

Transcript of FDA December 10, 2009 Key Stakeholder Conference Call

Note: This is not an official FDA transcript. This transcript was carefully prepared by a third party service provider. While we believe the content to be accurate, there may be spelling errors, and a few portions of the conference call were inaudible due to the quality of the recorded audio.

Theresa: Tim will lead today's briefing. He will be joined by CDRH Experts during the Q&A section who will identify themselves as they speak. The purpose of this telephone conference is to update healthcare facilities with important safety information about the STERIS 1 system processor and to answer questions facilities may have about the risks associated with the STERIS products and related questions on these topics that the facilities can't resolve through the healthcare professional notice and the Q&A document on our website.

We know that our recent action has generated questions from many facilities. We've been receiving many emails from individual facilities. We've got more than a thousand people registered for this telephone conference. We are very interested in being responsive to all the important inquiries you have for us. Given the volume of the inquiries, we're looking at updating our Q&A document. We also know that not everyone that is interested will be able to participate in the call today, therefore we will be providing a rebroadcast and a written transcript of today's telephone conference. The rebroadcast will be available shortly after the meeting today and the transcript will appear about one week after the call. Information on the telephone replay and the transcript will be on the FDA website in the updated Q&A document. In responding to questions, there may be items that cannot be discussed because of confidentiality limitations or areas that are not directly under the FDA's purview.

Today's call is related to the FDA's regulation of devices. Please keep this in mind while asking your questions. As a reminder, the FDA has posted three major documents related to the STERIS SYSTEM 1 processor that all callers should be aware of. First, there's the notice about the concerns of the processor. Second, there's the May 15th 2008 warning letter that summarizes FDA observations, deeming the STERIS SYSTEM 1 processor as adulterated and misbranded. The third is the Q&A document specifically addressing the December 3, 2009 FDA safety concerns that summarize what facilities should do, alternative products, notifying patients, and where additional information may be found for alternatives. We ask that you closely read these documents. If you have additional questions that are not addressed in these documents, or during this phone call, these additional questions can be submitted by email to CandaceMcManus@fda.hhs.gov, or by phone at 1877-260-3731. With that, I would like to introduce Mr. Tim Ulatowski, who is the director of the FDA's office of compliance and the center of devices and radiological health.

Tim: Thank you Terry. It has now been a week since the FDA issued its notice to healthcare facility administrators and infection control practitioners that we posted on our website, entitled "Concerns about the STERIS SYSTEM 1 Processor Components and Accessories. FDA recommended in the notice that if you have an acceptable alternative to the STERIS SYSTEM 1 to meet your sterilization and disinfection needs, you should transition to this alternative as soon as possible to ensure continued patient safety. If you do not have an acceptable alternative to the SYSTEM 1, you should promptly assess

your facility and patient care needs and sterilization and disinfection requirements, and take steps to obtain legally marketed substitutes for the SYSTEM 1.

In the notice we provided are links to the Q&A document that Terry talked about. In that document as well there are links to additional public information on cleared or approved medical devices. And that you can take into account to guide you when considering suitable alternatives. As I'll explain in a moment, early next week we'll be providing additional information to assist healthcare facilities in identifying alternatives to the STERIS SYSTEM 1 Processor. Notice on the question and answer document we describe the chain of events that led us to publish our notice, and summary, and in as plain language as I can use... FDA warned Steris that it made changes to the SYSTEM 1 that could significantly affect the safety or the effectiveness of the device. Those changes cause the modified device to be an unapproved device that violates federal law. Given the illegal status of the SYSTEM 1, STERIS needed to either submit a new application to FDA [inaudible] for the modified SYSTEM 1, and have the FDA clear the application for the modified SYSTEM 1, or STERIS needed to take their SYSTEM 1 off the market, including retrieving devices in use.

STERIS disagrees with our position on the need for a new application. They were afforded the opportunity to respond to our warnings, and did so. After careful review, we did not change our decision on the status of the SYSTEM 1. Steris then took steps to respond to the updated warning. They stopped selling SYSTEM 1s to new customers, they submitted an application for a new product. I cannot assure you when or if or for what scope of use their new product will be cleared.

We believe that since January, STERIS has been working to transition its customers with legally marketed alternatives to the SYSTEM 1. Based on communications with STERIS and an inspection of the firm, we determined that STERIS was not taking appropriate action to support this transition.

The FDA must be fair and consistent in our enforcements, and cannot permit an illegal product to remain on the market. Too much time now has gone by that could have been spent on that transition—the transition to legally marketed products must occur.

We had a stakeholder call last when where additional questions were posed of me. Since then we have also received numerous calls and emails with questions. Many of these questions have a common theme. Well that's the background I want to provide first thing, now for today's questions I want to answer several of the common questions we are getting that are not in our Q&A document or are not sufficiently clear in our document. You may have additional questions that I can then try to answer. As Terry said I cannot discuss confidential or trade secret information, for example regarding the pending [inaudible] and we cannot go into specifics on any communication the FDA is currently having with STERIS. So let me begin with these questions.

Question one: Does this FDA notice apply to the SYSTEM 1 in my facility? We've had our SYSTEM 1 for five, ten, or fifteen years. You have not told us specific model numbers that are affected. **The FDA's answer is:** our notice applies to all STERIS SYSTEM 1s. All models, all SYSTEM 1s you have.

Question two: Clarify what action FDA has taken. Is this a recall? **Answer:** this is not a recall. FDA has issued a warning letter to STERIS as I have explained. They've issued a notice to administrators and infection control practitioners. This notice expresses our recommendations for voluntary action on the part of administrators and infection control practitioners.

Question three: In regard to this transition period, how long will this transition period last? Will the FDA immediately pull the plug on my SYSTEM 1? **Answer:** we recommended that this transition process begin immediately with efforts to use suitable alternatives if you have them, or to proceed with assessment of what you need and to obtain them. Let me be clear that the FDA expects that for some time, healthcare facilities without alternative systems of sterilization and disinfection options will continue to use the SYSTEM 1 Processor. We have not directed that the use of the STERIS SYSTEM 1 stop immediately. We want you to have suitable alternatives in place, staff trained, and other necessary logistics attended to in a seamless process. Do not interrupt diagnostic and therapeutic procedures using devices reprocessed in the SYSTEM 1 until these suitable alternatives are in place. FDA believes that healthcare facilities should be able to transition to alternative sterilization and disinfection products in 3-6 months. FDA will not be an obstacle to STERIS providing medically necessary sterilant, current accessories and service during this transition period. Provided that the transition is occurring and we do not become aware of information indicating a need to take immediate action. But we understand that there may be individual cases in which healthcare facilities cannot complete the transition within this time frame. We want to be advised of obstacles to transition. Ideally, we will work with healthcare associations to resolve these obstacles. These associations are able to represent more efficiently in the interest of their members than by one-by-one conversations between FDA and individual facilities. We are prepared to engage with individual facilities as needed and as appropriate. FDA continues discussions with STERIS virtually on a daily basis concerning the process of transition. As noted, the transition is not open ended, so we recommend that healthcare facilities begin the process as soon as possible to ensure a smooth transition to alternative sterilization and disinfection products.

Number four: Can I not just use biological indicators and chemical indicators to verify that the SYSTEM 1 is safe and effective and therefore FDA clearance of the modified system is not needed. **Answer:** As long as you are still using the SYSTEM 1, meaning until you have a suitable alternative, you should continue to use the biological and chemical indicator accessories available and specific to the SYSTEM 1, according to the SYSTEM 1 and the accessory labeling. What is lacking is FDA's rigorous, scientific and engineering review of data and information submitted by STERIS demonstrating to FDA satisfaction that the modified SYSTEM 1 may be marketed for its intended use. The data and information needed, which are extensive, are based on current standards and current guidance well known to the industry. Hospitals are not equipped to do this evaluation. The FDA evaluates the system, and we evaluate the accessories like the biological indicators and chemical indicators, to make sure that the BIs and CIs are tuned correctly to monitor the operation of the modified device.

Question five: How do I know that the alternative that I'm choosing will not also be subject to FDA action at some point? **Answer:** I encourage you to ask the tough questions to the manufacturers you approach to discuss their products. Show me the FDA clearance or approval letter, is your question. How have you modified the device since original clearance or approval? Did any of these require new FDA

clearance or approval? The FDA itself is as vigilant as resources permit as we continue to inspect manufacturing facilities to determine if all the manufacturing processes are in place, that complaints are being address, recalls are occurring when needed, mandatory reports are made to the FDA, and submissions are being made to FDA when needed. Competitors sometimes help when they think another manufacturer has changed a product significantly. Tell us if you think you're getting the run around from a manufacturer or a manufacturer has made changes to its product that requires FDA approval or clearance.

Question six: I am confused regarding what alternatives are suitable for my facility. Can you help me?

Answer: FDA will post additional information early next week that specifically lists FDA approved sterilization and disinfection products. FDA will also post information and resources to help healthcare facilities to decide which sterilization and disinfection processors their devices require, and identify manufacturers of products that provide the requires level of sterilization and disinfection. As I noted earlier, FDA has links to products in our Q&A document. Let me just add this about choosing alternatives: I know that many devices are placed in STERIS SYSTEM 1— first identify all devices your facility reprocesses and all the SYSTEM 1s in your facility. The primary source of that information on how to reprocess any given device is the labeling for that device. If labeling does not say what to do or is not clear, call the manufacturer. Guidance from the CDCs infection control advisor committee is available to help guide your selection. As I said yesterday, we'll post additional information next week. When you've done this, determine what processing [inaudible] you have and pair them up with the reusable devices. Obtain alternatives as needed. Based upon all the calls and emails we're getting, I've answered those questions. I hope I have answered them sufficiently to reduce the number of additional questions you may have, but let me turn now to any other questions you may have.

Theresa: Robin, we'll open the line for questions.

Robin: thank you. At this time if you would like to ask a question, press *1 on your touchtone phone. Please unmute your line and record your name clearly as prompted.

Theresa: And as we're waiting for questions again I want to apologize for the delay in getting started. We wanted to wait and try to accommodate as many people as we could that were in the cue and therefore we started late and are prepared to run past the 2:00 deadline if need be. Robin we're ready if you want to give us the first question.

Robin: Okay one moment. Your line is open.

Calelr: What we want to know here about the STERIS is—can you use the STERIS to wash the scopes but then do a high level disinfection afterward with OPA or some other high level disinfectant?

Tom: hang on just a moment. We need to formulate an answer for you.

Tom: We do not advise this to take place, the SYSTEM 1 is not labeled for washing, I understand your concern and question but we do not advise this.

Theresa: Next question, Robin?

Robin: Thank you, our next question comes from Julie. Your line is open.

Caller: Okay, our question is: when burns from the sterilant have occurred to the users, how specifically did that happen? Was it sterilant left on the instrument that wasn't adequately rinsed, or was it from the external or internal defects of the device? Or is it occurring when handling the cassette that contains the acid perhaps spills when removed?

Tim: I'm going to put you on mute again as I discuss who is most capable of answering that question.

Dr. Sheila Murphy CDRH: This is Dr. Sheila Murphy, medical officer in the infection control device branch of the CDRH. The majority of the injuries, the burns, from STERIS SYSTEM 1 have occurred at the time of opening the device. There have been some lid malfunctions, there have been some spills related to deterioration in the sterilant cup. Both of those have been responsible. In some cases the mechanism [inaudible]. It has usually not been sterilant left on the instrument.

Tim: Okay, next question please.

Robin: Thank you, our next question is from Heidi Kelly. Your line is open.

Caller: We're confused over the term sterilization and the standard of care versus high level disinfection and, you know, it presents the opportunity for us to really reduce our standard of care here going from sterilization to high level disinfection. We're under the impression there's nothing else on the market that offers the sterilization claim. So can you elaborate on that please?

Tim: I'll begin and then I'm going to have my FDA technical people here insert additionally. First of all, let me remind you that as I've stated, the STERIS SYSTEM 1 is not a cleared or approved device—we cannot assure you that it is safe and effective for its claimed uses. I think your premise is somewhat at risk in regard to where you're at currently. But let me add my experts here to supplement further on disinfection and sterilization.

Sheila Murphy: Sterilization is a process which results in biological organism inactivation. When you talk about classical terminal sterilization as it occurs in a sterilizer, the end product of the process is a device that is not only sterile but is dry and packaged in a manner that it will maintain sterility until the package is opened. The STERIS SYSTEM 1 produces a device from the chamber in which a liquid chemical sterilant has been used, which does accomplish liquid chemical sterilization. It then rinses the device with filtered water, and it comes out wet and unpackaged. A device that is wet and unpackaged out of a "Sterilizer" is a device that is immediately picking up organisms from the surrounding environment. If you are talking about flash steam sterilization, this would be a flash cycle.

Tim: Next question please.

Robin: Thank you. Amy your line is open.

Caller: Hi, with that said as far as sterilization with the flash steam, then whenever you're biologically testing the STERIS, is that what's really in question here? To my knowledge, the STERIS 1 machine—the

differences that were changed was the tray itself was made slightly bigger, therefore they made the chemical sterilant slightly bigger to accommodate that change. Is that what's really in question as far as whether the biological or the chemical indicators are testing that correctly to maintain sterility?

Tim: Let me also ask—we have hundreds of people joining after I made my statement, so I'm not confident that everyone heard this, but let me just continue—Once again, let's remind ourselves that the STERIS SYSTEM 1 has been modified significantly, our warning letter identifies those significant modifications. Those modifications render the product a device that is subject to a new application by the FDA. We have not reviewed that application, we could not attest to our review and clearance process, whether it is safe and effective. That's kind of the long and short of it, I'm not sure if there's additional points we can make on our side. Next question.

Robin: Our next question is from Michael Williams. You may ask your question.

Caller: When you talked about suitable alternatives, you used the word manufacturers, devices, and products, and you talked about 3-6 months—but there was no mention of immediately correcting the problem of manually cleaning the scopes by soaking them in a OPA solution- is that something that you would like us to consider?

Tim: manual cleaning and reprocessing—and I think you're talking about scopes now, correct? Yeah, it's a process that requires significant attention to the detail of that process... various steps that must all be attended to very carefully, and rigorously and religiously in order for the process to be satisfactory. This has been used in the past, and still is in use. Machines have been marketed to automate those steps, but it is fundamentally still an option to take, but it is again, one that requires considerable training and attention to detail, and that's the case with manual processing.

Caller: So your recommendation would be if we're not going to immediately purchase alternate devices to replace the STERIS 1s to continue to use the STERIS 1s, not to manually clean the scopes?

Tim: As I've stated in my comments, the STERIS SYSTEM 1 can continue to be used. Manual processing is an option, my infection control people here may have additional opinions regarding manual processing and its use as—I wouldn't call it the alternative. I wouldn't want to see it as what you're planning on moving to from STERIS.

Caller: I'm talking about as an intermediate to our new devices. Should we continue with the STERIS until our new devices get here? Which is better? That manual? Or continuing with the STERIS?

Tim: Hold just a moment while we formulate our response. The FDA cannot say one is better or worse. I think these are the choices you have to accept in your institution based on your particular circumstances.

Caller: One additional question, when it comes out of the STERIS is it highly disinfected?

Tim: When it comes out of the STERIS? I don't know what to consider it because we haven't evaluated it.

Robin: Next question comes from Cynthia, your line is open.

Caller: Can you clarify at all what kinds of communication or guidance you're going to give patients who may have questions about this? What will be the information available to them?

Tim: That's an excellent point. It's a point that- to be frank- we haven't fully addressed. I believe we'll have to follow up for that information. Our question and answer document talks about communication with patients who are coming in for procedures. Some of it depends on your own institutional considerations. We know that patients that have already been treated, we advise there too but unless there has been documentations of outbreaks, that advising patients that have already been treated is not going to be probably worthwhile.

Robin: Thank you. Our next question is from Matt, your line is open.

Caller: Hello, yes, my question is a little more technical—with regards to the FDA's actual statement, and you mentioned it several times, also in the original stakeholder meeting on December 4th, that the unit itself is not an FDA approved device, or no longer an FDA approved device, as it stands – if you don't mind me asking, what were the more technical aspects of why a recall was not issued on this unit versus a recommendation?

Tim: I don't know if you were at the front end of this call where I posed a question on recall and provided an answer. As of today and at this juncture, this is not a recall, and we provided a notice for healthcare and medical practitioners to take voluntary action.

Caller: I actually did hear that question, sir, it just seemed a little open. I didn't know if there was any more you wanted to respond on that or if that was pretty much the answer you're going to give.

Tim: That's the answer I'm going to give.

Robin: Our next question is from Adam Shannon, your line is open.

Caller: Yes, I heard in the original thing that they were planning on stopping supporting in two years—what is the exact end date that STERIS is going to stop supporting this product, and stop selling that we're going to have to plan in.

Tim: Well, in my question that I posed based upon emails and calls and the answer that I provided, it's the FDA's opinion that 3-6 months is our consideration of the transition period. But as I said that there likely there will be outliers with specific individual circumstances that we will have to consider. We will learn more as we go along, working with you on this transition and working with STERIS on this transition. So, that's the best I can tell you at this time.

Robin: Our next question is from Anna Turner, your line is open.

Caller: Thank you, I really just—it's more of a concern. Since I think everybody is hoping we are going to come out of this without having to give up the STERIS systems that we have, and that doesn't look like what you're saying at all. Do you feel that there's going to be issues now that STERIS has to start pulling

out all their products and having them replaced with other companies kind of like, increasing their prices or putting more demands on the medical community because we're in between a rock and a hard place right now. If so, how would I handle that as a provider or the administrator of a center where I need to make changes but I also need to stay within a budget where I wasn't planning on making these kinds of changes.

Tim: I understand your concerns, and the FDA continues to consider what further advice and assistance we can provide, or to direct you elsewhere in regards to these very important issues that I know hospitals must contend with. I can't provide you at this point in time on issues regarding funding and replacement and things of that sort. I believe additional information will be forthcoming, so bare with us just a while.

Robin: Thank you, our next question is from William Perez, your line is open.

Caller: Yes I was wondering, when STERIS was allowed to replace these units, one for one exchange—was the FDA aware of that as we received in our documentation, and did we not know these issues were there at that time?

Tim: FDA was aware of the January notice that STERIS provided by posting on their website, and we obtained additional information we were not aware of in regard to communication STERIS has with customers and others, that we obtained through our inspection process, we were aware of this one for one replacement but considered during this transition period that one for one meant if the machine broke down and was not serviceable that there was an opportunity for the customer to obtain another unit in the interim.

Caller: Quite frankly, I don't think that was made clear to facilities, because we were allowed to replace units with new units thinking that that was okay because the FDA was aware and not putting a stop to that, that there was no issue.

Tim: As far as the activity was concerned it was, I believe it was how I described it to be

Caller: Thank you.

Robin: Thank you. Our next question is from Lees Cherry, your line is open.

Caller: Hello. As with most of the people on this line, there's literally hundreds of thousands of dollars at stake here. My question is if STERIS was to present their 510K application, how long will it take the FDA to do an evaluation so that we don't spend money needlessly?

Tim: I'll turn to those people who evaluate those sorts of documents that are close to me. Let me just begin, though, that STERIS itself has made its specifications regarding how to respond to the FDA warning letter. And so that's the first point. Any additional points? Dr. Murphy?

Dr. Murphy: This is Dr. Murphy, medical officer in the Infection Control Devices branch at CPRH. The review time that the FDA has allowed for the review of any 510K is, under the DAX, 90 review days. We will start the review of the document particularly if there is reason to give it priority immediately. When

we finish our review if there deficiencies in the data that we have received, if there are questions that would prevent us from making a final determination on the device we will then give those questions to the manufacturer. The manufacturer has up to six months to respond to us. This cycle may be repeated several times. So the amount of time that it will take to actually clear a 510K is dependent not only upon FDA but upon the quality and the amount of the data that we receive in the file, and the number of unresolved issues which the manufacturer has to provide more data on until we can come to a final conclusion.

Tim: Next question

Robin: Thank you, our next question is from Patricia Spuma (*sic*). Your line is open.

Caller: Hi. I was wondering if you could clarify why pre-2008 non-modified STERIS systems are included in this recommendation.

Tim: Well as marketed FDA is not aware of any STERIS SYSTEM 1's in the possession of healthcare facilities that have not been modified in the manner described in our warning pack. Therefore as I stated in the question and answer provided upfront, all SS1's are subject (inaudible) and the need for transition.

Caller: I'm sorry, I thought it said "Any that were modified 2008 and after" and...

Tim: No

Caller: You're describing the swap-outs also and that being one of the heralding moments

Tim: Now let me be clear: if you have a SS1 in your possession, you need to transition to a legally marketed alternative product. I didn't say what model. I didn't say when you think it was manufactured. I said all.

Caller: I'm sorry I thought it was due to the manufacturer changes made in 2008, to the model.

Tim: No, no. Next question.

Robin: Thank you. Susan Mantone, your line is open

Caller: Hi. Could you please help us understand if within the transition period of three to six months is there enough alternative equipment from other manufacturers for the hundreds of thousands of us to replace our units? Because I'm very concerned that it's going to be available to purchase even if we have funding.

Tim: We understand your concern and for this reason I mentioned that we want to be informed of the obstacles that you may be encountering and identifying and obtaining legally marketed alternatives. As you assess your situation, as you approach manufacturers, STERIS makes products that are suitable alternatives for some of the devices. And I advise that we will work with the associations to react to these obstacles however we may facilitate the transition we will do so. I hope that answers your question for now. Next question.

Robin: Thank you. Sherman Curtis, your line is open.

Caller: Yes, if the FDA is unable to see progress with STERIS, is it going to issue a warning and a recall of this product within six months, and the second part of the question is can you be specific as to what defines progress that relates to STERIS.

Tim: I can't, I don't want to predict how this will all unfold in the next three to six months. We're on a continuum. We're now a week hence from the notice. We've gone from a stakeholder call with 2 people to 2000 people. I understand institutions are now in the midst of assessing their situations and making their decisions and this is a process that will unfold that will take the amount of time I stated and may take longer for some. So we'll see how this all unfolds and we'll make decisions along the way as we map this progress and address obstacle. Next question.

Robin: Thank you. Timothy Dulack, your line is open.

Caller: Hi how are you. You basically answered the question that I had. If you owned an original SS1 that was approved originally by the FDA that has not been modified, why is it not suitable to be used now?

Tim: I'm not aware of any SYSTEM 1's that have not been modified by at least one of the methods described in the warning.

Caller: The mechanism prior to the STERIS 1 that was utilized in facilities...

Tim: I'm not understanding your question. The SYSTEM 1...

Caller: Prior to the SYSTEM 1, or the STERIS 1 what was utilized the facilities that warranted the modifications, I guess, that's been going on now for over five years

Tim: The SS1 510k was cleared in 1989. I'm not aware that the product has cleared as described in its specifications, its design, its operations... all of them on the marketplace have been modified on one way or another according to the modifications in our warning letters.

Caller: Is it one particular model that has been recalled versus another model? I mean is it an awful generalization to say that every STERIS machine that's on the market is basically being recommended to be moved from healthcare facilities?

Tim: No it's not a generalization, it's a factual statement based upon our inspection and now our sense of the data that we collected.

Caller: How many machines did you inspect?

Tim: Pardon?

Caller: How many machines was part of the inspection?

Tim: We inspect the manufacturer and evaluate their manufacturing and design records

Caller: Right, how many of these machines did you inspect that warranted this recall, or this recommendation?

Tim: Let me be clear again sir: all the SS1's on the marketplace are subject to our notice and you must transition to another legally marketed product. Unfortunately, that's where FDA stands and that's the completion of my answer. Next question.

Robin: Thank you. As a reminder, if your question has been answered and you're in queue you can press star 2 to withdraw that question. And our next question comes from Tom Hill, your line is open.

Caller: Thank you. Will the FDA dictate a final end date when the STERIS and accessories will not be available to customers? We had a call yesterday with STERIS and they kind of went over that. They initially had in one of the letters that that would be up to the end of 2010 but then they said that that went back to the FDA and they haven't made that ruling yet so we're trying to get clarification on that.

Tim: I've made a statement regarding what we consider to be a transition period of three to six months. We'll actually monitor the transition as we work with STERIS to provide legally medically necessary sterilize accessories and service. Beyond that that's the extent of what I can say about our transition period, next question

Robin: Thank you. Next question is from Kyle Nelson. Line is open

Caller: Yes this is Dr. Davis and [inaudible] Health Corporation. I have more of a practical concern. I'm an endoscopist also a consumer of medical processes. Is this just that it's an illegal device or is it not safe? Because if it's not safe I have to cancel all my cases this afternoon and tomorrow and for the rest of the year until I get an alternative system. I don't have the luxury as a physician and a provider of safe procedures to my patients to knowingly put them in harm's way by performing a colonoscopy with a cleaning system that can't be guaranteed. So what am I to do? As a consumer I would cancel my procedure tomorrow if I had a colonoscopy scheduled as soon as I heard about the STERIS findings. Please comment.

Tim: I appreciate your comment, doctor, and understand your concern. I recommend that procedures such as you have described not be interrupted. We want the devices to be substituted. We want substitutions of legally marketed devices for the SS1. To be sure as our notice indicated the SS1 is not immune to problems, malfunction. To be sure the issue regarding infections is a difficult one in regards to identifying post-op infections and getting the reports that are needed in so we can assess post-op infections. We also have to look at the balance of risk and benefit. We are working with you and with STERIS on a transition in best interest of your patients so that these procedures are not interrupted. We are monitoring daily any reports we receive of the SS1 (inaudible). If we see info that changes out about the case or duration of this transition we will certainly inform everyone immediately about any changes to this process. For now, as I said, I recommend that you proceed with procedures as this transition occurs. Thank you. Next question

Robin: Our next question is from Eve Taylor; your line is open... Eve Taylor? Your line is open. I'll move on to the next question. Keisha Hood, your line is open.

Caller: Hi my question is in your negotiations, your talks with STERIS is there any talk about the compensations for centers that have all these processors that we're going to have to replace? I know you don't know anything about recalls or anything like that but is this something that's being talked about? Or are we just all out this money and have to re-buy at this point

Tim: Okay, two points there. If there's a recall I'm going to know about it. But secondly... I'll be the first to tell reporters. But secondly, I can't discuss any specifics about communications and aspects to the point you made about financial [inaudible]. Next question.

Robin: Thank you. James Dickey, your line is open.

Caller: I believe that my question has been answered.

Robin: Thank you. Lynn Ray, your line is open.... I'll move on to the next question. Angela Cox, your line is open. I'll move on, Valerie Watts?

Caller: Hi my question is has the FDA discussed with OSHA the potential danger of the exposure to our employees with the [inaudible] oxide and the [inaudible] OPA, and if so what was OSHA's recommendation please?

Tim: Well, your question diverts us from the particular subject matter that we're talking about here. My technical experts might want to address that. I think you'll have to restate what exactly is your concern so we can understand it.

Caller: My concern is the health of employees using ethylene oxide and [inaudible] OPA and I wanted to know if the FDA had discussed with OSHA this issue and if so what was OSHA'S recommendation?

Tim: Well I think your question pertains to the alternatives you may be considering and potential risks involving those alternatives. Am I correct?

Caller: Yes

Tim: Yes. Well each alternative that might be considered has its own particular aspects that have to be evaluated. In regards to how it can be implemented in your facility and what additional... what's the electro-mechanical changes that are necessary to ensure that there is patient and user safety; accessories that are needed, placing those alternatives in your facilities. That we're aware of, through our own evaluations, all of these alternatives as we have looked at them and cleared or approved them: what are the risks pose by alternatives? We're aware of OSHA requirements and these matters. [inaudible]

Dr. Murphy: This is Dr. Murphy, a medical officer in INCD. The alternatives to the SS1 in terms of reprocessing devices such as endoscopes are not limited to either ethylene oxide or OPA. And we need to look at all the alternatives, consider all the pros and cons for your institution and for the devices that need to be processed. Next question.

Robin: Francine Paris, your line is open.

Caller: Hi probably about 45 minutes ago somebody was talking about manual processes versus SS1. Should an organization decide to remain with the STERIS 1, because we truly feel that it's a best practice as far as instrumentation, will our organization suffer any recourse from the FDA or any fines or anything like that?

Tim: I believe we had a question and answer regarding that where the question was, will the FDA take enforcement upon the health care facility if they continue to use the SS1. And the answer we provided was we do not expect to take action against the health care facilities solely because they are using SS1. However, these facilities including hospitals are expected to report suspected device-related deaths and serious injuries to manufacturers and FDA if the manufacturer is unknown. But underlying your question is, let me make it clear that SS1 is not a legal product. If your cardiologist using an illegal heart valve, would you have a cardiologist use a heart valve or pace maker or any other product that is considered illegal? We offer that you evaluate your situation and obtain legally marketed alternatives to SS1.

Caller: I was not referring that we would continue to use it indefinitely I mean during the three to six month period that you had allotted us, if we choose to continue using it...

Tim: In your assessment of the devices you reprocess— the need, the volume of reprocessing—you want to take a careful look at alternatives, you want to assess the alternatives. We don't want this to be haphazard, but we want to proceed expeditiously. And you may decide for various reasons given the factors of your institution that one device may serve your needs better than another device. I'll leave it at that. Next question.

Dr. Murphy: Robin, we have about 5 minutes left. We're not going to get to all the callers. We'll try to get to as many as we can. So if could give us our next caller.

Robin: Yes thank you our next question is Dorothy Small. Your line is open.

Caller: Yes you speak of modifications made to SS1 and I assume that these modifications are physical modifications. So if software upgrades were made to our systems once is this considered in your advisory?

Tim: There were software changes made to the devices listed in our warning letter to STERIS.

Caller: Thank you.

Tim: Next question.

Robin: Ken Mitchell, your line is open.

Caller: Hi, presently the SS1 is not a legally marketed sterilizer or high level disinfectant. What implications exist for health care facilities that continue to use the SS1 to process instrument for patients during this transition, period.

Tim: I think your question pertains to liability issues. If I'm not mistaken, is that correct?

Caller: Yes.

Tim: Let me just say that I understand your concern and the issues you're confronted with, with regards to this point. The FDA is working with STERIS to enable SS1 to be used during this transition period. You're working, I trust, to assess alternatives and move forward with those. I think further info will be forthcoming that will be useful to you [inaudible].

Robin: Thank you. Next question is from Randy Hillman, your line is open.

Caller: Thank you for giving this conversation. I really appreciate your stance in regards to the FDA viewpoint. The problem for me as a provider, this is extremely devastating to the whole hospital and surgical industry. That being said, I've also looked at other providers and other types of processing equipment. Those really... point blank, the Medicator (*sic*) has more spills and is more caustic to employees. Also the other processes, I'm having to buy more than one that SS1 can do all of that. Can anything be discussed with the Secretary of Health with regards to helping us out in the medical fields regarding replacing these equipments in a timely manner? Question's over with.

Tim: I understand your concern regarding how you view other alternative products. We are interested in understanding any obstacle or issues you have as you consider each product. Every device has pros and cons as I said SS1 is not immune from issues as well. We're on this continuum of transition and we'll work with you as best we can in providing information to assist you in this regard. Thank you.

Robin: Thank you, next question Lori Patterson, your line is open.

Caller: Yes my question is that with everything going on we know that we're finding different modes and methods for best standard and best practice. But with the Joint Commission taking their new stamps and with flashing and the process following with sterile processing, is this going to raise the flag for facilities that are already underneath the gun? Is this going to cause another alert to cause another problem for us?

Tim: Dr. Murphy?

Dr. Murphy: This is Dr. Murphy, medical officer in INCB. The action the FDA has taken with respect to the SS1 has been well publicized. The Joint Commission is aware of what we have done. The Joint Commission is aware that process of transition will take time. The Joint Commission, I believe will evaluate issues related to the SS1 on their own and separate from any other issues during inspection that a facility might have. Remember it's a question of how you are dealing with your problems and your issues; and are you using science; and are you moving towards improvement of quality care in your patients that are of particular interest to the joint commission.

Tim: Thank you Dr. Murphy. Next question.

Robin: Thank you. Mike Fuller, your line is open.

Caller: Yes sir, thank you for your time. The FDA letter dated the 3rd of December, third paragraph down made a reference that facilities should properly assess patient care needs. Can you expand on that recommendation please?

Tim: That phrase pertains to the assessment of your operations in your facility. Turnover needs of reusable devices, volume, and therefore what sort of alternative parts you need to bring to bear there that are legally marketed. That's briefly [inaudible].

Caller: So are we talking about not doing patients that are compromised and those kinds of things.

Tim: We have not provided a recommendation in that regard. That's an excellent point and we'll have it under advisement. But our recommendation stands as now [inaudible]. Time for two more questions.

Dr. Murphy: And there are other people with questions that we don't get to you can send them to us by email and we'll either consider them as updates to the Q and A document or address them individual as need but we have time for just 2 more so for those who are waiting just know that we'll be ending in about 5 minutes.

Robin: Thank you. Priscilla Mills, your line is open.

Caller: Thank you. This has been asked a couple different ways. Thank you for responding to our concerns. This device is illegal because you have discovered in the manufacturing process that since it was approved there were changes made in that process. Do you have any data that says that it is unsafe?

Tim: It is the responsibility of the manufacturer to demonstrate that it is safe and effective. As I said, STERIS SYSTEM 1 is not immune to issues, and there have been situations. Some of which are device related, some of which user related. That is STERIS' responsibility to follow up on and make corrections as necessary. We are closely monitoring the situation to see if any new information causes us to accelerate this transition. We trust that you're moving forward now to consider legally marketed alternatives?

Caller: My concern is do you have data that says that this machine does not sterilize or highly disinfect the instruments that we put in it? I would be interested to know if you have existing data upon which this recommendation was based.

Tim: hang on just one moment. Well, we don't have the information that you described because this is assorted information that [inaudible] submitted to the FDA to determine if it's safe and effective. And that is the long and short of it. Thank you

Theresa: one more question.

Robin: Okay, next question is from Kay O'Connor, your line is open.

Caller: I guess if you're using the STERIS processor only for endoscopes, colonoscopies—and actually to my knowledge, STERIS is the only one that claims sterilization when you get the medivator (*sic*), [inaudible]—their claim is high level disinfection. And the goal is the standard of high level disinfection as long as you're doing the process correctly with cleaning ahead of time prior to putting it in the processor and so on and so forth. I guess my question is, those that have purchased these—I mean, granted, once your through with the process you hang your scopes so they're no longer sterile, but I guess they're high level disinfected-um, so going to those other machines which says high level disinfection, as far as your stance is that acceptable then?

Tim: our information that we provided to you in our question and answer document does describe the aspect of critical, semi critical and not critical devices. The short answer is, you have accurately described the acceptable endpoint for [inaudible] processing, which is high level disinfecting. Thank you.

Caller: I have another part to that question then. So, if you don't manually do this with [inaudible] or metrocide OPA as the alternative as long as you're doing your entire process correctly with the right cleaning and you're doing your testing prior to each load and you're logging all the recommendations— why then, if you're really doing that correctly- the manual process- would that not be an acceptable alternative?

Tim: Dr. Murphy?

Dr. Murphy: Manual disinfection with adequate cleaning, proper checking of the quality of the liquid high level disinfectant before you use it, appropriate exposure time, appropriate perfusion, appropriate rinsing afterwards, is an acceptable process which has been used for many, many years. You do have to make sure that your staff are trained, you have to have all of your processors well set up, you have to make sure that the area is aerated... but yes, you are using a legally marketed product. This is a well-described process for accomplishing high level disinfection of endoscopes in contact with [inaudible] surfaces.

Tim: Thank you.

Theresa: Thank you Robin, and thank you to all of our participants. Again, given the volume of inquiries we have received and the questions still in the cue, we know that we still need to be more responsive to the inquiries, and as Tim mentioned we will be updating our Q&A document. There will be a rebroadcast for people who either didn't get on at the beginning or are still interested in listening to it. That replay will be available about an hour from now and the phone number you can share with your colleagues or if you're an organization can share with your members—it's an instant replay number included in the advisory. And that is 866-421-5878. And again as I mentioned, next week we hope to have the transcript posted on our website. So thank you all again for your participation and thank you to Tim and our CDRH colleagues for sharing this important information with our stakeholders. Thank you Robin and that concludes the phone call.