QFR Response

The Honorable Bill Johnson

1. Congress has passed several spending bills over the last few years, including the CHIPS Act, the Infrastructure Investment and Jobs Act, and the Inflation Reduction Act. These laws heavily rely on the presumption that simply throwing federal money at industries and people will make all these things magically appear. The lack of critical manufacturing and supply chains in the United States is a huge concern today.

Why doesn't simply throwing money at this problem work?

What is the real-world impact of duplicative, overly burdensome, or overlapping regulations?

A:

Safely sterilizing medical devices is not a problem to be solved with additional federal spending.

Further as you rightly note, EPA has issued two major and overlapping EtO proposals. 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. This uncertainty and at times conflicting provisions directly impact our ability to not only plan but comply with the updated standards. For example, we won't be able to comply with the exhaust rate in the rule when we must implement a fixed level of ventilation (e.g., air exchanges per hour) as proposed in the PID. I am hopeful we can address those inconsistencies as well.

And importantly, we are concerned with the substantial aggregate impacts to the supply chain of the two proposals collectively that jeopardize patient access to critical devices.

2. In comments filed with EPA, other agencies within this administration formally submitted comments about their proposals on ethylene oxide. Those agencies include the Small Business Administration (SBA) and the Food and Drug Administration (FDA).

Given that FDA is the agency primarily responsible for the regulation of medical technology and medical devices, what movement have you seen by EPA, if any, to listen and respond meaningfully to FDA's concerns?

A:

EtO sterilization is a critical component in providing safe medical devices in the U.S. and abroad and is highly regulated. FDA has emphasized the importance of EtO sterilization, as it is used on more than half of all medical devices annually in the U.S. And there are no viable alternatives for many devices currently sterilized using EtO. And amidst tremendous demand in the U.S. healthcare system for sterile medical technologies, EtO sterilization is already at capacity.

The proposed rules as drafted would create significant downstream effects on the medical device supply chain and critical medical care for patients. Unfortunately, EPA failed to conduct an appropriate impact analysis – despite its acknowledgement of likely supply chain impacts—for either of these proposals, nor did it even undertake an interagency review of the PID, despite assumption of supply chain impacts on U.S. healthcare.

We understand that EPA is now consulting with FDA on both proposals, but FDA's feedback and expertise are critical. The FDA Commissioner himself noted substantial concerns on impacts for healthcare professionals and the patients we serve. We should take care that the rules do not interfere and conflict with FDA's role. FDA's experience and authority are critical in this process to ensure we get this right.

In a recent article, the FDA reiterated concerns about the impact of the EPA actions:

"We have had a very loud voice, and we continue to speak to our concerns with regard to the potential for shortages of medical devices," said Suzanne Schwartz, director of the Office of Strategic Partnerships and Technology Innovation Center at CDRH.

Schwartz added that the FDA has been working closely with the EPA and other government partners "in terms of really giving them an understanding of what the potential devastating impact would be as a result of the rules as they have been proposed."

3. I am aware that under EPA's proposals, millions of products would require revalidation, including extensive testing and change management with U.S. and worldwide regulatory submissions.

What would this mean for capacity and supplies of the critical medical technology needed for patient care?

A:
The proposal does not appropriately take into account the time and cost of cycle revalidation that would be necessitated for changes in manufacturers' FDA-overseen sterility assurance processes. Millions of products would require cycle revalidation, which includes extensive testing and change management, with U.S. and worldwide regulatory submissions and approvals taking even longer. This validation work will also cut capacity sharply amidst sterilization capacity constraints and jeopardize U.S. supply chain resiliency and overall critical sterile infrastructure.

All of this in turn will likely result in a significant disruption and public healthcare crisis because AdvaMed's members will be constrained in their ability to serve patients with the timely and steady supply of safe, effective, and sterile medical technology that our healthcare system requires.

4. One of EPA's proposed rules would cap the amount of EtO used in each sterilization cycle. I am told, however, that some devices require a higher amount of EtO per cycle for full sterilization, and so multiple cycles may need to be run to sterilize these devices.

Will EPA's Cycle Threshold Levels Result in increased usage of EtO?

A:
Depending on product and cycle design, in some instances the proposed limit may actually increase totaleto usage —if facilities are required to increase the number of cycles they undertake as a result of reduced concentrations along with theextensive validation testing that will be required.,.

Moreover, a concentration limit is a blunt and ineffective tool for reducing EtO exposure. A concentration limit would not be feasible for some products or require additional exposure time during gas dwell phase and may require additional gas "top ups" to maintain phase conditions also resulting in more use of EtO.

Products that are pressure sensitive—such as devices with sensitive components or so called "complex geometries"—are often sterilized using a shallow vacuum cycle, which require a higher concentration of EtO to assure sterility.

Likewise, a minimum concentration of 550 mg/L is often required to ensure penetration to the device for products sterilized in the final packaging, and changing this would affect millions of products available currently for patients.

5. Each year, CDC's National Institute for Occupational Safety and Health (NIOSH), in consultation with the American Conference of Governmental Industrial Hygienists, reviews and updates a level for EtO exposure. The current CDC/NIOSH level is set at 100 parts per billion (ppb), significantly lower than the OSHA limit utilized today. The CDC/NIOSH limit is higher than what EPA has proposed in its rules.

Would industry support using the CDC/NIOSH limit – which again is significantly lower than the OSHA limit utilized today – for EPA's EtO rules?

A:
Yes, we would support using the NIOSH limit. We believe the 2019 NIOSH limit of (0.1 ppm) produced by the U.S. Centers for Disease Control and Prevention, which was updated after EPA's 2016 EtO IRIS Study and is based on an occupational health specific risk assessment, is the appropriate occupational exposure limit.

As OSHA explains, "RELs are authoritative Federal agency recommendations established according to the legislative mandate for NIOSH to recommend standards to OSHA." In developing its RELs, NIOSH evaluates "all available medical, biological, engineering, chemical, and trade information relevant to the hazard." The RELs are expressly and directly intended for "use in developing legally enforceable standards" that "limit exposure to hazardous substances in workplace air to protect worker health."

6. You testified earlier that EPA has two proposals regulating the use of ethylene oxide in sterilizing medical devices and that those proposals, as written, are flawed.

What would be the result of those two proposals if they were to be finalized as proposed?

A:
It would have a terrible effect on patients. It would bring surgeries and procedures in some cases to a screeching halt. You would have supply shortages of hospitals that we've never seen before. And it's real. This is not hyperbole.

The risk associated with executing this rule in its current form is a major risk to access and patient health. And at its core, that's why we're most concerned.

Now we've suggested FDA or the EPA a number of ways to make this palatable. We haven't yet to get an answer from them on that, but we remain hopeful that we can improve it.

7. In your testimony to the committee, you said there were significant problems with the EPA proposed rules on medical device sterilization.

Please outline for the committee the specifics of the problems with those proposals.

A:
We have elevated the issues requiring EPA's attention and guidance to maintain the stable supply chains necessary to serve patients. Those include:

Tech-neutrality – There are multiple ways to support the updated standards. Give industry the flexibility to customize member facilities to best address EPA's regulation.

Timelines are unrealistic – It is estimated that, on average, facility upgrades can take 18 months to two years, and that's just for 1-3 facilities per year. For an entire industry of 60+ facilities, that will take much longer. EPA should account for those practical realities.

All in one sterilization – Studies show this EPA mandate could actually lead to more EtO usage and not achieve any efficiencies. [additional info in comments]

Automation – Another example of a one size fits all approach that raise serious feasibility issues. Further, we have shown to EPA there must be a worker presence to ensure certain sterility guidelines are met. We are hopeful they move off of this mandate.

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.

8. Medical devices are manufactured and sold worldwide.

If the current EPA proposals on device sterilization (EtO) were to go through as written what is the threat to device manufacturing in the United States?

What would that mean to national security?

A:
If the rule goes into effect as it is today, it would be very difficult from a supply chain standpoint. Shortages are almost certain to happen and happen quickly. And companies would have to relocate facilities overseas in order to sterilize at the level they need to. When you have to do, that then you have to ship product back into the country. And the supply chain challenges are more complicated.

9. Whether one believes ethylene oxide is the risk that EPA claims or not, it is still prudent to seek alternatives to its use where possible.

What has the industry and government done to pursue alternative sterilization methods?

Are those alternatives as effective as EtO?

A:
There has been significant progress by industry to implement state of the art improvements and implement cycle optimization. At the moment, no alternative to EtO exists to use at the effectiveness, quantity and scale our health care system requires. Other proven sterilization methods such as radiation and steam are not compatible with the majority of medical devices currently sterilized by EtO. Many medical devices – like plastic tubing, for example -- are heat-sensitive and would be ruined with steam.

A number of companies are working with the FDA in the agency's program to develop alternatives and/or exploring alternatives on their own. Sterilization contractors themselves may offer a range of sterilization methods, knowing that what works for one product may not work for another.

10. Do you believe that you were able to appropriately comment on the proposed rules with the information that was provided at the time, especially since the risk assessment was not completed?

Do you believe that EPA should provide a supplemental proposed rule and opportunity for public notice and comment, before finalizing the proposals?

A:
As drafted, the proposed rules will profoundly impact the critical medical device supply chain and are in a number of respects technically infeasible.

Any opportunity for further meaningful review rather than rushing to decision would be important to ensure there is an uninterrupted supply of vital sterile medical technologies for U.S. patients while achieving our shared goals of protecting community members and employees.

11. You raised several significant concerns in your public comments, such as all-in-one sterilization is not feasible, nor is a 10ppb action limit.

Has EPA confirmed that these unworkable provisions will not be finalized?

A:
We've had a number of meetings with the EPA, both high level and with technical expert staff, to describe how the sterilization process works. In June, several company leaders met with Administrator Regan to share concerns about the impact on patient care if the regulations cause facility closures.

AdvaMed has met with EPA technical staff to answer questions and provide resources. The industry is a resource for the EPA in explaining the process as it currently exists and the potential challenges in complying with regulations that may be too prescriptive and rigid. Our hope is that we can achieve our shared goals of protecting employees, community members, and public health. At this point we do not know if those particular provisions have been removed.

12. I know the Food and Drug Administration (FDA) is trying to map the supply chain of sterilized medical devices, including those sterilized using EtO; but the FDA is, at least, one year away from its completion.

Has AdvaMed conducted an industry gap analysis to assess the impact and the risk of the EPA proposals to critical sterile infrastructure?

What are the results of that assessment?

A:
AdvaMed did perform a gap analysis, which found that there would be a 30 percent to 50 percent reduction in sterilization capacity. The supply chain impact is stark.

The analysis notes that these reductions in capacity are permanent, not temporary in nature as assumed by EPA. It further reiterates the point our industry has been making to EPA, as proposed the PID and the NESHAP will create significant supply chain impact and that are both substantial and permanent in nature.

13. EPA's two EtO proposals rely on differing legal authorities with differing focuses.

Are there elements of the two proposals that are conflicting or make implementation technically impossible?

What is needed to ensure workable rules can be reasonably implemented?

A:
We have elevated the issues requiring EPA's attention and guidance to maintain the stable supply chains necessary to serve patients. Those include:

Tech-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.

Timelines are unrealistic – It is estimated that, on average, facility upgrades can take 18 months to two years, and that's just for 1-3 facilities per year. For an entire industry of 60+ facilities, that will take much longer. EPA should account for those practical realities.

All in one sterilization – Studies show this EPA mandate could actually lead to more EtO usage and not achieve any efficiencies.

Automation – We have shown to EPA there must be a worker presence to ensure certain sterility guidelines are met. We are hopeful they move off of this mandate.

Further as you rightly note, EPA has issued two major and overlapping EtO proposals. 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.

This uncertainty and at times conflicting provisions directly impact our ability to not only plan but comply with the updated standards. For example, we won't be able to comply with the exhaust rate in the rule when we must implement a fixed level of ventilation (e.g., air exchanges per hour) as proposed in the PID. I am hopeful we can address those inconsistencies as well.

And importantly, we are concerned with the substantial aggregate impacts to the supply chain of the two proposals collectively that jeopardize patient access to critical devices.

14. The EPA's ethylene oxide proposals, in certain cases, call for technology that either does not exist or is in limited supply.

If this requirement were finalized, what is the signal that is being sent to your industry?

A:
The industry seeks to comply with all requirements at every level of government: local, state, and federal. From local zoning to state permitting to federal regulations, the industry has professional engineers and health, environmental, and safety experts promoting compliance.

An inability to meet compliance requirements and deadlines because technology doesn't exist or can't be sourced by tight compliance deadlines would leave some facilities with no option but to shut down. That would be disastrous for patient care and counter to the outcome we all agree is best: Facilities continuing to operate safely and serving the tremendous demands of our health care system.

It's important to remember that certain equipment is highly specialized and made by only a few vendors. If every facility seeks the same equipment simultaneously, suppliers might be unable to accommodate the demand.

15. Based on figures from your members and the Cleveland Clinic, each year 37 million separate medical instruments are needed for 1 million breast biopsies; over 10.8 million separate instruments are needed for 300,000 hysterectomies; 29.5 million unique instruments are needed for 500,000 open-heart surgeries; and 1.175 million c-sections are performed using roughly 43 million instruments.

Are the instruments for all these procedures sterilized by ethylene oxide?

If ethylene oxide sterilization in the United States were to become limited or sent overseas; what would be the impact on women's health care?

And women's health care is one piece of medical services. Would you expect to see similar outcomes in all facets of medical services and procedures?

A:
The impact could be severe. Our health care system operates on the premise that health care providers will have instant access to every piece of technology they need for every procedure, whether an emergency or scheduled in advance.

If medical technology supplies become limited, either because sterilization facilities shut down or because technology must be sterilized overseas and therefore is delayed, patients would suffer from delays and disruptions in care. Providers could be forced to determine which procedures are most lifesaving and therefore which take priority. Is a breast biopsy deemed a procedure that can wait until sterile equipment is available, for example? Would doctors have to choose which open-heart surgeries can be postponed? These are the kinds of questions providers should not have to consider amid so much other uncertainty in health care today.

Our health care system is full of challenges, including serious provider shortages and insurance inequities, but the adequate supply of safe, timely medical technology generally has been a constant. It would be a shame to introduce instability into an aspect of the system that has been stable and reliable.

The Honorable Larry Bucshon, M.D.

PFAS are a broad class of 14,000 chemistries, characterized by the strong bond between fluorine and carbon. Because of this strong bond, PFAS provides products with strength, durability, stability, and resilience required for the safe functioning of a broad range of products. PFAS are defined based on small chemical structural elements with diverse properties and effects. It is not scientifically accurate to discuss or regulate them as a single class.

Given that, do medical device manufacturers use PFAS within medical products? What would be the impact if there were bans on the allowance of medical products that contain PFAS?

A:
It is hard to imagine the medical industry without the many important products that contain fluoropolymers.

CPAP machines, prosthetics, IV bags, surgical instruments, and many other medical technologies contain PFAS. These medical devices are critical to the treatment and health of Americans.

Much like the regulations on EtO, it's essential that any regulation on PFAS takes into account the manufacturing and availability of essential medical devices.

The effects of bans on PFAS in medical devices would have a terrible effect on patients. It would bring surgeries and procedures in some cases to a screeching halt. You would have supply shortages at hospitals that we've never seen before.

AdvaMed has claimed that sterilization facilities are not uniform operations. Is there a "one-size-fits-all" approach to the medical technology industry and sterilization? What is the danger of any final determination of these proposals in not allowing for flexibility to prevent any delays in lifesaving, life-enhancing, timely patient care?

A:
Every device is designed for the most appropriate sterilization method for that device. Every facility accommodates the devices sterilized within it.

A facility that sterilizes custom-assembled surgical kits, for example, may be configured very differently than one that sterilizes syringes or IV tubing. The technical engineers at each facility are best equipped to describe these processes and designs.

Lack of flexibility would have a terrible effect on patients. It would bring surgeries and procedures in some cases to a screeching halt. You would have supply shortages of hospitals that we've never seen before. And it's real. This is not hyperbole.

The risk associated with executing this rule in its current form is a major risk to access and patient health. And at its core, that's why we're most concerned.