

**FDA Media Call on a Safety Communication on the Issue of Laparoscopic
Power Morcellation for Removal of the Uterus or Uterine Fibroids**

**Moderator: Jennifer Rodriguez
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. After the presentation there will be a question-and-answer session. To ask a question at that time you may press star-1 on your touchtone phone and record your name when prompted.

Today's conference is being recorded. If you have any objections please disconnect at this time. I would now like to turn the call over to Ms. Jennifer Rodriguez. Go ahead, ma'am. You may begin.

Jennifer Rodriguez: Good afternoon and thank you for participating in today's call. My name is Jennifer Rodriguez and I'm from FDA's Office of Media Affairs. This is the media briefing to announce an FDA Safety Communication on the issue of laparoscopic power morcellation for the removal of the uterus or uterine fibroids.

By now the press release on this announcement has posted to the FDA website and been distributed on the newswire.

Today I'm joined by Dr. William Maisel, deputy director for science and chief scientist at FDA's Center for Devices and Radiological Health. After Dr. Maisel's remarks we will move to the question-and-answer portion of the call.

Reporters will be in a listen-only mode until we open up the call for questions. When asking a question, please remember to state your name and affiliation. Also, please limit yourself to one question and one follow up so we can get to as many questions as possible.

With that, I'll now turn it over to Dr. Maisel for his remarks.

Dr. William Maisel: Thanks, Jennifer and good afternoon. Today the FDA issued a safety communication to discourage the use of laparoscopic power morcellators in women undergoing removal of the uterus or uterine fibroids.

Based on an analysis of currently available data we determined that the use of the device in women undergoing treatment for uterine fibroids poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus and can significantly worsen a patient's prognosis.

Uterine fibroids are non-cancerous growths that develop from the muscular tissue of the uterus. Most women will develop uterine fibroids, also called leiomyomas at some point during their lives, although most cause no symptoms.

In some cases, fibroids can cause symptoms such as heavy or prolonged menstrual bleeding, pelvic pressure or pain, and frequent urination. And occasionally these symptoms warrant additional therapy.

A number of options are available to treat symptomatic fibroids, including traditional surgical hysterectomy, which is removal of the uterus, and myomectomy, which is removal of the uterine fibroid.

Many women choose to undergo laparoscopic hysterectomy or myomectomy instead because these laparoscopic procedures are associated with benefits, such as shorter post operative recovery time and reduced risk of infection.

Laparoscopic surgery uses a thin tube called a laparoscope inserted into the abdominal and pelvic cavities through small incision. Morcellation refers to the division of tissue into smaller pieces or fragments and it's often used during laparoscopic surgeries to facilitate the removal of tissue through small incision sites.

Many, but not all, laparoscopic hysterectomies and myomectomies are performed using a power morcellator.

Based on an FDA analysis of currently available information, it's estimated that 1 in 350 women undergoing hysterectomies or myomectomies for the treatment of fibroids is found to have an unsuspected uterine sarcoma, as I mentioned a type of uterine cancer.

If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma there's a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly reducing the patient's likelihood of long-term survival.

For this reason, and because there's no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the

use of laparoscopic power morcellation during a hysterectomy or myomectomy for uterine fibroids.

Importantly, as I mentioned, there are a number of other treatment options available for women with symptomatic uterine fibroids, including traditional surgical hysterectomy, performed either vaginally or abdominally; surgical myomectomy; laparoscopic hysterectomy and myomectomy without morcellation; laprotomy, which is a surgical incision using a smaller incision, which is called a mini-laprotomy; delivered occlusion of the uterine artery during a procedure called uterine artery embolization; high intensity ultra sound; and drug therapy.

Evidence demonstrates that when feasible, vaginal hysterectomy is associated with comparable or better results and fewer complications than laparoscopic or abdominal hysterectomy.

Our safety communication contains specific recommendations for healthcare providers and patients. We recommend that healthcare providers be aware that, based on the currently available information, the FDA discourages the use of laparoscopic power morcellation for the treatment of women with uterine fibroids.

We recommend that healthcare providers not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer. And importantly, we recommend that healthcare providers carefully consider all the available treatment options for women with symptomatic uterine fibroids and thoroughly discuss the benefits and risks of these options with these patients.

For individual patients for whom, after careful consideration of the benefits and risks, laparoscopic power morcellation is still considered the best therapeutic option, healthcare providers should inform their patients that their fibroid may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis.

And healthcare providers should be aware that some clinicians and medical institutions now advocate the use of a specimen bag during morcellation in an attempt to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

For women considering treatment of fibroids, we recommend that they ask their healthcare provider to discuss all the treatment options available and to discuss the risks and benefits of each.

If laparoscopic hysterectomy or myomectomy is recommended, women should ask their healthcare provider if power morcellation will be used during the procedure and, if so, to explain why it's considered the best treatment option.

For women that have already undergone a hysterectomy or myomectomy for fibroids, tissue removed during the procedure is typically tested for the presence of cancer. If the patient was informed that these tests were normal and they have no symptoms, routine follow up with their physician is all that's recommended.

Patients with persistent or recurrent symptoms or questions should consult their healthcare provider.

In an effort to improve our understanding of the problems associated with the use of laparoscopic power morcellators for the treatment of symptomatic uterine fibroids, and to provide information on the appropriate use of these devices, we're taking several additional actions. We've instructed manufacturers of power morcellators used during laparoscopic hysterectomy and myomectomy to review their current product labeling to ensure it provides accurate risk information to patients and healthcare providers.

In addition, we'll convene a public meeting of our medical device advisory committee to discuss the role of laparoscopic power morcellation in the clinical treatment of uterine fibroids; to discuss whether surgical techniques and use of certain accessories, such as specimen bags can enhance the safe and effective use of these devices; and to discuss whether a boxed warning related to the risk of cancer spread should be required for laparoscopic power morcellators.

Finally, I'd like to underscore that our communication today is based on currently available information. We'll continue to review adverse event reports, scientific literature, and information from patients, healthcare providers, medical professional societies, and medical device manufacturers.

If we have new or different recommendations, we'll provide an updated public communication.

I've covered a lot of information in a short period of time so at this point I'll turn it back over to Jennifer, and I'd be happy to answer any questions.

Jennifer Rodriguez: Thank you, Dr. Maisel. At this time we'll begin the question-and-answer portion of the briefing. Operator, we'll take the first question.

Coordinator: Thank you. If you would like to ask a question please press star-1 on your touchtone phone. Please unmute your phone and record your name clearly when prompted. One moment, please, while we wait for the first question.

Our first question comes from Denise Grady of New York Times. Go ahead, your line is open.

Denise Grady: Thank you very much. Do you have any estimates on how many women may have had sarcomas that...

Dr. William Maisel: Can you repeat your question, please?

Coordinator: One moment, please. Denise, this is the Operator. Go ahead and hit star-1 again. One moment, we'll get Denise back. Okay, Denise, your line is open. I apologize, go ahead.

Denise Grady: Okay, thank you. The question is do you have any estimates on how many women may have had sarcomas spread by this morcellation when it was used during the operations?

Dr. William Maisel: We don't have precise numbers of women who have had spread of their cancer due to this procedure. At FDA we've received about a dozen reports of spread of cancer in patients who have undergone this procedure. We recognize that the adverse event reporting system for those type of events underestimates the number of true events that have occurred.

For this reason, we conducted a thorough analysis of the available public literature, which is where we arrived at the 1 in 350 number for the number of patients undergoing removal of their uterus or uterine fibroids that are found to have unsuspected uterine cancer.

So if we do a little bit of the math, based on the number of procedures that we have - that we know are occurring there are somewhere between 500,000 and 600,000 hysterectomies per year, about 40 percent of these - somewhere between a third and 40 percent are performed for uterine fibroids. And somewhere around a quarter of those are performed laproscopically.

So this puts us somewhere in the range of about 50,000 procedures a year that are being performed and, as I said, we estimate potentially that about one in 350 women will be found to have unsuspected cancer during these procedures.

Denise Grady: Thank you, okay.

Coordinator: One moment, please, for our next question. Our next question comes from Matt Perrone of Associated Press. Go ahead, your line is open.

Matt Perrone: Hi, Doctor. Can you tell us a little bit about the history of these devices at FDA - when did FDA approve them and what sort of application process did they go through? Were they subject to, you know, controlled clinical studies or was this a 510K type application?

Dr. William Maisel: So these devices are Class II devices, which is our - considered moderate risk. Medical devices are classified as Class I, Class II, or Class III. Class II devices typically are evaluated by the agency through the 510K program called the pre-market notification submission and that is the case for these devices.

We cleared the first tissue morcellator in 1991. The first power morcellator in 1995. And they were cleared on the basis of predicate devices, which means

they were compared to already marketed devices and the predicate devices for these type of devices actually are called pre-amendment devices.

So they were on the market prior to 1976 when the current medical device amendments were passed.

The basis for the approval was - sorry, for the clearance was primarily a comparison between the new device and the existing devices. The - there was not a requirement for clinical data looking at the risk of spread of cancer, but quite frankly I can tell you given the very low risk a conventional clinical study is not likely to identify this type of low risk in any event.

And so that is why the post-market surveillance that we conduct is so important and how we were able to arrive at the numbers we identified.

As an example, the analysis that was performed ended up analyzing data from thousands of patients and really only a handful of actual cancer events in order to arrive at the 1 in 350 rate.

Matt Perrone: And what prompted FDA to do this review? I mean you said it's - you approved the first one of these devices in 1995. I'm assuming - I mean this problem - I mean there's nothing recent. I mean this would have been a problem from the first day I assume.

Dr. William Maisel: Well, we certainly became more aware of the concern in the clinical community starting at the end of 2013 when some high profile cases that were covered in the media came to our attention. We've been looking at the information that's available to us.

You are correct, the clinical community has been aware of the risk of cancer spread with this type of procedure really since the advent of the procedure. So the existence of the risk is not new.

What is new is that the - the magnitude of the risk appears to be higher than was appreciated by the clinical community. In many cases, numbers such as 1 in 500 to as low as 1 in 10,000 have been used in the clinical community and in the literature.

So one of the most important pieces of information that we feel we're bringing forward today that according to our analysis the risk is approximately 1 in 350, based on currently available information.

Jennifer Rodriguez: Thank you, we'll take the next question.

Coordinator: Our next question comes from Jennifer Levitz of Wall Street Journal. Go ahead, ma'am, your line is open.

Jennifer Levitz: Hi, Dr. Maisel. My question is given that this was known by the clinical community, the risk of cancer spread, as you said, for many years, does it indicate any kind of problem with the approval process? I mean should they have had to go through a more strict procedure?

I've heard that criticism said and I just wanted to get your response to that, whether this is any kind of - illustrates some sort of weakness on the FDA's approval process for these kind of devices.

Dr. William Maisel: Well, I think that's a fair question. The evaluation of medical devices is always a balance of benefits and risks and getting important new technologies to patients quickly that are safe and effective.

And we almost always learn more about the procedure as we - more patients are exposed to the procedures, as physicians learn how to more safely use the products and devices.

You'll notice we're very careful in the way we communicate the information today. We are not removing the products from the market. We are simply discouraging the use of the products for this procedure and that's because there still may be individual patients who benefit from the use of this procedure who after a careful consideration of the risk and the benefits and discussion with their doctor choose to undergo this procedure.

And we believe that that's the most appropriate way for patients and their doctors to make decisions is to be provided with important information, with factual and scientifically accurate information. But the individual patients with their individual conditions need to have a conversation with their doctor to decide on the best use.

So circling back to your question and the point I made earlier, I do not think that this is the type of risk that would have been identified even if a large clinical - a large pre-market clinical study were conducted because the risk is so small.

And this is - this issue is not unique to power morcellators. This low risk but concerning adverse event profile is something that occurs with other types of medical devices and that's why post market surveillance is such an important component of the way we regulate medical devices.

Jennifer Levitz: Is it unusual for you to issue something like you issued today? How unusual - how common is that?

Dr. William Maisel: We issue a number of safety communications each year. There's - they all are - have their unique qualities to them. In this case, we're announcing an analysis that we've performed that provides important information, we think, that patients and clinicians should have. So I don't know that I could call this unique, but we do think it's important and it's important that patients have this information.

Jennifer Levitz: Thank you.

Jennifer Rodriguez: Thank you, we'll take the next question.

Coordinator: Our next question comes from Liz Kowalczyk of the Boston Globe. Go ahead, your line is open.

Liz Kowalczyk: Hi, thank you for taking my question. I was just wondering with this wording of this warning discouraging providers from using this, do you expect - given that the wording of that, that most will stop using this procedure for most patients?

Dr. William Maisel: We expect that there will be a decline in the use of this procedure. Quite frankly, that's probably already occurred because of the attention that this complication has already brought to the community. And we think that that is appropriate, that there's a reduction in the number of patients who are undergoing this procedure. And that's why we are issuing the safety communication.

But to reiterate, we leave room in our communication for individual patients and healthcare providers to make a determination based on the available information about what is the best treatment option for individual patients.

Liz Kowalczyk: Okay, thank you. And I have one follow up question, what is your view about the use of this technique within a bag? You had mentioned that a number of hospitals have gone to that. Do you discourage that as well or is that okay in the FDA's view?

Dr. William Maisel: Well, we want the clinicians and the healthcare providers to be aware that there are some clinicians and medical institutions that now advocate using a specimen bag during morcellation. The theory behind that is that it is an attempt to contain the uterine tissue, to minimize the risk of spread in the abdomen and pelvis. And there are potential benefits of that for obvious reasons.

It's important for people to understand that the use of the specimen bag is not a panacea. It will not completely remove the risk because the tissue can spread before placed in the specimen bag, the specimen bags can occasionally tear or perforate.

And so it is not a complete removal of the risk. And in addition there are some who aren't trained in the use of specimen bags, the specimen bags can obstruct the view of the operative field. There are occasional rare reports of organ damage that can occur during a use of a specimen bag.

So all in all, we want people to have this information available to them. It is something that will be discussed at the advisory panel meeting we will be holding.

And as I said, in general the theory behind the use of the bag appears sound, but the overall benefits and risks need to be taken into consideration as far as

the training and experience of the operator and appearance of the surgical field.

Liz Kowalczyk: Great, thank you.

Jennifer Rodriguez: We'll take the next question.

Coordinator: Our next question comes from (David Filmore) of the Grey Sheet. Go ahead, your line is open.

(David Filmore): Thank you, I just wanted to find out - is there a number of companies that currently manufacture or sell the devices and the number of devices that are cleared or actively marketed? Do you have any estimates on that?

Dr. William Maisel: There's approximately two dozen devices that are currently cleared for laparoscopic power morcellation for gynecological indications.

(David Filmore): Okay, two dozen devices but from some of the same companies, correct?

Dr. William Maisel: Yes, a number of different companies. Some may have more than one but about two dozen devices.

(David Filmore): Okay, thank you.

Jennifer Rodriguez: Thank you. We'll take the next question.

Coordinator: Our next question comes from (Lisa Stark) of Al Jazeera America. Go ahead, your line is open.

(Lisa Stark): Thank you, most of my questions have been answered but I want to get back to this comment you made about not taking this product off the market. Can you give a sense on why this product should remain on the market given the fact that there are so many other options?

Can you sort of postulate what sort of a patient would still be the correct patient for this sort of a procedure?

Dr. William Maisel: Sure, so we do have the authority to ban products from marketing. We have done that. The FDA has done that one occasion in the past for artificial hair implants.

In this case, after considering the available information we determined that it would be appropriate for these products to remain available as a therapeutic option for health care providers and patients that there may be occasions that a patient would choose to undergo this procedure, understanding the risks, because the available treatment options that - that this was the preferable available treatment option compared to some of the others.

There are times when other types of surgical procedures may offer either low risk to a patient but there may be patients who undergoing a traditional surgical procedure is not a very good option for them.

The other thing to keep in mind is that while we put out a single number, which we believe is the best estimate of the risk of an unsuspected cancer, 1 in 350, there may be individual patients who have a lower risk or a higher risk.

So for example, age is a risk factor. Now I'm not able to - and I don't think anyone is able to give you a precise risk associated with age, but I can tell you

that younger women will have a lower risk and older women will have a higher risk.

So as individuals are making decisions and assessing their own risk and their own options, we think it's important for individuals to make these decisions with their health care providers. And we feel it's important to remain a therapeutic option for patients.

(Lisa Stark): Thank you.

Jennifer Rodriguez: We'll take the next question, please.

Coordinator: Our next question comes from Dennis Thompson of HealthDay. Go ahead, sir, your line is open.

Dennis Thompson: I'd just like to get a sense, should a woman who's already had this surgery be concerned? Should she go for a cancer screen?

Dr. William Maisel: As we note in our communication we think that those women who have undergone these procedures just require routine care. So typically what would happen is the tissue would be sent for pathologic analysis. Patients are typically informed as a result of the analysis and notified of their analysis is abnormal.

And so if patients have been notified that their tissue analysis was normal and they don't have any ongoing or recurrent symptoms then all they require is routine follow up. We also indicate that if patients have recurrent symptoms then they should be communicating with their healthcare providers.

Dennis Thompson: Thank you.

Jennifer Rodriguez: We'll take the next question.

Coordinator: Our next question comes from Lynn Peterson of Trends in Medicine. Go ahead, your line is open.

Lynn Peterson: Hi, so what I'm struggling to understand is what if this device were not approved and you knew that this risk existed? If you know the information you knew today, would it be approvable?

Dr. William Maisel: Well, you've asked a hypothetical question. What I can tell you is we have taken a look at the information we have available to us and we have made a determination that we believe the device should remain on the market and available to patients and healthcare providers as a tool that they can consider using.

There is no medical device that we have authorized for marketing that doesn't carry some risk associated with it and some of them are severe, life threatening risks. It's always a balance of assessing the benefits and risks. We think it's important for patients and healthcare providers to have the information available to them.

We do not think patients should be undergoing this procedure without knowing the risks that they're facing. We think they should be explicitly told that they stand a risk of cancer being spread if they're one of the few unfortunate ones who have cancer that's not suspected.

But we believe it's important for this to remain a clinical tool available to patients and providers. And I think it's also important to note that the vast,

vast majority of people that have undergone this procedure have done so safely and without untoward consequence.

So again, I understand your question but we've made a determination that it's appropriate for these products to remain available as a tool for patients and providers.

Lynn Peterson: I'm not sure I follow that logic of keeping it available if you're saying it's this high risk and you're saying that if people have informed consent and you know that you've got a risk of 1 in 350 of spreading the cancer, if you're willing to take that risk it's okay?

Dr. William Maisel: Well, I think for individual patients who are warned that the risks and benefits of the alternative therapies - we can't look at a single procedure in isolation. There are other procedures that they may choose to undergo. For example, a conventional surgical procedure, which has its own risks associated with it.

And for individual patients it's conceivable that the risk associated with the surgical - the conventional surgical intervention could outweigh the risks associated with this laparoscopic procedure.

We don't think FDA is in the best position to make determinations for every individual patient. We think patients and healthcare providers should be making those decisions based on scientific information and so we're providing that information.

We think in general the procedure should not be performed and we're discouraging its use but we also acknowledge that there are individual cases in when it may be the best therapeutic options available for a given patient.

Jennifer Rodriguez: We'll take the next question.

Lynn Peterson: Just a clarification if I could?

Coordinator: Our next question comes from Mark McCarty of Medical Device Daily. Go ahead, your line is open.

Mark McCarty: Hi, thank you for taking the question. Dr. Maisel, it's probably rather simplistic to say that FDA decided to act once this hit 350. You know, especially considering that the clinical community had estimates between 1 in 500, 1 in 10,000 as you mentioned.

But can you fill in a little bit of the detail as to the internal discussions? You know, i.e. - you know, if this had been 1 in 800 would that had seemed like some statistical noise whereas 1 in 350 you felt was something actionable, things like that.

Dr. William Maisel: I think that's a good question. We did not draw a line in the sand and say a certain risk was acceptable and a certain risk was not acceptable.

Given the importance of this issue, the large number of women who undergo these type of procedures, we made a decision that we would communicate about this issue to make sure it was factual information available to the healthcare providers and women so that, again, the theme of the day - so that they could make informed decisions about their own care.

So we made the decision to communicate prior to the completion of our analysis, what the communication was going to say was certainly colored by the information that we determined from the analysis.

Mark McCarty: Okay, and sort of as a follow on there, I would assume that when you're looking at a procedure that has the - you know, the associated hazard of disturbing potentially metastatic tissue, now that raises, you know, a big red flag.

Is this an issue generally speaking that you feel like you have to address device by device and procedure by procedure? Or is there sort of a paradigm in the making at CDRH on this particular question?

Dr. William Maisel: I'm not sure I completely understand your question. What I can tell you is that we don't think this risk is unique to any particular laparoscopic power morcellator. We believe the risk is similar to different power morcellators that are marketed.

The focus of our advisory committee meeting will be laparoscopic power morcellators for use in gynecologic procedures generally not any one particular device. We do have a lot of experience in thinking about small risk that carry a high morbidity.

Medical devices sometimes have very unusual or rare events associated with them but those events can be extremely catastrophic sometimes, you know, heart valves, other types of life sustaining devices. So we're used to thinking about very rare risks. And again, it's why we think putting that information in the hands of patients and providers is the key so that they can make informed decisions.

Mark McCarty: Okay, thank you very much.

Jennifer Rodriguez: Thank you. We'll take the next question.

Coordinator: Our next question comes from Elizabeth Mechcatie of OBGYN News. Go ahead, ma'am, your line is open.

(Elizabeth Mechcatie): So did the FDA decide to conduct the analysis of the available data because of the reports in the media plus the reports you received of adverse events?

Dr. William Maisel: We decided - I mean first of all, we conduct analyses all the time and we get information concerning different types of adverse events and post market signals frequently. And we frequently conduct analyses.

But certainly the attention and the concern and the clinical community and patient community regarding this issue was a major determinant in our decision to conduct an analysis in this area.

(Elizabeth Mechcatie): Okay. And then I had two quick questions, could you elaborate on what the predicate devices were that were the basis of the approval and also will the advisory panel be asked whether they think the devices should be taken off the market?

Dr. William Maisel: So regarding your first question, the predicate devices were other types of devices that are used in surgery to cut tissue.

And regarding the advisory panel we've outlined in our communication the general types of questions that we will be asking, which include the clinical role of laparoscopic power morcellation in the treatment of fibroids, as well as a number of those other issues.

We do not anticipate explicitly asking them whether or not we should ban the device.

(Elizabeth Mechcatie): Okay, and what were the - what's the actual name of the devices that - the predicate devices? Do they have a technical name - version would recognize? Okay.

Dr. William Maisel: I don't know - as far as - at this time.

(Elizabeth Mechcatie): I mean not the trade name but just the name a surgeon would recognize.

Dr. William Maisel: Devices such as electrosurgical cutting devices.

(Elizabeth Mechcatie): Okay, thank you.

Jennifer Rodriguez: Thank you. We'll take the next question.

Coordinator: Our next question comes from Stephanie Beasley from Inside Health Policy. Go ahead, ma'am, your line is open.

Stephanie Beasley: Hi, yes. I was wondering if you could be a little more specific about the type of data that you all were looking at and what tools you are using to analyze that data including I guess future analysis? It sounds like you're planning on continuing looking at the data.

Dr. William Maisel: Can you clarify your question a little bit? I'm not...

Stephanie Beasley: Sorry, I'm trying to figure out what kind of information you all were looking at. I know you talked about adverse event reports and also some literature but if you could provide more detail about the type of information

you were looking at and how you collected it and how you plan to continue to collect it?

Dr. William Maisel: Sure, so the adverse event reports, as I mentioned, we had very few of them. So we certainly looked at them but they were not a major determinant in our decision.

We did post today a quantitative assessment of the prevalence of the unsuspected uterine sarcoma in women undergoing the treatment of uterine fibroids. It's an additional document that's posted today. And it summarizes our analysis of the scientific literature.

So we conducted a thorough analysis of the scientific literature in that analysis that is publicly posted.

We list the scientific publications upon, which we relied and that includes specifically nine publications that focused on women undergoing hysterectomy or myomectomy for fibroids. And that is the basis for the 1 in 350 rate that we published.

We also conducted an analysis of other available information, which helps - you know, including, for example, clinical practice guidelines, communications with - looking back over the information we have related to the manufacturers have submitted to us with regard to these devices. And so all of that information went into these recommendations today.

Stephanie Beasley: I also wondered if you could talk about the unique device identify system, how that might play into your future surveillance of this device?

Dr. William Maisel: Well, that's a great question. Unique device identifiers, unique number that will get assigned to each unique medical device products, the final rule for that was published last year. Starting in September of this year the highest risk devices need to have that number and in subsequent years ultimately all devices will carry that number.

It's conceivable that had this issue arisen and unique device identifiers were available that an electronic health system that contains information about the unique device identifiers as well as information regarding the patient's outcomes could have been tapped into if you will to learn more about the types of events that are occurring to these people.

I mean the truth is that rare events are extremely difficult to evaluate and that's one of the situations we have here. When you're talking about events that are as rare as 1 in 350, takes a very large number of - amount of information in order to identify the signal.

Jennifer Rodriguez: Thank you. We'll take our next question.

Coordinator: Our next question comes from Charles Bankhead of MedPage Today. Go ahead, sir, your line is open.

Charles Bankhead: Thank you. Do these devices have application for other conditions that are non - not gynecologic in nature, and specifically do they have other applications that might involve oncology?

Dr. William Maisel: The answer is yes, that there are devices that are used in other anatomic locations in the body. We are looking at information related to the use of these devices in other areas, although there is unique anatomy and unique issues with their use in gynecologic surgery.

And so the fact that this communication today is focused on that type of procedure as you might imagine is not a mistake. It's because this is the particular procedure for which we are concerned about its use.

Jennifer Rodriguez: Thank you. We have time for one more question. Can we have our last question, please?

Coordinator: Our next question comes from Elizabeth Orr of FDA News. Go ahead, your line is open.

Elizabeth Orr: Hi, thanks for taking my call. What I was wondering is if you've been in communication with the manufacturer of these devices? And if so what has their reaction been at this point? Thanks.

Dr. William Maisel: We have - I don't have specific information that I can provide you regarding the reaction to the manufacturers in this specific case.

What I can tell you is that when we identify risks and communicate to manufacturers regarding the type of information that should be included in their product labeling they typically are extremely cooperative and add the required information to their labeling if it's not already there.

There will be an opportunity for manufacturers to participate in the panel meeting. It is an open public panel meeting. So the public can come and provide their perspective, medical professional societies, patients, medical device manufacturers; it's an opportunity for all stakeholders to provide their perspective on this issue.

Elizabeth Orr: Okay, and because you mentioned the panel meeting, do you have an approximate date for it yet?

Dr. William Maisel: We certainly consider this an extremely important and high profile issue and so we're anticipating a summer panel meeting.

Elizabeth Orr: Okay, thank you.

Jennifer Rodriguez: Thank you. This concludes today's media briefing. A replay will be available in about an hour and will be made available for 30 days. Please remember to check the website for the press release and safety communication. Thank you for your participation.

Coordinator: This concludes today's conference. You may now disconnect.

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