AdvaMed
Advanced Medical Technology Association

Scott Whitaker Written Testimony Summary
House Energy and Commerce Committee
Subcommittee on Environment, Manufacturing, and Critical Materials
Submitted October 16, 2023

We appreciate the opportunity to testify in front of the committee. While we are submitting the full written testimony, we've also included this summary.

We represent more than 450 medical technology companies, from the smallest startups to midsize organizations to the largest companies. All of which serve patients in every health care setting with lifesaving, life-enhancing medical technology.

Our industry produces approximately 40 billion medical devices every year in the U.S. Half of these devices – 20 billion – are sterilized with ethylene oxide, an FDA-regulated process to ensure patient safety.

The list of critical, everyday medical equipment that relies on this sterilization method is long.

We have made it clear that we welcome and do not oppose these updated rules. After all, our industry's commitment to saving and improving lives does not end where the sterilization process begins.

We do have serious concerns with the EPA proposals as currently written.

Sterilization is at capacity. The reality is, unworkable rules will further strain medical technology supply chains, and could lead to facility closures that would significantly impact patients.

According to an analysis of our industry, if EPA's proposed rules were finalized as written, the U.S. could face a 30 to 50 percent reduction in the number of medical devices getting to doctors and patients, which would of course have a disastrous effect on patient care.

The EPA's mandate to protect the public is critical.

In our communications with EPA, we have elevated the issues requiring EPA's attention and guidance to maintain the stable supply chains necessary to serve patients. The critical concerns we have communicated are that the rules must be workable, feasible, and not conflict with each other.

When it comes to the regulatory process, congressional oversight is critical. Hearings like this are critical to making sure regulations meet their intent, and do not harm to the patients and innovators who are impacted by this.

Thank you.

Written Testimony Before the House of Representatives
Committee on Energy and Commerce Committee
Environment, Manufacturing, & Critical Materials Subcommittee
Hearing, "Exposing EPA Efforts to Limit Chemicals Needed for Life-Saving Medical Devices and Other Essential Products"
Wednesday, October 18, 2023

Chair McMorris Rodgers, Ranking Member Pallone, Chair Johnson, Ranking Member Tonko, thank you for the opportunity to testify at this important hearing.

I am Scott Whitaker, president and CEO of AdvaMed, the Medtech Association. We represent more than 450 medical technology companies, from the smallest startups to midsize organizations to the largest companies. All of which serve patients in every health setting with lifesaving, life-enhancing medical technology.

Our industry produces approximately 40 billion medical devices every year in the U.S. Half of these devices – 20 billion – are sterilized with ethylene oxide, an FDA-regulated process to ensure patient safety.

The list of critical, everyday medical equipment that relies solely on this sterilization method is long.

I'm talking about surgical kits with instruments like clamps, scalpels, scopes, tubing, staplers, drills, sutures. All the tools necessary to conduct a surgery.

I'm talking about heart valves, pacemakers, respirators, IV sets, endoscopes, kidney dialysis instruments, continuous glucose monitors and insulin infusion kits.

The FDA has been very clear about its concern over the availability of these critical medical devices if the EPA's proposed rules aren't done right.

In its official statement to EPA dated March 15 of this year, FDA said:

"Without EtO, there would be a significant sterilization shortfall with no commensurate sterilization alternative available." Supply chain disruptions "of a variety of critical medical devices would likely be imminent." These disruptions "stemming from a lack of EtO would have significant impacts on patient health and access to critical medical devices and patient care."

And in the same statement, using just one medical device as an example, FDA stated: "In the event of the closure or reduction in output of even one of these facilities, the lack of these [intravascular] catheters could impact ~210K procedures annually and will immensely impact patient cardiac care."

All of which led FDA Commissioner Califf to say to Politico in April, “This issue is very much on the forefront for us. We are highly aware of it and ... I’m very worried.”

And the scientific reality is, the decision about which sterilization method to use is driven by the device itself, and is part of the scientifically driven FDA device review process.

As FDA said above, many of these technologies cannot be sterilized using any other method. Whether because other methods would damage or destroy the devices, or because the other methods cannot sterilize the technologies at the scale necessary to meet patient demand. Or both.

Safe ethylene oxide usage in commercial sterilizers has been regulated by EPA since 1994 and we follow all federal and state requirements and consistently look for ways to improve our process for the public and patients. And our industry is actively seeking alternative sterilization methods, which currently do not exist at the scale and sterility assurance EtO provides to patients and their doctors.

In addition, for nearly five years now, we have been working directly with the EPA as it updates its regulations.

We have made it clear that we welcome and do not oppose these updated rules. After all, our industry’s commitment to saving and improving lives does not end where the sterilization process begins.

It bears repeating: We welcome updated rules.

But it is absolutely critical that the regulations be done right. That they are firmly rooted in science.

Sterilization is at capacity and no new EtO sterilization facilities are currently under construction in the U.S. The reality is, unworkable rules will further strain medical technology supply chains, and could lead to facility closures that would significantly impact patients.

According to an analysis of our industry, if EPA’s proposed rules were finalized as written, the U.S. could face a 30 to 50 percent reduction in the number of medical devices getting to doctors and patients, which would of course have a disastrous effect on patient care.

Because we know 95 percent of all surgical instruments are sterilized with EtO, virtually every patient awaiting necessary procedures could be impacted.

Procedures that range from C-sections to heart-valve repairs. Open-heart surgeries. Hip replacements. Brain surgeries. Cancer biopsies … all of those could be disrupted if not outright delayed.

We agree with FDA: We cannot risk that.

Finally, let me end with this.

The EPA's mandate to protect the public is critical. That's exactly why we have approached the EPA as partners, not adversaries. Our staff and member companies have offered technical depth in meetings with the EPA, including Administrator Regan, and in our written comments on the proposals. The EPA told us our comments were informative and helpful.

In these communications, we have elevated the issues requiring EPA's attention and guidance to maintain the stable supply chains necessary to serve patients. Those include:

- Technology neutrality: There are multiple ways to guarantee the safe removal of emissions. Give industry the flexibility to customize member facilities to best address EPA's regulation (i.e., do not impose a uniform or *one-size-fits-all* approach (e.g., all in one processing or automation)).
- Timelines are unrealistic: It is estimated that, on average, facility upgrades can take 18 months to two years, and that is just for 1-3 facilities per year. For an entire industry of 60-plus facilities, that will take much longer. EPA should account for those practical realities.
- More broadly, we have met with EPA several times to express concern that the two regulations they are considering on many levels actually work against each other. Changes in one regulation would negatively impact and have the opposite intent of the other regulation. I am hopeful we can address those inconsistencies as well.

In closing, let me say a quick word about PFAS, as it is related and I know it will be discussed at today's hearing.

It is hard to imagine the medical industry without the many important products that contain fluoropolymers. From CPAP machines and prosthetic devices to IV bags, medical implants, and surgical equipment, to seals, O-rings and quick connectors, these medical devices are safely used by millions of people, every day, in homes, doctors' offices and hospitals around the country.

Medical devices made with fluoropolymers are critical to the medical treatment and health and well-being of Americans. It is crucial that PFAS regulations address only those PFAS of concern to human and environmental health and do not jeopardize the healthcare industry with impacts on the performance, cost, or availability of essential medical devices.

When it comes to the regulatory process, congressional oversight is critical. Hearings like this are critical to making sure regulations meet their intent, and do no harm to the patients and innovators who are impacted by this.

So, with that, let me thank you again for inviting me to testify on this critical public health issue.