 6, p.p. 1482-1483

Found that the reuse of catheters resulted in important cost savings in an era of cost restrictions and containment. Recommends that hospitals practicing reuse have in place clear policies regarding catheter reuse. Also recommends that hospitals have standardized cleaning, sterilization and quality control procedures.

E.A. Aton, M.S., et. al., "Safety of Reusing Cardiac Electrophysiology Catheters," *The American Journal of Cardiology*, December 1, 1994, Vol. 74

Author found that electrode catheters could maintain their functionality after being reprocessed. Found that the catheters reprocessed using the Clinical Electrophysiology Laboratory at Barnes Hospital's reuse protocol had residual levels of ethylene oxide concentrations that exceeded the FDA's allowable levels. However, authors notes that the original device manufacturers eliminated this problem by extending aeration cycle or by defining the post sterilization interval to decrease levels of ethylene oxide. Recommends that laboratories reusing electrode catheters establish and implement a validation protocol for their catheter reprocessing.

1993

B. Avitall, M.D., et. al., "Repeated Use of Ablation Catheters: A Prospective Study," *Journal of American College of Cardiology*, November 1, 1993, Vol. 22, No.5, p.p. 1367-1372

Study of Ablation Catheters from a single manufacturer, Webster/Mansfield. Found that the Webster/Mansfield catheters could be reused an average of five times. Avitall wrote that, "clinical follow-up states that reuse of ablation catheters has yet to result in any adverse consequences to the patient." Avitall also found no complications resulting from the accumulation of ethylene oxide residues on the device after multiple resterilizations. The total cost savings for reusing ablation catheters in this study was \$128,133 for the 336 procedures performed. It was recommended that each catheter be carefully examined after each use to determine if it can be reprocessed and that validated cleaning, sterilization and functionality testing be in place for reprocessing of catheters.

1990

P. Bentolila, R. Jacob, F. Roberge, "Effects of Re-Use on the Physical Characteristics of Angiographic Catheters," *Journal of Medical Engineering and Technology*, November/December 1990, Vol. 14, No. 6, p.p. 254-259

Bentolila, Jacob and Roberge studied five types of angiographic catheters that were used at the radiological and haemodynamic clinical practice of Sacré-Coeur Hospital in Montreal. The devices were studied for mechanical sturdiness, and for the possibility that reuse of these catheters could be associated with blood contamination by loose particles. The study tested both new and reprocessed catheters, which had been used up to ten times. The doctors found no adverse effects on the maximum tensile strength and elongation at break of the reused catheters. There were some findings of biological debris on the reused catheters; however, the debris was fixed to the lumen surface and the doctors thought the chance of it being carried into the blood stream was unlikely. It is worth noting that the new unused catheters exhibited a significantly higher loose particle count than the reprocessed devices. Therefore, the authors concluded that properly handled reprocessed angiographic catheters are as safe for the patient as new catheters.

1988

S. O' Donoghue, E. Plana. "Reuse of Pacing Catheters: A Survey of Safety and Efficacy." *PACE*, September 1988, Vol. 11, p.p. 1279-1280

This study focused on the occurrences of superficial skin infections or bacteremia associated with new and reprocessed devices used in electrophysiologic studies (non-lumen, woven Dacron, multi-electrode pacing catheters). Found that the rates of infection were extremely low, with no significant variance between the reused group and the new group. Article states that the devices are sufficiently durable to allow them to be reused in excess of five times and that single-use appears to be an unnecessary and expensive policy.

1987

Dunnigan, M.D., et. al. "Success of Re-Use of Cardiac Electrode Catheters." *American Journal of Cardiology*, October 1, 1987, Vol. 60, p.p. 807-810

This five-year study of cardiac electrode catheter reuse occurred from 1981 to 1986, during which time 178 catheters were used 1,526 times for 847 electrophysiologic procedures with detailed records kept of the devices' use and testing. There were no complications due to reuse during the five-year study. All 178 catheters functioned for cardiac pacing and electrographic recording and the surveillance cultures and biologic indicators showed that adequate sterilization methods and procedures were used. The study concluded that electrode catheters may be safely reused as long as a thorough cleaning, testing and record keeping system is in place. Reuse potentially reduced the cost of the electrophysiologic catheterization to \$30 per use, versus \$200 per use for the single-use device.

Mr. Upton. Thank you.
Dr. Trotter?

TESTIMONY OF C. GRIFFIN TROTTER

Mr. TROTTER. Thank you. I am Griffin Trotter. I am an Assistant Professor of Ethics and an Assistant Professor of Surgery at Saint Louis University, Sciences Center. As a matter of record, I am not representing any particular organization and have not received an honorarium for this appearance. However, the Association of Medical Device Reprocessors has covered my travel and my lodging expenses. As an emergency physician and medical ethicist, my expertise is in general ethical and clinical considerations. I am not an expert in the reprocessing of medical devices, and hence will confine my comments about safety issues to general remarks concerning clinical risks and the moral requirement for informed consent.

In clinical medicine, healthcare providers are morally obliged to disclose significant risks pertaining to any treatment, test, or procedure that they have recommended or intend to undertake. Determining which risks count as significant for the purposes of disclosure is an important clinical challenge that is widely addressed by the use of a material risks standard. Risks are material when they are likely to be relevant to the decisions of reasonable patients. When risks are very remote, disclosure is not required and, in fact, may even detract from informed consent by inducing unreasonable fears. Physicians or other clinicians are generally the individuals who bear the task of disclosing risks. However, in an age of managed care, many decisions governing the practice of medicine and its attendant risks, are determined at an institutional level. In such instances, the moral obligation for obtaining informed consent may shift away from the individual clinician to the institutional provider.

For example, an institution that reprocesses the contents of its suture kits may have a moral responsibility to inform clients of this practice, if, indeed, it was determined that the use of these kits poses a significant risk. One problem is that it is not clear whether the material risk standard applies or even makes sense at this level. Informed consent in this context pertains not so much to decisions about specific treatments or procedures, but to patient's decisions about whether or not they want to subscribe to a given healthcare plan. The likely risk pertaining to the use of a reprocessed single-use medical device will vary depending on the nature of the device, the previous use of the device, the reprocessing method, and the proposed manner in which the device will be reused. These variations, along with the aforementioned intricacies that pertain to the material risk standard, make it very difficult to articulate a uniform requirement for informed consent. However, if standards for reprocessing medical devices are sufficiently rigorous to ensure that these devices may be used safely, then there is no more requirement for informed consent.

My opinion is that if the use of reprocessed single-use medical devices is not safe, then these devices simply should not be used. Ensuring that the devices are safe is a far better strategy than legislating burdensome requirements for informed consent that would amount to one more bureaucratic obstacle to the provision of a swift, efficient, and effective response to our patients' needs. Thank you.

[The prepared statement of C. Griffin Trotter follows:]

PREPARED STATEMENT OF C. GRIFFIN TROTTER, CENTER FOR HEALTH CARE ETHICS,
SAINT LOUIS UNIVERSITY

SUMMARY

In clinical medicine, health care providers are morally obliged to disclose significant risks pertaining to any treatment, test or procedure that they have recommended or intend to undertake. The determination of which risks count as "significant" for the purposes of disclosure is an important clinical challenge that is widely addressed by the use of a "material risks" standard. Risks are material when they are likely to be relevant to the decisions of reasonable patients. Physicians or other clinicians generally disclose these risks. However, in some cases it may be more appropriate if institutions obtain informed consent. If use of reprocessed single-use medical devices was shown to be risky, then hospitals or other corporate providers who systematically use these devices have a moral obligation to inform their clients of this practice. On the other hand, when risks are very remote, disclosure is not required and, in fact, may even detract from informed consent by inducing unreasonable fears.

The likely risks pertaining to the use of a reprocessed single-use medical device will vary, depending on the nature of the device, the previous use of the device, the reprocessing method and the proposed manner in which the device will be reused. These variations make it difficult to articulate a uniform requirement for informed consent. However, if standards for reprocessing medical devices are sufficiently rigorous to ensure that these devices may be used safely, then there is no moral requirement for informed consent.

In assessing the relevant scientific data pertaining to the reuse of single-use devices, objective sources (such as the FDA and the CDC) are preferred over other sources (such as original equipment manufacturers, reproducers and even the news media) that have important financial interests hinging on the interpretation of this data.

Health care policy concerning the use of reprocessed single-use devices should be guided by the Principle of Subsidiarity, which implies that regulatory authority and action should be concentrated at the lowest hierarchical level of government where there is sufficient competence. This principle points, once again, to the importance of garnering advice from important regulatory agencies such as the FDA.

WRITTEN STATEMENT

Mr. Slobodin has asked me to testify about safety and policy issues associated with the use of reprocessed single-use medical devices (abbreviated “RSUDs” in subsequent text). As a physician and medical ethicist, my expertise is in general ethical and clinical considerations that may pertain to the use of these devices. I am not an expert in the reprocessing of medical devices and, hence, will confine my comments about safety issues to general remarks concerning clinical risks and the moral requirement for informed consent.

Valid informed consent consists of three elements: disclosure, understanding and voluntariness. *Disclosure* involves the relay of relevant information (risks, anticipated benefits, costs and alternatives) about recommended medical interventions to medical decision-makers (i.e., patients or patients’ proxies). *Understanding* involves the ability of medical decision-makers to grasp the disclosed medical information and to deliberate about choices in a manner that integrates this information with the patient’s goals and values. *Voluntariness* is freedom from undue constraint. Undue constraints include various forms of coercion, as well as emotional and social constraints that hinder reasonable decisions.

If the proposed use of a RSUD bodes a significant risk, then this risk should be disclosed to patients. Various standards for what ought to count as a “significant risk” requiring disclosure, have been offered. In a landmark 1972 U.S. Circuit Court decision, Judge Spotswood G. Robinson articulated the “material risk” standard. According to this standard (which is now widely accepted) all material risks should be disclosed. A risk is material “when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy.” Robinson held that serious complications that occurred in less than 1% of cases were generally not material risks.

Robinson’s 1% standard probably does not apply for risks that could be easily avoided. Hence, even a 0.2% *additional* risk posed through the use of reprocessed medical devices may be material if the complications in question are serious and new devices are readily available and affordable. The rationale for requiring a higher standard of disclosure in such instances would be that the risks are clinically unnecessary. Where to draw the line for disclosing such risks is debatable, and our ultimate decision will of necessity be somewhat arbitrary (just as the standards of statistical significance that we use in estimating risk are themselves somewhat arbitrary).

Saving money is not an adequate reason for foregoing disclosure, unless there is an agreement (tacit or explicit) between patient and provider that the provider may pursue cost savings whenever the risks do not exceed a certain (more generous) threshold. The degree to which such tacit understandings operate in a managed care environment is debatable. Physicians and/or corporate health care providers often are not expected or required to disclose risks that may pertain when they employ cost-saving medical technologies or protocols that are less than the best available. For instance, hospitals with a policy of not providing pelvic ultrasounds after radiologists’ office hours are not required to post a warning on the emergency department doorway that announces this policy to patients. As another example, physicians generally are not expected to disclose whether the lab is measuring cardiac enzymes by the traditional chromatography method or with the newer, more effective mass spectrometry method. As a practicing clinician and patient advocate, I am more worried about these practices than I am about not disclosing the use of reprocessed medical devices, since I believe the potential risks are generally less serious in the latter instance.

If it is determined that risks of using reprocessed medical devices are minimal, then the process of trying to disclose these risks could actually *hinder* the integrity of informed consent by promoting irrational concerns (thus constraining understanding and voluntariness). Two pitfalls pertain.

1. Patients do not generally reason statistically. Even when a risk is statistically very remote, most patients will assume that if you mention it, then it is a clinically significant risk. I often illustrate this point to medical students by noting that if one pointed out the known risks of taking a bath (e.g., possible traumatic brain hemorrhage, drowning, and broken bones), then most patients unfamiliar with the process of bathing would refuse the procedure outright, even if you explained that the cumulative serious risks were less than one in fifty thousand.

2. Patients often maintain un-warranted superstitions about the hazards of contact with others’ bodies. Members of the media who hope to turn the use of reprocessed medical devices into a high-profile health care scandal have used these superstitions as emotional leverage. Magic Johnson’s decision to quit professional basket-

ball is an example of how concern about the transmission of AIDS is sometimes overwrought. Even health care workers tend to be irrational about the issue of AIDS transmission. A number of health professionals have expressed concern about occupational AIDS transmission and hope that their occupational risks can be minimized through the development of an effective AIDS vaccine. However, many of these same health care professionals have failed to obtain immunization against hepatitis B, despite data showing that the occupational risk of dying from hepatitis B is far greater than it is for AIDS.

In an age of managed care, issues about the context of informed consent emerge. Often, decisions governing the practice of medicine—and its attendant risks—are determined at an institutional level. In such instances, the moral obligation for obtaining informed consent may shift away from the individual clinician to the institutional provider. For example, an institution that reprocesses the contents of its suture kits may bear a moral responsibility for informing clients of this practice (if it was determined that the use of these kits poses a significant risk). One problem is that it is not clear whether or not the material risk standard applies, or even makes sense, at this level. Informed consent, in this context, pertains not so much to decisions about specific treatments or procedures, but to patients' decisions about whether or not they want to subscribe to a given health care plan.

Several public policy implications follow from these considerations about informed consent. First, the problem of determining the risks of using RSUDs is crucial. The likely risks pertaining to the use of a reprocessed single-use medical device will vary, depending on the nature of the device, the previous use of the device, the reprocessing method and the proposed manner in which the device will be reused. These variations make it difficult to articulate a uniform requirement for informed consent.

Second, if standards for reprocessing medical devices are sufficiently rigorous to ensure that these devices may be used safely, then there is no moral requirement for informed consent. One exception might be in unusual cases where patients could be expected to have religious or other doctrinal objections to any reuse of specific devices. But this sort of consideration applies to any device, drug or procedure, and is best handled at a clinical level rather than through government regulations. If significant dangers pertain despite adequate regulation, then informed consent may be morally obligatory. It will be important to ensure that the standards of disclosure in such cases are neither too rigorous nor too lax. Overly rigorous requirements would result in irrational fears based on the disclosure of clinically insignificant risks. It is also likely that overly rigorous disclosure requirements would place a bureaucratic obligation on clinicians that would impede patient care. Overly lax requirements would result in violations of the moral requirement for informed consent—in effect, exposing patients unwittingly to dangers that reasonable persons might not approve.

Third, regulatory requirements for informed consent for the use of RSUDs should be responsive to the context in which specific RSUDs are employed. In some instances, consent should be obtained by clinicians, in other instances the obligation should lie with hospitals or other corporate providers.

There are also ethical issues that pertain—apart from the Principle of Informed Consent—to the proper interpretation of risks and to the proper level of government intervention. If the risks of using various RSUDs are to be interpreted accurately, it is important that we obtain the best possible scientific data. Objective sources (such as the FDA) are to be preferred over sources that have important financial interests that hinge on the interpretation of this data. Even the news media is suspect in this regard, since they are exposed to financial incentives to find newsworthy scandals that will arouse an emotional response from the general public. Hence, they will be prone to exaggerate the dangers of RSUD use and to rely on anecdotal reports of untoward effects.

Finally, health care policy concerning informed consent for the use of RSUDs should be guided by the Principle of Subsidiarity, which implies that regulatory authority should be concentrated at the lowest hierarchical level where there is sufficient competence. This consideration enhances the rationale for looking to the FDA for input and guidance about risks and about necessary policy adjustments. Assuming that the FDA is properly motivated to represent patients' safety interests, the cumulative training and expertise of FDA officials is an important asset that should be maximally utilized.

I suspect, when all is said and done, that it will not be possible to articulate and legislate a uniform standard for obtaining informed consent for the use of RSUDs that is more effective or useful than general legal standards that already pertain in clinical medicine. A more promising avenue would be to rely on the enforcement of effective safety regulations, which would render informed consent into a moot

issue. The best available scientific evidence should guide the development of safety standards. This hearing attests to the serious efforts that are being taken in order to garner such evidence.

Mr. Upton. You get a bonus.

Mr. Lindsay?

TESTIMONY OF BRUCE D. LINDSAY

Mr. LINDSAY. Mr. Chairman and members of the subcommittee, I am Dr. Bruce Lindsay, a cardiologist and a member of the American College of Cardiology and the North American Society of Electrophysiology. And these organizations represent about 24,000 board certified cardiologist in the United States. I thank you for the opportunity to testify about the safety and efficacy of reusing electrophysiology catheters in patients who undergo procedures for the diagnosis and treatment of heart rhythm disorders. I have about 15 years of experience in electrophysiology and I direct the Cardiac Electrophysiology Laboratory at Washington University in St. Louis, where more than 1,500 diagnostic and therapeutic procedures are performed each year. In all my years of practice I have never encountered a complication related to the reuse of an electrophysiology catheter.

Furthermore, in my conversations with professional colleagues at other major medical institutions, I have never heard any of them describe this problem. I would like to emphasize that neither I nor the organizations that I represent have any direct or indirect financial interest in the reuse of electrophysiology catheters. Our position is rooted in scientific evidence and puts concern for patient safety as its first priority. The standard electrophysiology catheters that we use have several electrodes used for recording electrical signals. They cost about \$500 each. In fact, some of the newer and more advanced catheters cost \$2,000 or \$3,000 each. The cost of a reprocessed catheter is generally about half the cost of a new catheter. The first electrophysiology procedures were performed more than 30 years ago. Experience over the years has shown that electrophysiology catheters are durable and can be re-sterilized for reuse. The obvious motives were to reduce costs and eliminate waste. Clearly there are ethical, medical, and legal reasons for physicians to avoid any practices that we feel would add material risk to a procedure.

Sometimes several catheters are tried during a procedure before an optimal catheter is identified. Sometimes a catheter, whether it is new or reprocessed, does not have the right configuration to reach a specific target in the heart, or may become less maneuverable over a period of time. You can see how the cost of a procedure would escalate if we had to take catheters out and reuse them, meaning try other catheters and change the models that we are using. The costs begin to add up. Medicare and other third-party payers do not increase their reimbursement irrespective of whether we use one catheters, three catheters, or six catheters. Reprocessing is a way to help reduce the fiscal implications of using several catheters during a single procedure. I must point out that there are studies that have evaluated the safety of reusing electrophysiology catheters, and these studies have involved more than 15,000 patients. And in these studies the sterility of reprocessed catheters

was not a concern, nor was the incidence of infection increased. Moreover, several studies have demonstrated that the catheters are durable enough to be reused in excess of five times. The conclusions from these studies are that the catheters appear to be stable for reuse, that this can be done provided that they are carefully examined and that the quality assurance standards are observed. It is an expensive policy to preclude reuse of these catheters.

You are also aware that adverse events stemming from the reuse of medical devices are reported to the FDA. We have already heard today that some of these reports involve not just reprocessed catheters, but new catheters. So I think it is appropriate to emphasize that despite the reuse of hundreds of thousands of catheters, only a few instances have been cited in which they have proved to be faulty. We conclude that the risk to patients associated with reusing electrophysiology catheters is very, very small relative to the overall risk of the procedure. The risk, in fact, is so low that it is difficult to quantify. Policies that prohibit the reuse of electrophysiology catheters will not have an appreciable impact on risk, but they will most certainly increase costs. In a major medical center, the cost for example just of reusing electrophysiology catheters, the savings from that are in the range of \$250,000 to \$400,000. Both the American College of Cardiology and the North American Society of Pacing and Electrophysiology are working with the FDA to refine additional risk adjusted standards that can be applied to reprocessing medical devices and to clarify the criteria for single-use labels. We urge Congress to defer to the FDA as it perfects a regulatory strategy for the reuse of medical devices that is based on science and emphasizes the public safety as a first priority. Mr. Chairman, I appreciate the opportunity to speak before the committee. Thank you.

[The prepared statement of Bruce D. Lindsay follows:]

PREPARED STATEMENT OF BRUCE LINDSAY, ASSOCIATE PROFESSOR OF MEDICINE, DIRECTOR, CLINICAL EP LABORATORY, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ON BEHALF OF THE AMERICAN COLLEGE OF CARDIOLOGY

INTRODUCTION

Mr. Chairman and members of the subcommittee, I am Dr. Bruce Lindsay, a cardiologist and member of both the American College of Cardiology (ACC) and the North American Society of Pacing and Electrophysiology (NASPE). I thank you for the opportunity to testify before you today about the safety and efficacy of reusing electrophysiology (EP) catheters in patients who undergo EP studies for the diagnosis or treatment of heart rhythm disorders.

Over the past several months there has been much discussion, and unfortunately much factual distortion, about the reuse of certain medical devices. My testimony pertains to the reuse of EP catheters and is based on more than 15 years of experience in the field of clinical EP. I direct the cardiac electrophysiology laboratory at Washington University in St. Louis, where more than 1,500 diagnostic and therapeutic procedures are performed each year. During all these years, I have never encountered a complication related to the reuse of an EP catheter. Moreover, in my conversations with professional colleagues at other major medical centers, I have never heard any of them describe this problem.

The ACC and NASPE share several common objectives that promote optimal patient care, research, and education. These organizations also provide leadership in the development of standards and guidelines and the formulation of health care policy. The interest of these two organizations in the medical reuse debate grows out of concern for patient safety and the promotion of quality cardiovascular care for patients. Neither I, nor the organizations that I am representing today, have any direct or indirect financial interest in the reuse of EP catheters. The involvement of the ACC and NASPE in this issue is rooted in scientific evidence. The ACC and

NASPE have been working with the Food and Drug Administration (FDA) and believe that it has also taken an approach to the issue of medical device reuse that is based in science out of concern for patient safety.

Electrophysiology Procedures

Clinical cardiac EP studies are performed to diagnose and treat abnormal heart rhythms referred to as arrhythmias. Typically, three to six catheters are used during these procedures. Each catheter incorporates four to 20 platinum electrodes to record electrical signals or pace the heart. The standard EP catheters are solid nonluminal designs, which means they do not have a hollow inner core. Some catheters have special mechanisms used to deflect the tip to help guide the catheter to a specific target. Catheters with these deflection mechanisms are often used to deliver radiofrequency energy—a high frequency electrical current—to destroy a small amount of tissue on the lining of the heart that has been identified as the cause of a patient's abnormal heart rhythm. This curative technique is referred to as an arrhythmia ablation procedure.

The cost of catheters used to perform EP studies varies depending on the number of electrodes, steering mechanisms, or materials used for the particular model. Diagnostic catheters range in cost from \$100 to more than \$1,000. Deflectable catheters used for ablation of abnormal heart rhythms generally cost \$400 to \$800. Some advanced designs that provide feedback about the position and orientation of the catheter cost \$2,000 to \$3,000.

The first EP procedures were performed more than 30 years ago. The early experience showed that EP catheters were quite durable and could be sterilized for reuse, as has been the practice for many surgical instruments. The obvious motives were to reduce cost and eliminate the waste of catheters that could be reused without compromising patient safety. The physicians who perform these studies have no direct or indirect personal financial incentives to reuse catheters, and there are ethical, medical, and legal reasons to avoid any practices that would add material risk to EP studies. The cost of medical supplies is the responsibility of the hospital where the procedure is performed; however, physicians often consider it their responsibility to work with hospitals to make efficient use of supplies and reduce operating costs.

Arrhythmia ablation procedures typically take three to five hours to perform. In order to advance the EP catheters to the heart, tube-like sheaths are inserted into the arteries and veins to provide vascular access for EP catheters. The catheters are then inserted through the sheaths and advanced to the heart. The sheaths allow cardiovascular specialists to remove, exchange, or reinsert the EP catheters as needed during the procedure. Sometimes catheters—new or reprocessed—must be exchanged because they do not have the necessary configuration to reach a specific target in the heart, or because they have become less maneuverable during the course of the procedure. Sometimes several catheters are tried during a procedure before the optimal catheter is identified. Reprocessing allows the flexibility to use several catheters during an EP study safely and free of fiscal concerns.

In some cases the catheter is easily positioned at the target site and is subjected to very little manipulation. In more difficult cases a catheter may be removed and reinserted several times during the course of a procedure and is subjected to considerably more stress when extensive efforts are required to reach the target. Because the stresses that can be imposed on an individual catheter can vary considerably during a study, EP catheters are manufactured to be very durable. It is their durability which makes them reprocessable. Regardless of the amount of stress imposed on a catheter during a study, each one is carefully evaluated by the reprocessor to determine whether it is suitable for reuse.

The number of catheters used during an EP study can have a substantial impact on the cost of performing the study, but it does not change the level of reimbursement from Medicare or other insurance companies. When the cost of catheters exceeds the level of reimbursement, hospitals bear the loss.

Review of Published Clinical Studies

There 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 catheters is a concern or that the incidence of infection is increased. The results of four clinical studies are summarized:

1. The results of a study of 12 medical centers were published in the medical journal *Pacing and Clinical Electrophysiology* in 1988. The study looked at the safety of reusing catheters. The incidence of infection related to a total of 14,640 EP procedures involving 48,075 catheter uses was reported. At three centers, catheters were

automatically discarded after a single use. These centers carried out 1,245 EP procedures using 3,125 catheters. At the other nine centers, catheters were sterilized for reuse. There were 13,395 procedures using 44,950 catheters in the reuse group. The incidence of bacteremia (blood borne infection) and superficial skin infection at the site of catheter insertion is shown below.

Table 1: Incidence of Infection During EP Studies.

Group	Bacteremia	Superficial Skin
Single Use Catheters 1,245 studies 3,125 catheters	1 (0.03%)	1 (0.03%)
Reused Catheters 13,395 studies 44,950 catheters	8 (0.018%)	1 (0.002%)

The authors of the study concluded that sterilization and reuse of the catheters employed in this study did not result in any increase in the risk of infection. They felt the catheters were sufficiently durable to be reused well in excess of five times, and that one-time use of such catheters appeared to be a medically unnecessary and expensive policy to adopt.

2. Similar results in a prospective study were published in the *Journal of the American College of Cardiology* in 1987. The study evaluated catheter reuse over a five-year period during which 178 catheters were used 1,576 times for 847 EP procedures. Detailed records of catheter testing and use were maintained. No complications were encountered during the study period. All reused catheters functioned for cardiac pacing and recording of cardiac electrical signals. Surveillance cultures and biologic indicators revealed that adequate sterilization procedures were used. The authors concluded that EP catheters may be safely reused provided a thorough cleaning, testing and record-keeping system is instituted. They also concluded that the practice of reusing catheters would result in substantial cost savings to hospitals.

3. The studies mentioned above were conducted in patients undergoing diagnostic EP studies before the advent of deflectable catheters and arrhythmia ablation procedures. A study published in the *Journal of the American College of Cardiology* in 1993 prospectively investigated the time course of electrical, physical and mechanical changes in ablation catheters to determine the affect of reuse on safety and efficacy. The study included 69 ablation catheters made by a single manufacturer that were used in 336 procedures. Testing of physical integrity consisted of visual and stereoscopic (X30 magnification) examination of handle function, catheter shaft and the deflectable tip. Specific attention was paid to the ablation electrode attachment to the catheter shaft, and the ablation tip electrode was scrutinized for pitting. The electrical integrity of the catheters was measured by electrical resistance from the handle connector to the recording rings and to the tip electrode. Deflection and torque measurements were made to assess mechanical integrity.

During the course of this study 36 catheters (52 percent) were rejected at some point because of mechanical or electrical failure. Eighteen catheters were repeatedly sterilized and eleven of the catheters were used 10 or more times. The most common reasons for catheter rejection were tip electrode glue separation after an average of 4.3 uses and loss of deflection after an average of five uses. Electrical discontinuity was observed after an average of 10 uses. There was no significant decrease in catheter torquing ability that determines the steering responsiveness of the catheter. The medical records of 140 patients who had arrhythmia ablation procedures in this study revealed only one case (0.7 percent) of local infection at the insertion site that was treated effectively by antibiotics. There were no other complications.

The authors of the study concluded that the catheter model used in this study could be reused an average of five times. They recommended that after each use catheters be carefully examined under magnification with special attention to the tip electrode. They also recommended that the catheters be tested for deflection and electrical integrity after each use.

4. Another study published in the *American Journal of Cardiology* in 1994 looked at the effects of reprocessing on mechanical integrity, sterility, and chemical residuals. The study was part of an internal quality review process conducted by a hospital to establish and validate an institutional policy for reuse. A total of 12 commercially available catheters from two manufacturers were analyzed. Eleven of the catheters were randomly selected from the catheter inventory of the clinical EP lab-

oratory after being used one to four times. They were manually cleaned, repackaged, and gas sterilized with ethylene oxide. To assess the sterility of reused catheters, three were cut into two-inch segments, placed in bacterial culture media, and incubated for five days. Six of the catheters were analyzed for chemical residuals after gas sterilization. Two catheters were examined for evidence of component failure. Visual inspection and microscopy were used to determine mechanical integrity of the catheter surface, and x-ray inspection was performed to assess interior structures.

The results showed no bacterial growth detected on any of the cultures, which indicated that reprocessed EP catheters are effectively sterilized. The chemical analysis demonstrated that the concentrations of ethylene oxide detected in extraction liquid exceeded standards established by the FDA. Microscopic examination of reprocessed catheters demonstrated inconsequential metal and fiber particulates on the catheter surface and at some electrode-catheter interfaces. The shaft of the catheters and the electrodes remained intact. There was no evidence of electrical discontinuity, and the integrity of internal structures was confirmed by x-ray inspection.

The authors concluded that, with sterilization techniques frequently used by hospitals, the potential for chemical residual contamination might exist after sterilization with ethylene oxide. Based on these results the hospital changed its policy to single use. It should be noted that the hospital subsequently resumed multiple use of catheters that were reprocessed by a commercial vendor whose chemical residuals after reprocessing met FDA standards.

Medical Device Reports

Medical Device Reports (MDRs) submitted to the FDA contain information about three cases involving EP catheters. One case involved a reprocessed catheter. The other two occurred with new single-use catheters. It is appropriate to emphasize that despite the reuse of hundreds of thousands of catheters, only one MDR has been submitted to the FDA that involved a reused catheter. The reports are summarized below:

- A new deflectable ablation catheter was being positioned in the right atrium when the catheter tip was noted to be detached and wedged in the coronary sinus. The patient was observed overnight and discharged the following day without any reported symptoms.
- A small fragment of the distal tip in proximity to the electrode side of a new catheter broke away and the fragment could not be located. Further details are not available.
- A reprocessed orthogonal EP catheter was used without incident until it was removed from the heart. The physician felt some resistance during removal of the catheter. A subsequent x-ray showed a small electrode fragment lodged in the wall of the right atrium. It was presumed that a single platinum electrode mounted on the surface of the catheter might have been compromised during reprocessing. The surgical consultant decided that removal of the fragment was not indicated and the patient remained free of symptoms.

Impact of Reuse Policies on Physicians, Hospitals, and Patients

Most EP laboratories are staffed and administered by hospital employees. The cost of supplies and maintenance for EP laboratories is also paid from hospital budgets. The physicians' motive to reuse EP catheters has arisen from their experience that the catheters are durable and can be safely used for several procedures without posing an increased risk to the patient. As such, it would be a waste to discard EP catheters after a single use.

The risk to patients associated with reusing EP catheters is inconsequential relative to the overall risk of these procedures. The risk is, in fact, so low that it is difficult to quantify. Policies that prohibit the reuse of EP catheters will not have an appreciable impact on the risks of these procedures, but they will certainly increase the costs.

The cost savings realized by hospitals that reuse EP catheters depend on the volume of procedures and whether catheters are reprocessed internally or through a commercial reprocessing company. As a general rule, reprocessing companies charge 50 percent of the original cost of the catheter each time the catheter is reprocessed. Allowing for an 85 to 90 percent pass rate for each reprocessing cycle for a maximum of six uses per catheter (resterilized a maximum of five times), hospitals can reduce their catheter costs by about 35 percent. At large medical centers these measures may lead to cost savings in the range of \$250,000 to \$400,000. At smaller medical centers the total savings would be substantially less, but for both large and

small hospitals this practice is a significant cost-reducing measure at a time of escalating costs and declining reimbursement.

Development of Policies For Reuse of Medical Devices

The FDA has proposed a strategy to address the reuse of medical devices currently labeled for single use. This policy was developed in response to the concern that a device's performance, safety, specifications, or intended use might be compromised during reprocessing procedures. The policy would be applicable to both commercial reproducers and hospitals that engage in these activities. The FDA's strategy categorizes levels of risk presented by reprocessing and reusing single-use devices. Factors that would influence the risk category of a specific device include the complexity of procedures associated with reprocessing, the actual and potential risk for infection should the device be reused, and the quality and extent of published data on reprocessing for that device. The agency would consider "high-risk" devices to be products that may pose significant public health risk to patients and users after reprocessing. It is anticipated that the FDA would enforce all of the agency's regulatory requirements, including premarket requirements, for high-risk devices. The FDA has indicated that it would also enforce applicable premarket requirements for "moderate-risk" devices to ensure that the reprocessed device remains as safe and effective as a device that has never been used.

The FDA is examining the criteria used to label a device as "single-use." The new policy would potentially clarify or justify manufacturers' need for "single-use" labels.

The FDA has also questioned the need for informed consent when it is anticipated that reprocessed devices might be used during a procedure.

Summary

The ACC and NASPE support the position that reuse of EP catheters is a safe and cost-effective practice provided that these devices are meticulously cleaned, sterilized, and inspected in accordance with accepted standards of practice. Both organizations are working with the FDA to refine additional risk adjusted standards that can be applied to reprocessing medical devices and to clarify the criteria for single-use labels. We urge Congress to defer to the FDA as it perfects a regulatory strategy for the reuse of medical devices that is based on science and emphasizes public safety as the first priority. We firmly believe that no further congressional action is required at this time.

Mr. UPTON. Well, thank you all very much for your testimony and as folks could tell we wanted a diverse range of opinions and we got them. I compliment the staff, Mr. Ford and Mr. Slobodin. A couple of things. This is an enormously complex issue and Dr. Ganske, as an example, will be able to come back to discuss. He is one of the physicians that serves on this subcommittee. I know that the FDA regulations that they put out for comment only really came out this week. There has been a lot of talk about them in recent days, weeks. And Ms. Eshoo's bill has been out there for a little while as well.

I am wondering if any of you at the table have actually looked at the regulations that came out earlier this week, and might make some comment or indicate whether you are going to comment on them. And if so, maybe give us an advance in terms of where you think they are strong enough, where you think they may be too weak. Or maybe you do not think we need them at all or whether this is exactly the right direction that we are going to head. And I will just start, Mr. Lindsay. And if you have not had a chance to see them, I certainly understand. We understand. I appreciate your comments maybe in writing at some point if you, in fact, you do make those comments known.

Mr. LINDSAY. I just received the documents yesterday and was taking care of patients until late in the day, so I have not reviewed them. But I have spoken to people at the FDA this week, and we have talked about some of the common ground that as a professional organization we feel that we have with the FDA in trying

to address this problem. Physicians have no reason to use devices that are unsafe. It just makes our lives miserable and it is not why we went into medicine. Our interest is in protecting patients and in trying to help them, and we would like to work with the FDA to tackle this in a responsible way.

Mr. UPTON. So, you do not have a verdict yet whether or not it is the right course?

Mr. LINDSAY. From what I have read I think that it is a workable solution and one that will protect the public interest. I think it is one that would prohibit the recycling of certain devices that are not safe to reuse. I think it would permit the reuse of devices that can be safely reprocessed, and I think that is a reasonable approach to take.

Mr. UPTON. Dr. Trotter?

Mr. TROTTER. I too have not been able to review the written revisions by the FDA. I do think that it is important that we focus on the FDA recommendations. One of the things I appreciate about all the attention that was given to the FDA today is I consider them to be a relatively objective source. I think some of the other parties involved on both sides may have financial conflicts of interests that could implicitly or explicitly affect their testimony. I think there is less of that than on the FDA.

Mr. UPTON. You want to stay on the topic. The clock is ticking on me, too.

Mr. TROTTER. Okay.

Mr. UPTON. Mr. Feltner.

Mr. FELTNER. Yes. It is AMDR's view that FDA regulation of reprocessing is necessary, critical to ensuring the safety of reprocessed devices, and the patients. We believe that the current FDA regulatory regime which emphasizes compliance with QSRs is well-suited to meeting public health. We do not really believe that the pre-market review scheme proposed is necessary, but if there is a reason, and there is an assessment, and there are relevant facts that determine a pre-market review is necessary, we support it and we are willing to work and look forward to working with FDA on any path that it chooses.

Mr. UPTON. Dr. Maurer, and actually before you answer, I would just like to know what the difference was. You showed those saw blades that you said were recyclable. What was the other device that looked like a—

Mr. MAURER. Both of these are saw blades.

Mr. UPTON. Oh, they are? Okay. I did not see the other end of it.

Mr. MAURER. It has been coming for years and years.

Mr. UPTON. You had it covered up with your thumb.

Mr. MAURER. And it shows up on our door—

Mr. UPTON. I just saw the wrench.

Mr. MAURER. [continuing] you could be paralyzed. Same blade.

Mr. UPTON. Okay. Okay. I just saw the wrench at the other end when you—

Mr. MAURER. Put it with the other saws.

Mr. UPTON. So that is—all right. All right. Go ahead and answer the—

Mr. MAURER. Well again, we have not had much time to look at it. I looked at it briefly. I think the major thing that comes out of it, just on a cursory review, is it's got to be the same across the board. I think when you first read it, it looks like it is directed purely at hospitals and reproprocessors. We have free standing inventory, surgery centers, we have physician offices, we have a lot of people that are going to reuse these devices, and it has got to be a level playing field or we are going to have patient problems.

Mr. UPTON. Do you all at the Cleveland Clinic, actually keep track then of the number of times that things are reprocessed?

Mr. MAURER. Absolutely. You would have to be or we would not be able to limit it to five and those that come back from the reproprocessor have a mark on them. Half of the ones we sent out, they threw away because after they looked at them they felt they were unacceptable and we do not get charged for that when they throw them away.

Mr. UPTON. Dr. Fielder.

Mr. FIELDER. I very much like the direction that the FDA is moving. I did have a chance to look at the documents, but not terribly carefully. One of the things that, from an ethical standpoint, is important about their proposal is that they are going to have patient assurance that these devices can be cleaned and sterilized that is based upon an objective third party review rather than simply on what the manufacturers say, or on GMPs and quality assurance. And that is very important for patients.

Mr. UPTON. Dr. Grossman.

Mr. GROSSMAN. Yes. I'm sorry. I have had a chance to review them and have four specific areas. First, I think they are very commendable in that they do level the playing field and for the first time will force the production of reliable data, and that should be commended. Some of the specific devices, I think, probably should be in higher categories and I think that will probably evolve under their scheme up. The exemption issue concerns me because the very biopsy device I showed, although I am not an attorney, clearly, the reason for it in the past would be to allow similar devices. But in fact, if it would allow that kind of device with a sharp point to skate through and bypass the safeguards, clearly that would need to be tightened up. My last comment is again, the plea. This issue has been alive for longer than today. My concern is I start to see 6 months to 12 months to 18 months, a notice period. I do not know how much more it could be tightened, but that would clearly be a plea.

Mr. UPTON. Mr. O'Holla?

Mr. O'HOLLA. Yes. I have also had an opportunity to read them in between everything else I was doing this week, and I think FDA has come a long way, certainly from where they were 18 months ago. Certainly where they were even in November, and I would like to thank this committee and its members because I think it is a result of the attention you have paid to that issue that has caused some of that movement. I do, however, think there is one problem area where we need to talk with FDA a little more, and that is the area of exemptions raised by Dr. Grossman. The exemptions currently for medical devices did not take into consideration the risks associated with reuse and cleaning. I think, therefore, those exemp-

tions should not stand for a prolonged period of time. We are going to have to figure out how can we deal with that issue and make sense out of the scheme. But I think we are headed in the right direction. I think the nice part is, nobody has to believe me and nobody has to believe them. We will have a referee.

Mr. UPTON. Ms. West.

Ms. WEST. I think the recommendation certainly show progress. My concern is that it does not cover staff incompetence and question how they would be able to implement that without having someone on the floor continually for quality assurance.

Mr. UPTON. Thank you. Mr. Stupak, you ready or do you want me to come back to you?

Mr. STUPAK. Thank you Mr. Chairman. Dr. Lindsay, if the FDA is going to set a standard for a number of times the device is reused, how do you establish this number? Is there a community or an acceptable medical practice standard for a device established by ACC or NASPE or would it vary from hospital to hospital? Would the standard include a level of device integrity below which the catheter is discarded? How do you track and account for the number of times that the individual catheter has been reused? What happens if the numbers exceed it? I know there are a lot of questions there, but I am just trying to get it on the record.

Mr. LINDSAY. First of all the tracking is easy in that any catheter that is reused has a tag on it. It is a serial number and it is tracked by the reprocessor. So that there are limits that are set on that. Many hospitals with regard to electrophysiology catheters have set a limit of five reuses based on some information that is available from the literature. In some cases catheters in these studies have been used 10 or 15 times, but we do not want to push it to its limit because at that point I think you could have a greater risk for a breakdown. But certainly somewhere in the maximum of five seems reasonable. Now, having said that let me make it clear that not all catheters make it to five.

Each cycle, at least with our reprocessor, each cycle about 80 percent, 85 percent of the catheters will make it through that cycle and the others do not. They do not make the cut. So, I think that the criteria that are used has to be the same at each hospital or at each reprocessor. We cannot have divergent criteria.

Mr. STUPAK. So whether a catheter makes the cut, that is up to the reprocessor?

Mr. LINDSAY. That depends on the inspection and the testing that is done. So they examine it for nicks and electrical integrity, things that might potentially compromise it. Now, the other part of that question is that as catheter designs evolve, and the catheters we use today are different than they were say 10 or 15 years ago. It may be that with the newer designs, some of the designs will not be suitable for reprocessing. They may have sensors in them that would preclude reprocessing. We have that, for example, for some of the catheters that cost \$2,000 or \$3,000. They have sensors built into them that cannot be reprocessed. In other cases they may have mechanisms that may not lend themselves to reprocessing. So I think that one of the challenges before us is to identify these catheters, to look at their mechanisms, to look at the materials that they are made of, and decide whether they can safely be

reprocessed and used in patients in such a way that nobody has any question whatsoever about the integrity of that product.

Mr. STUPAK. Thank you. Dr. Maurer, in keeping with that same line of thought, in your testimony you talked about the fact there is a five time use limit for reprocessed non-aluminum diagnostic electrophysiology catheters. Would you outline for the committee how the clinic tracks the five times use to assure that is not exceeded? What mechanisms are in place that you use? Should it be accidentally exceeded? And is this a model for tracking limited reuse utilized on a hospital wide basis?

Mr. MAURER. Well, it is important to understand there is very little of this done. I mean, more sterile processing and so forth, I mean, 99.9 percent is with reusables. Scissors and clamps in ORs. So we are not, you know, just striking out on this.

Mr. STUPAK. True.

Mr. MAURER. This is a very small amount. I would echo what Dr. Lindsay says. We follow the same things. These are nationally published studies that are peer reviewed and have been around for years. We track them by serial numbers, there is a log kept, we have continuous quality improvement and statistical process control that is applied to these entire departments, not just in the reprocessing of catheters. It looks at all their infections, and all staff competency, and the review that has to occur on a regular basis. We are required to do this for Joint Commission. Believe me, when they come they bare down on this and if there is any problem, there is a root cause analysis done by us before Joint Commission does come and we have to show them that root cause analysis. So it is very stringent. I mean, you have got to understand, we physicians do not get any money from this. Can you imagine what it takes for us to grab a reprocessed device. We require that there be good quality control before we touch that and stick it in a patient.

Mr. STUPAK. Sure, but then a question I asked earlier about DRGs. I mean, DRGs source will only pay so much for a procedure. Now, if I can use a reprocessed catheter I am going to save some money, and the pressure on the hospitals, and clinics, and everyone else to keep within that amount, I mean, you know, we talk about these things, but there is also a responsibility here for the rest of us up on this side of the dias when we start putting on these standards or what we are saying has to be done. DRGs limited amount payment leads to this reuse.

Mr. MAURER. Yes. We charge less, and we so note that in the record that it is a reused device. I do.

Mr. STUPAK. But if it is a DRG, I mean, you get paid the same for the DRG whether you use reprocessed or not.

Mr. MAURER. That's true. That's true. But that charging less than when the DRG gets reevaluated by HCFA they will note that. And if it has become a standard thing that everyone reprocesses it, then they feel within their rights in terms of being budget neutral to cut back on that where they want to give money elsewhere.

Mr. STUPAK. I do not have any more for now.

Mr. UPTON. You are out of time.

Mr. STUPAK. Okay. Thanks.

Mr. UPTON. We are going to have another round though, I promise. Mr. Bryant.

Mr. BRYANT. Thank you Mr. Chairman. Dr. Trotter, on the issue of informed consent I kind of, first of all I want to apologize for being late. We have been in a prescription drug meeting right next door, and I missed, I think, the first four or five panelists testimony. But I did come in and Dr. Trotter you had mentioned something in your testimony about informed consent and when it would be appropriate. And as I recall it was based on, I think, the degree of risk involved, that being determined by I assume a physician, would determine whether or not the patient ought to be informed. And if I hear what you are saying that overall the gist of your testimony is that for a reprocessed medical equipment there should not be an informed consent by the patient?

Mr. TROTTER. That would be the end result that I would recommend. My opinion was that we ought to ensure that these reprocessed single-use devices are safe, safe enough so that there would not be a significant risk, and therefore informed consent would be a moot point.

Mr. BRYANT. And how do you do that? How do you ensure that they are that safe? You as a physician cannot do it, can you?

Mr. TROTTER. No. No, I cannot do it as a physician. I did read H.R. 3148 and I noticed though that many of the devices that I use I guess I count as the reprocessor. For instance, a stethoscope would count as a critical Class I device since I put it in unsterile areas of the body like the oscula and the inframamillary fold every time I examine a patient. So if something like a stethoscope, if that sort of risk was something where we required informed consent, then I guess, you know, I would need to be more involved in that sort of manner. But in fact, the specific requirements for ensuring the safety of some of these more complicated devices are far beyond my scope.

Mr. BRYANT. Yes. That should be at least the FDA's responsibilities?

Mr. TROTTER. Yes.

Mr. BRYANT. Okay. Dr. Lindsay, on reviewing some of the information here I find that the Association for Operating Room Nurses has developed a different policy from the one you expressed and the one that is endorsed by your American College of Cardiology and that is that in essence that unless the hospital can demonstrate the patient's safety and the medical devices effectiveness and integrity are not compromised, that reprocessing is not recommended by that Operating Room Nurses' Association. Do you have any comments on that?

Mr. LINDSAY. I think some of this may reflect the different types of devices that are reused. The American College of Cardiology and NASPE are not advocating that all devices be reused, and some of it may depend on what kind of things they come in contact with. That is a different group than nurses, for example, that work in cardiac catheterization and electrophysiology laboratories. I do not know that a lot of these devices clearly should not be used. I think there are some things in gastroenterology that probably should not be reused. And there may be some areas in cardiology that we have touched on today that they should not be reused. But that is what we have to examine carefully.

Mr. BRYANT. I would like to just throw this question open to anyone who would like to answer. I think some of you have touched on this already in other questions, but my question would be what more, beyond these two letters that the FDA has sent out, what more can they do now to advise and instruct or anything else the FDA can do to help ensure the safety of patients in this area of using reprocessed, I almost said repossessed, reprocessed medical equipment.

Mr. UPTON. You are thinking of NAPA auto parts.

Mr. BRYANT. We were talking about body parts a minute ago. Yes, doctor.

Mr. MAURER. Well, I think they have already done quite a bit. I have looked at their conferences that many on this committee have attended and given their views to, and they have taken views from everyone. I just think they need to continue to collect data, now that it is time to get the studies of large groups of patients that are peer reviewed and published, that have the chance of appropriate criticism of the design of the study and the results, and we get the data out in the open and let the public know that we are doing our job at looking at this on a scientific basis.

Mr. UPTON. Very quickly, one more.

Mr. O'Holla?

Mr. O'HOLLA. Yes. I think the FDA has done a great job in getting everybody's comments together and looking at the available data. You know, peer review is not the standard that FDA uses to establish safety and efficacy. I think it is time for FDA to act. They have already said that this is a device by device decision. The big studies are not necessary to make the device decisions. They need to act. They may need to act more quickly than they have published this week and start looking at the applications that show the particular device that the surgeon is grabbing tomorrow is safe.

Mr. BRYANT. Anyone else? I thought I saw a hand go up. Okay. Well, thank you very much, and I yield back the balance of my time.

Mr. UPTON. Thank you. I wish all members were able to spend the time like you have, Ms. Eshoo. Maybe you should think about getting off one of those other subcommittees and we will find a vacancy over here.

Ms. ESHOO. There are several people here that would not want me to.

Mr. UPTON. Go ahead.

Ms. ESHOO. Thank you very much, Mr. Chairman. I want to make a couple of observations before I ask questions of this very distinguished panel. A few barbs have been thrown around that the effort underway to take an even closer look at reprocessing, what that means relative to the public health and whether we have policies in place that speak to the best of what we could do. These are all very legitimate questions that are being asked. And I think that the, I know that the intent here, my intent of submitting the legislation was not to favor one group or another. Now, around here, you know, you punch the pillow, you put a dent in it, but there is always something else that pops up. I remember going back to FDA reform where medical device manufacturers were not happy with what I placed on the table because it was very stringent and it did

not always meet with what they wanted to do. There were some people involved in that debate that wanted to destroy the FDA. They did not want an FDA around. Now today I hear so many complimentary things said about the FDA and I welcome that.

I think it is important to the American people, and I reminded my colleagues during that debate that if they were to say otherwise they were frightening the American people. The American people want an Agency that is going to be a top watchdog that will step between whatever interests are out there and their interests. I think today by the questions that have been asked by my colleagues on both sides of the aisle, that you have all figured out that we are here for the public interest. So, you know, always in all of these issues someone's ox seems to be gored or the perception is that. I am here for the public interest and I think everyone here on the committee is as well. So I would hope that you would keep that in mind. I really want to work with everyone.

I really believe that the reason that all of these proposed guidelines were bragged about today, and I think it is terrific that they have proposed guidelines, is because we have pushed, and pushed, and pushed. That is what my colleagues and I are supposed to do. Because every 2 years our constituents hold us responsible for what we have done or have not done. So I think it is a very important background for each one of the people that comprise this very distinguished panel. Just one more observation, and that is in all of the research we did before we ever thought of writing legislation, yes each side has some studies, but the FDA does not on behalf of the public which raises another question. Of course an organization is going to bring information forward that is going to be favorable to what they do. I would be all over you, questioning you, why you had not done that. But the fact of the matter is, is that the public agency that is supposed to be guarding the best interests of the public health has not done that. Nor do the regulations, so to speak, or the guidelines, or whatever they have in place do not bring that about.

That is a big, deep, dark hole as far as I am concerned because we have to have a public yardstick by which we measure these things. I think it is important for organizations to do it. Certainly I will take that into consideration, but I want you to know that I think that at the top the absence of that kind of information, I think, is somewhat alarming and we need to do something about that. Now, I would like to go to Dr. Maurer, thank you for being here representing the American Hospital Association. I am very familiar with the Joint Commission standards because I chaired a hospital board of directors. So I know what those standards are, but I also know that as someone at this end of the table said that there really is a patchwork quilt throughout the country of what some hospitals may do, what some other hospitals may not. My question to you is do you pass the savings on of the reuse of a single-use device onto the patient or to Medicare?

Mr. MAURER. Well, like I said we charge less. It all depends on whether the patient—

Ms. ESHOO. Where does the savings go though? Does it go to the patient or does it go—if it is a HCFA issue—

Mr. MAURER. Whoever is paying the bill. If Medicare is paying the bill on a Medicare patient, the savings goes to Medicare.

Ms. ESHOO. Then it goes to Medicare.

Mr. MAURER. If the patient does not pay anything, we cannot impart savings to him.

Ms. ESHOO. If it is a private insurance, do you pass it up to the private insurers?

Mr. MAURER. Yes. Yes. The charge is made.

Ms. ESHOO. You do? And that is a consistent standard across the country or is it just where you are?

Mr. MAURER. That I do not know. I can only speak for what I do.

Ms. ESHOO. All right.

Mr. MAURER. And what my hospital does.

Ms. ESHOO. Well, I think the committee members need to keep that in mind. In your testimony you said, to go with the FDA's proposed guidelines, you have not read them thoroughly, but you said we do not need the bill. Have you read the bill?

Mr. MAURER. I have read the bill.

Ms. ESHOO. All right. Now, if you have not read the others and you compare and contrast the two, how can you come to that conclusion? I mean, I have said to the American Hospital Association, California Hospital Association, I stand ready to work with you. So it is a little disturbing to me because you have been my partner in so many things, and I have a deep regard for what you do and fought very hard, by the way, for the BBA refinements to take place because hospitals were really getting it across the country. Why would you say in your testimony not having read one, but read the other, to go with the one that you really have not read but disregard the one that you had.

Mr. MAURER. No. What I meant was, I have read the bill. I think the bill actually does exactly what you said it did. It is a wake-up call. This needs to be looked at. But all the bill can do is one thing. The FDA has a continuous regulatory process which they are putting in place. Which conceptually as we have heard today I fully agree with. In a cursory review of what I got less than 12 hours ago I have some concerns, but that is the regulatory process which will go on and on years and years after you and I are doing something else.

Ms. ESHOO. Well, good laws do too as well.

Mr. MAURER. Exactly.

Ms. ESHOO. So thank you very much. To—let's see who it was. I do not have a name. Is it Dr. Trotter? I think if you read page four again of the bill's language, it really applies to devices that are inserted into the body. And to take that, to pull that out of context I think is, well, I mean as the author of the legislation I can say it is somewhat unfair. If we need to go back and say that in a better way we will do that. But it was never intended, you know. I am a legislator, I am a politician. I do not consider myself a fool. I simply would not do that legislatively, because it is not necessary. So I just want to correct that.

Let me ask one more question and that is to Mr. O'Holla, and I want to thank you. Even though I am not asking all of your questions, I would like to thank you all for what you have brought for-

ward today. In your view should any single-use device be reprocessed without a 510(k)? This has gone on back and forth today and, you know, I think that I would like to have this set down for the record. For instance, if a new device is exempt, it is all around these exemptions and the consistency. Now, I heard Dr. Feigal say that under the proposed guidelines that there would be total consistency, and yet I do not hear a consistency of comments from the varying views that are a part of this panel in agreement that there will be consistency. So would you comment on that where a new device is exempt from pre-market requirements, should not the reprocessed one be exempt as well?

Let me just add a little asterisk to this. For those of you that cannot stand what I am doing, you must think that I am regulation happy. I am not. But I do think and if anyone ever wanted to go back and track this and we have talked about tracking today, in all of the years of my public service, both in County government and now here in the House of Representatives, there are two places where I think, regardless of what level of government we are at, that we have to have absolutely the highest standards when it comes to public safety and when it comes to public health. People cannot do these things for themselves. They simply cannot. They are reliant upon either very sound regulations and laws that are put into place. So, would you comment on this.

Mr. O'HOLLA. I am glad you asked that question, because I also got confused this morning, but I have worked it out in my mind and I hope I can clarify it for the members here. There are exemptions for new devices in two categories. There are exemptions for the disposable devices, and there are exemptions for reusable devices. For certain kinds of devices both of those are lumped together. So we have three different kinds. If a disposable device has been exempted, it has never been taken into consideration the risks associated with the reuse of that disposable device. That exemption does not address those risks and should not hold. If an exemption holds for a reusable device, it has been exempted based upon the fact that the device was designed to be reusable. It still does not take into consideration the risks associated with reusing a single-use device. So, my comment to the committee would be, be very careful about these exemptions. They have not taken the risks into consideration. They should not stand.

Ms. ESHOO. Thank you.

Mr. O'HOLLA. Does that help?

Ms. ESHOO. It does help. Thank you.

Mr. O'HOLLA. Okay.

Ms. ESHOO. It is clarifying and it is an important part of the record. Thank you to all of you and to Mr. Chairman.

Mr. UPTON. Thank you. I have got a number of questions left and I know Mr. Stupak is back and so I would expect the same as well. What is the number of single-use devices that are reprocessed about, percentage wise? Mr. O'Holla? Mr. Maurer, at the Cleveland Clinic?

Mr. MAURER. I can comment at our institution. We have just done a recent review of that. It is very hard to give an exact percentage, but of all devices that go through sterile processing, and that is what we are talking about. I think, you know, Ms. Eshoo's

comment is: Let us get away from this reuse of single-use devices. We are talking about sterile processing of devices, period. It is less than 1 percent, maybe even less than $\frac{1}{10}$ th of a percent.

Mr. UPTON. Mr. Feltner?

Mr. FELTNER. Yes. Overall it is very small. In fact, on the list that FDA published of commonly reprocessed devices, AMDR members do not do half of them.

Mr. UPTON. Well, that is my other question. In fact, I was going to ask Dr. Maurer, you know, as I look at—and you are a terrific witness. The Cleveland Clinic is up at the very top, so we are glad that you are here and I know my hospitals of Michigan are very good as well, and I am anxious to see exactly what they are doing. But of the devices that you watch over, how many of them will be sent out to one of the AMDR member versus what you do in-house?

Mr. MAURER. Most of the reprocessing is in-house. When it gets down to a critical device, the saw blades like I showed you, we send out. Now, the electrophysiology catheters, what if you were better at that. They are contained within the department of electrophysiology, there are trained people there, we have looked at them, we have continuous process control upon them. You have got to remember in terms of sterile processing, hospitals have done that ever since they opened their doors hundreds of years ago and, you know, Halsted decided that things should be sterile. That we should wear gloves. Hospitals do that, they are professionals in that. The people are trained. You cannot walk into those areas unless you are supposed to be there.

Mr. UPTON. And Mr. Feltner, as your organization brings things in, and obviously some things fail, what percentage of that? I mean, obviously if the average of—

Mr. FELTNER. It varies by product as you—I mean, saw blades, for instance. I mean, you cannot drop one and break it generally, but other products you could. So I would say we have some products as high as 60 percent rejection. Other products as low as 10 percent rejection. But I think there is something here that I am not comfortable that we are all speaking in the same language, because here is the thing.

Mr. UPTON. I know there are a lots of oranges and apples here.

Mr. FELTNER. Yes. One thing though that is very important that we have common language on. I am hearing a lot of concern that these devices that we are talking about I could not possibly think of having a device put in my body that was in the body of a previous person. Well, then you better never go to a hospital because every procedure that I have ever seen, someplace in that procedure is a product, whether it is reprocessed, or reusable, or new, that has been used on another patient. So what we are really saying is oops, I did not mean to say that I meant to say if it is single-use.

Mr. UPTON. Well, this happened. Yes.

Mr. FELTNER. Now, what we are saying then is we have two different standards of sterility. We have two different standards of cleanliness. One for a product marked single-use, and one for a product marked reusable. Well, that does not make any sense because the standard for validating the sterility of either product is the same. So, I think we have to look at this. Once a product is out of the package it has to meet the same standard. We were talk-

ing about which one would be exempt. The example just talked about. One of Dr. Maurer's saw blades would be exempt and one would not. Why? Because the manufacturer chose to label one single-use. It just so happened he sold the same one as reusable last week. Which one do you exempt?

Mr. UPTON. When an AMDR member rejects a product, is there some reporting of that? Do they go back to the OEM?

Mr. FELTNER. We manifest everything that we must turn that into medical waste or hazardous waste.

Mr. UPTON. Right. Right. But do you report back to the original manufacturer or to the FDA?

Mr. FELTNER. Oh, yes. Sure. Well, not back to the manufacturer. No. We report back to the hospital who sent it to us. See, that is another thing I want to make sure we understand. Hospitals who send products to us only get their products back. These are never owned by us. We do not sell products.

Mr. UPTON. Right. I understand.

Mr. FELTNER. So when they send us 50 saw blades and we reject five, they know that. We send them back and say we rejected five of these. We are shipping you 45 back.

Mr. UPTON. Well, what happens with devices that are used on someone with a disease like Hepatitis or HIV, what happens to those—are those automatically out of the stream? Are they reprocessed still? What type of—

Mr. MAURER. Well, I can tell you, we have a policy in terms of sterilization that is the same for everything, because you do not know who has the Hepatitis.

Mr. UPTON. Right.

Mr. MAURER. It was spoke about here that it may take 6 months to develop.

Mr. UPTON. But what if you do know that somebody has that? What if you do know that somebody has HIV, are any of those products that might have been used in that individual's body? Are they still processed with maybe more care? I mean, what happens?

Mr. MAURER. The processing is the same. The processing will kill HIV. It has got to because you do not know if they have it. It has got to. Now, to be frank, when I am in an operating room and I know the patient has got HIV, yes. I double glove and, you know, obviously that is just normal. But we cannot rely on that, so our processing has to be enough to kill that bug, no matter if we knew it or not.

Mr. UPTON. As I go back to, and I am going to use, you know, one of Mr. O'Holla's, I guess it is the lower picture there which is the tip of a catheter, is that what that is?

Mr. O'HOLLA. Ablation catheter, yes.

Mr. UPTON. Ablation residue, and I presume that this device that you came back to get had been reprocessed, right?

Mr. O'HOLLA. Yes, it had.

Mr. UPTON. So it was not perfect.

Mr. O'HOLLA. That is right.

Mr. UPTON. And if that individual whose residue is still there, in fact, had HIV or something else infection like that, it would be more than trouble?

Mr. O'HOLLA. I would think so.

Mr. MAURER. Two things. You have got to look at what the process is that delivered that to the physician. You know, it is probably not a good process. You also have to remember that residue does not always equal infection as was shown in some of the studies.

Mr. O'HOLLA. Right.

Mr. MAURER. Now, it is yucky. I agree and it should not be there and I would not want it in me. Okay. Absolutely. But you have got to look at the process. That is a good quality control. If that is coming out, the process needs to be looked at. The process needs to be improved, but do not throw out the baby with the bath water. We are not going to throw out reprocessing because the process is bad. That is where the data needs to come from, from the FDA, and that the processes are certified as not producing that product.

Mr. UPTON. Well, I guess as us novices sit up here on this dais, we want something that is going to work so that that does not happen.

Mr. MAURER. That is true.

Mr. UPTON. And we want some good housekeeping seal or something along those lines to ensure the safety to the patients, as well as to the hospital workers that are using those particular products. My time has expired here so I guess I go to Mr. Stupak.

Mr. STUPAK. Thank you Mr. Chairman. Dr. Fielder, in delineating patient alternatives, you used the example of offering a patient the choice between a used or reprocessed SUD with no difference in the cost to the patient. Would it follow then that a patient should be offered the same choice in a situation of two brand new devices, or one that costs the hospital less and at a smaller potential risk?

Mr. FIELDER. If I was a patient and they came at me and I had a choice between a new single-use device and a reprocessed one, I would take the new one, sure.

Mr. STUPAK. Sure. But I am saying should they be offered that choice?

Mr. FIELDER. Yes, they should.

Mr. STUPAK. Okay.

Mr. FIELDER. Because it is an alternative treatment.

Mr. STUPAK. But on two new ones, where one would cost less, both new, if there is one cost—

Mr. FIELDER. If there is no significant difference in risk, then that is the choice of the physician and the hospital. In the case of reprocessed devices, there is a significant risk. That crud that you see on the ablation catheter could be Hepatitis C that you are going to put into somebody else, so that is a risk. We do not know how high the risk is, but it is a risk.

Mr. STUPAK. If you have two new devices, brand new, and the question assumes a small potential risk with using one or the other, the patient should be made aware of that, right?

Mr. FIELDER. Not necessarily. I mean, there has to be some kind of, I mean, there is some risk in everything.

Mr. STUPAK. Sure.

Mr. FIELDER. And there is some level, as Dr. Trotter was saying, that the Courts have used the idea that material risk, is this something that the patient would want to know as part of his or her decision to have this treatment? So there is a kind of floor or level

beyond which the risks are so remote that that does not really matter and people need not to be informed. They need to be informed if this is part of their decision in their lives and in their healthcare. And I think the fact that we do not have a well controlled cleaning and sterilization process that has been approved by FDA, means that there is a significant risk that people ought to know about so they can decide if they want to go along.

Mr. UPTON. Mr. Feltner?

Mr. FELTNER. Yes. That is not entirely correct because all of the processes in commercial reprocessing are validated and the FDA has standards for sterilization validation. Now, if we ask or have the doctor get patient consent for every product that has been used, are we going to get patient consent for every reusable product? Every product has a life. We just do not happen to know what it is. I have seen \$4,000 instruments sold as reusable break on the first case. They were not meant to be disposable. They just happened to be that time. So we never know. Well, we say oh, take this out of circulation because next time it is going to break. We do not know that. So all of these products that are being reprocessed should they have patient consent as well?

Mr. STUPAK. Well, should a patient be asked their consent on whether they want a new one or reprocessed one?

Mr. FELTNER. If we do that we will run out of money by 7 this evening.

Mr. MAURER. Let me explain a little bit about patient consent because I do it every day. Every day I do anesthesia on somebody, I have to consent that patient. Okay. These people are very nervous. They are coming in for surgery on their bodies. Okay. What they want is quality care delivered to them in a safe environment. That is all our jobs here is to make sure that the regulatory, that the laws, that the FDA, that the licensing to be a physician, is done properly. Okay. I consent them for the serious parts of their procedure that they need to consent to. Okay. I tell you, to shirk our duties and think that somehow the consent issue is the primary one and that is going to solve this, is not going to work. Okay. We should consent patients. We should inform them, but when the risk is very low, and that is the thing that we are arguing here on either side, is how high is the risk. When the risk is very low and that risk is documented by valid data, then let us not confuse the issue with consent.

Ms. WEST. Excuse me. I want to know if there is a reused device going to be put into my body. I have suffered for 17 years because a C-arm was reused when they originally did the surgery on my head. And whether we run out of money or not, then we need to find another way to do that. But as a patient, I want to know if I am being given a reused or a clean device. And then in addition to that, I need to ask to be excused as I am supposed to be over at the Senate at 3 and I apologize for this, but my opinion is that I want to know. And I have many years of experience because I was not told, I was not given the option and everybody should be given the option.

Mr. STUPAK. Dr. Maurer, if I may, just a point of clarification on a question and answer with Ms. Eshoo. Maybe I misunderstood it.

But I understand that, Ms. West, you can go. Right, Mr. Chairman, she can go?

Mr. UPTON. Yes.

Mr. STUPAK. I understand that the Cleveland Clinic passes along savings of reprocessing to the government and the patient, but where does the Cleveland Clinic reduce cost by reprocessing? I got the impression that there was a reduced cost that was passed on to the patient and the Government, so where does the Cleveland Clinic reduce the cost by reprocessing?

Mr. MAURER. Well, if you reduce the cost and you deliver the same quality, you increase your value. And that is reflected in your market share because you then, the patients come to you more because you are delivering better value. So that is where the advantage is.

Mr. STUPAK. Okay. So it is not, that is value to the Cleveland Clinic then?

Mr. MAURER. That is right. Now in some instances, in terms of going out in the marketplace and then negotiating a managed care contract, if we can do it at a lower cost, we offer a lower managed care contract, as long as we deliver the same quality and can certify that quality to the people that are paying us, and we get the contract.

Mr. STUPAK. Okay.

Mr. UPTON. Dr. Ganske.

Mr. GANSKE. Thanks Mr. Chairman. I want to go back to a question I asked Dr. Feigal, and it looks to me like we have a cardiologist on this panel, and I apologize for not being here earlier, but I had some other meetings I had to be at. We have somebody from the reproprocessors, and the manufacturers. And now Dr. Maurer, are you representing the American Hospital Association?

Mr. MAURER. I have been asked to come here on their behalf, yes.

Mr. GANSKE. Okay. Let us go to this situation where we have a catheter used for balloon angioplasty to crack open a stenosis in a coronary artery. That little balloon, you know, is made of an inflatable material. It is manufactured, in my understanding to under a certain pressure go to a certain size, there are different techniques for sterilization, one of which though is a heat sterilization. The other would be a gas, but then you are also dependent on very meticulous cleansing, manual cleansing. I want to know specifically, does this panel think that the average hospital, I am not saying some hospitals cannot, but the average hospital, can they re-sterilize those catheters, and I am not talking about the reproprocessors. I will get to that in a minute. But the average hospital, can they re-sterilizing that balloon catheter, with a proper sophistication, to be able to certify that after multiple uses this catheter is up to par.

Mr. MAURER. Well, I can tell you that I cannot comment nationally, and I do not have the data on it, but in my hands, when I open a Swan-Ganz catheter with a balloon on it, even if I do not put it into the patient it goes in the trash. We do not even re-sterilize those that are open and not used because we have that concern.

Mr. GANSKE. So it is a Swan-Ganz?

Mr. MAURER. Well, it has got a balloon on it. That is what I have in my hands.

Mr. GANSKE. All right. I am talking about are balloon angioplasty catheters reuse?

Mr. MAURER. We do not reuse those at the Cleveland Clinic, no.

Mr. GANSKE. Are they reused, do you think they are reused anywhere?

Mr. MAURER. You can ask our cardiologist.

Mr. GANSKE. Yes.

Mr. LINDSAY. I'm Dr. Lindsay. There are some hospitals that reuse these catheters. My hospital does not, and I have some reservations about whether the data would support reusing those. I think there are some of these devices that probably should not be used. And I think as the FDA looks at them, that is one of the devices that I have questions about.

Mr. GANSKE. Mr. Feltner, what would your response on that be?

Mr. FELTNER. Some AMDR members reprocess balloon catheters, and when they do they use FDA published guidelines that assure bio-compatibility and physical testing. One company I know that is an AMDR member, they tested over 8,000 balloon catheters before they ever shipped their first one back to the hospital. And I am told now that they have processed over 3,000 without an incident. This—

Mr. GANSKE. Does this require some special type of technology and expertise to do that?

Mr. FELTNER. Oh, yes. It will require special technology, special equipment, but I think here what we are really getting to though—

Mr. GANSKE. Let me just ask you.

Mr. FELTNER. Yes.

Mr. GANSKE. Do you think the average hospital has that type of technology or equipment to do?

Mr. FELTNER. I would not think, and I use the word think, I would not think that today many hospitals would have all that equipment, but this is where we really need to zero in on the answer here. And the answer is process. Validation. I am aware of a major institution reprocessing in-house pace makers from cadavers. Now, that sends a little hair up my back when I first heard that and I heard no. If the process is right, if the cleaning is validated, if the sterilization is validated, and the functional testing is to a standard that could be validated, the process is good. Now, many companies may chose, or many hospitals may chose not to reprocess a product simply because of our litigious society. There are certain products that maybe the risk of a legal problem is greater than the possible return of the market.

Mr. GANSKE. Okay. Well, let me just follow this. I want an answer from everyone on the panel on this. Is the panel in consensus that at least for some types of single-use products that the re-sterilization should be done, not by hospitals, but only by certifiable re-processors?

Mr. MAURER. The hospitals could get certified if they had enough volume to get all the same equipment.

Mr. GANSKE. Okay. But they would have to go through a—that for some types of single-use products they ought to go through FDA

certification process. Is there any disagreement with that on this panel?

Mr. GROSSMAN. I would disagree because I think that the FDA themselves are saying that what they are going to finally focus on is the data that not what the process might have led to, but what actually happened. Because that is the burden they put when these products are originally created. The Office of Science and Technology recently did a study they presented publicly in May looking at the kind of catheters to which you refer. Took them from Walter Reed instead of discarding them in the garbage and performed functional testing and showed that they were a disaster. They were a disaster. The balloons changed compliance, changed shape, became sticky, so I think since—

Mr. GANSKE. So, you are agreeing with me?

Mr. GROSSMAN. Well, I am saying I do not think the process will protect it by saying you have handled it well. I think the FDA then needs to actually go to the device and say now that it has been processed, we are going to say that it is safe and effective just like we did when it was new.

Mr. GANSKE. Well, right. I am assuming that if it is processed—

Mr. GROSSMAN. Oh, okay.

Mr. GANSKE. That if it is processed that the process certification says that it works, not that you can just have a sterile one—but now it inflates to 3 millimeters instead of 2.5. Okay.

Mr. GROSSMAN. Yes.

Mr. GANSKE. So, at least the entire panel is in consensus that there are probably some sophisticated devices that are in use that it would be inappropriate for a hospital to be reprocessing and sterilizing themselves unless they have some extraordinary reprocessing/processing capability, and that these are items that could be identified by the FDA. Is that fair?

Mr. MAURER. It out to be a functional definition. I worry about location because things change over time. You know, so I think it is a functional definition. If you cannot meet the standard, then you should not be doing it no matter who you are.

Mr. GANSKE. Yes.

Mr. O'HOLLA. Congressman Ganske, I do not know if FDA can actually identify those a priority. I know that FDA can make a judgment about those if the person who wanted to do the act came to FDA and said I am going to reprocess this particular device this way and here is the data that shows it is safe and effective. I think they can evaluate that. I think you may be asking them to do an impossible task to identify a priority which devices can and cannot be done, because they do not know what people will be doing to them.

Mr. GANSKE. Okay. Let me get to my second question. And you know, pictures like this are disturbing to all of us, but matters of thoroughness, of cleansing can vary between let's say hospitals and professional reproprocessors. Is there anyone that would disagree with that?

Mr. MAURER. Well, I think it can vary hospital to hospital. It can vary reproprocessor to reproprocessor.

Mr. GANSKE. Right. But how many reprocessors are there in the country?

Ms. ESHOO. They do not know.

Mr. FELTNER. I cannot really say. I hear some stories that are amazing. I do not know if they are—somebody said there are 23. If there are, I do not know who they are. There are three major processors that are members of AMDR. I think that as FDA implements the proposed guidelines, they would all have to register, and then we would definitely know who they were. We have cooperated with FDA in giving them all the companies that we know of.

Mr. GANSKE. Well, are we talking about less than 20?

Mr. FELTNER. Oh, yes. Yes. Yes.

Mr. GANSKE. Okay. And how many hospitals are there in the country?

Mr. FELTNER. Six thousand, roughly.

Mr. GANSKE. It would be a lot easier to oversee whether less than 20 reprocessors are doing their job properly than to be thinking about looking at, for single-use devices, particularly the ones that can be identified as problematic, 6,000 hospitals. Does not that seem reasonable?

Mr. MAURER. On the surface, yes. Okay. But you have got to watch because, you know, hospitals have very good sterile processing departments and quality control systems in place, and those are well set up. They are supervised by Joint Commission and State health boards, and it is not just the FDA that is getting in on this. You know, processing and sterile processing has been around for years.

Mr. GANSKE. I understand. I am a surgeon. I have worked with instruments all my life.

Mr. MAURER. You know what I am talking about. We have got to look at those ones which are borderline, and we do not have the data on, and if they require functionally specialized techniques and the hospital cannot deliver that specialized technique, then a specialized person needs to do it. And if that is a reprocessor, then so be it.

Mr. GANSKE. I agree. Thank you. Thank you Mr. Chairman.

Mr. UPTON. Thank you. Ms. Eshoo, do you have additional questions?

Ms. ESHOO. Yes. Mr. Chairman, I would like to make a request and that is that if Dr. Maurer for the committee's record could submit to us copies of the hospital's billings that show the rates that are billed to HCFA when a reused device is used versus the other. Because I think it will show, you know, it is a demonstration and an example of the billing. And I also think that when we look at these things that are submitted for the record that we understand that while you may be doing that at your hospital, we do not know what is happening at others.

Mr. MAURER. We can do that.

[The following was received for the record:]

CLEVELAND CLINIC FOUNDATION

BILLING PRACTICE

FOR

REPROCESSED ELECTROPHYSIOLOGY CATHETERS

An electrophysiology examination or an ablation procedure are inpatient procedures which involve complex electrical mapping of the heart and corrections of the heart's electrical process. Routine procedures typically use three catheters, and complex procedures may use from four to six catheters. About a third of the procedures are complex.

The most common catheters and their price to CCF are listed below.

Bard Steerable Catheter.....	\$475
Webster Steerable Catheter.....	600
Mansfield Explorer.....	235
EPT Steerocath "T".....	745
EPT Blazer II "T".....	745
EPT Octapolar.....	800
Duo-Decapolar.....	995
USCI Quad Catheter.....	245

To establish our charge for the device, a mark-up schedule has been developed. It is as follows:

For devices which cost between \$0 and \$35, the mark-up is 100%
 For devices which cost between \$36 and \$150, the mark-up is 75%
 For devices which cost between \$151 and \$999, the mark-up is 65%
 For devices which cost over \$1,000, the mark-up is 50%.

Thus, the charge for a EPT Octapolar would be 800×0.65 plus \$800, which equals \$1320.

If this device is scheduled to be reprocessed and reused five times, the charge to the payer would be \$1320, plus \$40 for reprocessing, divided by 5, which equals \$272.

The process described above is the method by which CCF computes its charge to all payers, independent of the payer's particular form of payment. If the payer is discounted fee-for-service, the benefit to the payer is in the reduced charge due to reprocessing. If the payer is on a fixed payment scheme, such as Medicare, the payer obtains the benefit of the hospital's reduced cost in subsequent years when the fixed payments are updated, based on the hospital's charge data as reflected in the Medicare cost reports.

Ms. ESHOO. And I think that this patchwork quilt of issues has really been nailed down with me today. That we have some reproprocessors that are absolutely terrific. The gentlemen that represents them as a trade association cannot tell us how many there are in the country. We do not know how many hospitals adhere to the high standards that Dr. Maurer has talked about, nor do we have information and data that has been collected by the FDA, not the associations and the groups around all of this. They simply have not tracked and collected the data that we could weigh and measure in a hearing like this. So, it is a patchwork quilt. I think that there are some problems out there. We do not know in the reuse of these devices if, in fact, the record that we know about anecdotally is the best record of all. I mean, maybe that is the perfect good news. It is not perfect, but there is a lot of good news in it because people with legitimacy can say well, we do not have that many problems in the country. But do we really know that? So I think that this hearing was designed, or really offered us, what Congressional investigation and oversight is really meant to be. It has answered some questions, it has raised others, and because of each one of you I think that we are going to move on and keep examining this, at least I will. So thank you very much. And thank you again, Mr. Chairman, for allowing me to be here today and for the legislative courtesies that have been extended to me, and your patience as well. Thank you.

Mr. UPTON. Thank you. Again, I appreciate all of your testimony and your answers. We would be most interested in the future as you comment back to the FDA with regard to the regulations that they put out. You have done a fine job today and you are formerly now excused. Thank you.

[Whereupon, at 2:58 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF NATIONAL CONSUMERS LEAGUE

The National Consumers League is a national, nonprofit consumer advocacy organization founded in 1899 to represent consumers in the marketplace and workplace. NCL commends the Subcommittee on Oversight and Investigations for holding this hearing. As you examine the complex issue of medical device reprocessing, we want to bring to your attention important consumer implications of this issue.

NCL believes that Congress must do all that it can to assure that the Food and Drug Administration is doing its job to protect public health. We believe that the Commerce Committee is moving in the right direction as it investigates and oversees FDA's regulation of medical device reprocessing. The safety of medical device reprocessing must be the overriding concern of Congress, the FDA, hospitals, and physicians. Clearly, no amount of health care cost savings can be justified if safety is compromised.

In our view, the medical device reprocessing debate concerns two very different interests: the interests of consumers who expect safe health care practices and the interests of the medical device manufacturers who are working very hard to eliminate competition.

First and foremost are the interests of consumers. Through appropriate regulation, FDA must assure that medical device reprocessing is safe. Consumers must have confidence that when a reprocessed medical device is used in a procedure, it will perform as safely and effectively as it would on its first use. Consumers should be assured that they will not experience an infection or health complication because a device was reprocessed.

Once it is determined, through sound science, that medical device reprocessing can be safely performed and is adequately regulated, then and only then should the cost savings that such a practice provides be considered. Faced with overwhelming

cost pressures, hospitals are increasingly reducing staff and scaling back on the procedures they will perform. For many consumers, the result has been lower quality and less affordable health care. Measures that can help control health care costs must be encouraged but should never be considered if patient care is compromised.

As you know, medical device reprocessing is a practice aimed at reducing costs associated with medical devices labeled as “single use” or “disposable” by the manufacturer. We understand that many hospitals have been reprocessing “single use” devices for years and that a number of hospital and physician groups have sent letters to Congress expressing confidence in the safety and effectiveness of reprocessed devices.

FDA has a strong tradition of protecting the public health based on sound science. As FDA reviews its regulatory approach for medical device reprocessing, we expect the agency to continue this tradition. Even though there has not been any significant evidence of a public health hazard to date, FDA should be thorough and vigilant in its regulation of device reprocessing and should take a strong regulatory posture that is systematic, based on science and based on risk. If effectively enforced, FDA’s current regulatory regime affords consumers appropriate protection. FDA’s Quality System Regulation, which governs the reprocessing of medical devices by third parties, is similar to good manufacturing practice regulations and sets forth requirements designed to assure that reprocessed medical devices are clean, sterile, and functional. Through inspection, FDA must assure compliance with all of the QSR requirements, including process validation, acceptance activities, internal audits, personnel training, storage, and complaint handling. By requiring those engaged in the reprocessing of medical devices to withstand the scrutiny of FDA inspection, consumers can have assurance that reprocessed medical devices are clean, sterile, and functional.

We understand that FDA is reviewing its policy to require premarket review of reprocessed medical devices. To date, the agency has not believed premarket review is necessary to protect the public health. If risk warrants premarket review for certain device reprocessing, FDA should require it. NCL also believes consumers deserve more information about the risks and benefits with all health practices, including procedures that involve using all devices. FDA should work with consumer and patient advocates to ensure that the messages patients receive are accurate and thorough. To that end, statutory requirements for informed consent—in consumer friendly language to assure that the consumer understands—should be more broadly applied so that consumers may assess the relative risks of a procedure or a particular device. The FDA should require that all significant risks trigger an informed consent requirement. In this way, consumers will receive relevant information, communicated both orally and in writing in consumer friendly language, and the information that they receive will be put in the proper context with respect to their own health care regimen.

As mentioned, the issue of medical device reprocessing touches on two different interests: the interests of consumers and the interests of the medical device manufacturers. As the Subcommittee studies the safety of medical device reprocessing, we urge you to take note of the strong opposition to reprocessing voiced by the manufacturers of “single use” devices. You should be aware that the term “single use” is a term that is chosen by the manufacturer of the device; it is not required by the FDA. There is a clear economic incentive to label devices as “single use” in order to sell more devices.

As Congress considers the issue of medical device reprocessing, it should make sure that FDA has a sound science-based regulatory procedure for medical device reprocessing in place that will protect the public health and assure consumers that the devices used for their health care are safe and effective.