

## **Written Testimony of Lishan Aklog M.D.**

### **House Committee on Small Business Hearing “Burdensome Regulations: Examining the Impact of EPA Regulations on Main Street”**

**Wednesday, February 14, 2024**

**10:00 a.m. ET**

Chairman Williams, Ranking Member Velazquez, and members of the committee. Thank you for inviting me to testify today.

My name is Dr. Lishan Aklog. I am a heart surgeon, medical technology innovator, entrepreneur, and small public company chief executive.

Last July, I was honored to testify before the House Energy and Commerce Subcommittee on Health on the importance of transparency and predictability in Medicare coverage of breakthrough medical technologies, including the unique burdens faced by small innovative companies in the current reimbursement landscape.

My testimony today shares many of the same underlying themes but focuses on the challenges companies such as mine will face, and the substantial harm for the patients we serve, if we don't get the rules right surrounding medical device sterilization that EPA is currently proposing.

Industry supports an update to these rules regulating ethylene oxide sterilization, the primary mode of sterilization for the many billions of medical devices produced and used every year. However, these proposals as written, are projected to greatly reduce sterilization capacity for lifesaving and life-enhancing medical devices which means a reduction in patient access to care.

To be clear, the industry supports an update to the rules but it must be done carefully and in close coordination with FDA and medical device experts.

As I did at the prior hearing, I hope to offer an enlightening perspective on the issue at hand, both as a surgeon, who used such critical devices to care for patients every day for over twenty years, and as a medtech chief executive who is developing and commercializing such devices today. Let me note from the onset that I am not an expert on environmental science, toxicology, sterilization technology, or the deeper policy dimensions of this issue. I do, however, have a working understanding of the projected consequences of the proposed regulations, and hope to provide some useful context as a small company executive and heart surgeon.

Let me start with a simple truth: medical technology innovation has provided us with novel devices which reduce the burden of disease, relieve suffering, and save millions of lives each year. That is a fact. I chose to transition from heart surgeon to medical technology innovator and executive precisely because I appreciated that I could apply innovation to impact patients on a

larger scale than I could as an individual practitioner. The majority of medical technology innovation happens at small companies such as mine. Small companies comprise approximately eighty percent of the medical technology industry.

Governmental action can have a significant impact, both positive and negative, on the development of, and access to, innovative medical technology products. For example, governmental funding of basic science research often sows the critical early seeds for innovation. Nondilutive funding from SBIR and STTR grants can offer a lifeline to early stage small companies. I commend the Committee for helping to shepherd reauthorization of these programs in 2022. R&D expensing tax provisions are another important tool to foster innovation. I commend the House for including such provisions in the recently passed tax relief bill and hope the Senate will follow suit.

Finally, legislative reforms which seek to increase transparency and predictability along the path to Medicare coverage of breakthrough devices would be a powerful stimulus to innovation. I was pleased that H.R. 1691, the subject of my testimony last summer, made it out of committee and I am hopeful that it will eventually become law.

Diverse governmental actions have great potential to positively impact innovation and equitable patient access to lifesaving and life-enhancing products. In contrast, today's hearing addresses a proposed governmental action that has just as great, if not greater, potential to have a negative impact for our healthcare system and patients we serve if not done correctly. They could stifle development of new innovative products and adversely impact, in a dramatic way, the supply chain of existing life-saving products, put millions of patients at risk of delayed care and even death. This may sound like hyperbole, but I can assure you that it is not.

The reason that some provisions in this regulation, as well-intended as they might be, have the potential to create such issues is that sterilization lies at the very heart of medical device development and production.

When a company such as mine seeks FDA regulatory clearance of an innovative medical device, it must design, verify and validate the often-complex processes required to manufacture such a device. One of the most time-consuming and costly steps leading up to FDA submission is rigorously documenting that the sterilization process works to perfection for that specific product.

We must show that our final product remains sterile during its rated shelf life, posing zero infectious risk to the patient. We must also show that the process of sterilizing, packaging and storing our product does not damage or impair the function of what are often complex, intricately assembled structures packaged in single-use kits.

This is more difficult than it may sound. Sterilization techniques which use extreme heat or radiation to kill microbes can damage intricate components or fail to penetrate the inner parts of a complex assembly. The anti-microbial gas ethylene oxide, however, can penetrate the

packaging as well as every nook and cranny of the device, sterilizing it without damaging its structure or function. Ethylene oxide sterilization has emerged as the most effective, and in most cases the only, currently available technique to sterilize the majority of medical devices, and the vast majority of complex, life-saving devices.

Let me offer an example from my direct experience as a heart surgeon. Every year, nearly a million patients undergo life-saving heart valve replacement surgery. The implanted artificial valves, designed to open and close hundreds of millions of times over several decades, are marvels of modern medical technology, incorporating metal, plastic, woven fabric and biologic tissue in a complex, intricate structure. The majority of heart valve replacement procedures are now performed using catheter techniques without the need for open surgery, with even more ingenious and complex constructions than surgically implanted valves.

An artificial heart valve infection is a catastrophic, and frequently fatal, complication, so these devices must be perfectly sterile. There is zero margin for error. The only available technique to sterilize artificial heart valves and the kits which are used to implant them is ethylene oxide. The plastic and biologic components of the artificial valve cannot tolerate exposure to heat or radiation. The catheter components have tiny internal channels extending over several feet, called lumens, which accommodate guidewires and fluids. The only currently available sterilizing gas which can penetrate a long catheter lumen is ethylene oxide.

It is my understanding that a large percentage of heart valves are sterilized at a single facility. Any significant disruption in this facility's capacity to sterilize artificial heart valves would have a devastating effect on hundreds of thousands of patients whose lives depend on them. I cannot even fathom the impact that the sudden closure of this facility, even temporarily, would have. There is no question that many patients would die.

Of course, this is just one example that happens to resonate with me as someone who performed heart surgery for many years. Every year, tens of millions of surgical procedures are performed in this country, from relatively simple biopsies to the most complex and intricate open-heart surgeries. The vast majority use devices and/or surgical kits sterilized with ethylene oxide. Step out of the operating room to the intensive care unit, or any patient care area for that matter, and ethylene oxide sterilized devices and kits are literally everywhere.

I would now like to shift to the central role sterilization, and ethylene oxide sterilization in particular, has played, and continues to play, in my role as a medical technology innovator, entrepreneur and chief executive of a small, innovative medical technology company. Fifteen years ago, my partners and I founded our first company while I was still a practicing heart surgeon. We invented, developed and commercialized a life-saving cardiovascular device which has saved many thousands of lives. The device, which was acquired by a larger medical device company ten years ago, is called AngioVac® and is now the standard of care to treat a deadly type of heart valve infection without the need for highly invasive open surgery. It consists of two separately packaged parts, each of which is sterilized using the exact same ethylene oxide

process we meticulously verified and validated many years ago. Any disruptions in access to ethylene oxide sterilization would immediately impact the often gravely ill patients who depend on AngioVac.

Today, I proudly serve as Chairman and Chief Executive of PAVmed (Nasdaq: PAVM), a small diversified commercial-stage medical technology company which I co-founded, and its subsidiaries Lucid Diagnostics Inc. (Nasdaq: LUCD), a cancer prevention company, and privately held Veris Health Inc., a digital cancer care company. PAVmed and its subsidiaries have a portfolio of innovative medical technologies in various stages of development and commercialization which require ethylene oxide sterilization. We will or already have deployed substantial resources, precious financial and human capital for a small company, to complete the verification and validation processes necessary to receive FDA clearance and offer these innovative technologies for the benefit of patients.

Our experience commercializing one of our more impactful and innovative products, Lucid Diagnostics' EsoCheck® Esophageal Cell Collection Device, nicely illustrates the unique challenges small innovative companies face navigating the existing sterilization landscape and the devastating impact acute reductions in sterilization capacity will have on our businesses and the patients we serve. Lucid Diagnostics commercializes the groundbreaking EsoGuard® Esophageal DNA Test—the first and only molecular diagnostic test that can accurately detect an early stage precancer, specifically esophageal precancer, the precursor to highly lethal esophageal cancer which kills over 16,000 Americans a year.

Each of these tragic deaths could have been prevented if esophageal precancer had been detected using our EsoGuard test before cancer develops. This requires collecting cells from the lower esophagus, near the stomach, by some noninvasive means which eliminates the need for complex and invasive upper gastrointestinal endoscopy.

EsoCheck is a deceptively simple but powerfully innovative tool which allows just that—precise targeted collection of lower esophageal cells performed in a doctor's office. The patient swallows a vitamin-sized capsule tethered to a thin catheter. A small balloon gently swabs cells from the target area and the capsule protects the sample as the catheter is withdrawn. The whole thing takes about two minutes and doesn't require any anesthesia or sedation. EsoCheck's gentle approach to noninvasive cell collection is a dramatic and elegant improvement over an older, cruder technology which involves dragging a Brillo pad-like sponge on a string and indiscriminately scraping cells from the stomach, esophagus and mouth in an untargeted fashion.

We licensed the EsoGuard and EsoCheck technologies from a major academic medical center and advanced the EsoCheck cell collection device through FDA clearance and subsequent commercial launch. Over ten thousand patients have undergone EsoCheck cell collection and successful EsoGuard esophageal precancer testing, as part of our early assault on the scourge of esophageal cancer. The FDA clearance required that EsoCheck be delivered as a sterile device to

assure that the sample is not seeded with contaminant DNA which could interfere with the molecular diagnostic test. As a catheter device with a long, tiny lumen, ethylene oxide was and remains EsoCheck's only sterilization option.

We quickly learned that manufacturing a device sterilized with ethylene oxide was uniquely challenging for a small company as a result of limited nationwide sterilization capacity. Large companies can, and often do, bring ethylene oxide sterilization in-house. Small companies do not have that option and are dependent on a small number of third-party sterilization companies, with limited overall capacity. Not surprisingly, small companies such as ours are their lowest priority customers and we began to experience perpetual threats to our supply chain as demand for EsoCheck grew.

We soon realized that as difficult as our supply chain challenges were, there was a real risk of things getting much, much worse as result of potentially dramatic cuts in already limited sterilization capacity. In order to mitigate this risk, we made the difficult decision to proactively deploy precious resources, including capital, to resubmit EsoCheck to the FDA as nonsterile device. This required extensive additional testing to confirm that eliminating the sterilization step did not adversely affect the performance of the device or the EsoGuard molecular test itself. Fortunately, the testing went well and we were eventually granted a new FDA clearance for EsoCheck as a nonsterile device.

All remain at severe risk of encountering supply chain disruptions if the proposed regulations move forward as proposed. We need to get these rules right.

Although, as I noted in my opening, I am neither a policy nor technical expert on ethylene oxide sterilization, I am, as the title of this hearing alludes to, a "Main Street" small company medical technology company executive who has studied the issue in some depth and is alarmed at the likelihood that pending EPA proposals will have a devastating effect on patient care nationwide as they are currently proposed.

I will also note that I am first and foremost a physician and, incidentally, a member of a family recently devastated by a cancer death. No one in this room is more committed than I am to prevent cancer and cancer deaths. It is literally the sole mission of Lucid Diagnostics which occupies the vast majority of my professional time.

As a first-generation American who fled political violence in Ethiopia over forty years ago, I have enormous faith that this great country, which has given me boundless opportunities, can apply technology and common-sense solutions to address its challenges.

Surgeons are known for their bluntness, so let me be blunt. The EPA regulations on device sterilization require the surgical precision of a scalpel. There are a variety of sensible, targeted, and scalable reforms to ethylene oxide sterilization regulation which would not risk patient access or medical device sterilization capacity. We can keep communities safe and lifesaving medical equipment available for patients.

Again, the industry supports an update to the rules, and we appreciate our ongoing collaboration with EPA on a thoughtful rule but these concerns must be addressed before the rules are finalized.

I implore this Committee, and Congress more broadly, to urgently work with the Executive branch and ensure we get this rule right. We all share the same goal—of ensuring patients have access to critical and lifesaving technologies they need.

Thank you very much for this opportunity and for your attention.