Medical Device Sterilization Town Hall:
Overview of Sterilization Landscape and Role of Ethylene Oxide
January 10, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello everyone and welcome to today's Town Hall. Thanks for joining us. This is Commander Kim Piermatteo of the United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be the moderator for today's Town Hall.

During today's town hall, we will discuss the sterilization of medical devices, including ethylene oxide, or EtO, and other sterilization modalities. Specifically, we will discuss medical device sterilization challenges and activities leading up to the FDA's 2019 advisory committee meeting focused on EtO, review major discussion points from the advisory committee, and related FDA activities, describe the medical device sterilization landscape and supply chain integrity and discuss the need for forward-looking and collaborative activities and the role of FDA's new series of sterilization town halls.

For your information, printable slides of today's presentations have been posted to CDRH Learn. If you would like to reference these slides as you follow along today, please do so by going to CDRH Learn at www.fda.gov/training/CDRHLearn and selecting the section titled “Specialty Technical Topics” and the subsection titled “Sterility.” There you will find a link for today's town hall and the slides.

Before we begin, I'd like to provide a few reminders for the town hall. First, please make sure you've joined us through the Zoom app and not through a web browser to avoid technical issues. Second, trade press reporters are encouraged to consult with the CDRH Trade Press Team at CDRHTradePress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at FDAOMA@fda.hhs.gov. And lastly, we look forward to interacting with you today. If you have a comment or question, please wait and raise your hand at the end of today's presentation to get into the queue.

I now have the pleasure of introducing our presenters for today's town hall. Dr. Suzanne Schwartz, Director of the Office of Strategic Partnerships and Technology Innovation or OST within CDRH; Dr. Aftin Ross, Deputy Director of the Division of All Hazards Response, Science and Strategic Partnerships within OST as well; Dr. Ryan Ortega, Regulatory Advisor on the Regulatory Policy and Combination Products Staff within the Office of Product Evaluation and Quality in CDRH; and Dr. Tammy Beckham, Associate Director of the Resilient Supply Chain Program in OST.

Thank you all again for joining us. I'll now turn it over to Suzanne to start today's presentation. Suzanne.

Suzanne Schwartz: Thanks so much, Kim. Good day, everybody. My name is Suzanne Schwartz. And as Kim mentioned, I'm the Director of the Office of Strategic Partnerships and Technology Innovation at FDA's Center for Devices and Radiological Health.

I want to begin by extending a warm welcome to all of you who have joined us for today's FDA inaugural town hall on medical device sterilization. We are pleased to embark on what will be a series of town halls with you on this critically important topic area. With this format, our intent is to keep you up to date on our ongoing efforts as well as have open dialogue with our stakeholders. We want to hear from

you. And let me say up front, that while we may not have answers at our very fingertips to some of the questions that are asked of us, we are committed to getting back to you at a subsequent town hall to provide a response.

We encourage you to provide us with questions in advance of each town hall as well so that we can be most effective and efficient in addressing your questions. More information on how to submit questions is available on our web page and will be covered at the conclusion of the presentation component of today's session.

Our mission at CDRH is to protect and promote public health by ensuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices. Sterilization of medical devices is a vital process to help prevent serious infections. Consequently, inadequate sterilization can lead to life threatening infections in patients undergoing a wide range of treatment interventions, diagnostics, and medical procedures.

The delivery of health care across our nation depends upon the ready availability of safely sterilized medical devices. The resilience of our U.S. health care and public health critical infrastructure is predicated upon ready availability of safely sterilized medical devices. To date, the most commonly used method in the U.S. to sterilize medical devices is ethylene oxide, which has been widely used by medical device manufacturers and contract sterilizers across the globe.

FDA shares the Environmental Protection Agency's goal of lowering EtO exposure to workers and to community members while maintaining the integrity of the supply chain so that patients and health care providers have continued access to the sterile devices they need. To meet this goal, FDA continues to take a multi-pronged approach that you will begin to hear about today and in the town halls to come. Our approach includes regulatory flexibilities, collaboration, communication, and innovation. Now while some innovations appear promising, other methods of sterilization cannot currently replace the use of ethylene oxide for many devices.

Today, our team will be sharing more about the current ethylene oxide landscape and the forward-leaning approaches we are and have been taking to ensure that patients have access to the medical devices that they need.

And now to provide context to our efforts, it's my great pleasure to pass the baton to Dr. Aftin Ross.

Aftin Ross: Thank you, Suzanne. Next slide, please. Today's town hall on medical device sterilization marks a milestone as Suzanne said. In particular, in November of 2023, we had the four-year anniversary of our 2019 public meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee where we talked in depth about the challenges of how to reduce EtO environmental emissions without compromising assurance of medical device sterility.

For our first learning objective, we'll describe the medical device sterilization challenges in early 2019 that were turning points that led to the advisory committee meeting. The second learning objective will describe the advisory committee meeting and the advice and recommendations provided to FDA as a result. The remaining learning objectives for today's town hall will describe the current medical device sterilization and supply chain landscape and describe the need for forward-looking activities and the role of FDA's new series of sterilization town halls. Next slide, please.

In early 2019, FDA became aware that the Illinois Environmental Protection Agency issued a state EPA seal order that stopped all EtO sterilization activities or contract sterilizer in Willowbrook, Illinois. This action was taken due to concerns about the levels of EtO in the air around the facility. One of FDA'S immediate actions was to work with multiple stakeholders to help ensure that any medical device shortages due to loss of sterilization capacity were appropriately mitigated.

Subsequent to the Willowbrook Facility Seal Order, five additional contract sterilizers were either temporarily or permanently closed in other states. These closures resulted in an increased risk of shortages for more than 100 different types of sterile medical devices, and at least one actual shortage that I'll mention shortly. Next slide, please.

2019 was a watershed moment for medical device sterilization. As we began to see medical device availability concerns stemming from sterilization challenges, major activities over the last four years are included on this slide, and each will be mentioned in further detail later in this and in subsequent town halls.

With the Sterigenics closure in 2019, FDA took a proactive approach to ensuring patients and providers had access to devices they need. Specifically, we engaged in early partnering activities with industry stakeholders in the form of our innovation challenges in the summer of 2019.

This was followed by FDA'S advisory committee meeting in the fall of 2019. We'll also discuss our Master File pilot programs and the changes to FDA's statutory authorities enacted by the CARES Act in March 2020 during the COVID public health emergency that helped us learn more about potential and actual device shortages, so that we could proactively assess impacts to the medical device supply chain.

In addition, we'll affirm FDA's commitment to working with other government entities to address environmental health concerns while continuing to assure patient access to safe and effective sterilized medical devices. We'll also mention FDA actions, including the creation of a dedicated EtO Tiger Team, an additional Master File Pilot Program and standards recognitions in support of innovation and medical device sterilization and the resilient supply chain program's work to promote supply chain resiliency.

What has just been included in this timeline, which you can see on the far right of the slide, is our recent announcement updating the 510(k) Sterility Guidance, or The Submission and Review of Sterility Information in Premarket Notifications (510(k)) Submissions for Devices Labeled as Sterile. While we will discuss this guidance in greater depth in future town halls, this guidance is significant because vaporized hydrogen peroxide was moved from an established category B to an established category A sterilization method.

You may have noticed that I and others have mentioned that there will be future town halls. And in fact, we will provide an update on the guidance in a future town hall. As part of today's presentation, we'll be announcing that the town hall today is the first in a series of town halls that will focus on innovations and medical device sterilization and regulatory frameworks. We'll discuss this in greater depth at the conclusion of today's town hall.

I will now turn it over to my colleague, Dr. Ryan Ortega.

Ryan Ortega: Thanks, Aftin. Good afternoon, everyone or good morning or good evening, depending on where you're calling in from. For learning objective number two, I'd like to talk about some of FDA's early actions and some background for how our General Hospital and Personal Use Devices Panel of our Medical Devices Advisory Committee came about. And since that's a bit of a mouthful, I'll refer to that hereafter as either the advisory committee or perhaps just the panel.

So another one of our immediate activities following the Willowbrook Facility Seal Order was to hold this public advisory committee meeting that Aftin talked about before. One of the overarching goals here was to get input on how to reduce ethylene oxide environmental emissions without compromising assurance of sterility for sterile medical devices.

One of the committee's goals was to give advice and recommendations to help us understand and to mitigate the impact of the potential loss of ethylene oxide sterilization capacity in the U.S. We also heard technical presentations and we heard committee feedback about opportunities to either reduce or replace ethylene oxide use. We learned about the role that other sterilization modalities might play. We heard committee discussion and feedback regarding the potential supply chain and clinical impacts that might result from shortages of sterilized medical devices. Next slide, please.

This slide lists some of the key discussion points from the advisory committee meeting. I'd like to flesh some of these out a little bit more. We heard first and foremost that patient safety and access to sterile medical devices is absolutely critical. We heard the panel discuss how abrupt loss of ethylene oxide sterilization capacity would result in patient harm.

We talked about one specific shortage example that was from the closure and this committee meeting. And that example was that of a shortage of Bivona tracheostomy tubes. These are used in health care and at home settings for both adult and pediatric patients to help them breathe. And this was an example of how a particularly vulnerable population could be adversely impacted by shortages and by these perturbations of a very complex health care ecosystem.

All of the stakeholders involved in that example work to limit the negative impact of patients as much as possible. And we tried to work with the manufacturer to implement a real time review of the sterilization validation for the trach tube and a new ethylene oxide sterilization facility.

We also heard from the panel how ethylene oxide sterilization facilities, both in the U.S. and generally globally, have historically been run at full or almost full capacity. And this really leaves little to no margin to compensate for multiple facility closures, whether those closures are temporary or permanent.

Furthermore, other existing sterilization modalities really could not be adapted or retooled to replace the significant loss of ethylene oxide capacity. We also heard the panel discuss how these newer sterilization modalities really do show promise, but many are pretty early in the development stages. And there isn't currently sufficient infrastructure or big industrial scale ability to offset a major change in ethylene oxide usage.

Different modalities have different material compatibility considerations. And this can include what packaging might be appropriate for each modality and how the devices are packaged during production. The committee also discussed some potential opportunities to reduce ethylene oxide use and to optimize cycle design and cycle time.

For example, the panel talked about how we could explore the potential for using electronic labeling to decrease the amount of paper that's sterilized in an ethylene oxide sterilization process. This is important because paper is a large absorber of the ethylene oxide gas used in the process.

We also heard from the panel that implementing newer methods to take on a meaningful portion of ethylene oxide capacity would take many years. In fact, during some of our more recent outreach over the last year or so, we've confirmed that the number of years to move away from ethylene oxide could be as much as in the double digits. Regardless, material compatibility complexities and issues still mean that some products would likely have to be sterilized with ethylene oxide. For some devices, there really aren't currently any alternatives.

As we'll hear about more in the next learning objective, some of these challenges, particularly those around supply chain considerations from the advisory committee meeting haven't been fully resolved. The committee meeting concluded with some key recommendations. And we'll discuss these in more detail in the next town hall. But just in broad strokes, some of the types of recommendations that we received were in the area of providing regulatory flexibilities or incentives. We heard about potential ideas for supporting technological advances or changes to current sterilization processes. We also heard about the importance of continuing to work collaboratively with different stakeholder groups who are involved. Next slide, please.

And again, while I won't dive into the recommendations from the panel in great detail during this town hall, I do want to highlight some of FDA's actions that were in progress at the time of the panel meeting and others that were initiated as a result of the meeting. As I mentioned in the next town hall, we'll talk more about our three sterility Master File Pilot programs. And these are intended to give us opportunities to explore novel and creative ways to streamline the regulatory process for making sterilization process changes.

One of the ways that we've partnered with industry stakeholders is through our innovation challenges. These were announced in July of 2019 before the advisory committee meeting. And pretty much immediately, some of the information that we were getting from the innovation challenges helped to inform the advisory committee meeting and our subsequent activities.

In our next town hall, we'll share additional detailed information on these challenges. The first which explored alternatives to ethylene oxide sterilization, and the other that explored opportunities for reducing ethylene oxide emissions from sterilization processes that use ethylene oxide.

So now that I've covered some of the events that led to our advisory committee meeting and touched on some of the discussion points and some of our collaborative activities. I'd like to pass the baton over to Dr. Tammy Beckham to talk more about the current state of medical device sterilization with respect to supply chains.

Tammy Beckham: Thank you, Ryan. And in this learning objective, as Ryan just mentioned, we're going to talk a little bit about the current medical device sterilization landscape. So for this learning objective, we will cover that current state with respect to supply chains and some of the evolving challenges, and we'll talk a little bit about what the resilient supply chain program is doing as well. Next slide.

So as you know, today in 2024, the ethylene oxide sterilization landscape continues to be constrained. As many of you know, there are more than $20 billion devices sold in the U.S. every year that are sterilized with ethylene oxide accounting for approximately 50% of the devices that require sterilization.

Another 40% to 45% of medical devices are sterilized by gamma radiation. And the remaining 5% to 10% are sterilized by E-beam, X-ray, moist heat, dry heat, vaporized hydrogen peroxide, chlorine dioxide, and nitrogen dioxide. Each sterilization modality has specific attributes that make it more suitable than others for sterilizing specific types of devices.

EtO has a long history as an effective sterilant. It's unique combination of attributes, it's biocompatibility, device penetration and throughput make it ideal for sterilizing a diversity of medical devices. For example, ethylene oxide has excellent compatibility with a diversity of medical grade polymers used in the manufacturing of medical devices. And in fact, for some devices, ethylene oxide is the only sterilant available.

Operationally, ethylene oxide can efficiently sterilize large volumes of products in a single load, thereby, enabling the availability of products to patients in a timely fashion. And last but certainly not least, the need for manufacturers to co-package multiple components into a single kit for use during surgery or other lifesaving procedures increases the device complexity and density, thereby creating more material compatibility concerns when attempting to switch to other modalities.

At this time, ethylene's compatibility, efficiency, capacity, and throughput have not been mirrored by other modalities. Nevertheless, as we seek to reduce reliance on ethylene oxide usage for medical device sterilization, we must evaluate opportunities where possible to shift to alternative modalities and accelerate our innovation on these potential alternatives.

This work is extremely important because currently ethylene oxide facilities and other commercialization sterilization facilities are operating at capacity. And in addition, we know that geopolitical events have the potential to impact capacity of other modalities. Unplanned downtimes of sterilization facilities, even for short periods, can lead to significant supply chain disruptions. Next slide.

As we've previously stated, it is important to underscore that the FDA shares the concerns about the release of ethylene oxide at unsafe levels into the environment. And we are interactively collaborating with EPA and other jurisdictions to identify ways to reduce the use of ethylene oxide that also maintains safe and effective medical device sterilization without compromising patient care. Next slide.

In fact, in a better effort to understand the sterilization landscape and the ability of the industry to adapt to ongoing sterilization constraints and new regulatory requirements, the FDA has conducted extensive outreach to sterilizers, manufacturers of abatement and monitoring technologies and medical device manufacturers. During our outreach, we've gained a greater understanding of the diversity of sterilization facilities and the uniqueness of operations at each site.

We understand the complexities of implementing structural changes and the impacts that this can have on the availability of medical devices in an already constrained sterilization landscape. During our outreach, we also heard that longer lead times for designing, purchasing, installing, and validating equipment can lead to changes in medical device availability as well.

All these items and more are given consideration as we collectively work to reduce ethylene oxide emissions, while at the same time, assuring that patients and providers have the critical life saving devices required to receive and deliver health care.

Now I'm going to turn it over to Dr. Aftin Ross to speak about some of the next steps.

Aftin Ross: Thank you, Tammy. Next slide, please.

In the last learning objective, Dr. Beckham provided an overview of the current landscape, including potential challenges for medical device manufacturers, sterilizers, and other stakeholders and the potential supply chain challenges that may result in impacts to public health. Now, I'll share some activities as we look forward. Next slide, please.

Since 2019, the Agency has invested significant effort into supporting the development of alternatives to EtO and has implemented a number of programs and initiatives to support innovation in medical device sterilization. We recognize that collaboration is critical to solving these complex challenges. Collectively, we can work together to identify opportunities to reduce EtO usage, for example, through identification of devices that can be sterilized by multiple modalities.

Recognizing the challenges and that the use of alternative sterilization modalities, even for a subset of products, is a long-term goal. We continue to collaborate and accelerate innovation of new sterilization modalities. In doing so, FDA has been considering what might be in the art of the possible for transitioning some devices from EtO to another modality. And we've launched a cross-functional Tiger team to support efforts to reduce reliance on EtO. We'll be sharing more of FDA's recent activities when we meet next time. Next slide, please.

Our outreach and analysis over the last many months has uncovered a variety of questions, misconceptions, requests, and opportunities. We'd originally intended this town hall to be a single event, but the range of potential topics made it crystal clear that a single town hall would not allow us to discuss any topic in depth. And more importantly, would limit the opportunity to receive questions and feedback from you.

Therefore, this town hall is the first in a series focused on medical device sterilization. The goal for today was to set the stage for future town halls to continue sharing FDA medical device sterilization related activities in light of ongoing EtO challenges.

Future town halls may provide an opportunity to discuss potential mitigation topics, share medical device sterilization misconceptions, discuss logistical challenges and common regulatory approaches or questions and provide an interactive way for us to continue to receive your questions and comments.

Through these and future activities, we aspire collectively to advance innovation in the field of medical device sterilization. As such, these town halls are meant to support the sharing of information so that we can continue to collaborate and even accelerate our collective work on reducing EtO usage while ensuring the supply chain remains resilient.

To ensure we include the topics you are most interested in, we would like to hear from you during the Q&A today about potential topics of interest for future town halls. You can also reach out to us with topic ideas at medicaldevicesterilization@fda.hhs.gov. Next slide, please.

This slide and the slide that follows includes resources mentioned earlier in the presentation along with their full URL links. You can access these after the presentation.

In summary, we've described challenges in the medical device sterilization landscape starting with facility closures in 2019 that were turning point for our efforts and led to our advisory committee meeting and a number of FDA and stakeholder activities since that time.

We've also touched on other factors that have the potential to impact device availability and public health. FDA has prioritized reducing the use of ethylene oxide and taking actions to develop programs and initiatives to support innovation and medical device sterilization.

During our next town hall at the end of January, we'll share more about what FDA has been doing along with what we've learned from our outreach with stakeholders, like you. Regarding activities and challenges although we have some idea of the topics you might like to explore in future town halls we're very much looking forward to having continued collaboration and from hearing from you during today's Q&A to ensure we are meeting your needs. Next slide.

And I'll turn it over to Kim.

CDR Kim Piermatteo: Thank you, Aftin. And thank you everyone for your presentations today. We will now transition to our interactive comments and question and answer segment.

Before we begin, we will go over how we will manage the segment and a few reminders. To ask a question or provide a comment, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line, please identify yourself and your organization and then ask your question or provide your comment. If you have a question, please remember to limit yourself to asking one question only and try to keep it as short as possible. Then after you ask your question or provide your comment, please lower your hand in Zoom. If you have another question or comment, please raise your hand again to get back into the queue and I will call on you as time permits.

Now, as we wait to receive some of your questions or comments, I'd like to circle back to our presenters with a few questions. So Aftin, I'm going to come to you with a question. What are the other topics for this town hall series?

Aftin Ross: Thanks, Kim. Town hall topics may include but are not limited to FDA expectations for pre-market sterilization review for new submissions, modifications to existing submissions, and use of standards in review. We also anticipate that other topics could include collaboration and medical device sterilization, challenges and opportunities in switching sterilization modalities, and topics that we encourage you to identify, either in today's Q&A or after the town hall using the email address listed, medicaldevicesterilization@fda.hhs.gov.

CDR Kim Piermatteo: Thanks, Aftin. Next question, I'm going to direct that to Ryan. Ryan, the question is, what is the status of the innovation challenges? Are you accepting more applications?

Ryan Ortega: Yeah, thanks Kim, both good questions. And I'll start with the second one. The application period for the innovation challenges ended back in 2019. So we're no longer accepting new applications into those two innovation challenges. However, if someone has a new health care sterilizing technology, or maybe you have questions about sterilization for your device if you're a device manufacturer, we really encourage you to submit a Pre-Submission to CDRH to answer any specific questions you may have in these areas.

For the statuses of the challenges themselves, touching on the alternative modalities challenge, participants there are exploring the use of alternative sterilization methods. And in some cases, we're seeing that device manufacturers are working collaboratively with the contract sterilizers who are participating in the challenge to validate new, different, or improved sterilization methods as well as exploring the feasibility for scale up, which that industrial scale up component is really important here.

For the other challenge, focused on reducing ethylene oxide emissions, early observations and engagement with the participants of those challenges have suggested that participating facilities have been able to cut emissions ranging from about 20% to 35%. And this represents a potential impact of ethylene oxide reduction for millions of sterile devices.

CDR Kim Piermatteo: Thank you, Ryan. Alright, our next question, I'm going to be directing that to Tammy. Tammy, the question is, as a medical device manufacturer, what can I do if I have concerns about having enough sterile devices?

Tammy Beckham: Thank you, Kim. If you have concerns about device availability, please contact CDRH Resilient Supply Chain program and submit any supply chain disruptions through the 506J notification process. Manufacturers can submit shortages or supply chain disruptions through the manufacturing 506J site, and as well, providers, health systems, and patients and others can submit information about shortages to the device shortages mailbox as well. And we're happy to provide both of those links as well.

CDR Kim Piermatteo: Thank you, Tammy. Yes, we will be sure, if people have questions those links, we can recite them for them as well too.

Alright, so now we're going to move into our first question coming from our audience. That is coming from Mark Mortellaro. Oh sorry, Mark, I apologize. Can you raise your hand again real quick for me. There you go. Alright, so Mark, I've unmuted your line. Please unmute yourself and ask your question.

Mark Mortellaro: Hi this is Mark Mortellaro, Senseonics. In your presentation, you mentioned the alternative modalities such as nitric oxide and mentioned master file program. But manufacturers, frankly, don't always know how to find approved sites that perform these alternative modalities or sites that have master files. So my question is, what can FDA do to help manufacturers find if a master file is available or find sites that offer these alternative modalities, for instance, publishing lists on the FDA websites.

CDR Kim Piermatteo: Thank you, Mark, for that question. I'm going to turn it over to Ryan to provide you a response.

Ryan Ortega: Yeah, Thank you. And that's a good question. It helps to underscore the importance of these alternative methods. For the methods that have a master file, for example, in our master file pilots, I like to think of our medical device sterilization website as a one-stop shop for a lot of information related to a lot of these different projects we have going on.

In fact, that medical device sterilization website on the fda.gov site, it lists the participants that we have so far in each of the three master file pilot programs. Also, for a little bit more of an in-depth search, our registration and listing database might also include existing sterilization facilities that have previously been registered and listed for sterilizing medical devices.

While that's not exhaustive, I think those two resources are a potential first stop for looking for some of those sterilizers.

CDR Kim Piermatteo: Great. Thank you Ryan for your response. Thank you, Mark for your question. Our next question or comment is coming from Vanessa. Vanessa, I have unmuted your line. Please unmute yourself and ask your question.

Vanessa Rivel: Hi, my name is Vanessa Rivel. I'm an independent consultant. So my question is the FDA considering specific ways to encourage medical device manufacturers to move their devices to other sterilization methods if possible. I know some devices, and as you said, can only be sterilized using EtO, but if I have devices that can use another type of sterilization, there will be, let's say some type of program that the devices, I mean the manufacturers can and enroll in or something like that. Thank you.

CDR Kim Piermatteo: Thank you, Vanessa. I'm going to turn it over to Aftin.

Aftin Ross: Thank you, Kim. So I think we are addressing this in a couple of different ways. One is through standards. So we are aware that there has been activity in the standards in the standards space related to medical device sterilization. That is part of the reason that we recognize last year the VHP standards. There are other specific standards available for medical device sterilization.

FDA does have a list of recognized consensus standards. These are things that manufacturers can reference in their premarket submissions to the agency. That is certainly one way. The other is also having venues like this to make manufacturers aware of some of our policy considerations and our willingness to engage with them.

If manufacturers have questions with regard to potentially changing modalities for their products, we encourage them to come in. They can do a specific Q-Submission or Pre-Submission, focus on medical device sterilization where they can talk to us about some of the challenges and opportunities in that space, certainly understanding what some of those challenges are is very helpful for us as well as we think through ways we can help from a regulatory perspective. I'll see if any of my other colleagues want to respond as well.

I think we can take the next question, Kim.

CDR Kim Piermatteo: Alright, thanks, Aftin. And thank you Vanessa, for your question. Our next question is coming from a Mahek Laxmipriya. I apologize if I mispronounced your name. I've unmuted your line. Please unmute yourself and ask your question or provide your comment.

Mahek Laxmipriya: Thanks so much. Hi, everyone. I'm Mahek Laxmipriya from Medtronic. I just wanted to understand what drove the change of VHP to move from established category B to category A.

CDR Kim Piermatteo: Thank you, Mahek. I'm going to turn this over to Ryan.

Ryan Ortega: Yeah, Thank you, Kim. And thank you Mahek. We're excited about this update. And I would say it's been a combination of things. We'll talk more about this guidance and the guidance update in future town halls. But just very briefly, the recognition, FDA's recognition of the new VHP validation consensus standard was a big piece of this, being able to say that we have a scientific understanding of the VHP and now to have that recognized consensus standard to support validation and declarations of conformance we're really some of the leading points that allowed us to make the update.

But I'd also be remiss if I didn't touch on the fact that information that we learned from the innovation challenge, from actually being participants in standards development, from some of our outreach, and even going back to the advisory committee meeting were all contributors to that update.

CDR Kim Piermatteo: Thank you Ryan. And thank you Mahek.

Mahek Laxmipriya: Thank you.

CDR Kim Piermatteo: Alright, our next question or comment is coming from Mark Leahey. Mark, I've unmuted your line. Please unmute yourself and ask your question or provide your comment.

Mark Leahey: Great. Thanks so much, I'm Mark Leahey with the Medical Device Manufacturers Association. Just a quick comment and really thanks. I think today's town hall was a great overview of the collective efforts and FDA'S leadership over the past five years on a number of fronts. And I just again, our members are so appreciative of the collaboration and the real world dynamics of again we're all working to find ways to reduce the amount of EtO, but as was noted earlier doing so not at the expense of patient access.

So again, just a quick comment of thanks for FDA's leadership in this area, and MDMA and our members look forward to continuing this to ensure that any future changes make the necessary enhancements without adversely impacting patient access.

CDR Kim Piermatteo: Thank you very much, Mark. Much appreciated. Alright, our next comment or question is coming from Prashil Pranchal. I have unmuted your line. Please unmute yourself and ask your question or provide your comment or provide your comment.

Prashil Pranchal: Hi. I have a question about the innovation challenges, about other than innovation challenge, has FDA dedicated any resources towards making technological advancements to convert ethylene oxide to non-toxic compounds?

CDR Kim Piermatteo: Prashil, thank you for your question. I'm going to look to the team. Is there someone who would like to provide a response or a comment?

Aftin Ross: This is Aftin. I can start. And then if others have anything to add, please feel free to do so. So I want to remind or start out with what Suzanne kindly started with at the beginning with regard to what FDA's mission is. And it is really and in particular the Center for Devices and Radiological Health. And it is to ensure that medical devices are safe, effective, and available.

So our efforts certainly are focus in that medical device context. So we certainly will engage with different innovators in this space, but our primary responsibility and bailiwick is related to the medical devices themselves and the technologies. We are agnostic to some degree to the type of sterilization modality that is used. It needs to be able to be shown that it is safe and effective. And that's what we're looking at as part of our engagement and our review.

What I will say, though, is that we do, in addition to having-- certainly review is a big part of our activity at FDA, we do have a science and engineering labs component, our OSEL colleagues who also do some work in collaboration in the sterilization space to better understand modalities and where there might be opportunities.

But we're not-- in our day-to-day business focused on breaking down EtO in different ways. We're certainly happy to collaborate with other entities who might want to share that information with us. But that is not our bailiwick.

CDR Kim Piermatteo: Thank you Aftin for those comments. Thank you, Prashil.

Prashil Pranchal: Thank you.

CDR Kim Piermatteo: Our next comment or question is coming from Jake Gibbons. Jake, I have unmuted your line. Please unmute yourself and ask your question.

Jake Gibbons: Hello, Jake Gibbons, Genentech and Roche. Regarding the FDA's efforts to monitor and assess the potential impacts of changes that may impact the supply chain and potential shortages of medical devices, there's now pending requirements and timelines that will impact the use.

What is FDA's understanding of the potential impacts of the pending EPA changes that would impact ethylene oxide application considering the scope is potentially broader and more complex than simply the application for terminal sterilization of med devices? What risks has the FDA identified? And what risk mitigations are ongoing to help ensure the least amount of supply chain disruption and the availability of finished products and goods to patients?

CDR Kim Piermatteo: Thank you, Jake. I'm going to look to the team. Does anyone want to start by providing a response and then other people can join in. Tammy did you want to start?

Tammy Beckham: Sure, thank you. And thanks for those questions. Obviously, FDA has, as you mentioned, has been working very closely with sterilizers and manufacturers and even the companies that provide the equipment to understand what the potential lead times are, purchasing installation and also working clearly with our interagency partners as well, as we said, to achieve the goals to reduce

ethylene oxide usage as well as to continue to make sure that the devices are available to patients and health care providers.

And so, we continue to assess, continue to gain additional information and look at potential impacts regarding some of those challenges. And we will be working closely as we have been with the industry and our interagency partners going forward to fulfill our role of making sure that patients have access to the medical devices that they need.

CDR Kim Piermatteo: Thank you Tammy for your response. Thank you, Jake, for your question. Our next question or comment is coming from Gerald McDonnell. I have unmuted your line. Please unmute yourself and ask your question.

Gerald McDonnell: Hello, this is Gerry and thank you very much for the opportunity. It's good to hear you all and also echo what was said earlier on about the-- it's a fantastic update. We appreciate it, and we really appreciate the efforts and the collaboration with the FDA on this important topic.

So my question is regarding that some of the changes between sterilization technologies are relatively straightforward, should we say between radiation sources or location of radiation sources. But some are more difficult as you will as you will understand, such as the changes from EO to alternative technologies.

Is there any guidance, maybe pending, or more guidance pending on submissions and how the FDA could see where we could accelerate the clearance of submissions with such changes. And could there be a difference between a change that could be accelerated going from a category A sterilization process to another category A sterilization process as opposed to a category A going to a category B or C?

CDR Kim Piermatteo: Thanks, Gerry, for your question. I'm going to turn it over to Ryan.

Ryan Ortega: Yeah, Hi Gerry. Good question. And again, facilitating these changes to sterilization methods is a really important topic. While we can't necessarily discuss ongoing work on new guidance, what I-- there are a few things I can point to. Again, our 510(k) sterility guidance the one that was just updated talks about some of the information needs for some of these other methods and a new regulatory submission, but I'd also like to point to what we call our 510(k) modifications guidance, it's really focused on what sort of information might be needed and what a new submission might be needed for a change to a previously cleared 510(k) device.

This is also one that we're going to talk more about in a future town hall, but I do just want to put in a plug for that guidance because it does touch specifically on sterility in some sections and provides some guidance for when a new submission may or may not be needed going from one sterilization modality to another. That said, we also have our 510(k) sterility master file pilot, again, something we'll touch on in greater detail in a future town hall, so definitely, please tune in. But that was designed specifically to pilot creative ways of facilitating such changes.

And finally, if folks do have ideas or want to express ideas, we do have, again, that inbox that we created for this town hall series, we would welcome your feedback.

CDR Kim Piermatteo: Thank you, Ryan, and thank you, Gerry. Our next comment or question is coming from Sanjay. Sanjay, I have unmuted your line. Please unmute yourself and ask your question.

Sanjay Srinivasan: Hi, very good morning. Thank you, I'm Sanjay from Nevro. I work as a quality engineer. And my question is, we know that almost 50% of the medical device manufacturers use EtO. Now my question is, what incentive is providing for manufacturers to use alternate methods, most likely not financially, but most from a submission standpoint.

CDR Kim Piermatteo: Thank you, Sanjay. I think I'm going to turn this back over to Ryan, regarding the master file pilot, I believe.

Ryan Ortega: Sure. And I think this also goes back to some of the feedback we got from the advisory committee meeting, which was to wherever possible to provide some flexibilities or regulatory incentives. Like you mentioned, we can't really provide financial incentives, but those master file pilots where one of the ways that we are thinking about how can we be creative about reducing or even removing the timelines for reviewing sterilization changes.

Similarly, our innovation challenges were part of one of our efforts at advancing the development and really emphasizing the importance of the use of alternative methods. We have a lot of irons in the fire on this one. There really is no silver bullet for how we can develop and advance the use of alternative methods. So we're exploring, at least trying to explore lots of different areas that involve regulatory flexibilities where possible and appropriate.

Sanjay Srinivasan: Perfect. Thank you.

CDR Kim Piermatteo: Thank you, Sanjay, and thank you, Ryan, for your response. Our next comment or question is coming from Liz. Liz, I have unmuted your line. Please unmute yourself and ask your question or comment.

Liz Claverie: Hi, good afternoon, everyone. This is Liz Claverie, independent consultant. I have a quick comment and a quick question. I'd like to first thank the Agency for their continued work in this very, very important area for the sake of Public Health. And my quick question is, in the future, for any future town hall meetings, would you all consider covering the modality radiation to a broader extent whereby radiation would be used as an alternate.

I know, to Gerry's point, there are many companies that already sterilize their devices using radiation as a terminal method. But for those companies that manufacture products whereby a different forms of radiation, various forms of radiation have not been used as a terminal method, and they are using EtO in which wish to switch because of the times that we're living in, considering this, would discussion at one of the town hall meetings be able to be centered around the various types of radiation.

CDR Kim Piermatteo: Thank you, Liz. I'm going to turn it over to Aftin.

Aftin Ross: Thank you for the feedback and the suggestion, Liz. That is definitely something that we can consider for future town halls. And in fact, that is something that we definitely want to hear from you, from the audience what would be helpful for us to consider for future town halls. We want to make sure

that you are getting as much as possible as engagement and understanding which topics are most pertinent or salient for you certainly helps us to do that.

Liz Claverie: Thank you.

CDR Kim Piermatteo: Thanks again, Liz. And thank you, Aftin. I think we have time for one more question or comment, and that is going to come from Kyle. Kyle, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Kyle Dion: Yeah, hi, thank you for squeaking me in here. My name is Kyle. I'm from Blue Line Sterilization. And I've heard one of the potential upcoming methods to reduce emissions will be to require a reduction in EO concentration used per cycle and specifically for existing validated cycle. So however, I'm wondering if this same requirement will affect small scale EtO contract sterilizers who have a much smaller amount of yearly gas usage due to the sole use of hospital sized sterilizers.

CDR Kim Piermatteo: Thank you, Kyle.

Aftin Ross: Thank you Kyle for your question. That is outside the scope of this particular town hall and, quite frankly, outside of FDA's activities since that's related to an EPA action. I think if you have interest in that there's certainly opportunities to engage on that through other agencies.

CDR Kim Piermatteo: Thank you, Aftin. Alright, at this time, that closes out our comment and question and answer segment for today's town hall. And I want to thank you all for your participation today. And I'd like to turn it back over to Aftin to provide today's final thoughts. Aftin.

Aftin Ross: Thank you, Kim. And thank you for taking the time to attend our first town hall, or our inaugural town hall on medical device sterilization. We know schedules are very hectic as you are settling into the new year and appreciate how interactive you have been on a variety of topics, including medical device availability, alternative sterilization modalities, and better understanding FDA's regulatory flexibilities.

FDA is committed to advancing innovations and medical device sterilization while ensuring that patients and providers have access to the devices that they need. We hope you found today's engagement to be beneficial. I know we certainly did and we look forward to continuing to engage with you on this critical public health topic. We look forward to seeing you at the next town hall. I will now turn it back over to Kim.

CDR Kim Piermatteo: Thanks, Aftin. So in closing today, as I mentioned earlier, the printable slides of today's presentations are currently available on CDRH Learn at the link provided on this slide under the section titled “Specialty Technical Topics” and the subsection titled “Sterility.”

A recording of today's town hall and a transcript will also be posted to CDRH Learn under this same section and subsection in the next few weeks. A screenshot of where you can find these materials has been provided on this slide as well.

And if you have additional questions or comments about today's topic or presentation or for a future town hall, as all of our presenters have mentioned, please email

medicaldevicesterilization@fda.hhs.gov. This email address is also provided on this slide. And if you have additional questions about today's town hall in general, feel free to reach out to us in DICE at DICE@fda.hhs.gov.

And lastly, we hope you able to join us for our next medical device sterilization town hall scheduled for Friday, January 26, 2024. You can find a listing of all of our upcoming town halls and webinars via the link provided on the bottom of this slide at www.fda.gov/CDRHLearn.

This concludes today's town hall. And thank you all again for joining us. Have a nice day.

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