FOOD AND DRUG ADMINISTRATION (FDA)

WORKSHOP

ON

REFURBISHING, RECONDITIONING, REBUILDING, REMARKETING, REMANUFACTURING, AND SERVICES OF MEDICAL DEVICES

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OPENING REMARKS

MS. FLOURNOY: So, I am Valerie Flournoy. I'm the Deputy Director for the Division of Manufacturing Quality in the Office of Compliance CDRH. I thank you all for coming here today. And so I am going to give you some housekeeping information for you.

So, you know about ordering the box lunch and as we told you that we had to get orders and we will be talking with the Sodexo (ph) after this to determine like when lunch how it is easiest for you all that have not paid, how we can facilitate it much more easier than the long lines. But any time if you need any type of assistance there are supposed to have tags and it is really pink, not red, if you would just raise your hand or ask one of us anything, we'll be able to assist you with your questions if we can or direct you to the proper person. If you aren't already the restrooms are if you go out the door and go to your right and all the way to the wall past the dexo and to the right down the hall there's a men's

and ladies restrooms are, except where some of the overflow rooms are where there is only one bathroom stall.

Some of these sessions allow for questions and answers. So the people that are on the webcast we do have an email mailbox and you see it thirdpartyserviceworkshop@FDA.hhs.gov can forward your questions and our moderator will read the questions off to our panel. Those of you that are sitting in the overflow rooms, we have index cards and we will bring the index cards to you and we will pick them up and bring the questions in here for our moderators to read.

So just enjoy. Right now I'd like to introduce Dr. William Maisel. He's the Deputy Director for Science and Chief Scientist for the Center of Devices and Radiological Health that will provide the Welcome.

WELCOME

DR. MAISEL: Thanks Valerie. And good morning. On behalf of FDA and CDRH welcome to our workshop and we very much appreciate you being here.

It is a pretty amazing time to be involved in the medical device industry. We have devices that can help blind patients to see, paraplegic patients to walk, we have heart valves that can be implanted through a thin catheter without open heart surgery. Just last month we approved the world's first artificial pancreas that can control both low and high blood glucose levels; pretty amazing innovation.

We've seen innovation and creativity in digital health. Many of you have a smart phone in your pocket. Some of you may have some of your health information on there. We have patients who can control their medical devices literally from their pocket.

We've seen incredible innovation in device design and materials and manufacturing; the burgeoning of 3-D printing. And it is not just technology that has evolved. It is healthcare delivery that has evolved. And many of you are health organizations and patients are facing cost pressures, a lot of attention on cost effectiveness and value.

And so in this environment it seems very

timely to talk about refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices. And as an aside it might be our longest workshop title ever.

[Laughter]

And clearly these functions serve a critical role. And we recognize the importance of these activities not only to the health of the healthcare ecosystem but also to the health of our patients.

At the outset I'd also really like to acknowledge that we are aware of many organizations and many professionals who perform these activities very well whether it be an independent service organization, an original equipment manufacturer, a healthcare facility, biomedical or clinical engineers, healthcare technology management professionals or other entities.

But we've also heard from various stakeholders who have sometimes expressed concerns about the quality, safety and continued effectiveness of medical devices that have been subject to one or more of these activities. And we're really here to

get your perspective on these things.

We've heard about some stakeholders, for example, have expressed concerns about the use of unqualified personnel to perform service, maintenance, refurbishment and device alterations on equipment and that the work performed may not adequately be documented. We've heard from others that have noted the difficulty in gaining access to device specifications, access to service equipment and replacement parts needed to assure that the work being performed returns the device to the proper state.

And these are not just theoretical concerns. We've seen real world examples of improperly serviced and refurbished medical devices such as those involving radiological products and endoscopes that can result in disabled device safety features, improper unexpected device operation and most importantly that could have a negative impact on the safety of our patients or on the operators of these devices.

We've also heard about some of the best practices. We've heard about some organizations and

individuals that use these best practices to overcome and address some of these challenges that I just mentioned such as having a quality management system, training that assures that individuals performing these activities have adequate knowledge, skill and experience, and a focus on providing high quality service that restores or maintains devices to their original or intended specifications.

What is clear is that FDA can't and shouldn't tackle these challenges alone. We want to hear from you. We want you to share your thoughts, your perspectives, your insights, your experiences and your ideas and that is why we are here over the next two days.

The design of this workshop includes presentations from stakeholders, panel discussions on key issues and an opportunity for you to share your viewpoints on each of these topics. And we'll be discussing what's currently being done to assure patient safety and what gaps, if any, need to be addressed.

Ultimately it is our hope to identify common

ground and consensus around some of the best practices for these activities.

I should note that while I mentioned endoscopes the reprocessing of reusable medical devices is not within the scope of this workshop. The Agency has taken a number of actions and steps to strengthen the reprocessing of reusable medical devices and we won't be discussing that topic further here today.

And ultimately there is one common purpose that unites each of us in this room and that is our desire to focus on the health and well-being of our patients and on the individuals that use these products. We are here to listen to you so that together we can map out what, if anything, should be done; what additional actions or steps as a community we should think about taking. And importantly this is really the beginning of the dialogue; not the end. And so there will be additional opportunities beyond this workshop for public input on any actions or things that the Agency thinks should be the next steps following this workshop.

So again thank you for being here. We look forward to a productive two days. And now it is my distinct pleasure and honor to introduce our next speaker who is Bryan Benesch. Bryan is the Deputy Director for Regulatory Oversight and Analysis in our Division of Analysis and Program Operations in our Office of Compliance; and he's really a walking history book about FDA and these activities. And so you should be looking forward and I am looking forward to hearing from Bryan about our history of regulation in this area.

HISTORY OF FDA INVOLVEMENT WITH REFURBISHING, RECONDITIONING, REBUILDING, REMARKETING, REMANUFACTURING, AND SERVICING OF MEDICAL DEVICES PERFORMED BY THIRD-PARTY ENTITIES AND ORIGINAL EQUIPMENT MANUFACTURERS

MR. BENESCH: Thank you, Dr. Maisel.

So in the beginning FDA published its first guidance on refurbishers and reconditioners way back in 1987 in something called a compliance policy guide which is what our field organization would follow and these were public documents so manufacturers and other

regulated entities were aware of it. And back in 1987 our policy was that reconditioners and rebuilders were basically subject to all requirements. They had to register every year. At that time registration was free. If they were doing something to a product that required a 510(k) they needed to follow one; they had to comply with the labeling requirements in the 801; they were subject to inspection; they had to comply with GMPs and DR (device reporting). So in the beginning of the process we treated refurbishers and reconditioners no different than a manufacturer.

Then the quality system regulation came along. And there was a decision in '93 to update what was then the CGMPs and we wanted to codify basically what the policy was. And so the proposed rule included third-party servicers and refurbishers as being subject to all of the proposed changes in the new quality system regulation.

Well, there were a lot of comments about this; there was a lot of contentious discussions about it. And it got to the point where this particular subject could have derailed the proposed rule from

becoming final. So the Agency based on the comments and the advisory committee meeting decided not to include this change in the final rule.

So when the final rule for the quality system regulation was published it said FDA believes that persons who perform such functions as a servicer or refurbisher meet the definition of a manufacturer but that we've elected to address this in a separate rulemaking later this year, 1996. And a separate rulemaking would also cover third-party service organizations. So 20 years ago.

So 1997 we actually published what is known as Advance Notice of Public Rulemaking which is sort of the pre-step of having a proposed rule. And this is where the refurbisher, reconditioner, servicers, all that verbiage comes from. We had 89 public comments. We didn't do anything subsequent to receiving those comments except the following: So the ANPR said FDA's announcing its intention to review and if necessary to revise or amend the compliance policy guide that was issued in 1987 and the regulatory requirements related to remarketing of used medical

devices and the persons who refurbish, recondition, rebuild, service and remarket such devices. At that time no one could agree what the right term was. And I think we are still at that point where nobody really knows what the best term to use for this particular situation is.

We also went on to say we believe evolving industry practices warrant reevaluation of the current policy and the application of certain regulatory requirements in order to ensure that particular remarketed devices meet suitable performance requirements for their intended use and are as safe as the originally marketed finished devices. So 20 years ago we said the same thing that Dr. Maisel basically just re-indicated.

We went on to indicate what sections of the law we felt these entities needed to be subject to and it dealt with the same things, you know, recalls, labeling, quality, medical device reporting, the medical device tracking; and then because there are radiologic health products involved the imaging equipment x-rays, et cetera, all of those sections in

the electronic product radiation control portions of the act.

After that meeting there was a lot of discussion as to how to proceed and whether or not the Agency should promulgate a regulation or whether or not there should be a voluntary process. So FDA joined with AAMI and there was a public meeting, two days, in September of 1998 to discuss what the best approach would be.

Out of that meeting there came a task force which met for about a year that had representatives from all of the affected parties and they drafted a report, a joint medical device industry proposed alternative to the regulation of servicers, refurbishers and remarketers. The proposal suggested that there be voluntary controls that the industry itself would administer and monitor so that FDA would not have an official role. Some of those things that were proposed at the time was a voluntary registration process; I believe a voluntary certification process so that user facilities that were using these parties would understand that they had met a basic level of

understanding as to how to appropriately refurbish and service the products. That report was submitted to FDA I believe in late '99 or maybe the following year.

Then we decided we had to do a little housekeeping. So we still had that 1987 compliance policy guide that was still out there saying that we were going to continue to regulate refurbishers and reconditioners. But since we had said in the preamble of the final quality system regulation that we were going to not do that we issued a notice saying that basically we're withdrawing all regulatory oversight of refurbisher and servicers with the exception of the overarching Food, Drug and Cosmetic Act requirements that if there is a public health issue we can still assert our authority.

Since 1998 no one has had to register with us, no one has been subject to inspection except for cause if there is a concern that you are not really refurbishing but you are actually remanufacturing a device because you are changing the intended use. So the industry has not really had any involvement with FDA except our interactions with some of the trade

associations since 1998.

So here we are today. So in March we published the request for comment about this subject. We got 177 comments, more than twice what we got 20 years ago. And we are here today to talk about what those comments said and some of the other issues that were raised.

Now I was here 20 years ago. So I'm one of the few people that have been through this process for quite some time. In fact I was here in 1987.

Now I have the pleasure of introducing Rob Sauer. Rob is a Policy Analyst in CBH's Office of In Vitro Diagnostics and Radiologic Health. Rob has experience as a reviewer of pre-market submissions and compliance issues for both medical devices and radiation emitting electronic products. Rob will be presenting working definitions for this meeting and an overview of stakeholder input to date. And I believe we were going to post the definitions.

Rob?

WORKING DEFINITIONS AND OVERVIEW OF STAKEHOLDER PERSPECTIVES

MR. SAUER: Thank you. So I will be presenting working definitions today. And in the agenda everyone received on the second page you should find a copy of those working definitions.

So Mr. Benesch just finished reviewing the history of FDA's involvement on this issue. And I now have the opportunity to review some of the more recent history in this space.

First I'll go over some working definitions that were developed for the purposes of this workshop and then I'll review some of the other feedback we've received.

In March we proposed and requested feedback on definitions for six different terms that relate to the topic of today's workshop. The terms were recondition, service, repair, refurbish, remanufacture and remarket. We requested feedback on these terms because we've encountered people applying them differently and we want to know how people are actually using them. We also wanted to know if there were any activities that we hadn't considered that we should consider and also to establish working

definitions for the purposes of this workshop.

On the next few slides I'll list these working definitions; they are changed slightly from the definitions proposed in the FR Notice. And these changes were made based on the comments we received and to improve clarity. We don't think that we had enough information or feedback to provide a final and comprehensive set of definitions and we realize that clarifications may be needed as we go forward with next steps.

So just to make sure we are all clear on what these definitions are. They are working definitions for today. They are not new regulatory definitions. And if you are speaking at this workshop and you want to use these terms in a way other than how they are defined that is okay. Please just be clear about that to avoid any confusion. And as I mentioned revisions, clarifications and distinctions may be necessary going forward.

So the first definition we have here is remanufacture. And so that is to process, condition, renovate, repackage, restore or any other acts done to

a finished device that significantly changes the finished devices performance or safety specifications or intended use. This is only slightly modified from the FR notice and that is because there was a typo. This is intended to reflect what is in the CFR and on here it should.

The next set of definitions is recondition, refurbish and rebuild. And so here we have restores a medical device to the OEM's original specification or to be like new. The device may be brought to current specifications if this change does not significantly change the finished device's performance or safety specifications or intended use. That is to contrast it with remanufacturing. And this could include the repair of components, installation of certain software or hardware updates that do not change the intended use of the original device and replacement of worn parts.

We received a lot of feedback that the definitions we provided for recondition and refurbish were too similar. So we agreed and we combined them for the purposes of this workshop.

In addition the original definition of recondition had a piece that stated under certain circumstances the device could be brought to current specifications and many commenters pointed out that that was ambiguous and so we inserted the second bullet here to make it clear that we are trying to distinguish it from remanufacturing.

And certainly further distinctions can be made, for example we could further define like new or OEM specifications, or current versus original specifications. Here in particular we felt that more of a discussion would be useful to make these distinctions. We intentionally made this definition broad so it can be usable in this workshop. And again there may be many ways to break this down into a final definition but that is beyond the scope of the reasons we were coming up with definitions for today.

The next definition we have, service. We view service as repair and maintenance essentially. And this definition the biggest change is that we've clarified that maintenance is preventative or routine. So the definition we have here is repair and/or

preventative maintenance of one or more parts in a finished device after distribution for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing cannot change the intended use of the device from its original purpose. Again we are trying to distinguish this from remanufacturing here. And again this is a very broad term.

And what I'd like to point out is that servicing doesn't say anything about the overall state of the device. If you service a device, you may only be working on a single component and/or a few components. And this is in contrast with refurbishing, reconditioning or rebuilding where you are describing something about the state of the whole device.

Here we have our definition for repair. And it is to return a component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device. Again we don't view this as

implying anything about the state of the device overall. Repair work may be isolated to a particular component and not consider the overall state of the device. With that being said repair is one of several activities that may be needed to recondition, refurbish or rebuild medical devices.

Lastly we have remarket. This was not changed from the FR Notice. And this is the act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift or lease.

And I just want to remind everyone that these are only working definitions for today's workshop. They are not new regulatory definitions and if you are using these terms in a different way than we have defined them here, again, that is okay but please just be clear about it.

So now I'd like to present some of the stakeholder feedback we received in response both to the FR Notice and also unsolicited feedback we've received. And so first I'd like to talk about some of the feedback on the importance of service quality.

We've received feedback that quality service maintains device conformance with specifications and performance standards. Quality service resolves unintended or improper device function and doesn't contribute to the recurrence of these problems. And lastly quality service should produce sufficient information for the facility or anyone servicing the device in the future to know the service history and current device configuration.

We received lots of feedback on contributing factors to quality service and I've listed some of those themes here: we have quality management systems, training, availability and use of quality replacement parts, and access to device specific information.

So we received feedback that organizations that have implemented a quality system may be better suited to perform some of these activities. And that there are certifications available that may be relevant, these include ISO 9001 and ISO 13485.

In addition to broad comments about the quality system there were examples provided and those include supplier qualification and process validation

and service documentation. And we think those examples in particular could be related to some of the other themes that were brought to our attention.

Another theme was training and this was that service personnel should only work on those devices for which they have adequate knowledge, skill, training and experience. And this is really going to vary. It is going to vary on the complexity of the medical device. It may change between different models. And it could depend on the type of service needed.

Next we have replacement parts. There was concern that low quality parts may lead to repeated or additional device malfunction and the need for re-service or repair of the device sooner. Some stakeholders expressed concerns about the limited availability of certain replacement parts.

And then lastly we have device specific information. And so not all device specifications or test procedures are publically available or able to be measured with generally available test equipment and that limits some people's ability to do what they

believe is a quality job. And device specific equipment may be needed to perform certain types of service or testing.

And then we also just wanted to point out here that manufacturers of radiation emitting electronic products have additional requirements about information that manufacturers have to provide that don't apply to medical devices generally.

So to summarize we propose some working definitions here. They are for clarity; they are not new regulatory definitions. Some of the themes we saw in the stakeholder feedback we received included the importance of a quality management system, the importance of proper training, the availability and use of quality replacement parts, and access to device specific information.

And in the workshop today and tomorrow we hope to expand on this feedback and learn more.

Thank you.

CAPT. MITCHELL: Good morning and welcome again. My name is Diane Mitchell and I am the Assistant Director for Science in the Center for

Devices and Radiological Health.

We are now going to begin the stakeholder presentation section so I'm going to ask the people who are presenting to come up to the table while I give some housekeeping remarks.

So during this section each speaker is going to have 15 minutes to talk and there is no Q & A during this section. We actually will be timing the speakers and so we have a timer up here but we also have a timer in person, Astin Ross, and she has a yellow card for 13 minutes and a red card for 15 minutes. Astin I'm going to ask you to sit a little bit closer over here.

The speakers, I'm going to ask that when we call the speakers, they do come up to the podium for the presentation.

And if those in the back cannot hear the speaker if you wouldn't mind just raising your hand and that way the speaker knows that they need to do a little bit of an adjustment. So thank you for that.

I'm going to introduce each speaker by name and title but I will tell you that I have had the

opportunity to read the bios and CVs of these speakers and I just want to make a comment that each of these speakers brings a wealth of knowledge to this discussion that we will be having today.

So with no further ado our first speaker is going to be Peter Weems. He is the Director of Policy and Strategy affiliated with Medical Imaging & Technology Alliance, MITA. Peter, thank you very much.

STAKEHOLDER PRESENTERS

MR. WEEMS: Thank you. Good morning. My name is Peter Weems. I'm with the Medical Imaging & Technology Alliance, also known as MITA. We are the leading trade association representing the manufacturers, medical imaging equipment and radio pharmaceuticals.

I'd like to start by thanking the Food and Drug Administration for holding this public workshop and for their continued engagement on the very important topic of proper servicing of medical devices.

I'd also like to thank the other

stakeholders for coming together today and tomorrow to discuss the issues facing the industry and how we can best ensure patient safety and effective device performance.

As manufacturers our member companies are responsible for the innovation, original design, manufacture, packaging, labeling, assembling and upgrading of medical devices. Manufactures or OEMs also often provide servicing activities for installed devices both their own and those originally manufactured by other companies. Whether or not the OEM is also the entity which services a device it has a stake in all service activities.

Improper servicing presents significant concerns including creating challenges such as difficulties in future OEM provided servicing operations and the potential for significant periods of downtime if poor service must be remedied, difficulties in providing future field upgrades or field corrections to the device if improper parts have been used or if the device has otherwise been altered. Lack of required regulatory reporting and incomplete

device history does not allow for tracking of significant events, root cause investigation or prevention of adverse events. Further there are concerns about voiding existing device certifications such as UL certifications and liability concerns if a device causes injury, damage, or other significant problems.

Because our member companies and their service departments regularly encounter these and other challenges we have raised this issue with the FDA several times over the past few years. In raising this issue our goal is to ensure the performance of these activities always results in the safe and effective operation of medical devices.

We believe that the most efficient method for ensuring this would be to extend regulatory oversight including minimum quality, safety and regulatory requirements to all entities which service medical devices. And just to be clear when I say service I mean the entire bucket of activities listed, it is just shorter to say it that way than the entire paragraph of things we are talking about today.

Further I'd like to state right now very clearly and unambiguously that it is not our position that performance of these activities should be limited to only the original equipment manufacturers. It is not our goal to limit competition or drive anyone out of business. I will repeat this later in the presentation because it is true and because it is something we firmly believe.

We recognize that many third-parties including in-house hospital engineering teams, Independent Service Organizations and others are currently performing quality service. There is, of course, the problem of right now, only service activities performed by an OEM are regulated by the FDA.

As discussed earlier non-OEM service activities do not have the same oversight and are not held to the same quality, safety and regulatory requirements. This is an important problem because performance of these activities within a quality system by properly trained personnel using qualified properly sourced parts greatly reduces the risk of

harm to the patient or operator and greatly improves the performance of the device.

This matters to us for two main reasons: patient safety and device performance. It was because of patient need that medical imaging equipment exists. For this reason the patient is the most important stakeholder in device servicing. Safe and effective operation of medical imagining equipment allows for views into anatomical structure and physiological function of the patient which are otherwise impossible barring surgical intervention. Patients and healthcare providers count on the safe, effective and reliable operation of medical devices. If medical devices do not perform properly or do not perform at all due to improper servicing patients may not be able to receive the care they need and healthcare professionals are unable to do their job effectively.

In general there are two main ways that harm can be caused due to improper servicing: First, direct bodily harm resulting from improper functioning of the device due to mechanical, maintenance or calibration issues such as excessive radiation from

incorrectly calibrated equipment or physical injury from mechanical failure. There is also the risk of health care associated infections such as infections resulting from improperly sealed ultrasound transducers. Patients, operators, physicians and anyone else in close proximity or in contact with the device may be subject to this kind of harm.

Less noticeable however is indirect harm which may result from delayed diagnosis or misdiagnosis due to poor image quality. For example images of non-diagnostic quality due to miscalibration resulting in tumors not being visible. This kind of harm is unique to diagnostic equipment including medical imaging devices.

I will repeat patient has the most at stake if the device fails to perform in a safe and effective manner due to improper servicing. Patients should be able to assume an equivalent level of safety and efficacy regardless of service provider. Performance of these activities within a quality system by properly trained personnel using qualified properly sourced parts greatly reduces the risk of harm to the

patient.

So as was mentioned earlier there were a number of comments received to the docket. I read all of them. And I think there was a lot of very interesting material there for discussion but there were also a lot of misconceptions I think about the manufacturer's goal and interest in this. And I would like to take the opportunity to clear up a couple of misconceptions.

First it is not our position the performance of these activities should be limited to only OEMs. Many third-parties including hospital service teams, Independent Service Organizations and other are currently performing quality service.

Second it is not our belief that applying QSR to third-party servicers would be unduly burdensome and we believe that it is a reasonable expectation. The QSR is scalable meaning it applies to large entities with considerable resources as well as small entities with more limited resources. Further certain elements of the QSR may or may not be applicable depending on the nature of the activity

being performed. As an example the document controls element would look very different in practice for a $1 billion enterprise and a $1 million enterprise. However, the same principles would apply.

Finally a major misconception that we'd like to clear up is that we are not asking for a solution to a problem that doesn't exist. We are, in fact, asking for a solution to a known and ongoing problem.

Improper servicing unfortunately has led to a number of incidents. Through public comments, meetings with the FDA, MDR submission and other means the device industry has submitted numerous examples of improper servicing that posed serious problems for patient safety and device performance.

Now the FDA has only given me 15 minutes to speak so I can't go through all of the examples I have sitting on my desk but I did bring along a couple.

Right here is an improper part in an angiographic power injector system. This was discovered during a recent service call and it was observed that a third-party service vendor had inappropriately substituted a wood screw, like the

kind you would find at Home Depot or in a drawer in your garage for what is a sophisticated very strong turret. So an angiographic power injector of this kind can inject fluid at pressures of up to 1200 psi which is very powerful. So if this substituted wood screw were to break or otherwise fail during a procedure the turret would break free potentially causing the turret and the connected syringe to act as dangerous projectiles injuring or even killing anybody in the room. Additionally this improper part could cause vibrations during the injection thereby leading to ancillary issues such as delay of procedure and eventual diagnosis due to unexpected equipment behavior.

Next up I have an example of an improperly serviced MRI system. As you can see here there was a bit of an explosion. What happened here was a third party service subcontractor hired by an onsite contractor was working at a customer site trouble shooting an MRI system. The servicer was working in the service panel on the MRI with the power on when an ARC flash occurred resulting in burns to the

contractor. The blast knocked him back and onto the floor. Other people in the vicinity said that the event sounded like an explosion. The event also resulted in approximately half of the hospital losing power. It is not known with total certainty what the servicer was doing at the time of the event or what caused the event to occur. He was going to be hooking up a power monitor to the system but at what stage of that process he was in is unknown. He could have been checking the voltages prior to connecting the monitor or performing some other trouble shooting activity. It is known, however, that he did not have on his ARC flash personal protector equipment or PPE at the time of the event. The PPE itself would not have prevented the incident of occurring but it would have prevented or lessened the severity of the injuries that occurred. This is an example of inadequate training and non-compliance which resulted in bodily harm, equipment damage and loss of power to a major medical facility.

Here you can see an improperly service nuclear medicine camera, the kind that looks at your

heart. In this instance an OEM was contracted by a dealer who is dealing with a customer complaint about this nuclear medicine camera. The customer had been using a third-party servicer which improperly serviced their device and was now refusing to return and correct the issue. With respect to the improper power connection of the cooling system the way in which the system was connected violates the manufacturer's power and grounding isolation scheme potentially compromising patient safety and device performance. Further this issue could have lead to the detector overheating and pixels failing. These modifications also violate the nationally recognized test lab listing of this device. This resulted in such great degradation to the detector head that the customer could not use the device.

Also with this device several pixels on the camera had been masked. And what this means is that when the device would have been used significant parts of the heart would not have been visible on the image. Also the cooling unit was improperly connected to external power bypassing the systems isolated power

and grounding system potentially compromising patient safety and device performance. You can see that here where this entire box has been disconnected and put outside of the nuclear medicine camera. It is right there on the floor. Obviously this is not how it is supposed to be.

So here with the pixels when adjacent pixels are removed a portion of the imaging detector is lost. So portions of the heart would not be imaged meaning a heart defect could go undetected by the reviewing physician. When the pixel fails the system uses data from adjacent pixels surrounding the failed pixel to extrapolate. If two adjacent pixels are bad then the system does not have a complete sampling of data. The resulting image would have had a blurred spot resulting in lower diagnostic quality.

Now as I mentioned we have a number of examples and I presume that others will discuss some of these examples during other presentations but I think it is very important to point out that these examples are not representative of the entire problem. And the reason for that, the reason we cannot

understand the entire scope of this problem is because currently there is no requirement that every problem be reported. And until that requirement exists there is absolutely no way that we can understand the scope of the issue and no way that we can address the issue.

So in conclusion it is our strong belief that controls should not be voluntary. All entities should be required to have an appropriately scaled quality system adequate to the activity being performed, meet minimum quality, safety, and regulatory requirements and have proper oversight. We believe that the best and most efficient method for ensuring this would be for the FDA to extend currently existing regulation and oversight to all entities which service medical devices.

Thank you.

CAPT. MITCHELL: Thank you, Peter.

Our next speaker will be David Anbari, the Vice President and General Manager of Mobile Instrument Service and Repair, Incorporated.

MR. ANBARI: Good morning. And thank you for the opportunity to present at today's workshop.

I'm commenting on behalf of companies that repair surgical equipment for healthcare providers nationwide. To be clear with respect to the definitions that were discussed earlier we are not remanufacturers, we are not remarketers but we probably fall into the other three categories.

Unlike most of the other presenters today I'm presenting not from the perspective of a trade association or an industry group. We don't have one today. Instead we have a loose consortium of three of the largest nationwide surgical equipment repair companies in the United States.

We have collaborated to prepare these comments. They reflect the consensus views of our organizations today. We do intend down the road to form an industry that can focus on education, advocacy and advancement of our businesses in general.

So on behalf of my colleagues who happen to also be my very direct competitors we'd like to share our collective views with you today.

Like the FDA, like the device manufacturers, like virtually everyone in this room and everyone

watching we share a commitment to patient safety above all else. That is our number one priority. And it is achieved today, that patient safety is, through the multi-layered regulatory scheme that exists. It includes governmental oversight from the FDA, the Center for Medicare and Medicaid Services; it includes quasi-governmental regulation through the Joint Commission and organizations like AAMI and ISO. And it includes industry organizations again AAMI falls in that category, so does the International Association for Central Services and Materials Management who sets forth guidelines for surgical equipment, the AORN and physician led organizations like the Gastroenterology Association. This current oversight framework is ultimately what governs both what we do as independent device servicers and what the manufacturers do in keeping their equipment in great working condition. And beyond that we all share the concern for public health that it could be our loved one who is on the table and we want to ensure that the equipment works properly.

So much like OEMs we have invested heavily

in quality management systems. With each maintenance or repair event that takes place we ensure the device works the way it was originally intended to. And according to the data we are both doing a pretty good job, both the OEMs and the independent service organizations.

The first point of control with respect to the use of a device and ensuring that it works correctly is the clinical staff in a provider organization who tests the device prior to its use in a surgical procedure. Regardless of whether an ISO or manufacturer performs service it is that test and that review process prior to the use of a device that ensures nothing gets used on a patient unless it is truly patient ready.

But more according to a recent survey that was update by ECRI we are both doing a good job because there are very, very few reported incidents of failure of devices that results in an adverse patient outcome over the past ten years worth of data that they searched. We're talking about 96 out of yearly 2.1 million reports that they looked at of adverse

impacts with less than .005 percent incidents. And that doesn't account for the hundreds of millions of devices that we repair successfully both OEMs and ISOs every year. But more importantly in these numbers there is no statistical difference between the performance of ISOs or OEMs in terms of adverse impact to patients. We are both doing an effective job.

So at this point our belief is that there is really no evidence to support that there is a problem here that needs to be solved. And thousands of provider organizations, hospitals, surgery centers, doctors' offices and clinics vote every single day by continuing to use our independent services that that is their preferred method of obtaining service and repair on their surgical equipment.

We think it is important for you to understand why they make that choice and why patient safety would be compromised if they were to choose differently. So our industry maintains tens of millions of surgical devices annually, devices that are critical to healing patients and used by surgeons every single day. These devices include stainless

steel instruments, laparoscopic minimally invasive surgical instruments, powered surgical equipment, both rigid and flexible endoscopes and case carts that are used for the transport of equipment throughout the OR and central sterile processing departments.

One highly unique aspect of our service is that we deliver most of our services on location at the hospital's physical facility. We bring fully equipped mobile service labs right to the hospital's door and we provide convenient local expert access to our health care solutions. This minimizes the downtime for the equipment in the OR and our proximity to end users gives us a unique ability to help those end users improve the way that they care for and the way that they handle those devices on a daily basis. That results in reduced damage to that equipment and making it more patient ready on a daily basis. It enables us to be proactive in providing preventative maintenance services; services that avoid failures of the device when it is in the operating room. When we detect a dull, damaged or misaligned device we can correct it before it ever reaches a surgeon's hands.

We thus help improve patient safety by ensuring that the OEM's devices work correctly each and every time.

Another critical aspect of our service is that we make it easy to maintain equipment through this on-location approach to service. Because we service devices from hundreds of different manufacturers the hospital can contract with one provider to ensure that all of its equipment is maintained properly. This significantly streamlines their operations, reduces their costs and makes preventative maintenance more accessible. The alternative would be contracting with literally hundreds of device manufacturers for direct service resulting in significant disruption to their operations.

With patient safety at the top of mind we help OEMs ensure that their equipment is always patient ready. And that is why we employ quality management systems. The basis for our quality management industry wide is to return a device to its original operating condition. We do not modify devices as a part of our service. So all of the

advantages that are inherent in the manufacturer's quality systems, manufacturing processes, et cetera, those are all retained in the device post service.

To achieve this we think it comes to three key components. First off training; much like manufacturers we operate training programs that use apprenticeship based training and often times include individuals who have been employees of or contractors for device manufacturers in their prior careers. It also includes clinicians, so we are able to bring an actual end-user experience and end-user perspective to the maintenance of these devices.

Secondly, we source only new, unused parts and components from a robust global marketplace. With today's technology we can safety ensure that a component is an exact match for the OEM's component using the exact same type of materials as the OEM used.

And finally we quality check every single device against specifications or measurements that we've taken off of a new unused manufacturer's device. We incorporate these multiple quality checks

throughout our repair process so that we detect any deficiency in a repair or any abnormality in the device prior to its completion. We also check the device as a final quality assurance check to ensure that it operates to its original approved specification. In some cases the quality checks that we apply are greater than those that manufacturers themselves apply. A manufacturer assumes that their parts employed by their technician is going to result in a proper repair. We have to go above that standard and test final device in a semi clinical setting so that we can ensure it operates the way it is supposed. As evidence of these quality management systems most of our firms, if not all, are certified to ISO standards, in some cases we are certified to multiple standards. It is the same reason that we are granted liability insurance and make that investment the same as what manufacturers do for those never sentinel events. Despite these investments some manufacturers continue to argue that only they can complete a repair effectively.

In the comments provided by the device

manufacturers and I'm certain we'll see more of them today you'll see photographs of damaged equipment that's been repaired improperly. These are anecdotal examples; they don't reflect the tens of thousands of repairs that are affected properly. Like OEMs we have a file cabinet at every one of our companies loaded with photographs of repairs that were completed improperly, either deliberately or as a band-aid in an effort to rush a device back to the operating room so that a case could be completed.

We've included in those examples devices that were repaired by manufacturers exclusively and when they came to us they had failed for various reasons: wear and tear and parts or through their just normal use of the device.

So one could argue if we are already doing these things, if we are already implementing quality systems and we're already doing a good job what is the risk of FDA oversight? And we feel that the answer to that question lies in our value to our customers. Our industry is typically thought of as repair guys because that is our heritage for over four decades of

consistent service. But today we deliver tens of thousands of hours of consulting, training and advisory services to healthcare professionals nationwide. Our education programs are proactive, they help providers reduce damage to equipment before they create it thus bringing down their cost for repairs but also providing better patient care and improving the readiness of those devices in the operating room.

Through our equipment expertise we help ensure compliance with the manufacturer's instructions for use and multi-society guidelines with respect to how devices are to be used and reprocessed. And in cases where manufacturer has changed the design of a device or changed the instructions for use of a device or how it is to be reprocessed we help educate the industry, the healthcare providers and individuals that support them on how those changes impact them and how they can ensure compliance.

In many ways we are helping manufacturers ensure that devices are used and reprocessed as intended.

My company, speaking on my behalf, has attempted to forge partnerships with a number of manufacturers over our time period. We've had various levels of success with that but none of them has endured the test of time largely because our commercial interests and their commercial conflict at some point.

The biggest benefit that providers do see from working with Independent Service Organizations is clearly financial. By reducing repairs and helping them learn how to not damage their equipment we significantly can reduce their spend on repairs. At the same time we help improve the efficiency of their operating room.

And with the advent of the Affordable Care Act and pressure on the financial performance of provider organizations being able to help them improve efficiency and drive top line revenue is of top mind concern.

We help extend the useful life of devices which helps them avoid premature replacement; it is an area where we simply aren't aligned with most

equipment manufacturers who are incented to drive the sales of their devices. We can dramatically impact the replacement of devices through preventative maintenance, through proper repairs but also by maintaining perfectly good equipment that's been declared obsolete by a manufacturer. So we still maintain devices that are no longer maintained by manufacturers simply because they've upgraded the technology.

Most providers that we work with choose to invest a portion of the savings that we help them achieve on repairs and in reduced replacement spend to invest in better and more proactive preventative maintenance programs. That helps them avoid future failures in the operating room and helps improve patient safety.

And again the local presence of our people on a national scale helps promote routine maintenance that would otherwise be nearly impossible for a manufacturer to deliver at the scale that we do.

What concerns us as an industry is with these clear benefits and evident benefits from what we

do there is no evidence of a quality problem, why raise the cost? Why implement a regulatory system or oversight system that would potentially degrade any of these benefits that we provide with no clear indication of a benefit?

We believe the key is for the FDA and others to promote a robust marketplace that offers providers choices. The robust market for Independent Service Organization regulates itself. First off poorly designed devices, devices that don't function that are manufactured by a manufacturer are quickly removed from the market. Independent Service Organizations that don't do an effective job repairing on a consistent basis or servicing on a consistent basis they're driven from business. This happens because providers have a choice when they choose where to source repairs. And most importantly the multi-layered oversight structure that exists today with government, quasi-government, and trade associations and industry groups provides more than sufficient oversight and guidelines to direct healthcare providers. It is the strength of the market and

existing oversight framework that ensures patient safety and is the reason we see as strong performance as we do as evidenced in the ECRI study.

So the question becomes how can the FDA help the industry as a whole advance. We believe the answer does lie in cooperation. It involves promoting cooperation with OEMs and other service organizations while protecting the confidential information of both entities. It involves making parts and service information available to everyone that works on these devices. It involves ending the prospect or ending bundling of sales of capital equipment with maintenance contracts which can result in predatory pricing that does nothing more than drives down competition. It involves removing unnecessary locks and technology that are placed in devices today that do nothing to serve the actual use of the device in its clinical efficacy and instead simply serves to block third party organizations from being able to access the device. In the extreme it could involve promoting manufacturers working directly with and certifying third party organizations.

But the current multi-layered regulatory framework provides adequate oversight. The answer is thus not in regulating the market but it is in guiding the market and not losing track of the advantages that I've discussed today.

We shouldn't put the risk to benefits of that local responsive service being able to handle repairs from multiple manufacturers' devices, helping control capital spending and avoid premature failure of devices and premature and unnecessary replacement of devices and ensuring that the critical advice and advocacy that we bring to healthcare organizations on a day-to-day basis nationwide doesn't end. Losing these benefits is not automatic but there are often unintended consequences of oversight and regulation that limits competition in the marketplace.

Considering that there is no clear evidence of a difference between the performance of reputable service organizations, independents and manufacturers we believe the risks are too great. And the fact is that it remains the potential for a de facto OEM monopoly with respect the service of their devices in

the extreme.

The greater risk to patient safety is to eliminate all of the good things that we bring to healthcare providers who choose to work with our organizations on a daily basis to lose those to the unintended consequences of regulation. So on behalf of the companies that I work with and compete with on a daily basis we support patient safety and we also support cost efficiency in the marketplace.

Thank you very much for your time.

MS. MITHCELL: Thank you, David.

Tara Federici, the Vice President of Technology and Regulatory Affairs from AdvaMed will now speak.

MS. FEDERICI: Thank you. Good morning. My name is Tara Federici. I'm the Vice President of Technology and Regulatory Affairs at AdvaMed.

AdvaMed advocates for a legal and regulatory environment that advances health care by assuring patient access to safe and effective devices.

By way of explanation in my comments today I'll be using the term servicing to broadly refer to

all of the R words that we're focused on here today.

OEMs are mandated by FDA to design their devices under strict quality system regulation requirements to ensure their safe and effective use. The QSR requirements were establishes by the Safe Medical Devices Act of 1990 after a lengthy congressional investigation into device safety issues. When the quality system rule was implemented as we've already heard third-party service providers were exempted from the same level of regulation and scrutiny. As a result patients and providers my falsely believe all devices are as safe and effective as the OEMs are capable of making them. I would note that since the passage of SMDA 26 years ago many devices have become significantly more complex.

AdvaMed's members manufacture and may service their own devices and some may also act as third-party service providers for devices made by other companies. Many OEMs publish service manuals or make them available for sale to biomedical technicians at healthcare facilities and to other third parties and they may similarly make their replacement parts

available. OEMs may also offer training to third party entities to service their equipment. Other OEMs may service their own equipment and may not make manuals or copyrighted parts available as this could disclose trade secret information to competitors. In short are companies who use a variety of business approaches and models all of which are appropriate and are designed to ensure that products are safe and effective for patients.

AdvaMed has three overriding concerns relating to the safe and effective performance of devices and third-party repair. First device repairs are being performed by untrained personnel who may not be using the necessary specialized equipment, are performing the needed calibration and testing to ensure that the product is safe and effective before it is returned to use. Second, device replacement parts or components of unknown providence such as those cannibalized from non-functional equipment or manufactured by third-party entities claiming OEM device compatibility are being used in the repair of devices. Use of these defective parts can result in

adulterated devices. Last, device repairs are being performed without required compliance with core servicing standards to which OEMs are held under the QSR. Standards which AdvaMed believes are essential for the safety and efficacy of medical devices.

That said we believe many third-parties already meet many of the key elements of the QSR because they understand the benefits of implementing a quality system both for their business and for patients. Importantly the QSR is risk based and scalable. It applies to all device manufacturers no matter their size from the very smallest device manufacturers with a handful of employees to the very largest. Patients have the most to lose if devices fail to perform safely and effectively. And all three of the situations I just mentioned can significantly impact patient safety.

Although some have argued there is no evidence of unsafe devices related to third-party repair, over the course of just three years AdvaMed has become aware of at least 137 MDRs for just three device categories. This is despite the fact that many

OEMs do not currently report MDRs associated with third-party repair and that it is difficult for OEMs to detect problems related to third-party repair. Because third parties are not required to mark the devices they service or to identify the components they use the end user may not know that the failed device was serviced by a third party.

In addition third parties are not required to submit MDRs. As a result all the reportable events are associated with the OEM rather than the third party. Another reason that MDRs associated with third parties are low. Often the use of non-OEM parts or unauthorized repairs is discovered serendipitously by the OEM. A common scenario is that a device has a difficult to repair failure and is sent to the OEM for repair. Once at the OEM site the OEM discovers mismatched serial number parts or internal forensics logs would show unauthorized repair.

For all these reasons adverse events related to the use of non-OEM parts or repairs by third parties are going unnoticed and uncounted. AdvaMed's member companies have assessed the risks associated

with third party repair and found increased safety and performance failures due to devices being modified or used in unapproved configurations. If non-validated parts or configurations are added to a device the previously validated performance of the device now becomes unknown. This can impact the safe use of the device. Products which are altered from what was initially cleared or approved may be considered adulterated under FDA's current regulations.

Third party activities can also cause other intended consequences. Examples include non-valid interactions between hardware timing circuits and software or firmware timing responses in devices in unapproved OEM configurations. These unapproved configurations can result when substituting parts from one OEM approved and tested device into a different OEM approved and tested device.

Some third party repairs may allow a device to pass functional testing and operate normally in a nominal mode. However, when the device is stressed to it edge conditions the unapproved configurations can result in unpredictable device behavior.

OEMs and OEM qualified servicers are aware of all updates and product changes and test the devices according to current specifications using validated processes. As a result OEMs and their qualified partners are more equipped to limit the risks associated with service. Importantly as required by the QSR the OEM has the most current device master record which is linked to the original documentation in the design history file. Information about reliability is needed to make decisions for what should be replaced when the device is being serviced and to understand the expected life of the device.

In contrast, third parties have no requirement to analyze service reports with appropriate statistical methodologies to determine when events need to be reported and then to actually report them to FDA. This adversely affects public health as it prevents both the OEM and FDA from having important information about device performance issues that could require a correction or a removal.

By comparison OEM technicians conduct repairs using documents written by the device's design

engineers and use tools created by the design team. Third parties may not be using the latest documentation and may have to rely on trial and error for product repair. OEM technicians frequently repair many of the same items per day while third parties may have limited exposure to many different types of devices.

Some OEM products require in excess of 90 custom tools along with a custom programmer. It is not clear how third parties are disassembling or reassembling these products and what impact the use of non-custom tools has on device performance and safety.

For these reasons AdvaMed believes repair of devices whether performed by OEMs or third parties should be subject to FDA regulation and oversight by key elements of the QSR.

As I mentioned earlier the QSR is scalable and risk based thus certain elements of the QSR may not be applicable to third parties depending on the nature of the activity they are performing.

AdvaMed outlined the key elements of the QSR we believe apply to third party repair in our docket

comments. However briefly at a high level we believe third parties should obtain training related to the level of repair they are performing, have access to proper OEM approved equipment, components and service manuals related to the level of repair they are performing, establish processes to control purchasing of qualified components and maintain device history records for repairs, inspection and testing. In general third parties that are OEM qualified would have access to all the elements I just mentioned.

In closing OEMs are already subject to and meeting all of the requirements of the QSR to ensure the safety and effectiveness of devices for patients and users alike. Notably if an OEM used parts from an unauthorized supplier or relied on untrained personnel for repair the affected devices could be considered adulterated and could be subject to field action. But third parties continue not to be subject to QSR potentially imperils patient and users. It seems to us that QSR requirements in the safety and effectiveness of devices is equally applicable to third-party repair thus ensuring the safety and

effectiveness of devices for users and patients.

Thank you for the opportunity to share our views on this topic.

CAPT. MITCHELL: Our next speaker will be Barbara Maguire, the Vice President, Quality and Geisinger Clinical Engineering ISS solutions.

Now before Barbara speaks I'll just give you a heads up that we will be taking a break just before ten o'clock for 15 minutes for planning purposes.

MS. MCGUIRE: Good morning. My name is Barbara McGuire and on behalf of the American College of Clinical Engineering I would like to thank the FDA for this opportunity to present the viewpoint of the clinical engineering community on this very important topic.

Numerous colleagues from ACCE have contributed to this presentation and I'd like to particularly thank Malcolm Ridgway, Alan Lipschultz and Mark Bruley for their contributions.

I'm here today representing the ACCE viewpoint. I currently work as Vice President of Quality at ISS Solutions. We are owned by Geisinger

Health System. We provide clinical engineering and IT services to both healthcare and non-healthcare clients. Geisinger Health System is also our largest client in clinical engineering. So I have the unique position of running an in-house clinical engineering service at Geisinger Health System and then also overseeing the quality of the services that we provide as an ISO to our clients outside of Geisinger.

We've partnered successfully with many of the manufacturers who are represented here in this room and we think that is an important part of the services that we provide to patients. We invest a lot of time and resources into ensuring that the services we provide are of the highest quality.

As I said I'm representing ACCE today so I just wanted to briefly mention the mission of the ACCE is to establish a standard of confidence and promote excellence in the clinical engineering practice and to promote the safe and effective application of science and technology in patient care. So we represent just over 750 members and we've been around since 1990.

I wanted to start out by noting one of the

FDA's priorities is to use real world evidence in making regulatory decision making. So that is what ACCE attempted to do in their presentation is to point out this real world evidence.

With respect to the additional regulation of servicers the position of ACCE is that the vast majority of servicers are already regulated mainly through CMS as well as through other agencies. And that third parties as well who are working within the healthcare organizations are also as a secondary measure subject to the same regulations by the healthcare organizations that they work for.

So for example we have a laser service company that we use extensively and they readily provide to us the credentials for their servicers, documentation that they inspect to manufacturer's guidelines. And we ask for the same information from any company who is servicing critical equipment at our facilities. We also review the credentials and quality programs for all vendors who come on site or who work on our equipment. And we expect them to have this program in place.

Thirdly it is the ACCE's position that additional regulation would be redundant and even counterproductive to providing the highest level of patient safety.

There are three basic reasons for the ACCE's position. One related to the real world evidence is that since this is the FDA's own standard for decision making we think this is the most important and no evidence has been presented showing significant patient safety issues related to equipment service.

There are also many possible downsides to additional regulation. Likely downsides include higher cost for healthcare institutions; elimination of some in-house and third-party servicers due to this additional burden; and this would decrease competition and decrease the choices available to healthcare organizations.

Some of the arguments that have been proposed in support of added regulation we feel are not topics under jurisdiction of the FDA and these are arguments such as increasing fair trade and correcting a liability imbalance.

First I'll address the issue of the real world evidence. Here we are looking for statistics, not just anecdotal evidence. So despite the small number of anecdotal reports we feel that there is an insufficient level of evidence of service related incidents to justify any additional regulation. The primary body of this evidence are the seven studies listed here. So notably there is one from the UK, their Medicines and Health Care Products Regulatory Agency which is an executive agency of their Department of Health. And when they classify the primary cause they found that improved maintenance was tenth on the list of causes after much more common ones related to the design of equipment, labeling, packaging, improved QA.

The 2012 study done by the Joint Commission reviewed 1526 responses and found none that were related to maintenance omissions. There was also a 2013 analysis of sentinel event data covering the period 2004 to 2011 and showed that the sentinel events caused by maintenance omissions were between 0.14 to 0.74 per million.

And in 2014 Aramark data was presented over a ten year period which was analyzed and showed only six incidents traced back to maintenance. And these were spread across stakeholders and did not show a higher incidence from third-party servicers.

Details of all these studies will be covered as well in later panels and were also included in the ACCE's docket comments.

I wanted to note though the two studies done by ECRI which actually showed a decrease since this issue was last looked at in 1998. The review completed in 1998 demonstrated less than a quarter of one percent incident of service related patient issue. They recently repeated a similar analysis and the data showed a decrease to .005 percent.

Many have pointed out that the low incidence may be due to significant underreporting. But we feel that there are already sufficient requirements for reporting under the SMDA and FDA regulations which require user facilities to report incidents. OEMs are also required by 21 CFR to report malfunctions of a device that would be likely to cause or contribute to

death or serious injury.

Even if we assume there is significant underreporting if the incidence were doubled it would not be significant enough to warrant action from the FDA.

However, there are opportunities for improving reporting such as getting buy-in from the different sector organizations to try to encourage further reporting to address this.

We could forge a consensus on what should be reported; better standardize the format of reporting and the method, identify who should receive the reports to ensure that confidentiality is preserved and look at how to analyze as the overall data and statistics on an industry wide basis so that we are all working with the same information.

The second part I'd like to address are the likely downsides due to added regulation. So the additional regulation would certainly increase the cost of onsite service. This may result in reduced levels of onsite service which could cause delays in repairing of devices and therefore delayed patient

care. Higher hospital expenses would reduce capital that would be available to acquire additional devices. And reduced onsite support would also reduce other safety enhancing services that are currently provided by those onsite resources.

So the overall effect would be to increase hospital costs and therefore increase the cost of health care. Some organizations could comply but their costs would still increase. Even if they are meeting the existing requirements it would mean another registration, another set of audits and some would not be able to bear the cost of this and would cease to function.

So why is this so important? The value of onsite technical support really enhances patient care. There is faster response time by having individuals who are right there onsite with the clinicians. The people onsite are best able to troubleshoot systems of multiple devices that might come from multiple manufacturers. They provide support for clinical staff even during procedures. They can work on integrating equipment from multiple stakeholders.

Onsite servicers can also provide ongoing training for clinical staff and input into systemic improvements that would prevent further incidents. Onsite staff can also provide input into capital planning to encourage standardization and efficiency down the road.

Addressing the third point that some of the issues are outside the jurisdiction of the FDA. The issue of the uneven playing field we feel is a complaint or issue that belongs in the purview of the FTC instead. And the liability imbalance is a judicial issue that should not be addressed here.

There are many issues which differentiate the environment in which the manufacturers and third-party servicers must function in; mainly that we already must comply with CMS, Department of Health, and local regulatory inspection requirements. The fact that we are exempt from one regulation that the manufacturers are subject to is not by itself a reason to impose that on onsite servicers.

In summary additional regulation of servicers would be redundant and the evidence does not

show that patient safety would be improved. There is no real world evidence of significant level of problems. There is no prospect of significant benefits from added regulation, and the potential downsides are significant including the increasing cost of health care.

Instead our recommendations are that the FDA continue to work to encourage collaboration from the manufacturers and the onsite servicers including things like education and training, and encourage more community based initiatives such as these that many of the manufacturers and stakeholders are already involved in successfully. And this involves efforts to standardize maintenance documentation, to work on interoperability between various devices, and to encourage further voluntary reporting so that there is no concern about missing evidence.

Also to encourage manufacturers to provide better support to users after the sale we feel as clinical engineers that that would be the single most significant improvement that we'd like to see that would help us to improve patient safety. If we have

access to good documentation at the same level that the manufacturers provide to their own servicers, access to parts, and access to training that that would really help to improve patient care.

So we'd like the FDA to encourage ongoing collaboration between manufacturers and the healthcare technology management community and not to impose additional regulations on third-party servicers.

I thank you for your attention.

CAPT. MITCHELL: Thank you, Barbara.

We will now be hearing from Robert Kerwin, General Counsel from the International Association of Medical Equipment Remarketers and Servicers [IAMERS].

MR. KERWIN: Thank you. I'm the last speaker before your break. I'm only grateful I'm not the last speaker before lunch. So, yes, my name is Robert Kerwin on behalf of the International Association of Medical Equipment Remarketers and Servicers for which it has by my privilege to serve as General Counsel for 20 years.

We wish to thank the FDA for this opportunity to participate in a workshop and as with

the prior speaker we hope there will be future opportunities for workshops of this type and collaboration and that the FDA consider this type of engagement well into the future for all stakeholders.

Because our association name is a little long I'll be referring to it as we refer to it as IAMERS. A few words about IAMERS, for almost 24 years now IAMERS has been the leading voice of secondary diagnostic imaging marketplace. All IAMERS members are diagnostic imaging industry members. We note this as there are some companies here today who focus on the sale and service of endoscopic devices. The imaging modality of IAMERS members are MRI, CT, ultrasound, nuclear medicine and general radiography. IAMERS members include original equipment manufacturers such as GE, Siemens, Toshiba, and Philips. The majority of IAMERS members are made up of small independents including servicers, re-conditioners of systems and parts, re-manufacturers and brokers. Many are alumni of OEMs and have started their own businesses.

In 1993 IAMERS was founded to encourage

adherence to the highest standards of ethics and professional practice, to fulfill the demand for used and refurbished medical equipment. We've been busy these last 23 years. Among the things which separate us from other organizations is that we require our members to adhere to a code of ethics. This just isn't lip service. If a complaint is raised by a hospital or group medical practice or other IAMERS members the complaint is considered by the ethics committee. Adverse determinations have resulted in very public reprimands or expulsions. No member is excluded from this requirement.

We maintain a robust educational agenda for our members which occurs at every meeting we have. In the past we've conducted programs on FDA inspections, UDI [Unique Device Identifier] requirements, reporting of adverse events and many other areas which impact our members and we were fortunate to have Mr. Benesch participate and we've been fortunate to have Mark Leahey participate and many other important representatives of the industry.

Our president Diana Upton has traveled the

country encouraging our members to pursue best practices and ISO compliance certification. We've been fortunate to have as we mentioned the FDA participate in our annual meetings and programs. We hope the FDA will continue to participate.

We've also been fortunate to have other contributors from the Center for Medicaid, Medicare and Medicaid devices, the Department of Commerce, other original equipment manufacturers. IAMERS has a proud tradition of education and outreach and we wish to do more.

At our annual meeting in May of this past year our members adopted recommendations for best practices on meeting customer requirements and patient safety. All members are expected to employ quality management in their organizational structure, policies, procedures, processes and records. Quality management will be adopted regardless of whether the member is a broker, servicer, remanufacturer, re-conditioner or original equipment manufacturer. These recommendations were unanimously adopted at the suggestion of the IAMERS best practices committee both

here and with our European members. The committee had recommended it as a diverse group who had reviewed quality objectives, quality policy inventory management, customer complaints and data management. And of course there is more work to be done.

In a recent meeting with FDA we discussed IAMERS concerns and also IAMERS recommendations and frankly we welcome further suggestions to the extent the FDA has them.

IAMERS members are committed to quality. IAMERS members represent viable solutions for hospitals, group medical practices and other healthcare providers. Indeed IAMERS believes it meets or exceeds the service expectations of the imagining centers they serve. Not only do our members live where they often provide the service but they service geographic areas underserved by other OEMs including rural America. IAMERS subscribes to a big tent theory. If you are a medical imaging company and committed to quality and comply with IAMERS standards you will be welcome as a member.

Pre-owned doesn't mean safety concerns. In

2009 the FDA issued in response to an IAMERS request a letter to advise as to what post-market adverse events had been submitted to the FDA associated with refurbished or remarketed devices. Though a diligent search was conducted at the FDA's official records for Fiscal Years 2007 to 2008 which included I am told 400,000 reports related devices; that search revealed no pattern of adverse events or incidents indicating that refurbished or remarketed devices have been associated with or contributed to a death, serious injury, or malfunction. We have no reason to believe that this has changed in the ensuing years.

It may prove convenient for some to show pictures of equipment without attribution, unattributed except to nameless independents and to suggest that certain levels of uneven performance are being implemented and to claim that minimum requirements are not being met. Although convenient to use such anecdotal evidence in a market that demands exactitude and quantification we find such supposed evidence less than helpful as well as a resolution of whatever concerns. We are confident the

FDA will not regulate by anecdote.

Not every healthcare provider is in a position to purchase new equipment. IAMERS members provide important options for healthcare providers in a marketplace where revenue is not keeping track with growing costs. Purchasing from an IAMERS member is a safe solution for equipment, parts, and service. Independent sellers and servicers who are IAMERS members are often as mentioned alumni from OEMs and operate successful small businesses. They enjoy a strong reputation in diagnostic imaging. And how do we know this? We know this because the OEMs themselves use IAMERS members. It is common for an OEM to contract with IAMERS members for the supply and parts as well as service as well as assisting in the installing, uninstalling, transporting and storing of equipment. It is therefore important to note that the greatest outlet for equipment taken in trade by the OEMs appears to us to be IAMERS members involved in the secondary equipment.

Notwithstanding our strong reputation at MITA's request for more regulation seems to exist as

Mr. Weems has indicated MITA has meet with the FDA since 2014 to express concerns about levels of performance. In an August 5, 2015, a MITA PowerPoint that we obtained in a FOIA request MITA acknowledged that there is greater pressure on hospitals to drive cross training and therefore a greater opportunity for alternative service providers; that would be IAMERS members. MITA advocated that all service providers should register with the FDA as they have advocated here today. That is not something I recall hearing when IAMERS met with MITA two days earlier to discuss the situation and to discuss in general our interest in collaboration.

I note they say not to polarize but we seek collaboration. The section of the PowerPoint entitled examples is, however, blank. We were pleased, therefore, to observe MITA's submission that it is impossible to provide a statistically valid analysis of the extent of the problems.

Our members have reminded me several times including today we service better unless of course AIAT information is not readily provided. We could

show cannibalized equipment from devices that had been worked on by independents. We've declined to do so. As mentioned OEM members frequently rely on IAMERS members to fulfill their contractual obligations and that speaks loudly in the marketplace.

Query then if the IAMERS member is working independently for healthcare providers on service calls and later in the week at the request of the OEM assisting the OEM's own healthcare provider relationships is it really appropriate to now claim a lack of uniform performance. OEMs frequently, indeed very frequently, purchase parts from IAMERS members.

So I submit IAMERS members are necessary and important contributors to the healthcare ecosystem and no one knows it better than the OEMs.

We are confident that the FDA will not regulate by anecdote and hope the FDA and the attorney from the FTC who are present here today will recognize that there may possibly, possibly be something more afoot than claims of uniform performance. The motivation may well have competitive origins.

So let's look at the market snapshot. One

industry study has reported that in 2014 General Electric, Philips, Siemens accounted for 70% of the diagnostic imaging system market. That study also reported that in 2014 original equipment manufacturers including all other OEMs accounted for all by 9.7% of the diagnostic imaging system revenue market shares. We are concerned that healthcare providers may down the road if further regulations and further activities take place see fewer options and reluctantly be pushed to buy new equipment when that may not be the appropriate decision for their organization. As we've noted not every hospital group practice can afford new equipment. And the presence and success of secondary service providers is essential to the marketplace.

Our concerns about the marketplace were further stoked with the July announcement by GE of its intention to enforce software license limitations. As you know when hospitals and group medical practices purchase or lease imaging equipment the return on income commonly anticipates a resale on the secondary market with no additional license cost to the new purchaser. In July, just a few months ago, GE issued

a letter sent to independent brokers of used healthcare equipment stating that unless otherwise explicitly stated by GE Health Care in writing software that is not part of the equipment's base system standard software is non-transferrable and only the original equipment purchaser has a non-exclusive landed license to use such software. In these statements GE has advised of its intention in the not too distant -- in subsequent statements I should say to undertake imaging equipment work in a cloud based platform. It is not entirely clear to us how this may be done and how AIAT responsibilities for the applicable modalities will be observed. This license limitation was not to my knowledge previously enforced and may well come as a surprise to healthcare providers who purchased imaging equipment a few years ago and expect to seek a certain price in the marketplace, a price which now must take into account potential relicensing costs.

IAMERS member have noted to me the chilling effect that it already has on their GE equipment sales. We are concerned that this position if

enforced in an already high marketplace will increase substantially licensing costs in the secondary imaging market. We are looking at whether these license restrictions are being enforced only as to some stakeholders but are not being enforced to other stakeholders. We are looking at whether this license limitation enforcement is in the totality of the circumstance an appropriate activity. We have sent a letter to General Electric in July to put our questions and concerns in writing. It is now almost November and we are awaiting a reply.

I love movies and in particular enjoy the movie Independence Day. I haven't seen the sequel. In any event there is a scene in which I am reminded in which the U.S. President played adroitly by Bill Pullman has an exchange with the captured alien who is attacking the earth. Pullman asks the alien, what do you want us to do? And the alien as some of you may know ominously says "die". Okay. This is an obviously dramatic reference made just to draw attention because we are concerned that MITA as they are advancing their rulemaking initiative when coupled

with the license limitations may limit healthcare provider options, in effect, the continued existence of independents. We hope that concern is badly misplaced.

We believe, however, that the FDA would fairly and appropriately examine the initiative, the evidence behind the initiative and whether compelling evidence exists for a change, not to regulate by anecdote. We will be separately looking at the situation and hope the FTC does as well.

We have a hope for a different future; a future of collaboration and cooperation. I, too, was at the Joint Committee meeting of the task force in 1997. And that included some who are on the dais today including MITA, including the American College of Clinical Engineering, although I will say that I had understood that that was an interim report and Malcolm Ridgway who is here could probably speak to that because I know he too was involved. In any event it is our hope that the future is one of collaboration, one of training, that training is accessible to the independents.

It has been an honor of appearing here. And we note that when the meeting and the FDA occurred in 1997 the joint task force that all who participated, participated in a respectful way at which issues were addressed and consensus development took place. Perhaps it is time to reconstitute a committee of this type.

Having spoken to our President Diana Upton earlier today I'm confident that IAMERS would participate if the paramount issues are patient safety and health care costs.

Thank you.

CAPT. MITCHELL: Thank you, Rob.

We are now going to break. According to our computers up here we have 9:59; it will be for 15 minutes. And then we will come back.

Thank you.

BREAK

STAKEHOLDER PRESENTERS (continued)

CAPT. MITCHELL: So we are going to continue now with our stakeholder presentations. And our next stakeholder is Mark Leahey, the President and CEO of

Medical Device Manufacturers Association, MDMA.

And Mark Leahey will be here in just a minute.

Thank you Mark.

MR. LEAHEY: And the good news is I only plan to speak for about five to seven minutes so we'll still be on time.

But thanks very much to FDA and to all of you for coming here today.

My name is Mark Leahey. I'm the President and CEO of the Medical Device Manufacturers Association. We are a trade group here based in D.C., we represent about 300 primarily small to midsize medical technology companies from very sophisticated products to very simple products and we try to be their eyes and ears here in Washington. And the ultimate objective is to ensure that patients have timely access to safe and effective products.

Again just hearing a lot of discussion this morning I'm actually encouraged that there seems to be a lot of alignment from all the parties up here about the focus on patient safety. We heard from Dr. Maisel

at the outset some of the key themes here that I think have been reiterated throughout out the panelists.

The first being that you need to make sure that there is a quality system and elements of a quality system in place for both the OEMs and third-party servicers. Again, let me say at the outset we have small companies, medium size companies; some of these are OEMs, service providers; some of them use third parties, some of them third-parties to OEMs. So we do represent I think the totality of the ecosystem here. And let me also say that there are absolutely a significant number of high quality service providers and no one is trying to somehow suggest that the OEMs are the only ones who can do this right. That is simply not the case.

We also aren't here to suggest that somehow we want to increase costs. And it is interesting a lot of the presentations here about cost, cost, cost and I agree we should keep this within the parameters of what the FDA's jurisdiction is which is safety and efficacy. So I think moving forward we'd all do better in not bringing up issues about market dynamics

because I think we do need to focus on the impact on patient and having validated systems in place, et cetera.

And then finally we certainly wouldn't want as it relates to patient safety don't want to do anything that would limit options and servicing in geographic areas. Again, this is an area we want to make sure that patients and the hospitals have access to the service they need to ensure again collectively everybody in this room wants to focus on making sure the patient is best served.

So what I'd like to do is try to discuss what I hear are the three things that seem to be consistent thus far in the earlier speakers and I echo hope that we can have a very thoughtful and cordial and meaningful discussion over the next two days here and hopefully end at a place where there are common themes that emerge and then again thus far a few that I've heard is again that high performing third-party servicers whether they be the OEMs or the third parties have quality system in place. It is scalable as Tara said but I think to somehow suggest you are

doing a great job of servicing and you don't have elements of a quality system I think that would be hard pressed to make that case.

The second element that I think we've heard all the parties speak about is that you need to have adequate and appropriate training. And again I think everybody here has talked about that that is a key element for both the OEMs and the third parties and again I'm sure there is variation within the OEMs about how they perform and there is variation in the third parties. But adequate training and appropriate training is another core element. And again these are things that I think all the speakers thus far have raised and also the folks at FDA.

And then the third element I think is the importance of validated parts. And I am not suggesting that all of the parts have to come from the OEM. We've heard that again if you have systems in place and you can manufacture parts or source parts that are validated that meet the specs and conformance, absolutely they should be able to be used in the marketplace. I don't think anybody up here has

suggested otherwise.

So when you look at those three elements here of: elements of a quality system, appropriate training and, validly sourced parts again there is alignment there and I guess the question I have is if we all agree that these are the things that need to be done that are being done; not validating that they are being done seems to be you know that missing element here.

And what that solution, and what that validation looks like hopefully we'll discuss in the next two days. I'm sure we have a variety of ideas but to somehow suggest that we all agree these three things are important, but we don't want to you know it is kind of that trust but verify doctrine that I think is important for us to consider as we move forward here. And I hope that as we have this discussion we can find the right size approach here to address these issues to make sure that patients are being best served.

And again I think the key here, to close on and I told you I'd be under five minutes so certainly

have about 13 to give back, again no one is suggesting, particularly coming from a group that represents many small manufacturers, that we want to do anything to limit choice, competition, et cetera. But again if this is about the patient having elements of a quality system, adequate training, and a validated source parts and being able to again validate that those systems, those elements are in place I think is critical.

So I look forward to the discussion of the next two days and I am confident, maybe I'm the eternal optimist here but we can all find an area of agreement, alignment, and really just solidify the best practices that many in the industry are already doing and make sure that we have consistency across the board.

So thanks very much.

CAPT. MITCHELL: Thank you, Mark.

We will now hear from Tim McGeath, Senior Vice President and General Counsel, TriMedx.

MR. McGEATH: I can't promise five to seven minutes but I'll do my best to speed it up.

Thank you and good morning. On behalf of TriMedx I'm please to have the opportunity to address the FDA and interested stakeholders on the important issues on review at this workshop.

As was evident by the large volume of comments there are many divergent opinions as to the need for some level of additional regulation or involvement by FDA regarding medical device service.

We at TriMedx believe all can agree that the imperatives of patient safety and quality should drive the conversation. And for that reason we applaud the FDA for looking at this issue.

My focus today is on service and repair. In short we believe that there is a definite place in the market and a need for third-party service organizations such as TriMedx; that third parties and in-house departments can and do service and repair equipment safely and effectively and that increased collaboration between the parties is essential to providing safe high quality and cost effective patient care.

First I want to briefly introduce TriMedx.

TriMedx was formed in 1998 out of the clinical engineering department at Saint Vincent Hospital in Indianapolis under the premise that there was a more efficient way to manage a hospital's diverse and growing inventory of complex medical equipment. TriMedx is one of the country's largest third party provider of healthcare technology management services serving approximately 240 hospitals and 1,800 healthcare providers across 34 states.

We like to say that TriMedx was created from healthcare to serve the needs of healthcare. TriMedx maintains data for more than 1.4 million pieces of medical equipment and employs nearly 1,500 associates nationwide.

Our model is to serve as an extension of an in-house clinical engineering team with a goal of using our size, scale, and concentrated expertise to provide a more robust level of service than many individual hospitals or systems are able to provide on their own.

We all know that providing that providing the highest quality patient care is the most important

part of our job. I want to state that point very clearly because all of our comments stem from that critical underlying premise.

I would now like to briefly address the benefits of a holistic equipment management approach through an Independent Service Organization or ISO which we believe has relevance to the discussion at hand. While our perspective is that of an ISO certainly TriMedx is not alone in this space. Many of our comments apply equally to other ISOs and in-house departments in many cases.

There are compelling reasons for holistic equipment management service and repair program. First it is a very provider centric approach to managing medical devices. As opposed to dealing directly with several vendors of the service of a hospital's diverse inventory, providers are able to rely on a single accountable organization to manage all such issues and seamlessly maintain required service information in one comprehensive database. ISOs can often leverage scale to better meet provider needs.

Second, from accountability perspective persons providing equipment repair and service via an in-house or comprehensive ISO model are part of the hospital's team and far more accountable to physicians, the clinical staff, and perhaps most importantly to patients. Their continuous onsite presence allows them to participate in hospital safety environment care meetings and provide clinicians with the comfort of knowing that a member of their clinical engineering team could jump in on a moment's notice.

A third-party's responsiveness; it is simply not feasible for an OEM to have trained technicians in close proximity to every hospital. ISOs and in-house models results in boots on the ground enabling them to regularly round on hospital equipment and positioning them to address issues in real time either on their own or by coordinating service from OEMs or other outside parties when needed.

Finally, a fourth factor is cost and competition. A competitive market is critical to keep costs down and further drive the efficiencies necessary in today's healthcare industry. The cost

associated with the exclusive use of an OEM to service equipment can be significantly higher than an in-house or ISO model. A medium size facility can spend three to five million dollars per year in equipment maintenance and repair and a modest size system could easily spend five to ten times that amount. It would not be unusual for 60 to 70% of a hospital or system spend to be on high margin service contracts in non-contracted parts and labor even though the in-house team may perform the bulk of the PM and repair work.

Importantly these costs we talk about contribute to the country's already over burdened health care expenditure with healthcare in general making up roughly 17.5% of the GDP. It is clear that an effective equipment management program is key to reducing costs, optimizing services, and ultimately freeing up the financial resources that can be redirected to focus on other areas that are critical delivery and better patient care and serving those in need.

As I will mention in order for ISOs and in-house models to be successful there must be increased

collaboration with OEMs including appropriate access to training, parts, supplies and service manuals.

Assuming the cited benefits of a third-party service model the question then is whether ISOs and in-house teams can provide quality services in a manner that enhances patient care. A consistent theme in comments by OEMs dealt with safety and the potential for patient harm when service is performed by third parties. However, despite claims to the contrary and beyond isolated examples there are neither data nor trends showing an increase in patient harm when it is serviced by third parties. ISOs and in-house department can equally point to isolated incidents of failed equipment operations which resulted from service by an OEM.

Recent studies performed by the ECRI Institute indicated from 2006 to 2015 0.005 percent of reported incidents were related to post-market services compared to 0.2 percent from 1977 to 1998. You've heard that statistic cited by a few other speakers. Failure rate is extremely low suggesting that there is not a systemic problem that the FDA

needs to address. And certainly no problem has been identified that relates to who performed the service.

We'll also hear from AAMI about its recent adverse events survey. Its evidence and conclusion also support the notion that there is not a greater risk when service is performed by third parties.

Finally other unbiased parties such as the joint commission did not identify evidence of more significant public health or safety concerns in connection with third party servicing of medical devices.

Of the issues we do see, many result from user error rather than an error by the servicer of the equipment. These findings may be attributed to the fact that many ISOs have already developed and implemented robust quality programs in response to the existing regulatory and accreditation framework. Organized programs like that of TriMedx have policies and procedures that align with the federal, state, and hospital required regulations and standards pertaining to medical equipment management and record retention to ensure compliance, equipment efficacy, and safety.

Our hospital customers are subject to continued review by government authorities including CMS, state departments of health, as well as accreditation bodies. These regulations and accreditation requirements have shaped policies and programs we maintain. Governing procedures such as inventory management, preventative maintenance scheduling, alert and recall management, incident investigations, and a risk based supplier quality management program. In addition our organization's quality regulatory teams routinely conduct surveys and audits to test the program's quality standards, verify adherence to policies and procedures and ensure our customers are always well prepared and in compliance.

We agree with the comments of our competitor Aramark that when servicing activities are conducted by highly trained personnel in accordance with established standards practices and requirements of our regulated healthcare customers such activities are safe and effective way to maintain medical devices.

Adding further regulatory oversight or requirements for utilization of OEM services to this

list will not necessarily improve quality of care and patient safety but it will likely increase overall costs.

Accordingly, TriMedx firmly believes the existing regulatory and accreditation framework to which in-house departments and third party service providers must comply is sufficient to address patient safety and qualify imperatives.

As discussed end users service, repair and maintenance of equipment is currently subject to a multi-layered regulatory and accreditation framework. TriMedx must constantly assure that its services comply with applicable law so that our customers by extension always remain in compliance. We take this obligation very seriously.

We appreciate that FDA is charged with regulating the safety and efficacy of many types of equipment used to provide patient care. However, we believe that the current system under the watchful eye of accreditation bodies and CMS is sufficient to ensure that equipment is maintained in the manner that results in safe and high quality patient care.

Further, the lack of empirical evidence to suggest a significant amount of adverse events caused by device services not performed by manufacturers supports the belief that there is no need for additional potentially redundant regulation by FDA.

Still if it is determined that additional regulation is needed, such a determination should be made with caution prompted by verifiable data and should not have the unintentional effect of stifling competition and adding further unnecessary cost to health care. At a minimum there should be a focused effort to understand what the potential problem is that needs to be solved before we try to solve it.

At TriMedx we enjoy strong collaborative relationships with many OEMs. In our view these OEMs see the forest through the trees and recognized that although we compete at some level working with third parties, indeed all parties in the care continuum leads to efficient service and ensures high quality healthcare delivery. Several OEMs collaborate with TriMedx by offering training courses for our technicians, negotiating discounts on service

contracts and labor, and providing seamless access to parts, service manuals, and materials to name just a few things.

However some OEMs serve as blockers and in certain cases we believe engage in anti-competitive practices. Such practices can frustrate the preferences of healthcare providers who ultimately are prevented from implementing a comprehensive in-house program or from purchasing the same services from qualified ISOs. The end result is an increase in the overall cost of health care and a diversion of the health care dollar that could otherwise be allocated to enhancing the patient experience, improving population health, or serving the disadvantaged.

These anti-competitive practices take many forms. We have seen OEMs tie agreements for ongoing service and maintenance to the original purchase of equipment, refuse to sell parts unless those parts or repairs are provided by OEM service personnel, refuse to provide service manuals, and even attempt to preclude a purchaser or its agents from performing maintenance or repair on its equipment. Some OEMs go

so far as to pressure purchasers not to use third party service providers under unsubstantiated outcome claims.

In the past few months alone we documented communications from at least 18 different OEMs with the following statements or claims. Number one, that only OEMs are qualified to service equipment and that they will not sell service parts but also do not offer training programs of any kind. Two, that they refuse to train any third party employees and this refusal is often tied to a restriction on the purchase of parts. Three, that they refuse to train or work with anyone related to a third party. And four, even blanket communications categorizing all third parties as unqualified and raising the specter of safety concerns without substantiation.

This behavior is deceiving and distracting to the goals we have as an industry. The FDA can help break down the walls that certain OEMs have put up. One outcome of this inquiry should be to address OEM practices that restrict healthcare providers or their chosen third party providers from reasonable access to

training, service manuals, parts and diagnostic software.

Some stakeholders express concern that third parties may use unqualified personnel to provide maintenance and repair services or do not use properly sourced parts. At TriMedx we budget and spend large sums on training our technical personnel both through internal programs and through OEM or other qualified third party training. Many of our technicians have OEM backgrounds. If OEMs believe a lack of qualified trained third party personnel is a problem then they should agree to provide training to those who will pay a fair price for it and agree to protect the manufacturer's proprietary information. It is neither an answer or accurate to claim that an OEM is the only party qualified to perform service. Thinly veiled excuses intended merely to protect profits or restrict competition can no longer be tolerated.

Manufacturers cannot have it both ways. They cannot claim a lack of qualified third party personnel yet specifically deny access to training, parts or even service manuals when a third party is acting as

agent for its hospital customer.

In sum we believe the one key outcome of this inquiry should be to address OEM practices that restrict the abilities of third parties and in-house departments from reasonable and affordable access to the training and tools needed to safely and effectively service and repair medical equipment.

Collaboration is key and market competition is necessary to drive innovation cost reduction.

Another outcome should be consideration of appropriate standards to address legitimate concerns. TriMedx welcomes the opportunity to work with all interested parties to develop appropriate training, quality or certification standards that can serve as industry guidelines.

We urge the FDA to assess the above-mentioned issues and clarify the scope of the existing body of applicable law. We believe that to hold the third party service provider accountable to the same standards crafted for manufacturers would ignore how the marketplace has evolved and the complex set of end user regulatory requirements already in play. Simply

adding further regulatory oversight or requirements for utilization of OEM services will not improve patient safety but it will increase costs and may unintentionally reinforce anti-competitive positions a number of OEMs have taken.

We recommend clear requirements on access to service and parts and related materials so that healthcare providers can meet the regulatory requirements to which they are subject regardless of whether service is provided by an in-house team or an ISO.

Thank you for the opportunity to participate in this important discussion.

CAPT. MITCHELL: Thank you, Tim.

We will now hear from Katie Ambrogi, Attorney Advisor Office of Policy Planning, U.S. Federal Trade Commission.

MS. AMBROGI: Thank you. I have to give a partial disclaimer today that I do not speak for the Commission at large or any individual commissioner. But my comments today do draw heavily on the work of FTC staff and reflect staff's general approach to the

interplay between competition and regulation.

I appreciate the opportunity to speak on the FDA's efforts to study the medical device industry and healthcare community that repair medical devices including all the other terms that we've heard here today. I may use some shorthand like presenters before me.

The FDA should be commended for its work on evaluating this important issue and for opening up this dialogue to industry stakeholders. At the outset we would urge folks here to consider the significant benefits to competition including price, access, and quality as the agency continues to examine the need for regulatory action and to narrowly tailor any potential future regulations to those addressing well-founded patient safety concerns.

Let me take a step back and provide a little context for the FTC's interest here. At the FTC we were founded in part due to a belief that competition is at the core of America's economy and vigorous competition among sellers in an open marketplace gives consumer the benefits of lower prices, higher quality

products and services, and increased innovation.

The FTC is charged under the FTC act with preventing unfair methods of competition and unfair or deceptive acts. While the commission is primarily a law enforcement agency it has long recognized that competition may also be affected by the actions of public entities including regulators and legislators. Because of the importance of healthcare and competition to the economy and to consumer welfare competition in healthcare markets has long been a focus of FTC advocacy, research and of course law enforcement.

But each federal agency has a role to play when assessing regulation and furthering competition mission through its practices. In fact, recognizing the vital role of competition to U.S. consumers and the economy in April 2016 President Obama issued an Executive Order to increase competition. That order stated that promoting competitive markets must be a shared priority across the federal government. It explained that executive departments and agencies can contribute to that goal by competitive rulemaking and

regulations and by eliminating regulations that create barriers or limit competition without corresponding benefits to the American public.

Indeed these things are consistent with long-standing FTC advocacy and outreach. Through written comments in agency to agency relationships we have encouraged legislators, sector regulators and other policy makers to integrate competition principles into decision making processes so that law, rules and policies incorporate competition principles to advance the interest of consumers and citizens.

To that end we thank the FDA for hearing our policy perspective today and respectfully suggest that the FDA as it evaluates the need for potential regulations incorporate the role of competition in its analysis and avoid unneeded or unduly burdensome impediments or barriers to competition that importantly would not have countervailing benefits.

It may be helpful as these complex issues are considered to evaluate the following framework. First, what is the likely impact of any proposed regulation? Second, what specific and evidence based

justification exist for any regulation that may affect competition? Third, are there any alternatives to broad proposals that would fulfill the important public policy goals including patient health and safety without restricting competition or unduly burdening legitimate business activity?

I'll turn to each of these principles in turn. First the FDA may examine the benefit to healthcare providers to having alternative providers for servicing and repair of medical devices. Hospitals today can face significant expenses across the board including the expense of medical device repair. One study published on AdvaMed's website estimates that spending on medical devices and in vitro diagnostics was over $171 billion or 5.9% of the total national health expenditures in 2013. And the Association for the Advancement of Medical Instrumentation has conservatively estimated the medical device service aftermarket at about $50 billion per year. Third parties, that is either independent service organizations or employed in-house teams, today may serve as viable alternatives that

compete against OEMs to provide servicing, repair, and refurbishment of medical devices and equipment to customers.

Now certainly there are legitimate competitive reason why a healthcare provider would choose to purchase both medical devices and repair services from an OEM including potential discounts from receiving products and services together, convenience or any specialized expertise that OEM may have. Indeed the ability to choose to contract with a vertically integrated OEM can be considered a form of competition in and of itself.

Nonetheless the public record also has evidence of customers benefiting from in-house or ISO providers competing against OEMs in the form of lower prices, expanded offerings, quality, service, and access. For example one large public healthcare system cited that its biomedical engineering program which gives in-house support for medical technology systems collectively saved the organization $3 million in Fiscal Year 2015. Another large health provider stated in its public comment on the FDA docket that it

realizes significant savings through the use of a large third-party medical repair company and the savings it derives from the use of that third party entity allows it to invest in improving its care delivery model.

Yet another mid-sized healthcare systems public comment likewise explained that unnecessarily mandating medical devices and equipment to be repaired or serviced by an OEM or third party outside of the organization that owns the equipment does not best serve patients, adds to the cost of care, and increases unnecessary resources. That evidence as well as other comments in the record suggests that some healthcare providers are benefiting from meaningful competition from in-house service teams and ISOs and that high quality third party repair groups which employ knowledgeable and trained professionals can offer providers significant savings and expand access to these services.

Second on the issue of specific justifications for any future potential regulation folks may wish to continue to closely analyze the

available empirical evidence to determine the extent to which health and safety problems are verifiable and connected to OEM or non-OEM repair.

The FDA announced that it is evaluating the issue of medical device service and repair in part because some in the industry have expressed concerns about quality safety and continued effectiveness of medical devices subject to service by both OEMs and third-parties. And indeed the FDA's mission is to be responsible for public health by assuring the safety, efficacy, and security of medical devices as well as drugs or other products.

Certainly patient health and safety is of critical importance. The FTC frequently grapples with health and safety concerns raised in the context of our anti-trust work and we often turn to independent experts, clinical and economic, to ensure that we are getting the analysis right.

Evidence of specific safety issues as well as identifying the root cause of such issues will best guide policy decisions. To that end the FDA correctly put the question to stakeholders; what evidence exists

regarding actual problems with the safety and/or performance of devices? We take note of the comments in the public record and the statements here today that data on faulty or flawed repairs are difficult to collect and so may be unavailable for stakeholders and the FDA to study. And certainly several responders to the public record submitted comments presenting examples of certain medical devices that do not appear to have been serviced correctly leading to concern on the part of some stakeholders.

At the same time the public record also has comments by organizations on whether medical device repair has resulted in safety risks to patients. For example the ECII Institute which monitors medical device problems and hazards and which has been talked about by others this morning conducted database searches spanning the last ten years and based on those searches does not believe that a safety problem exists for servicing, maintenance and repair of medical devices by OEMs or third party organizations. In addition the Joint Commission having conducted a large scale hospital survey including such issues in

2012 said that it has no knowledge of any statistically significant level of safety problems resulting from the activities of any kind of maintenance or service provider.

So we would urge that to the extent that such information is available that stakeholders continue to seek out and thoroughly study independent sources of data and information to determine the existence and degree of legitimate safety concerns tied to servicing and repair of such devices.

Third if the FDA ultimately determines that regulation is needed here we would encourage any regulation to be narrowly tailored to remedy the evidence based source of patient harm. Such an effort would examine exactly where and how the compromised conduct occurs and work with stakeholders to construct solutions designed to address that specific conduct. For example in the public record some OEMs expressed concern that they did not know whether an ISO had worked on one of its devices and so did not know what was done or when to change it from its original state. If such behavior has indeed led to health and safety

risks one suggestion also made in the public comments was that OEM devices repaired by a third party could be labeled to indicate that the repair had been performed.

Other suggestions offered that ISOs could be made to notify customers that they are not an OEM authorized service provider and they could be prevented from using registered OEM trademarks that may confuse or mislead.

Such provisions which focus on improving communication and potentially giving more information to the customer would be less restrictive alternatives to broad prohibitions on ISOs or in-house groups competing in the after-market. And indeed the FTC through our consumer protection arm has long worked to ensure that any advertisement in any industry are truthful and not misleading.

It is also worth considering as others have mentioned whether there is existing governance in this field and whether additional regulation would be constructive. To the extent that organizations are already regulated or overseen in certain aspects of

medical device repair and servicing one may consider whether additional regulation would add anything additional to the mix.

The goal of narrowly tailoring regulations is first to cure any legitimate harm while preserving the benefits of competition.

In conclusion we once again appreciate the opportunity to be heard on this issue and commend the FDA for bringing together such a wide variety of stakeholders. We welcome future participation and discussion and other organizations as this continues.

Thank you.

CAPT. MITCHELL: Thank you, Katie.

We will now hear from Mary Logan, President and CEO of the Association for the Advancement of Medical Instrumentation, AAMI.

MS. LOGAN: Thank you. This is my last public appearance today and tomorrow as AAMI's President and CEO because I'm retiring at the end of the year. So I'm going to say something at the end of my remarks but I want to start my remarks by doing something really fun.

I went to my first baseball game, professional baseball game when I was nine at Wrigley Field so that is what I am going to say, "GO CUBS".

[Laughter]

I think most people here know who AAMI is but I wanted to put a slide in the record for anyone who might not. AAMI is an association, but we are not a trade association, we really could be a charitable organization, a 501(c) (3) because we don't do lobbying or advocacy.

What makes people want to participate in AAMI is that we are all about the technology. Our focus is on the technology itself and the whole community of people who work with healthcare technology. Our members are all tech oriented. So sometimes nurses, sterile processing professionals, physicians, other clinicians, healthcare technology management professionals, technology folks who are in the C-suite in healthcare delivery, medical device manufacturers, distributors, parts companies, ISOs, refurbishers, third party repair. We have the gamut. That makes this issue really interesting for us, also

very complex.

We normally don't submit comments to the Federal Register for the many, many opportunities that we could because we normally don't have anything to say. We might file a letter reminding people to remember person safety is really paramount.

In this instance we wrote a very lengthy comment because we thought that we had a unique perspective of speaking to the whole industry, the whole service industry rather than to any one of its component parts. So it is a lengthy document.

The survey that was mentioned earlier is attached to that. AAMI was asked by the Joint Commission to perform that survey unrelated to this particular docket item.

So our focus, our mission is advancing safety in healthcare technology. So it is all about the safety and performance of the technology itself.

We are primarily known for standards development and the next slide I'm going to show will explain why we are primarily known for that. We also do a lot of education, training. Our foundation has a

lot of focus on patient safety initiatives and we address other technology oriented issues like wireless, cyber security. We are a convener and I think we have become perhaps as well known as a convener as a standards developer because to quote Pat Baird from Philips we are known as Switzerland because we don't advocate for anyone position or another. We're a great place for people to come together to develop consensus and to try to find common ground.

We also do a lot of publications and we have staff here. Our publication staff are here today, we are always looking for ideas for new issues to write about. So if you have suggestions for that, please let us know.

And personnel certifications; a lot of you might not know that we are ANSI accredited as a personnel certification organization for our BMet certification. So we have a certification program that verifies the credentials of the biomedical equipment technicians.

These are select examples of AAMI standards in this space. And tomorrow at the end of the day I'm

on a panel with five minutes to talk about standards. So I'll do a little bit more about those but I wanted everybody to see the overall scope of our standards development program. And we have over 10,000 volunteers who help serve as the subject experts and help write the standards.

There are a number of standards that apply to service. So when I speak of service, repair, and refurbishment I am using all of those definitions just referring to the service industry in a very broad way. As a result of this docket we have a brand new committee that will have its first meeting in December to develop definitions. It was really clear in looking at the comments submitted and in the questions that the FDA asked that there is a need for standardized definitions. So we have approval from ANSI to start a committee to develop the definitions. So we hope that many of you will want to join and participate in that activity.

We also have a new committee that is going to be looking at a standard for acquisition of technology. So I think you are going to see more and

more standards being developed on the service side as opposed to on the manufacturing side. Very strong and many standards on the manufacturing side and the industry side; not as many on the service side and there is a great need for more which I'll say a little bit more about tomorrow.

Interestingly electrical safety, sterilization, industrial sterilization, quality systems has been mentioned earlier, risk management, cyber security, network risk management, and software are all areas where AAMI standards could apply to service.

This is the cover of the most recent issue of our peer review publication BINT. And it is about this issue. So it is a very jazzy cover and Sean stand up for just a minute. Sean Loughlin is VP of communication at AAMI, if you don't have a copy of this, if you are not an AAMI member or you missed it, Sean has copies, you can see him at lunch and he'll be happy to give you a copy.

The common thread of every single person who participates in AAMI on this issue and every other is

I care about patient safety; that is what makes the staff at AAMI inspired to come to work every day because that is really what it is all about. That is the common ground.

There is a lot of other common ground though with this issue in spite of the cover which is also very true. There is common ground that folks who work on technology should be trained properly; that onsite support has great value; that people should have the right credentials and qualifications before they work on equipment no matter who they work for; that sourcing of parts is very important and access to validated parts is real important; access to information; access to the information that people need to be able to assess what is going on with a device, to be able to repair it, to be able to troubleshoot it, and to be able to know if there is actually something wrong with a device for purposes of a full life cycle improving the design, updating a design.

Whether or not the folks in this room and folks who are listening out in the field would agree

with this you are all inextricably linked of that life cycle of the device itself. And the feedback of good information among all of you is essential to patient safety.

Process validation, I think everyone would agree process validation is something that where there is common ground.

There are differences of opinion about whether there is a problem, whether there is evidence, what the extent of the problem is, the cause of it, and interestingly there is a pretty significant difference of opinion about whether or not there should be additional regulation. Normally AAMI members share a view that additional regulation is not a good thing. Folks like standards as an alternative to regulation across the spectrum.

On this issue there is a divide and I think this slide, it is going to be a little hard for you to read the details but I think you can get the sense of it. This slide says it all to me. So this is from a Systems Engineering textbook from when Wil Vargas on our staff went to engineering school and the title is

"Dream Airplanes" and its photos of the drawings are of dream airplanes from the prospective of the engineer and what group the engineer worked in. So you have the fuselage group, the controls group, the hydraulics group, the service group, the wing group, et cetera, et cetera. And the airplane looks very different depending on what group the engineer works in. I'm a big proponent of systems engineering and systems thinking because unless you have everyone in their full life cycle together in the room solving a problem you are going to create an airplane that looks like this.

And that sometimes happens with regulations as well. Sometimes when the FDA doesn't get the perspective of all the stakeholders what they end up with as a regulation might look like it came from the loft group or the stress group or the power plant group instead of an airplane that everyone has imagined together.

So AAMI's primary role and the role that I envision, easy for me to say because I'm a short timer now, is building from the common ground. Since I have

been at AAMI and before I came to AAMI there was a consistent drum beat from healthcare delivery organizations on the service side of the business that AAMI needed to do something to help with the problem of industry and service organizations not seeing eye-to-eye on the supportability issues around medical devices.

So we were crazy enough to have a forum last year on supportability. And this artwork you can find on our website or if you see Patrick, where are you, Patrick Bernat from my staff was the host of that event if you want to learn more about it. We had in an artist map the discussions and map the common ground. This particular slide shows the "we believe that" statements. This one shows the building from the common ground. It was an event that was attended by both industry and folks from healthcare delivery all again with that common goal, that common interest of advancing the safety of technology.

As a result we have now a supportability task force and that supportability task force has two immediate deliverables. One to define and fill the

gaps in terminology. The language used by service organizations and manufacturers is very different. So one of the things they are working on is filling that gap to have the common understanding of terms. Their other deliverable is to have a template for service level agreements which should help industry and healthcare delivery organizations.

I mentioned we have two new standards committees that are starting up, they are both meeting in December -- two new standards that will be developed by our EQ committee. One to work on the definitions that are part of this docket. So thank you FDA for identifying that there was a need for definitions. We think our committee can define the terms better than the regulators can. Sorry FDA. We'd like to see that done in a standard. Another committee on acquisitions.

We also think there is a lot more that AAMI can do. The cover story from the October issue of BINT really laid out all the issues. We need more articles like that to identify where other areas where we can find common ground as well as annual conference

sessions, webinars and whatever else any of you from our community might suggest that we can do, please let us know.

If you are interested in being a part of the standards work, Amanda Benedict, her email address is on this slide, would be the person to contact. She needs you, she welcomes you.

The supportability task force, Patrick is here, you can speak with him at a break or send him an email as well.

So I want to just take one moment of personal privilege since this is my last public meeting. I'm retiring at the end of the year. And the search committee that has been working hard all year has named my successor, Rob Jensen who is a senior leader at MITRE, MITRE's health IT practice -- health IT business will be joining AAMI on November 14 and I hope that you all will be as wonderfully supportive of Rob's success as you have been of mine. It has been such a privilege to get to know all of you, to serve you and to be in this space of convening people to do their best work. I am going to miss

that.

Thank you.

CAPT. MITCHELL: Thank you, Mary.

Just hold on for a few minutes. In just a few minutes we are going to go ahead and break.

Let me just first say thank you to all the panelists. It is clear from this first session that it is really, really helpful to have everyone together talking to understand the depth and breadth and complexity of this issue.

Certainly we have differing opinions but as many people have already identified there are some commonalities. I just want to highlight a couple.

One is the value of the ISOs, the importance of collaboration and cooperation. And finally that each and every patient encounter should be both successful and safe.

And lastly but not least is that decision making should be based on data.

So with that I want to give you some instructions for lunch and then because we are convening early I'm going to ask that you all come

back at 12:30 instead of a 12:00 to 1:00 lunch. So I hope that is going to work for everyone.

With regard to lunch you've all pre-ordered in different ways. Some of you have paid and some of you have not. When you go outside you will find three lines. If you have exact change, $11.00 you are in one line. If you are going to use a charge card you are in another line. And if you don't have exact change but you do have cash you are in another line. And then if you've paid already, I didn't get told about that one but I assume that there is another line.

[Laughter]

Thank you very much for your attendance this morning and we'll see you at 12:30.

LUNCH

CAPT. BOYD: So welcome back to our workshop. My name is Sean Boyd. I'm the Deputy Director for Regulatory Affairs in CRH's Office of Compliance. And I'm just going to lay out an introduction of what this afternoon's program holds.

But before we get to that we are going to

continue the discussion of lunch. Tomorrow to avoid some of the issues that we had today the vendor is going to be available during the break this afternoon to take preorders and payment for lunch tomorrow. We anticipate the break is going to be between 2:00 and 2:30 based on adjusting our schedule so if you would like to preorder today you can go and do that this afternoon. They'll also arrive earlier tomorrow morning by 7:00 a.m. so that you'll have an opportunity to do that early tomorrow morning.

Moving on with our program; this afternoon we have a panel on the benefits and risks associated with refurbishing, rebuilding, remarketing, remanufacturing, and servicing activities. The panel session will have presentations from each of the three stakeholder groups represented that include manufacturers, service providers and hospital end users and engineers. Each group is going to present their viewpoints regarding the benefits and risk surrounding these activities with medical devices.

And following their presentations the floor will be open to questions and you may address the

panel as a whole or individual speakers on the panel.

Following the panel again we are going to have a short break and continue with presentations by workshop participants. Due to the overwhelming interest in this workshop and in speaking during the event we've pre-scheduled several speakers for the session and with time permitting the floor may open to the audience as well. Each presenter that has been allocated time will have five minutes this afternoon to make their remarks.

So thank you again for being here.

And with that I'm going to allow Pam Scott to moderate this session.

MS. SCOTT: Good afternoon. Again thank you all for attending this important workshop. So we are going to get right into our next session, Panel Number 1. And at this time what I'm going to do is I'm going to introduce our panelists. And I hope that I pronounce all my names correctly. If I don't please feel free to correct me.

And I'm going to give just a bit of an overview, just a quick snapshot of the bio of the

wonderful expertise and knowledge that we have as a part of our first panel this afternoon.

We have Mr. Pat Baird. He is the head of Global Software Standards with Philips. Mr. Baird has extensive background in risk management and chaired international conferences on medical device risk management in 2011 and 2012. He has chaired and served as a member on numerous technical committees focused on medical device safety. He also serves as an adjunct instructor for topics such as insurance cases, risk management, human factors, and software validations.

Next on our panel we have Mr. Mark Leahey. He is the President and CEO for the Medical Device Manufacturers Association. Again this is the national trade association that represents medical technology companies. His current responsibilities include advocating on behalf of the entrepreneurial sector of the medical device industry to Congress as well as federal and state agencies. Mr. Leahey has a background and experience in both law and business.

We have Ms. Kanchana Iyer; did I get it

right? Almost, close. Kanchana I believe that is better Iyer. She is a Senior Regulatory Affair Specialist at PENTAX Medical and Endoscopic Imaging Company. She is a biomedical engineer with background in biomaterials, computational modeling and tissue engineering. She formerly served at FDA as a lead reviewer within our Office of Device Evaluation as well as a Regulatory Communications Project Manager in the Office of Communication and Education.

We also have on our panel Mr. Hans Beinke. He is the Vice President of U.S. Quality and Technology with Siemens Health Care. He has been in the pharmaceutical and medical device industries for nearly 40 years. He has extensive background in pharmaceutical development, clinical trials, medical device, environmental health and safety, quality, regulatory and clinical affairs.

We also have Mr. Scot Mackeil. He is a Senior Anesthesia Biomed at the Massachusetts General Hospital in Boston, Massachusetts. Mr. Mackeil obtained his CBET certification in 1994 and is currently responsible for providing technical support

to staff in the Departments of Anesthesia, Surgery and Perioperative medicine in direct support of patient care activities. He also performs preventative maintenance and repair on medical equipment and systems throughout the OR and anesthetizing locations around the hospital campus.

We have Mr. Mark Bruley who is a Biomedical Engineer and Vice President for Accident and Forensic Investigations at ECRI Institute. Since 1982 he has been responsible for ECRI's accident and forensic investigation program. He has published extensively and lectured on medical device accident and investigation, health care and medical device problem reporting programs and a wide variety of patient safety topics.

We also have on our panel this afternoon Dr. Robin Hemphill. She serves as the acting Assistant Deputy Under Secretary for Health for Quality, Safety & Value at the VA National Center for Patient Safety. Dr. Hemphill has extensive experience in emergency medicine, disaster preparedness and healthcare quality. She currently focuses her efforts on

aligning the VA's quality, safety and value offices as well as developing a strategic plan to build process improvement on top of a foundation of patient safety.

We have Ms. Wanda Legate. She is a partner and serves as the Vice President of Sales and Marketing at Tri Imaging Solutions. She has over 20 years of experience in the diagnostic imaging industry both with an OEM as well as independent providers. Throughout her career Ms. Legate has held various management positions with a focus on customer service, sales and creating a market presence.

We have Mr. David Anbari. He is Vice President and General Manager for National Sales and Operations at Mobile Instrument Service and Repair. Mr. Anbari leads a team of field service and repair engineers and technicians in the delivery of services to healthcare facilities nationwide. He blends a respect for the technical elements of the central sterile environment as well as the materials management, biomed and operating room environments with over 24 years of business focus operations management expertise.

And we have Mr. Rob Moorey who serves as Division Vice President for TriMedx, LLC, a service organization in healthcare. He leads the East Coast or the East Central Division and he has over 20 years of experience leading operations for industry, spearheading many initiatives that have delivered sustainable programs and serving on international medical mission efforts and consulting to Catholic Health Care in Haiti on the structure of their national service organization.

This concludes the introduction of all of our panel members. And at this time I am going to hand it over to Mr. Baird to begin our discussion with the first presentation.

PANEL 1 PANELISTS:

BENEFITS AND RISKS ASSOCIATED WITH REFURBISHING, RECONDITIONING, REBUILDING, REMARKETING, REMANUFACTURING, AND SERVICING ACTIVITIES

MR. BAIRD: Great. Thank you.

Okay. So first of all I'd like to just sort of thank the other members of this panel for helping me put together this presentation to begin with. We

had a couple of iterations clarifying some things.

And then I also wanted to mention that my wife is a technical writer and occasionally I will pick not quite the right word and she'll correct me immediately and I know that while some of these definitions for manufacturing, refurbishment, et cetera, they are not finalized. I'm sure sometime during my presentation I'm going to use a little different word than what it needs to be in the end. And so I'm trying to get across to you the intent of what we're trying to do even if sometimes I pick just the wrong word by a little bit.

And really we are focusing on the big picture risks. Of course there is going to be some difference in risk say from a servicing activity than a remanufacturing, remarketing activity. The main focus is on some of the key drivers beneath that.

So I always like to start with some take aways, just to say this is what I'm going to be talking about. To me this is a patient safety issue. My background is in risk management and patient safety. My background is in making customers as happy

as possible in a safe and effective way. This is a patient safety issue. That is why I'm participating here.

Another thing that has been touched on briefly but I want to go a little bit deeper is what I'm calling the invisibility factor. I should have actually called it invisibility factors because there are many ways in which things aren't obvious and that is driving certain behaviors and that is driving certain conclusions. So I'll talk about that in a little bit.

I also wanted to mention that when I walked in the doors today I thought that I was at a AAMI conference because Mary Logan was talking in the morning and I recognized about a half dozen HTM (health technology management) professionals from this. So it is like, oh, yes, these are people that I already know and I want to be clear on this is that lots of service providers are doing the right things and have good controls in place. There are other service providers that don't appear to have some of these capabilities. And as a manufacturer I know that

the service activities that are done by any manufacturer aren't 100% perfect all of the time. Completely taken and understand that. One think that I like on the manufacturing side though is that we have non-conformances and CAPAs and things to detect problems as quickly as we can and act on them and put the things in place. This is one thing that I actually like about quality management systems is that continuous improvement and including those things.

Also wanted to mention as part of the take aways from this is the documentation and the reporting of things back to the OEMs. I'll go a little deeper on another slide about this. But this is one of those things where having a holistic picture of the health of individual product and how well is it performing is being skewed, is being clouded by not having all of the information that we could have. That of course could lead to more safety and performance issues.

So I do want to talk about the benefits of sort of good servicing practices. Obviously devices will last longer, right, if they are serviced and maintained appropriately. Not only do they last

longer but there is a longer mean time between failures, right, so it doesn't have to go back in the shop so often.

Competition; there was some discussion about competition. When I talk to other manufacturers we're all for competition on these things. That is how our economy works. I was talking to a small company a few months ago and they had brought up the broader geographic coverage and this was a small manufacturer who is very happy to be a small manufacturer. And they had a good product, they wanted to take and expand into other regions but they don't have the infrastructure to set up the service depots; they don't have those things. So as we are having these discussions they are like make it clear I am relying on ISOs to support my business model. This allows me to go into new areas that I wouldn't be able to get to otherwise. I love this stuff.

And then also back to that we have a cloudy picture of what's going on but the OEMs have responsibility to take action when we see an uptick in certain kinds of complaints, certain kinds of

failures, et cetera. And when we have all of that information back in our hands we get a much fuller picture of the health of the device and where we need to work on things.

So again this is a patient safety issue. I view the world as patient safety. Regulations exist because if you have untrained personnel, you have uncalibrated test equipment, you are buying parts from unapproved supplier; there is a risk there. And to me that risk is the same no matter who the person is doing this. And so if regulation is important for safe and effective products shouldn't it apply to everyone that is doing those types of activities.

So going just a little bit deeper into risk, again this is about patient safety, it is about product performance. If the device isn't performing as it should, well then healthcare professionals can't do their jobs. The device isn't meeting all of its specs and the patient is the person in the crosshairs when it comes to safe and effective matters.

I've been on some of my own devices in my past life. I've been on some competitor's devices.

And I shouldn't have to worry about whether or not there is an equivalent level of safety depending on who it is that last touched that device.

Additionally talking about sort of that documentation on the manufacturing side we keep track of all the changes made to an individual device. We know the service history for all of these things. And if some things happen that we don't know about next time it comes back to our shop we might end up doing the wrong thing. If parts get swapped out back and forth between different devices there is a certain traceability. On many designs it doesn't matter. On some designs, on some situations it really matters that this subassembly only works with this version of that subassembly.

Additionally if we can't trace those products, if we do have a field issue, if we do need to take and communicate to all of our customers some people are going to get missed because we have incomplete records about some of those devices, about where those devices have been.

Some of the contributing factors to these

things really comes down to the complexity of these medical devices. Things are a lot more complex than they used to be. And so there is that extra level of training, that extra level of understanding that you need to do. Some of this complexity comes in just the components themselves. Sometimes the components are very unique or made of special materials. You can't just reverse engineer something. I have used the example in the past of there is a part that looks relatively innocuous but there are some features on it that as a manufacturer I control to within a couple of thousandths of an inch. If someone else has reverse engineered this part think that they've made a comparable part but don't know one particular dimension is really, really critical well then they are going to miss some of the safety features; they're going to miss some of the aspect of that design.

Also some specialized knowledge depending on the type of the device. Obviously equipment that emits radiation, things with big magnets, there is extra physics involved with some of these things. Even for something as straight forward as an infusion

pump, there are some interface things between how the sensors interact with the tubing and that is not necessarily common knowledge. You might think you know how this thing works but there is actually another level of understanding that needs to happen.

And I also wanted to mention, highlight this last point particularly with the rise of hospital acquired infections cleaning agents, disinfecting agents have changed over time. The type of material selection that goes into some of these devices, some of these components can be really, really important. And just because the thing is the right shape and has the right couple thousandths of an inch as I was mentioning before and fits right in doesn't mean that it is actually going to hold up in this clinical environment with some of the chemicals that are out there.

I happen to be extremely sensitive to this topic of HAIs [Healthcare Associated Infections], I'm just admitting my bias, because I lost my mother to one. And so I'm trying to be really, really careful when it comes to how do we make things as robust as we

can for the current healthcare environment. And if you don't know those material factors that is going to be a problem.

So I talked about invisibility before and we did have some discussion, well, there was an abundance of discussion earlier through multiple speakers on this issue doesn't really show up in the complaints, this issues doesn't show up in the MAUDE database. And so there is some discussion about whether or not things are being reported, there is underreported, et cetera. I know from my life of two incidences that were filed as MDRs happened I believe within 12 months of each other where medical intervention was required to prevent catastrophic outcomes to two different patients. So I think that we should take a really hard look at whatever data sources that we are using and making sure that we do know the extent of the problem.

I also think that there is a challenge on how do I tag this inside of MDRs so that someone that is trying to do data mining later knows what to look for and the key word that my department is using is

that the same or different than the key word that my competitor is using. And so maybe something that we can take and talk about is is there a common taxonomy that we should take and use to identify some of these items so that we can truly see how big of an issue it is.

Another part of the invisibility it is not just about the underreporting as it were but it is also when performing some of these repairs and performance of these process steps if -- you can take a look at the processes say I don't see the value in this, I'm going to save time, I'm going to skip this step. Sometimes I completely understand you don't understand why you need to do something so I'm under time pressure, let me skip that thing. Let me go buy a cheaper part from some other supplier because it looks the same, I measured it, they are the same dimensions. And there are subtle things in there that aren't visible to the person performing the service that actually end up being rather significant.

There are changes to the design over time. And there are some configuration management issues

which OEMs have to take and deal with those headaches all of the time but that's part of our job is managing those configurations and knowing that this part really is just compatible with this version of that other part.

And then finally for the invisibility factors sometimes when there is an error in servicing and it's the OEMs or ISOs or whomever the error might not get detected right away. It might be not until months later that the thing manifests itself. My examples about the disinfecting agents; it takes time for those chemical to take and attack the plastics and make the plastic brittle and then suddenly you see a spike in the number of complaints related to broken things. It could take a while for the effects to accumulate or it could be that this one particular feature is put in for a certain situation. That is not a situation you run into everyday in the hospital. But it is part of the bounds of how the device performs. I'm thinking hot days, humid days, heat and transport kind of uses where the device just sitting there might perform perfectly but because of some of

these configurations issues, because of some of these other errors, you don't really notice that something bad has happened until you are in that situation.

And then it was mentioned before I wanted to mention again is that Image RA actually has a nice guidance document on running the HTM departments. I did a quick check last night sort of bouncing what I would think would be in the QSRs that are appropriate for servicing of devices against what this guidance document says. And about 80% of what I think the QSRS for good servicing would be are including in this already. And so I thought it was very interesting that across the pond they sort of have these things in place.

And thank you very much.

MS. SCOTT: I failed to mention that of our panelists Pat actually represented the OEMs.

Now I believe for the hospital end users and engineers I believe some of you were going to split that up in terms of the presentation. So do we want to start with, so we have 15 minutes for that whole segment so you all probably would have about five

minutes each. So Mark do you want to start -- note Mark Bruley, Mark Bruley do you want to start out that segment or we can have Scot Mackeil or Robin or Dr. Hemphill? Well, let's start with Dr. Hemphill. It seems like you may be ready.

DR. HEMPHILL: All right. You can see we really organized on this one.

Just a couple of thoughts and this is from the section for the hospital end user and engineers. So as you can imagine from a VA perspective I would try and speak to really sort of a high level of issue and how we try to think about these and very much how we're trying to learn as new technologies come in. So you know VA is a large integrated healthcare system and we are trying to serve upwards of nine million lives in that system. So it is a broad portfolio in technology that is being brought into the system and a very skilled set of health technology managers, biomedical engineers that we try to train effectively, maintain their skill sets and then help them do their jobs. And when we think about technologies we view them very much as a continuum of activity. So we are

really trying to think all the way from how is the manufacturing thinking, designing, testing their own systems. So it goes from that design and build into use life cycle management and ultimately you might say age out, so to retirement.

Now when we think about retirement we think of them in terms of old stuff that certainly might be perfectly appropriate for people to reuse, refurbish. And then things that we'd be concerned about and we always wonder if something is a really design flaw, a bad design flaw how do we ensure that that doesn't really ever get into a reusable market. And again we feel sometimes there is not always good eyes on that to really track those through time and effort to say this is something we wouldn't want to use. And we see examples of this so I often bring it into your real life. If there is a problem with a phone that has an exploding battery and you can't figure out how to fix that I think most of us probably don't want a refurbished one of those at this point. So again, this same kind of thinking.

Now from our perspective in the VA we're

very much trying to imagine life cycle management of amazingly robust and complex technologies. And we understand that many of the manufacturers they test these in the environment as they know it and understand it but it is almost impossible for somebody to think of all the ways once we bring it into a myriad of hospital systems that that device is going to interact with the environments that are now facing it. So I kind of call that the complexity of bringing these devices in here.

We feel that the biomedical engineering community along with clinicians are going to be an amazing set of eyes and ears to tell you how those things are engaging and interfacing with systems in unexpected ways as well as expected ways. So in many instances we do have an expectation that the manufacturers are going to bring in devices and they will be the people who will put those into our systems. But we also have seen instances where the manufacturers themselves have not always put them in correctly despite their own people or their own contractors. And really our own biomedical engineers

are the ones who were able to find that and really do the deep root causes which then inform our own systems.

So that again is very much, it is a high level view I know but it is the sense of how we're trying to think of these things and learn from them.

I'm going to end just very quickly with the sense of from our perspective transparency is critical for us both in what the manufacturers believe their designs are, our ability to learn from what they think is imperative for how their systems work. We then can look and say how is this applying, is it working as you expected, that key question that we often don't ask.

And then we want to report systems back up and we think it is imperative to create better reporting systems across that continuum and life cycle so that we learn from refurbishing, we learn from what doctors are seeing. I still worry that when we say we're not seeing enough examples of how equipment fails either as it comes into the system new or how it gets brought back in once it has been fixed,

refurbished, reused, is more a lack of awareness and thinking about this device isn't working as it is supposed to rather than a lack of problems with the devices themselves.

Again from the clinician's perspective I was never really taught to think this way about is this device working as expected. And so as an ER doctor if you give us an ultrasound we'll break it in a day because we are like a bunch of children but if it breaks early is that because I misused it, I miscleaned it or is there really a problem within the device itself. I wasn't taught to think that way and we are very much trying to redo our thinking to say the simple question in a complex world is this device working as anticipated, as designed, as we thought it would. And if not how do we get the wealth of experience internally and externally reporting it through systems which I think transparency is critical to make it work better.

And I'll stop there.

MR. BRULEY: Hi, I'm Mark Bruley with ECRI Institute. I'll give a few perspectives before we get

another set of thoughts from Scot Mackeil from the clinical, the setting itself and the Biomed programs.

In regard to adverse events, accidents, injuries and deaths with medical devices based on the work I've been reading and doing over the decades about 80% of the adverse events are caused by you name it whether it is user error, use error, or what I call the technique of use and as opposed to issues related to servicing, maintenance, refurbishing and so forth.

One of the things that Dr. Hemphill and Pat Baird just mentioned was about consistency in reporting and getting better data and information. It may have been forgotten but about eight years ago AAMI had a committee on establishing a uniform taxonomy for labeling the types of repairs that were needed for medical devices. I was on that committee. And perhaps that could be reinvigorated if another AAMI committee wants to take a look at that again. And it was developed in collaboration with some of the FDA staff that are in CDRH.

The inspection and preventative maintenance of medical devices has been interesting in its

development over the years. One of the things that I think has really advanced the safety of medical technology in the clinical setting has been the education and certification of biomedical engineering equipment technicians by AAMI over the last 20 years or more. We now have I forget how many thousands of certified biomedical engineering or equipment technicians in a variety of subfields including clinical lab and I think there is radiation as well. And those certifications and that education has gone a long way to I think prevent adverse events that may have been caused by inappropriate service in the clinical setting itself.

One other thing to consider when you are looking at a medical device and its failure as Dr. Hemphill had suggested in being able to destroy an ultrasound probe within a day when we investigate an adverse event we consider four basic interfaces between the device in question and the rest of the world. We consider the interface between the user and the device where the device this is mainly for capital equipment but it can also be applied to the single use

disposables, the interface between the device and the user where the user programs it or applies it to the patient for monitoring care or therapy and in many cases the device provides information back to the user concerning the patient's status or other diagnostic information. There is then the link between the product itself and the patient which is a variable biological system. The device provides diagnosis of therapy and treatment, sometimes the patient provides information on biophysical signals back to the device. But then with the exception of a tongue depressor can you think of a single medical device adverse event that involves a single stand alone medical device. What about a Pulse Oximeter? You have the piece of capital equipment, you have connecting cable which could be made by a third party, you have the probe, those are three devices from three potentially different manufacturers. A critical care ventilator with the heater humidifier, the ventilator, the trach tube and then the big piece of capital equipment. Virtually all medical devices used in the clinical setting are connected to some other medical device.

And the cause of the adverse event has to consider whether it was, in fact, the accessory device from a different vendor that caused the adverse event.

And the fourth interface aside from the user, the patient, the accessory devices is the hospital setting itself which frequently provides unique power, water, treated water, and sometimes unique reprocessing and sterilization conditions for that product. If you take the medical device out of that system of four interfaces and simply test it in most cases in our experience it checks out fine and works according to specifications. So when we analyze problem reports that come in to ECRI Institute or that we look at in various databases we consider those four interfaces when trying to assess what bucket that report may go into in regard to a generic range of causes.

So I'll stop there. I do want to touch base with the AAMI people later about the work that was done eight years ago related to the taxonomy. And please see me afterwards. And if you don't have the information, this predates Mary's coming at AAMI. I

can get it to you.

Scot?

MR. MACKEIL: Okay. Thank you. I'm a little out of my element here because we are not wearing hats, masks, and blue pajamas today. But as a Biomed in a thousand bed academic medical center I'm taking care of 66 to 70 something ORs depending on the state of closures, renovations. And I carry what is called the BAT phone, the Biomedical Assistance Telephone. And I am responding to the needs of caregivers immediately in real time. We have a team of biomeds that I can call over a voice IP(Internet Protocol) device and a kit will arrive in the room and the doctor, nurse, anesthesiologist will be looking at us for an immediate solution.

One of the most important tools that we can have is the knowledge of these devices. We really, really need complete comprehensive service manuals because that's how we develop the knowledge that we have to apply to the context of the problem and meet the needs of the caregivers immediately.

We like to have a ready source of parts

available for immediate use. For example I carry in a pouch on my belt the flow centers for the Apollo anesthesia machine and we'll actually if they have a flow sensor issue and the screen is grayed out and they are not getting gas values the anesthesiologists get really antsy. So I can do that gas sensor, flow sensor exchange in less than 30 seconds. And that is very important because what I do for the anesthesiologist and the anesthesia machines is an example of what I would call the best practice in our industry. I have full training from Drager. I have a full set of tools. I have all the parts that I need. I have a laptop loaded with diagnostic software. And working on these anesthesia machines is a natural as breathing, pardon the pun.

But in another scenario certain other pieces of equipment, you know energy device X, the manufacturer absolutely will not share their service manual with me. I can't get into the service mode and when I'm called to the room I said well maybe we can reboot it, maybe it will power up and start and work correctly. But that is not the service model that I

like to provide to our caregivers.

So to me empowering -- being a biomed here and asking our industry to empower us to provide care for our caregivers and their patients is the most important job that I can be doing because when I walk into the operating room to provide assistance to the doctors and nurses in support of their providing patient care I'm standing there with them and standing behind me are all of you. So I really need you all on my team helping me and all the other biomeds like me to do what we do.

And that is the most important benefit that I could give the FDA and all of you today because by helping me and my coworkers provide our services to doctors and nurses and their patients we reduce the risk to our patients that need our services.

So with that I will hand it back over to the next speaker.

MS. SCOTT: Okay. Wonderful. So now we will move on to our representatives from ISOs and I'm going to ask maybe Ms. Legate if you'd like to start out and then we will move -- oh, we are going to start

out with Mr. Anbari. Excellent.

MR. ANBARI: No slides that is the good news. Real briefly I'll try to get us caught up a little bit. The Independent Service Organizations that are represented on this panel are showing up on the screen. They include myself, Wanda and Rob. We've collaborated in advance of the meeting to try and come up with a consensus view from our perspective as Independent Service Organizations on how we look at the risks and the benefits.

And I think as we've already established through a variety of the stakeholder presentations and the discussion here clearly nothing is more paramount than the patient safety and positive outcomes from their healthcare experience.

The devices have to be safe and they have to yield positive outcomes. And I think the reality of healthcare is that there are risks inherent every time a device is invented, every time it gets used, every time it gets services, every time it gets reprocessed. And those risks are fundamentally the same risks whether an Independent Service Organization is working

with a device or whether a manufacturer is.

There is ample anecdotal evidence that we've talked about previously. There's obviously some good data to support the fact that ISOs and OEMs do an equally good job at performing servicing events.

I recognize there is also some question about whether there is underreporting that takes place but the evidence in the data that exists today certainly supports the fact that we do a pretty good job as it stands today both manufacturers and Independent Service Organizations. And in large part that is due to the protocols that exist in a hospital requiring self testing and testing of devices prior to their use along with the quality systems and the regulatory frame work that sits on the top of our industries today.

In terms of the benefits a robust competitive marketplace helps manage costs and I know there has been discussion earlier today about the fact that perhaps costs don't belong in this part of the conversation. And perhaps reprocessing activities don't belong in this conversation, certainly not for

single use devices but for multiple use devices. And I think the challenge that we all face as an industry is balancing the fact that you can't just look at risk. You have to look at the benefits and you have to look at the overall system that these devices exist within. So to suggest that cost is irrelevant when it is fundamental to as a benefit of these third-party activities in driving preventative maintenance and in creating the funding so that there can be local responsive service is really to not look at the issue in its entirety.

Preventative maintenance does save lives. Deficient equipment is detected and it can be addressed before it causes harm to a patient. And that competitive marketplace that we operate in is what allows Independent Service Organizations to provide more than just the repair and maintenance services that they provide but to really help coach end users, clinical engineers, and clinicians alike on how they can most effectively avoid damage to equipment and keep it in top working order.

That convenience factor of local service

representatives can't be understated, not just from the perspective of what my company does, but from the perspective of imaging solution providers, from the perspective of clinical engineering organizations both in-house and out sourced organizations; local presence matters and helps improve safety.

So taking an aggregate we look at it like this. We think the evidence is less than convincing; we think that there is clear evidence of the benefits that Independent Service Organizations provide to the healthcare system and to clinicians and that that robust marketplace really manages itself and maintains itself and drives out poor performers.

As has been stated previously and in a number of presentations we think the key really does lie in cooperation and in guiding the market as opposed to regulating it or overseeing it with a heavy hand. By promoting cooperation we think that we can do better than where things are today which is in a pretty good place.

The unintended consequences of regulation or oversight that is applied improperly or without

thorough thought put too much at risk for the benefit that we believe exists based on the evidence.

And that really is the sort of consensus view of the Independent Service Organizations.

Back to the moderator's table.

MS. SCOTT: Okay. Excellent.

So with that I'm going to hand it over to the audience to ask if there are any specific questions for our panelists at this time. Any questions from the audience?

If you have questions please feel free to come to the microphones in the middle aisles.

Q&A

MS. FEDERICI: Hi, Tara Federici with AdvaMed. I heard Dr. Maisel state at the beginning of the workshop that reprocessing of reusable devices is outside the scope but Mr. Anbari brought in the idea of single use reprocessing of single use devices. And I would just point out that FDA agreed to add to the MedWatch form a checkbox so that we could capture data related to problems with reprocessing of single use devices. So that might be an option that we should be

thinking about in this particular instance.

I also have a question for Mark Bruley. You cited today, your report, your analysis of adverse events has been cited and I'm just curious if you can explain the methodology of the report and then whether you looked at adverse events reported by OEMs, facilities and third parties?

MR. BRULEY: Sure. That was part of my five minutes for later but I'll be happy to address some of it now. We looked at -- all of our strategies for doing the analysis is contained in our submitted comments if those have been read. It says all the text string and search terms that we use and we looked at the MAUDE database using ECRI Institute’s search engine that we put on the MAUDE database. Considering the size of that database it is very difficult to use the FDA's online system for looking at large text strings and then downloading the hits because you are limited to 500 hits per search.

We looked at the health devices, alerts, tracker database which covers recalls for medical devices and potential reasons for them. We looked at

the National Library of Medicine PubMed database. And we looked at ECRI Institute's confidential contracted investigations that we've been performing. But we did limit all of this to the last ten years.

The data that are in the reports include third parties, OEMs and the hospital as well.

MS. FEDERICI: I don't know if you are aware but FDA just recently released a report saying 90% of facilities aren't reporting --

MS. SCOTT: Can you move a little bit closer to the microphone so those who are online --

MS. FEDERICI: I'm just curious if you are aware that FDA just released a report stating that 90% of facilities aren't reporting appropriately.

MR. BRULEY: Did everyone hear the question about the FDA's recently released report suggesting that 90% of healthcare facilities are not reporting to the MDR MedWatch MAUDE system. I'm familiar with the MedWatch system. I changed the reporting law in 1998 because had certain provisions in the original legislation not been included the system would be dead because FDA was going to be publishing hospital's

names on the internet in regard to all the MAUDE reports and that wasn't the intent of the original legislation.

Subsequent to the MDR 1990 regulations there was a development of the MedSun program. Are you familiar with MedSun? Yeah. Which is a more focused program, gives more feedback to the hospitals based on the reports that they submit, similar to the NEISS, National Electronic Injury Surveillance System that CPSC (Consumer Product Safety Comission) runs for consumer products. And so they are looking at a group of hospitals that are more tied in to the concept of reporting medical technology related failures with capital equipment as well as with single use and disposable products including reprocessed products.

As far as the issues of underreporting let's look at that for a minute. If a manufacturer has any inkling that an adverse event that has come in through the MedWatch system or the MAUDE MDR system if there is any inkling that the problem was related to inadequate servicing by the hospital itself or a third party or a faulty third party repair part it is in

their interest and they have every incentive to state so in their comments in the MAUDE report. It is to their best interest to deflect attention to them in their design and marketing of that product. So I don't see that there from a standpoint of manufacturers underreporting that they are underreporting in that regard.

In addition it was mentioned earlier today and sort of glossed over that there is supposed to be routine analysis of the manufacturer's service records by the manufacturer themselves. Well, if that is being done and if the analysis is properly assessing whether a need for service related to a problematic servicing could have caused or contributed to a patient injury or death then why are they not reporting it themselves; they can do so voluntarily. They do not have to have report initially coming from the hospital in order to report to the FDA MAUDE system.

So unless there is someone else out there that has done a lot of data searching I don't know of any other database that is available with data yet

that can be compared and contrasted to the work that ECRI Institute did this year and what I did 19 years ago for the previous conference on this.

MS. FEDERICI: Well, I invite my colleagues to comment. Part of the challenge is if OEMS are not getting those reports --

MR. BRULEY: Can you speak up for the microphone.

MS. FEDERICI: I invite my colleagues to comment. Part of the challenge is OEMs aren't getting those reports either.

MR. BRULEY: My comment was about the service records that they have in their own system that can be another source of data.

MS. SCOTT: And I think Scot wanted to -- I'm sorry, we'll let Hans go and then Scot you had a comment as relates to the last question.

MR. BEINKE: Yeah, I would agree with that. We are analyzing our service reports. The issue is when we're now out of the service picture and we don't have visibility to that. So the report that you've done honestly I haven't gone through it to look at the

methodology. I'm hard pressed to believe it includes all events. And I will also go on to point out that industry is not interested only in things that lead to harm and injury. We are interested in other MDRs, we are interested in trending. And unless we have links to all this information we can't do what we are required to do. And it is not just what we are required to do; it is the bottom line of what that leads to which we've all agreed on which is the safety to the patient.

MR. MACKEIL: You know speaking from the level of the workbench I've been a biomed for a long time and I know a lot of biomeds. And when it comes to getting involved with things like the safety reporting system in the hospital knowing what the MAUDE database even is, knowing that the Safe Medical Device Act even exists you know for a lot of biomeds that are working today it is so far down on their list of concerns and priorities because you are really working hard to keep up to get to the next service call to take care of the next piece of business. The demands are absolutely incredible. And I've been

online looking at the MAUDE reporting system and it is not the easiest thing in the world to do.

In the hospital we have all this mandatory education that we have to do, blood borne pathogens, fire safety, all this other stuff. It is amazing what you have to do to meet your annual education quota and then you start getting the nasty-grams. You haven't filled out your health stream documentation.

If we really want to get this data from the workbench up to this level I would suggest we have to do more education that penetrates much deeper to the level that I work at and maybe come up with an easier to use system that looks more like a work order that biomeds are more familiar with. I hate to say it but I could do a much better job reporting on things that I see and I know about the MAUDE database and where it is. But a lot of biomeds just aren't there and if you really want to improve this reporting I would suggest that the FDA go there and start working with biomeds and raising awareness of this. I don't know of a hardworking biomedical engineer that if you explain the necessity and the reasons that they wouldn't

become diligent about doing this type of thing.

So that is the comment that I would put forth. And if anyone has anything else to say on that line I'd be interested in hearing it.

MS. GEORGE: I was going to actually continue in this topic so if I could interject because I do like your idea of what you are saying. I'm Elizabeth George with Philips.

One of the things that I am just curious about from not from the OEMs because I know their answers but as an OEM one of the things we have obviously we have our MAUDE reports but that is a really tiny, tiny, tiny, tiny bit of information that we have as a manufacturer. We have all of our service reports which talks about installation, which includes all those issues that you talked about when we screw up when we install it; it includes all the parts that we replace. We do trending on that. Every time a hospital calls us and says this doesn't work we have a complaint we have reams and reams and reams and reams of data on our own products. And only a miniscule amount of those go to the FDA as a MAUDE report. But

when the FDA comes in and looks at us the first thing they do is pull that data and they ask have you been trending it. And 90 -- I'm probably off, at least 75% of our recalls if not more have nothing to do with a MAUDE report; they are a trended issue for a failure.

So the question I actually have for you guys is just what you are saying is how can we get that data of all the wonderful service activities, the fabulous highly qualified service people are doing work but we don't know that you are replacing parts because you may be buying them from us or from somebody else. We don't know that you've serviced that part. And that data you only have a slice of the data on that product. We have all of the places that you are not working on and that might be the amount of data that could tip us to fix or improve the quality of our product sooner.

So I am just curious as to what your thoughts are on how keep the FDA out of it, they don't need to get all that data, they don't want all that data. They get enough data as it is. The manufacturers would like to have that data to help

improve the quality of the product, make the issues better, maybe help you guys service it better.

DR. HEMPHILL: I have a simple thought but I'm an ER doctor so we try to keep things very simple. So something that we've tried to do is we are really trying to understand how you help people report, report anything. And so to the point made by Scot is if the reporting system is hidden and you can't get to it, you are not going to get reports. And if it is hard to use because its 30 pages long you are not going to -- people just say never mind.

So we try to have an entry system into reporting for the VA that is based on a couple of pretty simple concepts. One is is it an adverse event. But we also do near miss. So we are really trying to redo people's thinking so you say you know dodged a bullet or wow, better lucky than good, which is a mantra we have. You start saying that was a near miss, not just wow we got away with it, that is a near miss. And the next question then is to prime people to say was this related to a device you were using and if so, check the box. So simple form to enter, easy

to get to, check the box it might have been related to what you were using and now you already have the ability to say okay let's go dig deeper.

Now do we share that with -- I mean if we find enough concern then yes we put those into our MAUDE MedSun and other databases so that it can get up and then we engage very quickly with the FDA to say are you seeing this, what are you seeing and try to help us with this.

I don't have a great model for engaging with the industry itself because the more you fracture your time you really, there is just so much to be looking at with each day. But again I think that if we have ways to think about sharing that information certainly we can share some with what we send to the FDA. We will bring in manufacturers when we are really concerned and try to begin that conversation early because we do have an awfully big system to look at to try to help figure out trends early on.

MR. BRULEY: This is Mark Bruley again. To Scot's point about the process of reporting they do have to differentiate that from a patient safety

standpoint certainly almost all adverse events may have some aspect of risk to patients as it relates to cause or contributed to specific injury or the potential for an injury. But to the reporting issue biomeds would have to go through and should be going through the risk management departments at the hospitals. And they work in collaboration with risk managers and those haven't really been mentioned here yet. The role of risk manager in reporting to the FDA, that is where most of the reports come from from the field itself. The injuries and deaths are separate from malfunctions. Now malfunction may well be related to improper service as we've seen with perhaps some of the anecdotes here. But if you are talking more about patient safety you are really looking at the injuries and deaths. And although we looked at all issues as it is pointed out in our submitted comments to the FDA and our strategies for doing that. But from a process standpoint the biomeds typically do have to collaborate with risk managers to get the reports to FDA whether it is with the MedSun hospitals for which I think there are 316 hospitals

that are bought into that system or it is with the rest of the healthcare institutions across the country. So if you are talking about potentially educating on better reporting you need to include risk managers.

MS. SOCTT: We are going to take one more question from the floor, then I have a question from online and then we will jump back to the floor again.

MR. LIPSCHULTZ: So I submitted this question via an email, then I realized you were going to do it on a microphone so you may be able to pull that one out of the queue if that's where it is.

MS. SCOTT: Okay.

MR. LIPSCHULTZ: This question is primarily for the manufacturers.

MS. SCOTT: Could you state your name and affiliation. I'm sorry.

MR. LIPSCHULTZ: Oh, I'm sorry. Alan Lipschultz, President of Health Care Technology Consulting and I come primarily from a clinical engineering background. So this is really aimed at the manufacturers particularly looking at those

products for which there is not a complete service manual that is available to third party servicers. And the issue is that when you become aware, actually it applies to all manufacturer when you become aware of parts that third party servicers are replacing in the field with non-manufacturer parts that is causing a problem A or B but they are doing activities that you didn't recommend or maybe because there is a lack of information in the field and that users are doing and that you are seeing is causing a problem with your devices then you have a residual risk that should play into your risk management strategy. And if there is a residual risk then you should have some sort of strategy to mitigate that risk. And I'm questioning whether or not there is a way -- any reason why you then couldn't issue a service advisory or safety advisory not aimed at clinicians but aimed at the people who are the root of the problem, namely you have third party servicers that gives them information in terms that we are aware that a particular part is being replaced by and some of these are available if you look at the advertisements you can see which

companies are advertising parts to replace yours, my point is if the people who are doing the service in the field are aware of the risk involved with it then they may think twice about it and that is a way for manufacturers to mitigate the risk.

Second comment/question regarding making it easy to report problems in general. The only way from -- that I see to do that is to start talking about standards in terms of how we code problems as third party servicers. It is coded in a standardized manner and have data interchange protocols to be able to say that this is something that should be reported to the manufacturer, let's shoot it off, we had a service event so that the right information goes automatically to the manufacturer and you don't have to start then retyping it all into a whole separate form. And these protocols can be set up in advance; work through the risk management department it is not being worked exactly how you'd do it but you can make it automatic and it is a lot easier to make it work.

MS. SCOTT: Go ahead. Scot.

MR. MACKEIL: You know that is an excellent

point when you talked about coding and standards. You know if we are trying to identify, track and trend service error events I could see where that would go but how would we turn that into a way to educate my colleagues about how to recognize what is a service error event and what level of service error event is reportable. It is a very large broad topic but if it was properly defined and standardized I know I could do it. And I do think it is an important thing because we recognize and code different types of reports now. But you know service errors that one needs some work.

MS. SCOTT: Did any of our panelists want to tackle the first part of our participant's question.

MR. BEINKE: The question about the advisories I think is what -- is that what you are referring to?

MS. SCOTT: Yes.

MR. BEINKE: I mean I think we would be hesitant and I'm speaking for my company to send out a general advisory for kind of an incident over here or an incident over here. I think that would create a

lot of confusion and suggest a general problem. So our issues are more one offs and how to communicate on that specific issue. I think we do, you're right, have an issue of needing to communicate the problem that goes with some of these unapproved parts or improperly validated parts. But in terms of an advisory I think generally that probably doesn't make sense unless we see that there is a general trend to use X instead of Y.

MS. SCOTT: Okay. Anyone else from our panel who would like to address that question; the last question?

Okay. I'm going to jump to a question from online.

We have Tom Quinn who is the President of MRA and his question starts out with the MITA representative and some OEMs are reporting safety issues involving ISOs. His question is did these OEMs or MITA file a 3500, a radiation overdose form, a trade complaint or any notification of these safety issues which are of such importance in this workshop? If not, why?

MR. BEINKE: I mean again that's a very general question and I think it depends on the specific situation. Again speaking for my company when we have some of these events I would not say generally but we have filed trade complaints when we think that it is significant enough or we have communicated with the so-called offenders.

I don't know if anybody else from industry wants to comment.

MR. BRULEY: I'm not from industry but the question ties into the comment I had that there is nothing keeping manufacturers from based on their own analysis separately reporting service related errors to the FDA via MAUDE or any of the other avenues.

MS. SCOTT: Okay. I did see some people standing in the back of the room so I'm going to jump to our back microphone.

MS. KAY: My name is Janet Kay (ph) and I work for Intrega Life Sciences and we would be considered an OEM in this conversation. So for the ISOs we've actually had some great engagement with ISOs ourselves with my company and we think they do

provide a great service. We do struggle a little bit with the things we're talking about training, using validated parts, we like you guys to use parts that we use in our products as we validate with. So for those gentlemen that are on the board or on the panel that are from the ISOs what are your thoughts about quality agreements; you working with the OEMs to develop a kind of agreement with that OEM so one we know who you are, we know what products you are working on that are outs and then we could work towards agreements about how you get trained, recertification on your training and that you are using validated parts. Your thoughts on that?

MR. ANBARI: So I mentioned in the stakeholder presentation that I did that we have approached over our 40 years of business virtually every major manufacturer of instrumentation and devices in the marketplace to try and establish some form of a partnership. In some cases that has resulted in our ability to buy parts directly from them. In 99% of the cases it's resulted in no, that is too much of a direct threat to our commercial

interests, we need to maintain our devices because that's what we do. We have piloted very strong strategic partnerships on very complex devices with manufacturers where we essentially said because your market share Mr. Manufacturer is so low when we have our customers come to us out of convenience and out of availability because we are there in the hospital everyday and bring us one of your devices we would like to be able to send that to you directly. We are happy to pay whatever price you tell us we need to pay and we're going to handle it as a pass through with our customers. And the reason that we wanted to do that was because of the convenience and the overall relationship with the healthcare provider facility. Unfortunately within 90 days of establishing relationships like that they end up going wrong and it is largely because of sales and commercial interests on the part of the manufacturers.

I will tell you any manufacturer that would like to work with us to establish that type of relationship we are more than happy to have those conversations and by no means certainly should those

be considered to be exclusivity. And that is not a sales pitch, that is simply saying our industry as a whole speaking at least for the surgical device repair companies I think we are all wide open to finding ways to work with manufacturers and some of us; to be fair about it a number of my competitors do have some good relationships. We just haven't been able to get one that has lasted.

MS. KAY: Do you have a comment, sir?

MR. MOOREY: Actually I do. I've been in this industry for a long time, worked for some of the larger Independent Service Organizations. I can tell you these are already happening; they've been happening for my entire career. It is in our best interest to seek out those people that are going to have the biggest impact on our customers and find ways to work collaboratively. And I can tell you we have some very strategic partnerships where the OEM is actually sitting at the table as part of my team in some of these discussions. So that is where we are in healthcare today. We have to have those types of relationships; it can't be us or them. Many of the

OEMs are realizing that they need us and part of their strategy for service is by utilizing our local service, our local talent. So I'll tell you there's already in place, we are already working through that.

MS. KAY: That's great. May I have a follow-up?

MS. SCOTT: Yes, go ahead.

MS. KAY: So then if that is true for the biomeds are you guys doing anything on the hospital side then to ensure that when --

MS. SCOTT: I'm going to ask that you speak into the microphone though so people online can hear you. Thank you.

MS. KAY: I apologize. So is at the hospital side though with biomed then are you doing anything on your side as these ISOs are coming into your hospital because you know people are coming and going in hospitals all the time. Are you aware of who is touching equipment and that person that is touching that equipment is truly certified to touch that equipment?

MR. MACKEIL: So one of the interesting

duties that I perform are what I call vendor support and escort calls. And it is a pretty common thing and it is usually originated because I've had a service call encounter with a caregiver on a piece of technology and we've decided that the solution to this problem is to bring in the manufacturer to repair the device. So I've already talked to that rep on the phone. It is usually somebody that I know very well and have had a long standing relationship with, someone like Dave Young from Philips who takes care of my IE 33s, the hardest work in biomed in the world by the way and Dave shows up, I get him into scrubs, we bring him to the cardiac OR and we deal with this problem. And I may have to go off and do a couple of other things but when he calls me and says Scott, it is all set, all right, Dave, I'll meet you back there, you can run me through it and I'll sign your service order. So after I sign his service order I have to go close the work order that I opened to call him on and I'll type in a description of what Dave did.

So we are very closely monitoring what our third parties and manufacturers and ISOs are doing.

But I treat them equally regardless of what badge they are wearing. I work with them. I make sure that they are doing what they are supposed to do. I support them. I get them stuff. You know I get them in, I get them out. I help them with parking. In some cases just the other day one of my C elements went down because the pendant broke and the pain management doctors were frantic because they need this C element. I called up my rep and I said I've got a broken pendant, I know we are under contract. He drove by the hospital with a pendant. I ran out and grabbed it. And he talked me through it on the phone how to install it and we did the whole work order and paperwork trail, so yes, we are really watching what is going on and making sure that the right things happen and all the documentation is done. I mean that is something that is common in my workday.

Does that answer your question?

MS. KAY: It does. Thank you very much. Thank you.

MS. SCOTT: Wanda, do you have a response.

MS. LEGATE: Can I just touch on the first

part of her question about the quality metric with ISOs and things like that. You know we're from the parts industry. So but I can tell you that we have high quality metrics with our customers. They are requiring that of us. So for example if we go into an agreement with a customer, one of the first things they ask for what is going to be your DOA (dead on arrival) rate. I think the biggest thing as I've listened to all of this is around the ISO you'd be surprised how many independent companies are going through ISO certification or have already been there. And so when you talk about the CAPAs and things like that, we are already doing those things. So I think we are a lot further along than I think maybe the FDA realizes and maybe some of the OEMs realizes. But at the end of the day we do have those metrics or we wouldn't be in business.

MS. SCOTT: Okay.

MR. BEINKE: Can I ask a question?

Yeah, I have no doubt that you are far along and many of you are. The question I was more interested in is the upfront part, not the monitoring

part and watching what is taking place and make sure that it is appropriate, but you know in industry we refer to it as supplier controls. So you pick an ISO and what is the process for qualifying that ISO. So you can have a certification. I mean a lot of times people talk about oh, I'm ISO certified but that doesn't necessarily mean that they have the specifics for the service or the product that they are providing so I'm just curious as to how you go about supplier controls, the ISO being the supplier to the hospital.

MS. LEGATE: Well, for us being a supplier to hospitals, most of the hospitals have their own quality management system. We have to pass those requirements just like we do with OEMs. So we currently do business with several of the OEMs and we went through their quality process, we are actually going through stage two of our ISO now. We are still a young company. I have been in this business for over 25 years. The previous company that I worked for we've been 13485, ISO 9001 so I think all of that is mandated by our customers which are the ISOs that are going through quality. But also the OEMs; we do a lot

of business with OEMs.

MR. BEINKE: So they would provide documentation that they have training for this product, that product and the next product?

MS. LEGATE: Absolutely. Again I'm just on the parts side of the business. I'm not on the service.

MR. BEINKE: Yeah.

MR. MOOREY: I'll add to that. I'll say hospitals are already required to ascertain the competency of people doing work in their facilities. That is part of requirement for regulatory accreditation. So they are already going through that process. In my particular case my company and some of my competitors sitting in the audience today we sit in the place of our customers. So instead of them having somebody do that we take on that responsibility and we absolutely have the responsibility to ensure that folks we are using meet those requirements within that hospital so that they can receive their accreditation.

MS. SCOTT: Any other comments from the panel? Scot?

MR. MACKEIL: Yes, you know the qualifications of vendors is something that takes place at a little higher level than where I sit but I know we do have extensive controls we use the Vendor Mate Process, everybody has to be vetted. And at my particular level when I go on a vendor escort and support call the relationship between the company and myself has already been well established. But I know that there are significant controls in place at the administrative level. And it is pretty rigorous where I work. We just don't let anyone in the door. But the relationships we do have with both manufacturers and third parties are absolutely essential to what we do and we really definitely need to make that better.

MS. SCOTT: Okay. We are going to move back to our audience for another question.

MR. LESLIE: I'm Mike Leslie. I'm Vice President of Regulatory Compliance and Quality for Roche Diagnostics here in the U.S. And as I've listened to the first panel discussion this morning and then this panel this afternoon I've heard about

four things that I think are very kind of repetitive. And so first thing a lot of good dialogue and I have not heard a single thing that I've really disagreed with from an opinion standpoint so that's good.

One of the things though that I keep hearing is an issue around competitive advantage or disadvantage with the OEMs and the ISOs. Another one is associated with cost. Another one then is around the data that would justify change. And then the last one is everybody is agreeing that patient safety is number one.

So I guess as I look at the purpose of being here today and what we're trying to accomplish the first one around competitive advantage or disadvantage really the FDA had no oversight and really very, very little care into the competitive landscape that is out in the marketplace. So to me it is kind of not worth talking about any further.

The second thing when I look at the cost we are absolutely right. This is the medical device industry. You know we are not manufacturing bottle caps, picture frames, bicycles; this is an expensive

industry. People rely on these devices to sustain or to help them live healthy lives. And because of that there is going to be cost associated with it. The FDA exists for a reason. That oversight is there for a reason to protect public health. And that is not cheap for anybody to do.

The last one then around issues with saying to .005% or whatever and that OEMs do well, the ISOs do well, then I'm -- my next question is do we regulate everything. So why not all post-market support? Why are we doing anything if everybody does everything okay now? Which the FDA, of course, is not going to agree with.

So my point to this is that if we are really doing that good as an ISO provider or from an OEM provider I don't understand what the issues are of being registered with the FDA, having a compliant quality system, following the QSRs, all the reporting accountabilities that are there so that we can all ensure patient safety. That's what we are here to talk about.

And the competitive landscape, the dollars,

all of that, yeah, that is true but that is not the focus. The focus is patient safety. The FDA holds the OEM manufacturer accountable for that device no matter who works on it. So our ability to know where that device is, what's happened to it, any spare parts, any issues, the FDA doesn't look the other way and say oh, well, hey, an ISO was taking care of that instrument, well, you don't have to worry about it anymore. ISOs play a very vital role in the healthcare of the United States. For the smaller medical device manufacturers, there was an example earlier where you don't have the resources; you do have to partner with an ISO organization. But the FDA doesn't say okay, well, you know what since they're providing that service you are off the hook for MDR reporting, you are off the hook for trending parts and complaint investigation and corrections and removals because this other company does it; that is not the case and it never will be the case. So everybody playing by the same rules so that we can make the overall health system better and compliant and help us generate more input into better designs and more

technology is what we should all be here for.

So I don't understand what the issue is of having a compliant quality system in your organization, being registered with the FDA and being open to the same audits and same scrutiny as everybody else. I don't know why we are stuck on that. And if you could help answer that I would appreciate it.

MR. ANBARI: Yeah, I mean look I think as a practical matter if you are going to impose oversight and you are going to impose rules that are the same rules that apply to a manufacturer you also have to level the playing field with respect to the technology that is available to Independent Service Organizations to deliver the service. And if that means making parts available, documentation available, reporting available to the third party in addition to the third party making reporting available to the OEM; it is all helpful. And it is one way that this could be approached.

But the bottom line is that without -- when you impose the oversight without also addressing the structural changes that effect the level of

competitiveness and competition that is in the market hospitals will spend more for, in their total cost of ownership, for equipment. It will cost them more to repair it. They will be driven to replace it more regularly as they reduce preventative maintenance on a regular basis. And frankly they are going to be forced in, we've seen it time and time again, they get forced into upgrades of perfectly good equipment because a manufacturer has decided we've moved on to the next generation now, we think it is better, and we are telling you Mr. GI doctor you'll be able to find polyps better because they are high definition. I mean that is the practical reality of how the competition comes into play. And oversight and regulation will have a cost. And I think that is really what the fundamental question is is we're balancing those costs and those benefits.

MR. LESLIE: But again the competitive piece FDA doesn't have jurisdiction.

MR. ANBARI: They have to have.

MR. LESLIE: They don't have jurisdiction over that.

MR. ANBARI: No, the point is if you look at --

MR. LESLIE: I don't disagree with what you are saying; so fine the ISO then you are going to maintain this piece of equipment for the next ten years that the manufacturer is not responsible for or is no longer supporting. How is that not still subject to post market review and MDR reporting, any corrections, anything else associated with that instrument. That is what we are talking about. That is what we are talking about the regulations covering, making sure that all of that data continues to flow into both industry and into the Agency.

MR. ANBARI: Yeah, I mean changing reporting requirements and saying you should report whatever the event is or whatever it might be, that is one of those potential outcomes from this process. And I think that is part of what people are exploring.

MR. BEINKE: Can I make a comment on this regulatory oversight. We've said it I don't know how many times today but we haven't really said what that means. I think the FDA has some flexibility in terms

of what that looks like. There are various costs for registration. FDA looks at risk base and determines what their inspection schedule is going to be. So if you are making pacemakers it is one thing, maybe if you are service providers it is something else. So I find it a little bit difficult to understand this fear of the unknown. I mean it has not been defined and so I'm not sure at this point what that cost implication would actually be and I think -- I guess I have some trust in FDA that they are going to hear all of this and look at it and gauge what level is appropriate.

MR. MOOREY: Well, I'd like to add I'm not sure where this perception comes that we are not already regulated. I mean if you look at the healthcare industry as a total I mean we have every three years an inspection agency is coming in to certify the hospital and the program that is being run. In that is a flurry of policies and procedures that we need to measure up to to show data that we are complying to those things. We have the same requirements if we are replacing a tube we have to fill out the same paperwork, if it is a major imaging

repair there is a physicist coming behind us just like they do at the OEM to certify that device meets that. There already is regulations. CMS is providing guides, the state departments of health already providing regulation. What you are talking about is additional regulation. And the question is why? Where is the data that shows that this is required?

MS. SCOTT: I'm going to jump in here. We are going to get into more of the discussion related to challenges as it relates to this overall issue on day two in some of our other panel discussions. So I do want to encourage us to refocus our questions now in terms of the particular focus for this particular panel discussion which are the benefits and risks associated with refurbishing, reconditioning, rebuilding, remarketing and remanufacturing and servicing activities. So if we could refocus the discussion to really focus in on the benefits and risks at this point.

We will take two more questions and then we are probably going to need to wrap up our session.

MR. GRIMES: Hi, my name is Steve Grimes. I

am the principle consultant for Strategic Health Care Technology Associates in the Boston area. And I've been in this industry, clinical engineer for over 40 years now working either with probably about 20 years Independent Service Organizations another ten years working as a clinical engineer director of academic health centers and also was probably another ten years as a consultant. So I've had fairly extensive experience on the supplier and the advising side. I'm also involved in the AAMI standards group that Mary Logan was referencing earlier that does equipment management standards or establishes equipment management standards. So one of the things we are looking at coming up is the acquisition of medical technology.

Couple of things that I just wanted to point out is with respect to the benefits and the risks one of the things I think is very important from the standpoint of those of us who were involved as healthcare technology managers running the programs that manage the technology in hospitals and when I talk about managing the technology, it is not --

servicing is certainly a part of it but we are also involved in the acquisition and the training and the ultimate disposal of the technology. When it comes to service it is important for me to be able to have access to a wide variety of tools in terms of resources, the manufacturer service, Independent Service Organizations, in-house staff and I apply those based on what I think the particular problem or the particular issue warrants; what type of risk is involved and what type of resources are appropriate to apply to it.

One of the concerns I do have is I certainly have seen that there have been regulations not put forward fortunately by the FDA but other government agencies have established regulations often without having looked at the evidence to demonstrate that there was in fact a problem that needed to be solved. And as a consequence one of the challenges we face is that we are having to apply resources that we could otherwise use to address the real problems in our industry, solving real issues, you know making the environment safer to meet regulations which frankly

often there's no real merit in addressing those regulations. There is no evidence that again they are really solving a problem. It is one of the challenges.

And then just the other point that I originally wanted to make is that there are -- I'm not sure how familiar on the OEM side they are with respect to the kind of documentation that we maintain. All hospitals are required to maintain an inventory of all of the medical equipment in their organizations and the service on that medical equipment and in that we include what parts are used on each piece of equipment, the nature of the service and often code the equipment as to what the nature of the service was. Was it a maintenance related issue; was it a user related or process related problem; was it a spontaneous failure? Again the idea being each of those problems has a different type of mitigation. If it is a maintenance related problem then we change the way we were doing maintenance or who is performing the maintenance. If it is a use related problem then it may involve some additional training. But these

systems, these documentation systems do exist in each institution. And there are perhaps venues that we could look at in sharing this information. It certainly would be beneficial I'm sure for the manufacturers to have access to the kind of information, the data that we collect. And I know from my standpoint it would be useful for us to have access to the information that manufacturers have in terms of the service and reliability of their equipment.

There are forums, PEMI has a, it was mentioned earlier a supportability work group or task force where manufacturers and members of the healthcare provider community work together to talk about how to effectively exchange information and provide support of the technology that it out there. And also the equipment management company that I was referring to that is a part of the standards group would be another example of another area that we perhaps could talk about how do we come up with ways of standardizing this information in a way that it can be conveyed to manufacturers in ways that it would be

useful to them but also perhaps make use of information manufacturers would be willing to provide us.

So that was my comment. Thank you very much.

MS. SCOTT: Any comment from the panel?

Okay. We'll have one more question from the floor in here. And I believe we also have another question -- if there is anyone else online who has additional questions please feel free to email those questions to the email address that is posted online. And we will take one more question from the floor and if there are any other questions from those online please feel free to email that question.

MR. RIDGWAY: Thank you. My name is Malcolm Ridgway. I've been around for a while. I see an opportunity to come together here. Just very quickly not every piece of equipment if it is not working properly and safely can injure a patient. So for those items that have the potential to injure a patient if they are not working properly and safely what we can come together on is defining how to test

that it is, in fact, working properly and safely and then everyone who signs off after maintaining the equipment for its scheduled maintenance or whether it is repair will certify to the user this equipment is working properly and safely according to the proscribe procedure that we come together and put out there. I think this will work. There is a complicated way of doing that called failure modes and effects analysis. But cut right through that there is a way of defining a subset of equipment, call it critical equipment or whatever you will and let's have an agreed set of procedures on how you establish the safety and performance effectiveness of that device and use that as a test that the equipment is left the way it should be for the user. And I would suggest that whether you use manufacturer part or another part the proof test that's a good part is whether or not you can bring the equipment to the point where it is working properly and safely.

And I think that is something both sides of the house could get together and work on that.

Thank you.

MS. SCOTT: Scot?

MR. MACKEIL: So Mr. Ridgway really hit the nail on the head here. One of the things that I do in my job is every day I have to face a doctor or a nurse or a team leader and bring to them a piece of equipment that's been in my lab at my workbench and say Janice, it is all set. And she'll say in her British accent, well thank you luv. Janice is one of the toughest nurses in the world and she is a very hard clinician to make happy. But that is part of my job; that is what I do.

As a biomed I really depend on the manufacturers providing me the documentation, the test procedures. And one of the tough things is some of these procedures aren't really that black and white, they are difficult to follow on the workbench. I have a certain set of industry standard test equipment and I'm going to bring a piece of equipment out of my bag here as an example just for fun if I can find it. So this is a little test cable and I built this as a result of reading a service manual and in the service manual the manufacturer literally described how to

build out of electronic components what most of us know as an electrosurgical analyzer. It was written like they didn't have a clue that biomeds didn't have electrosurgical analyzers out in the world. And another piece in this bag this is brilliant, this came from J&J and it allows me to plug into the front of their harmonic scalpel, connect my electrosurgical analyzer go through the settings and see quantified values throughout the range of that device's function. So when I go back to Janice and I say Janice your harmonica scalpel is all set, you know I tested it and I'm going to put it back in OR 34 for you I know that because of the really excellent procedure that was written on that manual it is laid out step by step and this device, this little dongle allows me to perfectly quantify the function of that device before I return it. You know this is an example of the way it should be. And from my world at the workbench I want to bring perfectly functioning and safe devices back to my caregivers. That is my job; that is what I do.

MR. RIDGWAY: And to dream a little bit if it was really a critical device like an MRI wouldn't

it have been nice if it was built in and there was an idiot light at the front of the MRI that says if this light is green; it is working as it should. I don't think I'll live to see that day but I think that is what we should move towards.

Thank you.

MS. SCOTT: I do want to mention that we had one question received online that was really focused more toward again ISO regulation and so we are going to save that question for later. We have documented it but we are going to save it for the later discussions.

And I did want to ask one more question that we had and I think it is a good question and I'd like to ask at least one representative from an OEM, one representative from the hospital, end users and engineers, and one representative from the ISOs to give your feedback related to this question.

How do you approach risk mitigation and how can servicers and OEMs work together to mitigate risk?

MR. BAIRD: Could you repeat the first question because it sounds really big.

MS. SCOTT: How do you approach risk mitigation and I guess from an OEM's perspective how in general do you approach risk mitigation if we put it in the framework of this workshop in terms of repair and refurbishing and risk association with this whole general issue. Does that help?

MR. MOOREY: I'd be happy to jump in there from the ISO perspective. So I'll speak from my experience. We have a quality department whose job is to do nothing but review the data and look at trends. When we have those trends, we see alarming trends we do deep dives and we develop CAPAs against those as an organization to make sure we address those.

From a vendor side we have a whole department that does nothing but quality vendor analysis. They do site surveys; they do analysis of them to make sure that the parts are coming in. They look at the data to see if we have higher failure rates; those type of things. And they are engaging with our suppliers to make sure they are supplying us the type of parts, the quality of parts, the timeliness of parts that we need in order to support

our customers.

And then ultimately like I said we are surveyed every three years at each of our sites from a regulatory perspective to assess our total program effectiveness. I can tell you, all of my competitors will tell you this we meet on a regular basis, if not weekly, certainly on a monthly, quarterly and annual basis to review our program and provide them with metrics so they have the data to assess are we doing what we say we do. And if we are not, then we work together to create those correction plans to address those.

DR. HEMPHILL: So I can try a little bit on that one because it is a big issue. We're trying to and whether it is devices or other things we're trying to think you know what do high reliability organizations do and in part it is measures that matter and things that you can look at that are supposed to be those kind of early warning systems. I mean we would have said that today's problems are yesterday's unmanaged risks. So yet through all the noise how do you figure out what's really truly a risk

that you should be trying to do. I think we would look at this from a couple of different ways. In terms of equipment that we have in our systems that we've been using for a while we really are trying to get the human intelligence system because sometimes we think by the time it's an obvious trend it is actually already a big issue, is to really give them easy ways to say this just doesn't feel right, it doesn't seem right and allow them the ability to report through those systems so that we can try to do a deeper dive on equipment. And so that would really be for anything in the system. Are you feeling like this isn't working quite right? And then if we see that -- and is it happening there, then could it be happening everywhere. Where else do we have those pieces of equipment?

But in terms of what we really would like to think of in terms of bringing equipment into our system that's where we really want to try and say to a manufacturer what are you seeing in your own systems already. I mean everything that you design most people feel like they've made some tradeoffs in design

and feature. Where do you worry about some of the things that don't work quite as or where you've seen a few vulnerabilities. We understand that it is very difficult to make a perfect device, a perfect piece of equipment. And again getting back to what I said before and assuming that that piece of equipment is going to seamlessly weave into what is an almost infinite number of systems, people, and just sort of processes. But if we know some of your areas of vulnerability and if we can sort of also try limits of use testing in some cases we are better prepared for the things that we know aren't perfect about these systems that you are designing already. And so we think of this under a broad heading of purchasing for safety which is how do we work with many of you to figure out your systems, what you know about them, what you don't know about them, test them a little bit in advance but then also create those early systems to get word back to you about what's working or not working well for us. Easy to say, very hard to do. But again you want a green light on an MRI. I would never trust the light.

[Laughter.]

I'd be like is the light working. And so it still gets back to that but what you said was right. I mean how can we create a better awareness of what right looks like whether or not I'm bringing it in to begin with or whether or not it is in that life cycle of use and re-use. And that has to be kind of a transparent system of this is what right looks like. And this is how you would know a year from now that it still is what right looks like. So that I know it is going south, I can get somebody in the moment, my biomedical engineer to help me figure out how it is going south, bring in manufacturers to also help us figure this out. But certainly for the point that we are also using other companies to help us with some of our refurbishing, reprocessing they need to know what a right looks like as well so that we all have a shared mental model of this machine is working as designed.

MR. BEINKE: I mean I like much of what Rob and Robin said. I mean especially what Rob said it sounds like what we do as manufacturers. You know we

have a systematic approach to evaluating the data that we have and we have a feedback loop and it forces us to analyze and react to that. This is a key point to exactly what we're as OEMs trying to point out. If we are missing segment of data then we can't appropriately do that. We can't do the mitigations that you ask about. So for us it is incredibly important that we get all of the information so that we can have that feedback loop and do the mitigations as necessary.

MR. ANBARI: And similarly from an independent service repair organization we take a true enterprise approach to how we manage risk and mitigate risk I should say. For us it is less about detection and it is more about prevention. And it reflects the way that we handle our sourcing; it reflects the way that we handle our staffing and training of our technicians, it reflects the way that we handle our repair process with interim quality control checks and the quality control technologies that we use and it reflects the way frankly that we even return the device back to the hospital knowing that sometimes

shippers aren't the most gentle of all creatures. But we really look at the risks across the entire spectrum of our services and have mitigation programs that we put in place that are appropriate to that very stage whether it is sourcing and how we select suppliers, how we ensure that materials are the same as what a manufacturer used, or in many case from a sourcing standpoint trying to identify the same sources that were used by a manufacturer.

So in some cases that works. In other cases it doesn't. But regardless it is about that enterprise level strategy that we take from top to bottom.

MS. IYER: I'd like to make a comment. So I've had an interesting experience being on the research side of medical device development and now being with an OEM I work very closely with those who perform the research and the engineering behind it. And so sometimes when the device is very early in concept you sometimes lose sight of what the ultimate fate of that device will be. But we as the OEM we carry that with us throughout the life cycle of that

device no matter who touches that device. And during this panel today I hear themes about what is the intended use of the device, what are potential errors and use errors, risk mitigation, risk management strategies; these are all things that we have to take into consideration before we can market a device. There are already formal mechanisms in place. And I think ultimately what we need to do is work together to leverage the mechanisms we already have in place keeping in mind that the ultimate goal that all of us share is patient safety.

Thank you.

MS. SCOTT: And Mark.

MR. LEAHEY: And just a final point. And again I think to touch on what Hans said is just having that complete service record of knowing every hand that touches the product so we can make sure that it all feeds into the same quality system. And maybe David you just said you are more focused on prospective I guess but I think at the outset you talked about a file cabinet of OEMs of poor service. I just would like to ask when you have that file

cabinet do you provide that information back to the OEM or does the hospital report that? Has that file cabinet been reported and if so, who gets that information?

MR. ANBARI: We routinely provide when we find inappropriate repairs we routinely provide those photos back to our customers. And we don't always, like the manufacturers we don't always know the service history because customers are fickle and they tend to move from service provider to service provider at times. We know our history with it and we have that visibility and we can certainly provide them insights. But we use those images for two purposes. One, we do provide it back to the customer so that to the extent that they've had someone else working on the equipment or working with the equipment they can coach them. But more importantly the majority, the overwhelming majority of the damage that we see is the direct result of wear and tear or inappropriate use of the device in some way whether it is in use or reprocessing and we use those pictures and that imagery to be able to create a story that we go back

to talk to the customers about about how they can avoid those kinds of problems in the future.

So in many ways if the information were to flow back to the manufacturers it would flow back through the customer as opposed to directly through us at this point in time.

MR. LEAHEY: Great. And again I think getting that totality it is important to make sure that that information gets to everybody and you just acknowledged that when you service it you don't even know who serviced it before you which demonstrates that although the hospitals may have requirements in place to document all the servicing it is clearly not being implemented across the board consistently right now.

MS. SCOTT: Okay. Well, I'd like to thank our panel for this afternoon. This concludes Panel 1 this afternoon. We are going to take a ten minute break. I would like to ask for those participants who registered to present for the session this afternoon if you are confirmed to present for the session this afternoon please come to the front at this point for

additional instructions.

And with that again I thank our panelist and we will have our ten minute break.

BREAK

MS. SCOTT: Thank you. Again for those who registered to present this afternoon we ask that you can go ahead and you can begin to line up at either the front or the back microphone.

Okay. Excellent.

When you do come to the microphone again I ask that you state your name and affiliation. We're going to jump back and forth between the two microphones. We will start with the front microphone. Then we'll go to the back microphone. Then we'll come back to the front microphone. And we'll keep alternating like that. Okay.

PRESENTATIONS BY PARTICIPANTS

MR. McBRIDE: Good afternoon. My name is Jeff McBride. I am the President of Red Lion Medical Safety, Inc. Red Lion has been in business for 38 years. We are an ISO and we service anesthesia machines biomedical equipment and medical gas and

vacuum systems in hospitals and healthcare facilities from Washington, D.C. up through New York City.

In the late 1990's Red Lion Medical Safety was the lead plaintiff in a lawsuit against a major OEM in the medical equipment field. We filed the lawsuit against the OEM for restriction of trade, monopolization of the service market. This case was settled out of Court in 2000.

Here we are now 16 years later and Red Lion Medical again is the lead plaintiff in another lawsuit against a successor OEM for restriction of trade, monopolization of the market; some of the same exact plaintiffs, some of the same exact arguments, some of the same exact problems against essentially the same exact OEM. We did not want to have to file this lawsuit but they gave us no choice. It seems very clear that the OEM is using this as a bully pulpit to force the competition out of business.

By not supporting the ISOs the OEMs can create the appearance that the ISOs are not trained properly, that we do not have the technical expertise to service the medical equipment and that we cannot

obtain parts. This stance by some OEMs can as one writer put it cause patient harm indirectly by not providing the parts in a timely manner some equipment goes months without repairs. Some ISOs are being charged a flat rate of $1000 for an overnight shipment of parts. Currently for a one week training class by a manufacturer it is in excess of $15,000 for one machine. To put that in perspective my son is currently going to a university and is working on his Bachelors degree. For two semesters, 32 weeks, it costs approximately $12,000; $3,000 less than what it costs to take this one week training class.

Some of the manufacturers will provide access to training classes only on a limited basis; they will provide a class just for ISOs. If there are not enough ISOs registered for the class they will cancel this class. By using these tactics they can force ISOs into losing service contracts because we do not have proper training.

There are some OEMs that charge for dial-in tech support. Before you can even start a technical conversation you have to provide them with a credit

card. The cost for this can be $675 per hour and it is based on 15 minute increments.

These increased costs have to be passed on to the customers who eventually pass them on to the patients. During the time that Red Lion has been in business we have not had any major incidents that have caused patient harm. Red Lion ensures that our technicians are factory trained and we only use OEM parts.

I have read several reports from the manufacturers and their leading associations. I noted that they identify numerous instances that third party companies or ISOs have improperly repaired equipment. However, I did not see one instance reported that the OEM made a mistake. Do they not make mistakes as well?

In closing even though the ISOs have to pay a higher cost for training, parts, shipping, and technical support, we can still provide a better customer service and at a cheaper price. If the FDA is truly concerned about patient safety and the increased costs of health care I would recommend that

they take a closer look at how the manufacturers impact and support the Independent Service Organizations and third party service providers.

Thank you.

DR. HEMPHILL: Robin Hemphill again from the Veterans Health Administration. I am struck a little bit by a lot of things that are coming out of this discussion. And I try to have that inform comments about how we are trying to approach things. It is striking to me that at the beginning of my career, I would have said I came to work with a pen and that felt like it was about all I needed, along with a scalpel. And I don't think I am dating myself entirely by sounding like a dinosaur because how things have changed has been almost explosive.

So as we look at the thing that we begin to try and track and trend certainly the interaction of devices as they come into our system, and I mean really all devices, and I would also throw in there the sense of medical IT, same type of thing, its interface with people, end users as us, our patients and then the other environment around it is really an

area of enormous growth for us. And we are still trying to get our arms around it. So when I say what keeps me awake at night it is very much this exploding world of fascinating technology and the double-edged sword that it really is for us; all of the promise but, of course, much of the peril.

So we are trying very, very hard to get arms around it and understand it and so again that gets back to the reporting systems and the importance of them. Providers today still struggle greatly with the sense that we contribute to medical harm. And we still as providers are often in a lot of denial about that. And yet more and more data comes out and we still often deny, deny, deny; we don't have a problem.

So I feel like we are going through the five stages of death and dying; making our way finally to acceptance. We have a lot of errors that we make and so I would encourage again this group across both the front-end OEM as well as the providers and those who use it and then those who try to fix it and keep it up I think the absence of data is not an absence of a problem. I think we are still widely underestimating

that. So we are trying to collect that information as much as we can and understand when is it the device, when is it the provider, when is it a mix.

We are also committed to in the next couple of months to try and understand across our enterprise what is the history of devices and how they are being reused so that we can get to that sense of when is even the way we try to reprocess or refurbish or fix up when is that contributing to some of the harms. We hope to be working with the FDA in trying to create those systems of reporting.

But again as frightening as that can be to report our problems both when you bring something in and they are brand new as well as when they are getting used throughout the life cycle, as frightening as that is we can't fix what we don't know about. We're going to try and commit as an enterprise in the system from the VA to understand and report to FDA as wonderful partners for us and to manufacturers when we can; and we will try and expand that knowledge into how we're reusing, reprocessing; so in other words, that life cycle in between that cycle and get that

information and make it as transparent as we can as well. But certainly we need partners who are willing to hear those messages.

Thank you.

MR. BRULEY: Thank you. And good afternoon. I'm Mark Bruley, Vice President for Accident and Forensic Investigation at ECRI Institute.

FDA's proposed rule request for comment seeks to aid them in exploring the issues of medical devices that are subjected to post market activities performed by original equipment manufacturers and third parties including the hospitals themselves.

ECRI Institute's response focused on FDA's question number two on evaluation of risk with these third party and OEM activities. And to paraphrase that question asked what evidence exists regarding actual problems with safety and/or performance of devices from activities of refurbishing, servicing, et cetera. Specific examples should be submitted.

Let us begin with the tenant that specific examples and anecdotes are not data. Regulation that affects the safety and cost-effectiveness of the

application of medical technology to patient care must not be entered into without evidence of a problem that needs to be remediated.

So let's look at the data both from the 1997 FDA regulatory initiative on this topic and for the past ten years. ECRI Institute has nearly five decades of experience monitoring problems with hazards of medical devices and is well qualified to speak to the issues of what evidence exists.

To answer the question on evaluation of risk we conducted extensive searches spanning ten years from 2006 to 2015 of FDA's MAUDE database, ECRI Institute's Health Devices Alerts Tracker Recall database, National Library of Medicine PubMed database and ECRI Institute's confidential contracted investigations of medical device incidents that have caused serious injury and death. We used extensive key word and text string search strategies to identify records that describe problems with capital medical equipment related to refurbishing, reconditioning, rebuilding, et cetera. We omitted from the analysis reports on prostheses, implants, reagents, and

disposable devices. Our search strategy of denominators for the data are in our comments submitted to the FDA. The current search strategies are similar to those performed in 1998 that I presented at an FDA AAMI conference about the 1997 proposed regulations.

At the 1998 conference I presented the data from our analysis from FDA's then 18 year old device experience network and at that time the two year old MAUDE database. More than 750,000 records were searched; approximately 137,000 which is 19% of these were related to capital equipment. Of those reports for capital equipment spanning 20.5 years 241 relevant reports were found representing 0.17 of those capital equipment reports. There was no evidence that a safety problem existed that needed to be addressed by regulatory action.

FDA at that conference was then asked what it found in their analysis. They too said they could find no evidence that a safety problem existed. That is in 1998.

In the current ten year analysis we searched

more than 3,600,000 records of combined MAUDE health devices alerts and ECRI Institutes Accident Investigation case files. There was nothing in PubMed. Of those more than 2,115,000 related to capital equipment. Based on searching for possible relevance thousands of reports were then read. We found a total of 96 relevant reports out of the 2,115,000 records. That is an incidence of as mentioned before 0.005%.

That incidence related to the theme of this workshop is now two orders of magnitude smaller than what was found in 1998. Based on the results of ECRI Institutes detailed searches spanning the past ten years and on our monitoring of medical device problems for more than 40 years we do not believe that a safety problem exists with refurbishment, remanufacturing, servicing, maintenance and repair of medical devices by either third parties or OEMs.

We see no valid argument for an FDA regulatory initiative on the premise that there is a history of safety or performance problems that are compromising patient safety.

Thank you.

MR. SCHNEIDER: Hi, Rich Schneider from TriMedx.

I wanted to spend my five minutes really reemphasizing some of the key benefits and address some risks that we've heard today.

The first one is really around responsiveness. ISOs like TriMedx or in-house clinical engineering programs really act as an arm of the hospital of our customer. We don't go around wearing TriMedx badge, logos on our shirts; we are seen as partners and part of the hospital. What that allows us to do by being co-located within the hospital is really improve responsiveness. So when a mission critical device is hard down because we are there we can get that device back up and running within hours. Most of them are done within four hours, within 24 hours over 95% of hard down mission critical devices are back up and running. That addresses really provider satisfaction but most importantly patient safety. So that is a key benefit that ISOs provide to our customers.

From a cost perspective, we heard a lot about cost savings as well. And we can't minimize that. A lot of hospitals have financial difficulty and they need these cost savings in order to provide a service to their patients, an effective service to their patients.

From a risk perspective obviously mitigating risk is key. And at TriMedx, I think you've heard this a couple of times today, we put in place quality management program where we have an internal audit team that goes out to each of our hospital sites and reviews the processes and documentations that our engineers go through.

We also have a supplier quality program where we are going out and visiting our partners who provide us parts and do third party repairs for us to ensure that we are providing that quality necessary.

Why are we doing this? Obviously patient care, patient safety is number one. Number two is if we didn't do it we'd be out of business. So it is important for us to do it from a pure business perspective.

And third I think you heard this earlier and I really want to emphasize this is that we are regulated. We are regulated, maybe not directly, but through our customer, through the hospital. Hospitals are regulated by the CMS, we've got Joint Commission auditors coming in, we've got state health regulators coming in. If we don't provide that service, if we don't document our repairs and preventive maintenance properly and on time those hospitals will be seen at fault, we'll be seen at fault. And they'll either be fined or put out of business and we can't let that happen.

So to me we don't need that additional regulation by the FDA. What we need is the walls to be knocked down between the hospitals, the ISOs, the in-house clinical engineering programs and the OEMs. At TriMedx we have some great OEM partnerships. Some other OEMs really don't want to work with us. And we need the training, we need the access to parts to really provide service to the hospitals and improve patient safety and care.

Thank you.

MR. LERSCH: Good afternoon. My name is Jeff Lersch. I'm the Vice President of sales at Karl Storz Endoscopy America. Karl Storz for those who do not know is a worldwide leader in the production and sale of medical instruments and devices including a broad range of reusable rigid and flexible endoscopes, instruments, camera systems and other accessory devices used by healthcare providers to conduct minimally invasive medical procedures.

On behalf of Karl Storz I'd like to thank the FDA for hosting this public workshop to gather insight on this critically important patient issue.

During my brief comments this afternoon I will provide Karl Storz' perspective on the benefits and risks associated with the five R's as I refer to them in a regulated versus unregulated environment.

In the current unregulated environment of device repair Karl Storz believes for specific categories of products the risk to patients outweigh the benefits being realized by other stakeholders. In our filing to the docket we surfaced evidence that substantiates what can happen when a patient critical

or semi-critical device is repaired by a third party in unregulated environment. Patient critical devices can be defined as a device which comes in contact with blood or sterile tissue including mucous membranes. Patient semi-critical devices work hand in hand with and are necessary for patient critical devices to perform a medical procedure.

The common thread in each of the examples we surfaced in our submission was that somebody other than Karl Storz opened and actually repaired the device compromising its integrity. And lastly in each of the instances we surfaced there was an adverse patient outcome.

Two examples in particular further amplify the need to change the status quo. In the first which was included in our submission material from the outer sheath of an endoscope flaked off inside a patient and an investigation concluded that the insulation cover material was different from the material Karl Storz uses in its manufacturing and repair processes. The hospital that sent the device to Karl Storz confirmed that it had used a third party repair company to

service the device.

More recently we received a flexible endoscope that had been repaired by a third party. Our investigation revealed that a chewing gum like substance, no kidding, had been used to repair the shaft where it connects to the handle.

Both of these examples demonstrate why standards for repairing medical devices must be established and that regulatory oversight is required to drive accountability.

Another concern is a lack of labeling. ISOs currently are not required to clearly label devices they modify leaving users with a false perception that a device adheres to OEM and for that matter applicable FDA standards. As mentioned third parties are not required to document or report their 5 R activities so there is no mechanism for any stakeholder to know who has repaired a device, what modifications were made to the device and how the device performs versus original OEM specifications.

This begs the question how is this lack of information in the best interest of patient safety.

Conversely OEMs are required to document and report all activities associated with their devices establishing standards and initiating regulatory oversight for all parties will level the playing field, drive accountability and have a positive impact on patient care.

Karl Storz strongly believes the FDA can, in fact, develop and implement a regulatory framework that protects the proprietary interests of OEMs, preserves a vibrant third party repair marketplace, and above all else protect patient safety.

DR. BITTLEMAN: Thank you Jeff. Sorry, we have to move on. That was your five minutes. Thank you.

MR. FRANCOEUR: Thank you. My name is Dave Francoeur. I've been in the healthcare profession for greater than 30 years. I've worked in every facet of this industry possible, insurance, OEM, in-house, third party, done it all. I've had thousands of technicians that reported to me through the career. I've had millions of work orders that have been processed under my indirect or direct responsibility,

a lot of which was responsibility for the quality.

I want to first start out by saying we have to understand the way I work on things it is around understanding the why. So why are we here? And my perspective I feel that we are here because we are focused on patient safety. Well if we are truly focused on patient safety then we are going to have to break down the walls because whether we want to admit it or not cost and competitiveness are definitely two factors that are causing the problem for the reason why we are sitting here today.

Second thing that's an issue that I think we need to address is we're here because we are either going to ensure increased or improved patient safety. Well obviously we don't know which of those it is because again if we did I don't think we'd be sitting here today. So the fact of the matter is I think we have to decide what it is that we are trying to achieve and how we are going to do that. And the only way it is going to happen is if we break the walls down between the OEMs and non-OEMs because really whether you are in-house or ISO doesn't really matter

because you are not OEM. And as I said I've worked for OEMs in the past.

Next think I want to say is that I've changed my view a little bit just since I've been here today and over the day. I think there may be some merit to some sort of validation which shows and demonstrates there's somebody that is working on a piece of equipment that has some level of criteria and the ability to make sure that they can work on those pieces of equipment. I don't disagree with that. But the fact of the matter is the challenge we are going to have is how are we going to measure that. And how are we going to monitor that.

Next thing I'll say is that if you are going to go down that road then we have to make sure it is on both sides because I do believe regardless of whether your paycheck comes from OEM or comes from In-house or comes from ISO or comes from wherever it comes from, whether your training comes from an ISO or independent third party group or someplace else the fact of the matter is the skill and the level that the person who sits in front of that piece of equipment is

only as good as that person that is there at that time. And I can demonstrate time and time again it doesn't matter again where you paycheck comes from or where your training comes from because if you are going to circumvent the system, if you are not going to do it because you're not the type of person that is going to do it in the first place it is really not going to matter where your training came from or your paycheck comes from.

So with that I would just say that the benefits would be if we all did come together and we truly did do what we're professing we say we want to do in this room which is to increase patient safety then lets break down the walls and make that happen.

But the challenges are going to be to figure out how we are going to do that because we don't have the tools that we need, we're not willing to share the information back and forth, and so much as the OEMs have told us on numerous occasions if they had the data they could make decision, well then let's do it the other way, give us the data and let us help you make the decisions.

So all I'm saying is we can sit here and banter this forever; it is never going to change unless we decide to change it. So I'll just throw that out there. With that that is my perspective and I appreciate your time.

MR. GREEN: My name is Thomas Green. And I'm the President and Owner of Paragon Service located in Michigan. My company services, we're an ISO. Actually we were the very first anesthesia ISO in the country. We were the second anesthesia refurbisher in the country. We are also distributor of anesthesia equipment.

And I wanted to get up and speak because I've heard some things I really don't like hearing right now. And I wasn't going to speak but I'm going to.

There are some things bantered around that are gray areas. You want to hear facts well first of all I'm going to speak on behalf of Thomas Green of Paragon Service. Tomorrow I'm on a panel. I'm going to be representing ISOs but I want to speak on my behalf today.

I have been in the anesthesia equipment business for over 35 years and 26 years ago I started Paragon Service. You want to talk about critical equipment, anesthesia equipment. It doesn't work, people die. You want to hear facts, 15 to 20,000 service procedures have been performed by my little company; we've sold between two and three thousand refurbished anesthesia machines, thousands of patient monitors; no returns. No adverse events. No patient harm.

You want to hear stats. No patient harm. And yet we have to stand here today and hear that ISOs and refurbishers are unsafe. Mark can talk about his statistics of five thousands of a percent including OEMs.

Here is an example of a company that has no patient harm. Yet we are here today. This is crazy. Needing further regulation; MITA just wants this to put us out of business and increase their costs period.

ISOs are safe, fast responding and can do it forty to fifty percent less than OEMs. They don't

like us. Further FDA regulation will not improve the statistics of Paragon Service. 26 years from now we are still going to have no patient harm and we don't need the FDA to regulate us.

Thank you.

MS. WILLIAMS: That is going to be hard to follow.

[Laughter]

Good afternoon. My name is Nicole Williams. I'm a microbiologist and Vice President of Medical Optics. We are a third party repair company out of Tamarac, Florida.

I've actually been doing this for over 16 years. I know it doesn't look it by my young exterior and so I've also worked for the OEMs and ISO so I see this from both points of view.

It is as the day has gone by today I had a little speech prepared but it is very hostile and I think this subject is always going to be a hostile thing. And it doesn't have to be. I've been actually disavowed by my previous OEM. They are like we'll at least pretend she doesn't work there anymore which

why? I have that knowledge; it doesn't go away just because I don't work there anymore. I am a microbiologist; I'm all about effects control and patient safety. And that is what is important. And that is what everyone is forgetting with the fighting that has been going on today.

What is important is that there are very, very good companies here that do very, very good work. And there are companies that do very, very bad work. There are people that replace stuff with bubble gum in their garage. And there are people like my company who are ISO certified by both 9001 and 13485 that do material compatibility on every part that touches a patient, every part. And I will gladly show anyone the test report for that because I make sure it happens, because that is important.

We do reprocessing testing on everything. We also have huge complaint procedures just like you are required to if you are ISO regulated. If they come in and check you then you have to have everything that you do. I don't know why this is a surprise to everyone here and why we are having a battle. It

needs to be fixed. It is important. It is money. I don't care what anybody says, it is. All you have to do is cooperate. If Olympus would like to have our repair data, I will happily give it to them. I have a lovely online program where my customers can log in and see it. This is not a surprise.

We do this, third parties care about their patients. We are more fit to represent our hospitals than some OEMs. We do better training. One OEM in this room I went to do training with their supposed clinicals and they made me do their clinical training because they didn't know the product. It is very important. Customers need training. They need those special things that the ISOs give them that the OEMs do not. You have other things to worry about; let us worry about the customer service.

And honestly we can rehash the same thing over and over again but I feel like this is what we are going to talk about for two days and not get anything done.

Maybe you need an Italian up there and we'll just take a vote and figure it out. Now my boss is

going to be mad at me because it is nothing I wrote down and made him read today.

[Laughter]

Sorry, Frank, because I know you are watching me right now.

So in closing since I've said nothing that I was supposed to say in the first place, I think that we can make this work. We don't need to have FDA regulations if everyone has their 13485, everyone does what they are supposed to do and we all share a little bit of information. There is enough business to go around for everyone and it is for the betterment of the hospital.

Thank you.

MR. BEINKE: I'm Hans Beinke with Siemens Healthcare. I don't have anything too formal prepared. Just a couple of notes that I took as we went through the session today.

First thing I thank FDA for organizing this. I think it is valuable. One of the speakers just said that he's modified his thinking by some of the comments here. I've certainly learned some things.

So I want to thank everybody that's provided comments.

Again as has already been said I think Mark Leahey said it first there is a lot of agreement in this room. And I think that is what we need to focus on. I think there is a lot of detail that we need to get to and there is some work to get there. I think FDA has a lot to consider.

We've said it and I'll say it again this is not about trying to put ISOs out of business. I suspect that most, if not everyone in this room, there is not an issue. I think it is others that we need to be concerned about. And that is true for OEMs as well. We have good players, we have bad players. We have regulations to keep up with what they do.

So I don't hate ISOs.

To reiterate what we've said, what we do believe as OEMs is that you should have a quality system and again many people in this room have a documented quality system. So I think for those people that is covered.

I think one of the areas I do worry about is the reporting. We need that reporting so that we can

do trending. And I think we need to have better communication in that area.

I do think that we have a need for regulatory oversight. I think patients and again this is not something that hasn't already been said patients should be able to assume that there is no difference, they walk into the hospital, they are treated and they don't have to sit there and worry about who did the service. And again I think that there are many, many good players.

We need to protect ourselves; ISOs, OEMs, industry in general by making sure that we are constantly driving quality.

We talked about anecdotal information. I think there is some truth to that because we don't have access to all of the information but I will remind you for the person that it is anecdotal it's important for that individual. We can't dismiss everything as anecdotal. There are people behind this.

Also there has been a lot of talk about event reporting, harm, death; we need more than just

that. We need again to be able to do the trending.

Now, I'll mention just some statements that have been made that I either want to comment on or have some resistance to.

The statement has been made a couple of times that this person used to work for an OEM. I think there may be some help there but I don't think that is the end of it. Our OEM service providers are trained and trained and trained again. We have new products. Those new products require new training. So great that there are some prior OEMs in ISOs and hospitals; it is not the end of the process.

Only a few problems. I don't see us regulating OEMs or I don't think that the ISOs or the hospitals should be regulated by some belief criteria that the level is too low to regulate. I mean if that were the case then maybe we should all have a submittal to FDA and if we were below a certain criteria, we are off the hook, we are not regulated. What about tomorrow?

There was a presentation or mention at least that there is going to be some tomorrow about

standards. I am a fan of standards. We've worked within MITA to develop some standards. But a standard on the shelf doesn't do much. What is the oversight to see that it has been implemented and that it has been implemented properly?

Also there were some statements that said our organization is committed to quality. I've never heard an organization say they are not committed to quality. Quality is number one. Oh, well, for our organization it is number two. Okay.

The other thing and I said it earlier up here what is regulation? Don't have a knee jerk reaction and say it is terrible. I think we have work to do to decide how much makes sense.

And finally a steal from Mark Leahey again trust is great but verify.

Thank you.

MS. SCOTT: Are there any others from the people who actually registered to present who have not yet come to the microphone?

Okay. If not, we can move on. I think there was at least Scot Mackeil wanted to present this

afternoon, he has a few more words he'd like to share, so go ahead Scot.

If there are any others from the audience who would like to share, again, you would only have five minutes to share a perspective if you would like to, you may come to one of the two microphones.

MR. MACKEIL: My name is Scot Mackeil and I'm a Senior Biomed at Mass General Hospital. And I am a quality system.

We spoke today of benefits and risk. In my 36 year biomed career I worked in many roles. I work in the OR at a thousand bed academic medical center. I worked 19 years in a financially disadvantaged community hospital. I worked ten years as a clinical lab equipment specialist and refurbisher for regional ISOs and equipment remarketers.

From my workbench I have seen many benefits and risks as technology and economics are connected to patient care and safety. In years past the level of corroboration between biomeds and manufacturers in our industry was much better. Today it is increasingly difficult as collaboration is in short supply.

The words liability and proprietary are used to build walls between manufacturers and servicers. When discussing benefits and risks let's focus on patient safety, caregivers, healthcare systems and leave the wall building out of our conversation. And the cause of patient safety and equitable and affordable care we can all be stronger together.

It is common for biomed to be called to the point of care to resolve emergent technology problems. Biomeds are often able to respond immediately, mitigate risk and solve problems with little delay.

In scenario A biomed is empowered by the manufacturers. He studied the comprehensive factory service manual, had training, can access diagnostics, has parts, the issue is quickly resolved, care is resumed, risk to the patient is minimized.

Biomed B in scenario B is denied access to these resources, the device's role, the treatment is essential yet the biomed must say I'm sorry doctor I think it is broken; we have to take it out of service. I'll call the company, we might be able to get them here early next week or I'll have to get this boxed up

and send it to the factory. I'll see if I can get a loaner and I'll get this fixed as soon as I can.

In Scenario B the doctor must stop, modify or limit the procedure and the patient's care is impacted. Risk factors multiply. The patient may not have received the treatment they needed or the case may need to be rescheduled. Other cases that depend on this device must be modified, cancelled or rebooked. Schedules and care of many patients and caregivers are impacted as the ripples of the failure spread out.

The manufacturer provides service for the device by generating service revenue. The hospital experiences risk to patient care and safety and downtown while the device was out of service.

Which scenario does the FDA see as being more beneficial for the patient? Can the FDA see changing its regulatory framework so that biomed A scenario is tomorrow's standard?

Today I'm asking the FDA not to impose regulations that would limit or restrict a biomed's ability or choices in servicing the needs of my

caregivers. I'm asking the FDA along with medical equipment manufacturers to empower biomeds and clinical engineers who are your customers, your colleagues and allies. I would also ask for recognition of the value brought to the industry by our trusted third party service providers and similar stakeholders. Delivering safe affordable equitable healthcare with less risk benefits all of us and is tied to a simple equation. Healthcare dollars do the most good when they are spent directly on care.

To the FDA from my perspective at the workbench I must have ability, choices of third party services and collaborative relationships with manufacturers to safely serve the needs of caregivers. The combination of manufacturer's reps like my buddy Dave Young from Philips and our industry's third party ISOs and vendors is essential to me because it allows me to present the best options to safely and affordably meet the needs of my caregivers.

Moving forward I would ask the FDA for at least this: Please settle the issues around service manuals in the industry, define what must be in them,

adopt industry standards for service manuals content and preventative maintenance procedures and require that service manuals along with access code software and repair parts be available to biomeds without question.

Lastly I speak to the FDA as my regulatory partner and to manufacturers as your customer, I need both of you on my team when I am at the bedside or on the workbench. You are both valued partners that can contribute to patient safety and affordable equitable care by empowering biomeds with knowledge and support as we serve our clinicians with a shared goal.

This is from Jeff Cooper, the founder of my department, and this is what we should be doing: To provide outstanding innovative technology services, solutions and systems for excellence in patient care and to ensure that technology never harms a patient.

Thank you very much.

MS. HORN: Hi everybody. My name is Heidi Horn. I'm the Vice President of Clinical Engineering Service at SSM Health. SSM Health is a non-profit Catholic health system based out of Saint Louis. We

have about 21 hospitals now, actually a couple more as of today. And we are providing, my clinical engineering service department has about 110 clinical engineers, biomeds and imaging technicians who provide obviously clinical equipment maintenance and management services to all of our hospitals system wide. I've been in this business for about 18 years.

So a couple of things that I wanted to bring up that I know other people have brought up but I wanted to make sure that it was kind of clear and said in the context of a healthcare provider to the FDA. First of all just kind of a show of hands, just curious, how many people in here by show of hands is actually employed by a health system or a hospital. Okay. So not a lot.

So we come from a little bit of a different context here and I wanted again to make sure that was clear and actually official docket here. So from a hospital perspective there is nothing more important obviously than patient care. Our sole business is to care for patients, make sure that they are taken care of and that they leave the facilities in better

condition than when they entered facilities. This goes into play also from the clinical equipment standpoint.

So when patients are injured unfortunately by a medical device end user whether it is a malfunction of the device, a service issue by anyone, the hospital themselves are actually directly responsible for that. The hospitals are the ones that are accountable I should say. The hospitals are accountable for that.

And so, therefore, we must be the ones who are making sure that the vendors whether they are OEMs, ISOs or our own folks are doing what they need to be doing. There is no other, well, I shouldn't say no other, but health systems in general are more regulated than any other industry out there. We have I can tell you SSM in particular we have the FDA coming in on a regular basis at one of our hospitals. We have CMS coming in. We have Joint Commission coming in. We have the State. We have CAP.

People are coming in and making sure that we are doing what we say we're going to do and are making

sure that we have that documentation. Somebody else was talking about having documentation from the ISOs; we as an in-house organization and as a hospital are required to keep all the documentation whoever provides that maintenance service. So if it is in-house we have to provide it but we also have to have it available if the OEM provides and we have to have it available if an ISO provides it. So from a documentation standpoint it is the hospitals again that are accountable for this.

My point to all of this is that I mention that we are one of the most regulated industries out there. We self regulate because of that. If an ISO or a vendor or a OEM or whatever we are going to call them or an in-house person for that matter, if one of our technicians is not doing what they are supposed to be doing because we are accountable for that, because we are liable for that we are going to dismiss them; we are going to no longer do business with them. And I've done this quite often, I've had to fire ISOs and OEMs and vendors who have not done what they are supposed to be doing.

So ultimately what I would like to relay to the FDA and make sure that you do understand is that we are self-regulating. And we are regulated as a healthcare organization. So it is very important to point that out.

One other piece I just kind of want to touch on, you know, and I won't go into it too much because I notice they are giving me the five minute warning here but in my health system we have 85,000 devices that we manage. This past year I budgeted $30 million, $30 million to maintain that equipment. That was almost double from what it was ten years ago. So, when we talk about having access to parts, having access to training, having access to service manuals, technical support, affordability is also accessibility. And having to pay $30 million which by the way I am not even sure my whole health system is going to make that much this year as a non-profit, so having to pay that sort of thing is not making it accessible. And so again it is something that we as an industry as a whole and I am including everybody in this room really has to come back together and talk

about because we cannot keep seeing these costs skyrocket like they are and expect us to be able to get the training we need, the parts we need, the support we need and do a good job for the benefit of the patient.

So that is all I want to say. Thank you.

DR. DOMINITZ: Hello. I want to thank the FDA for this opportunity. My name is Jason Dominitz. I am a gastroenterologist. I think I am one of the few end users here at this meeting who is actually handling these devices and putting them into patients or dealing with them directly with patients.

I'm the National Director for Gastroenterology for the Department of Veterans Affairs. I'm speaking as an individual today. My comments may or may not be those relevant to the official policy of the VA.

When it comes to endoscopy there is over 14 million colonoscopies done every year, there is over 500,000 ERCPs done a year. In the VA we do about 400,000 GI procedures a year. So 500,000 ERCPs done a year in the U.S. and many of you may be familiar with

the horrible situation we had in the last couple of years with the duodenoscopes; the superbug infections as they were known, the Carbapenem-Resistant Enterococcus, so 500,000 procedures but we didn't discover that there was a problem with these endoscopes that have been in use for many years until these rare infections turned up and those were largely discovered by luck. It was almost entirely by luck. So I think you have to think about that when you talk about the low rates of problems being discovered.

I helped write infection control guidelines for endoscopes and we talked about how the risk of infection was less than one in a million; we were all very convinced that the risk of problems was incredibly low but we just didn't have the right data. So I am very concerned as Dr. Hemphill said earlier the lack of data is not the same as the lack of a problem.

So I think we need better data. We shouldn't bury our heads in the sand. We have near misses. As a gastroenterologist we have problems when the endoscope doesn't work like it is supposed to, the

wheels don't turn quite right, we've had lenses or the cameras mounted upside down, we've had cables mounted improperly, improper angulation. I don't know if it is ISOs or the OEM doing these repairs. I don't really care. I just want to make sure it works. And it doesn't always work right. And it is not going to result in serious harm but it could delay the care. We may have to switch out to another scope which, of course, increases the cost.

So I think we need better reporting systems for when we have these problems. How do we synthesize this data? You know it is not being synthesized right now. I don't know if the third party vendors are doing, the OEM are doing the repairs, maybe they need service bulletins to say that this scope had this kind of problem, you need to trend that data. So I do think we need better training, availability of parts and manuals to make sure that our patients are getting high quality equipment being used in the hands of the physicians.

Thank you again for this opportunity.

SPEAKER: Hi, my name is Cory. I'm from an

OEM manufacturer of dental, mostly dental chemicals like composites and things. We have a couple of piece of hand held equipment.

I am not speaking in my company's capacity. I am regulatory affairs manager. I would like to point out to FDA that not all equipment has the same risks; not all equipment is installed; not all equipment is used in hospitals; not all of it is serviced in the field. We do not have any field service engineers, all of ours are very small; they are sent back to us. We repair them; they are not used in high risk types of procedures.

So a final regulation should also be sure to cover devices like these, you know, scalable to small specialty, low-risk, non-installed devices that are serviced by the OEM. Most of the parts are specialty parts. You can't buy them off the shelf.

So I just want to be careful that the final regulation does address that as well.

MR. WHITLOCK: My name is Rodney Whitlock. I am Vice President for Health Policy at ML Strategies in Washington. I am also a 21 year hill staffer

retired.

Start with this which is the Food and Drug and Cosmetic Act speaks to safety and efficacy. It does not speak directly to cost nor does it require FDA to do so. That doesn't mean that it isn't a public policy issue. But when we talk about what the requirements of FDA are that is something to keep in mind is the importance of the value of safety here.

Now what is crystal clear about listening to this room is no one here does a bad job. And not surprisingly no one here came to say I'm terrible at what I do and I want to make sure that I have the opportunity to continue to be terrible. Clearly, clearly everyone in this room does an extremely good job and they care about doing so. But that to a degree should guide FDA as they approach this which is if you are trying to set standards which is an FDA requirement to be able to show consistently that they are doing what is in the interest of patient safety it is important that those that are not are weeded out. And currently everyone in this room who does the jobs they do to the level that they do it of damn near

perfection as described no one here should be in any way, shape or form afraid of any standard that FDA could set because you absolutely will meet it; wouldn't you? You've certainly testified to that today. So the question is what is ultimately in the interest of patient safety as FDA moves forward.

And I think the argument should be fairly clear that the standards that are certainly in place for the OEMs have a certain expectation for patient safety, without question. And so for ISOs for both in what they do to repair to the previous level, they should have no fear of meeting those levels.

And secondly they should have no fear of putting their name on it, on their work. And for the FDA the challenge is what is in the interest of patient safety for this accountability gap to exist moving forward between OEMs and ISOs where there are just functionally different regimes for both when these are issues of patient safety.

And finally to say that there is an existing regime out there and particularly to say that ultimately liability is a safety regime, liability

while waiting for a seminal event to occur is no public policy. And FDA certainly knows that for the existence of this entire campus. If they treated drugs that way that would be utterly ridiculous and we all know that. Seminal events as a matter of public policy waiting for those to occur is no public policy.

Thank you.

MS. SCOTT: Are there any other comments from our audience?

If not, I'm going to turn it over again to Sean Boyd who is going to close us out for this afternoon.

WRAP-UP

CAPT. BOYD: All right. Well thank you all very much for participating in the workshop today.

We heard a lot of things that we expected in terms of passion on all sides of this issue to identify the risks and benefits and some of the challenges that we are facing in identifying a path forward.

Let me go through some logistics items for tomorrow and then I'll do a little bit of recap in

terms of what we heard and try to clarify some things.

So in terms of housekeeping items hold on to your name badges and bring them with you tomorrow. You'll need them to check into the workshop. We are going to start promptly at 8:15 tomorrow morning. And again the food vendors will be available early in the morning if you haven't already had an opportunity to preorder your lunch for tomorrow.

In addition to that people that are traveling and if you have luggage, we've reserved room 1406 which is one of the break-out rooms that -- help me Valerie, where -- oh, we've changed it to 1504 and it is that direction; is that correct, so if you turn out and go left toward the end of the hall.

And I think that is it for logistics and housekeeping items. Am I forgetting anything?

Okay. And there will also be some additional table in the back of the large area for any overflow of luggage.

So in terms of what we heard today. We started out with a history of some of FDAs efforts and starts and stops in addressing this issue and

certainly we're reconvening today so that we don't find ourselves here again in another 20 years to be tackling this issue once more.

We heard some proposed working definitions that are really trying to define the scope of activities that we're talking through today and for future benefit of really the ecosystem that is involved with these issues.

We've heard the perspective of a variety of different stakeholder groups and we heard a panel discussion on benefit and risk associated with each of these activities.

And I think we heard a lot of common themes and I just wanted to touch on some of those. I certainly might not hit all of them or I might not articulate them in the same way that you would but permit me to share a little bit of what we learned today.

First everybody is putting the patient first. We are all focused on patient safety and that is our top priority and our singular priority as we move forward. And that is something that I think is

going to help us continue to come together and focus on lasting solutions as we continue to talk about this tomorrow and after the workshop.

Second I think we need to better understand kind of the scope of the problem. We heard varying perspectives on data and anecdotes and what do we really know about what types of risks or issues are going on with servicing activities whether they are performed by and OEM or a third party.

We heard a lot of discussion of the importance of visibility and transparency of information really for purposes of documenting the activities that are ongoing for a device's useful life and that is something that I think needs more discussion and exploration.

We heard the importance and the value of quality management across all stakeholders that are involved in the issue.

There has also been a lot of discussion regarding and a focus on regulation. And one of the things I want to share from an FDA perspective is that we don't have any preconceived solutions to this

problem. We are not necessarily convening this event to publish a regulation that is going to define a future state. We don't know what solutions we're going to bring to the table in partnership with you. And that is something that I really do want to emphasize. We clearly heard that we need to discuss more what is the appropriate level of oversight given the current state of affairs and the varying responsibilities that FDA and other entities might have in ensuring that these activities are performed for the purposes of maintaining patient safety again over a device's useful life?

There are a variety of options that we might consider in this.

And lastly I want to emphasize that one thing is clear FDA alone is not going to solve or resolve this problem. We together are going to solve and resolve the issues going forward. And I think a lot of these things I was taking notes for kind of closing remarks tomorrow but based on some of the discussion today I wanted to share it early. I think this is a starting point. This workshop is a starting

point, maybe 20 years later a starting point to look at what are we going to do next. And we view our role as convening the key stakeholders around these issues for purposes of defining what solutions we should being to address the concerns that have been raised over this two-day workshop.

So with that again I thank you for your participation and I thank you for the passion and the energy that you bring to this. And I look forward to hearing everybody's contributions tomorrow.

Have a good night.

[Applause]

(WHEREUPON, the public meeting concluded for the day.)

CERTIFICATE OF NOTARY PUBLIC

I, NATE RIVENESS, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was recorded by me and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

NATE RIVENESS
Notary Public in and for the
State of Maryland

CERTIFICATE OF TRANSCRIPTION

I, CHERYL LaSELLE, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.

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Date CHERYL LaSELLE

Transcriptionist