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House Energy and Commerce Committee, Subcommittee on Health, Hearing,
"*Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology***"**

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Chair McMorris-Rodgers, Chair Guthrie, Ranking Member Pallone, and Ranking Member Eshoo. 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.

Let me express my gratitude for starting the title of this hearing with a simple truth:

Innovation Saves Lives

Those three words form an incontrovertible statement of fact upon which we can, and should, all agree. I am grateful because this fact, which you have chosen to highlight and explore today, has been the driving force of my entire professional life spanning over three decades.

So, for me, those words mean that, at an accelerating pace over many decades, medical technology innovation has provided us with novel devices, diagnostic tests and, more recently, digital health tools which have reduced the burden of disease, relieved suffering, and, yes, saved millions of lives.

I hope to convince you that, as a result, medical innovation is an <u>imperative</u>—not a "nice-to-have" when resources are flush, or after other priorities are addressed. It is not something we <u>should</u> do, but something we <u>must</u> do, i.e., an imperative. The imperative is not simply that brilliant scientists and physician innovators must use their boundless imagination and scientific advances to develop these innovations, or that as a society we must nurture and partially fund such innovation. That is not enough.

The process of taking such innovations and translating them into actual life-saving products is long, arduous, and expensive. Research and development of innovative medical technologies is complex, resource-intensive, and subject to innumerable project risks along the way. So is the process of securing regulatory clearance and establishing a manufacturing footprint. Making this process as streamlined and predictable as possible, while maintaining the highest standards of evidence for safety and effectiveness, is a critically important part of this imperative. But that is still not enough.

The final, and perhaps most challenging, part of this imperative is that we, as a society, ensure that our citizens have equitable access to these life-saving technologies once they are available. This is also a moral imperative since taxpayer funds contribute substantially to the initial stages of many innovative technologies, including EsoGuard. The lack of a clear path to coverage is a major obstacle to maintaining funding during the precommercial process and then to getting patients equitable access to these technologies. Addressing this access and equity challenge is especially critical for the elderly and other Medicare beneficiaries, for whom the burden of disease and the unmet clinical need these technologies address is greatest.

Our nation is uniquely positioned to assure our patients access to innovative life-saving technologies. I am a first-generation American who fled political violence in Ethiopia over forty years ago. This great country has given me boundless opportunities and has allowed me to live the American dream. That is why, in my professional realm, I am extraordinarily proud that America has always been, and is unequivocally still today, the world's engine for medical technology innovation. We have the world's best universities, research institutions and academic medical centers, along with a plentiful supply of scrappy, audacious individual innovators. Our uniquely American spirit of entrepreneurship and our access to the world's most robust source of early-stage risk capital fuels this process, transforming these innovations into actual live-saving medical technologies which benefit the entire world. For Americans to

fully benefit from these home-grown innovations, however, our systems must evolve its processes to further embrace innovation.

The key factor, as we consider how to do this, is that most medical technology innovation occurs in small companies, such as mine. Small companies usually lack the resources to weather prolonged unpredictable stretches in the process of securing regulatory clearance and payment coverage for these life-saving technologies. Their ability to raise capital to bring these technologies to patients, and, therefore, their long-term survival as a company, is predicated on the transparency and predictability of the system. Promising life-saving technologies can wither and die as small companies try and fail to navigate these often-treacherous waters.

Congress and the relevant governmental agencies must play a critical role by keeping up with the pace of innovation and updating our systems to facilitate it. For example, as recently as ten to fifteen years ago, the industry norm was that Europeans patients got access to groundbreaking technologies developed and manufactured right here in America—five or even ten years before our own citizens. That is no longer the case due to improved and more predictable processes at FDA. By providing similarly predictable paths to Medicare coverage of emerging technologies, Congress and CMS have the opportunity to assure equitable access to live-saving innovations for Medicare beneficiaries.

This is not just high-minded rhetoric, so let me tack sharply to concrete examples from my own personal journey following the innovation imperative. Ten years ago, while I was still an active, full-time academic heart surgeon, my partners and I successfully commercialized a life-saving cardiovascular device, AngioVac®, which we had invented. We sold the company, Vortex Medical Inc., to a larger medical device company and AngioVac has since benefited at least ten thousand patients around the world. Having caught the entrepreneurial bug, I hung up my scalpel and co-founded a diversified medical technology

company, PAVmed, to be an innovation engine to bring our own innovations and those arising from the ecosystem of academic medical centers and individual innovators to patients and their physicians.

Today I am proud to serve as Chairman and Chief Executive of PAVmed (Nasdaq: PAVM) which is now a diversified commercial-stage medical technology company operating in the medical device, diagnostics, and digital health sectors. I am also the chief executive of its two majority-owned subsidiaries—Lucid Diagnostics Inc. (Nasdaq: LUCD), a cancer prevention company, and privately held Veris Health Inc., a digital health company focused on enhanced personalized cancer care through remote patient monitoring. Our small but mighty team of approximately one-hundred thirty high-skill employees (in my humble but admittedly biased opinion, the best team in medtech) works tirelessly to provide patients access to our life-saving technologies, skillfully navigating sometimes numerous obstacles and challenging capital markets.

Lucid Diagnostics was launched five years ago to advance and commercialize diagnostic technologies designed to prevent deadly esophageal cancer—technology developed by three brilliant Case Western University faculty, with millions of dollars of National Cancer Institute support. These technologies are now commercialized as the EsoGuard® Esophageal DNA Test and EsoCheck® Esophageal Cell Collection Device. NCI itself highlighted these technologies in its 2020 report to Congress as "one of the year's significant advances in cancer prevention". Soon after, FDA granted the technologies coveted Breakthrough Device Designation.

EsoGuard is the first and only molecular diagnostic test that can accurately detect an early stage precancer as well as all stages along its progression to cancer. Even more impressive, it can do so on a sample collected in a physician's office in less than five minutes using EsoCheck, a simple but innovative non-invasive cell collection device, avoiding the cost, complexity, and invasiveness (including general anesthesia) of traditional upper gastrointestinal endoscopy.

Let me offer a statistic to illustrate why this technology is so important. During this course of this hearing, a dozen or more Americans will undergo an upper endoscopy procedure which will culminate in a likely death sentence. Their executioner will be esophageal cancer, our second most lethal cancer, which has exploded five-fold in the past four decades while the incidence of other cancers has remained flat or fallen. This year, approximately 21,000 Americans will be diagnosed with esophageal cancer and approximately 16,000 will die as a result of it. Two-thirds of these deaths will be in the Medicare population. Each of those 21,000 individual stories will be eerily similar. A person, typically a 55- to 85-year-old white male with longstanding heartburn, develops new symptoms and undergoes an endoscopy which shows an ugly advanced stage tumor in lower esophagus. Despite what is usually gruesome surgery and extremely toxic adjuvant treatments, the patient will very likely die within five years. Even Stage I esophageal cancers carry a 50% mortality.

Those 16,000 individual stories of death from esophageal cancer are all equally tragic since they were almost all likely preventable using innovative technologies. It is well established in professional society guidelines that esophageal cancer can be prevented if esophageal precancer is detected before cancer develops, monitored for progression to late-stage precancer, and treated with a highly effective ablation procedure which reliably prevents progression to cancer.

EsoGuard and EsoCheck are incredibly promising given the profound unmet clinical need for widespread testing to detect esophageal precancer and prevent a preventable cancer. The results of a multi-center NCI-sponsored study, recently posted as a preprint prior to peer review process demonstrate this. It showed that EsoGuard detected 100% of esophageal cancers and over 80% of esophageal precancers. Similar results from a smaller VA study were recently presented at Digestive Diseases Week (DDW), a major GI conference. These results, which I believe are unprecedented in the field of early cancer detection, are exciting but of course not definitive. These are emerging technologies and additional clinical

trial and registry data is being collected to corroborate these results and further document their clinical utility.

Lucid's intense efforts to prevent esophageal cancer through early precancer detection is tightly aligned with public sector initiatives such as Congress' 21st Century CURES Act and the Biden Administration's Cancer Moonshot. Successfully preventing highly lethal esophageal cancer will have a significant impact on the Moonshot's goal of cutting cancer deaths by half in twenty-five years.

Let me offer an example, in a real patient, of how such innovation saves lives:

In the first quarter of this year approximately two thousand Americans underwent EsoGuard testing to detect esophageal precancer. One of those patients, Steve, a 70-year-old white male with longstanding heartburn was visiting his allergist where he saw an educational poster we produce on the relationship between heartburn and esophageal cancer, along with professional society guidelines on who should be tested for esophageal precancer. Seeing that he had five of the seven risk factors listed, he took it upon himself to inquire about receiving the EsoGuard test. The test came back positive and confirmatory endoscopy showed high grade dysplasia, the most advanced form of esophageal precancer, one step short of highly lethal esophageal cancer. He completed a series of ablation procedures and with monitoring he should remain cancer free. He told the team:

"I am damn lucky…I think I saved my own life."

He did save his life, so did the team who ordered the test, and those who confirmed it, and those who destroyed the abnormal cells. But for all his astuteness and the skill and dedication of the clinicians who cared for him, without innovative technologies the odds are exceedingly high that he would have progressed to cancer and died from it.

Innovation…Saved…Steve's Life.

Steve is of course just one extremely fortunate beneficiary of innovation. Although his story has a happy conclusion, it illustrates some of the challenges we currently face in getting patients access to these emerging technologies, which Congress and CMS can eliminate or at least substantially mitigate.

1. We have been working with CMS and its designated Medicare Administrative Contractor, for just under four years. The process of securing a Medicare payment rate was completed three years ago, a year after EsoGuard was commercially launched. The Medicare coverage part of the process has progressed in the recent past but is not yet complete and we went through years of uncertainty, including long stretches of silence, to get here.
2. Steve is a Medicare beneficiary but since we do not yet have Medicare coverage, we did not submit a claim. The entire cost of testing him, and all Medicare patients, is currently borne by us, and will be until we secure Medicare coverage.
3. We are a small company which continues to raise capital to fund its operations. Lucid's investors have invested over $100 million to get us here but the unpredictability and binary nature of securing Medicare coverage makes raising capital much more difficult than it should be for such promising technology.
4. These serious challenges are already creating a serious healthcare equity problem based on age—one which is only likely to get worse in the near term. Less than 10% of patients currently undergoing EsoGuard precancer testing are Medicare beneficiaries even though two thirds of esophageal cancer deaths occur in this group. Although not a cakewalk, securing in-network commercial coverage for new molecular diagnostic tests is a much more predictable, and at least incremental (i.e., non-binary) process. Unlike for Medicare, we do submit claims on all commercial patients and are receiving payments on some while actively engaged with payors through the review and appeal processes, which include peer-to-peer interactions with medical

directors. We have a lot of remaining work but there is a clear path forward. As a result, we are approaching a day when a 64-year-old with commercial insurance will have access to potentially life-saving esophageal precancer testing but a 66-year-old Medicare beneficiary may not, since, as a small company, we cannot indefinitely cover the costs of testing Medicare patients whose physicians order our test.

I have a deep personal commitment to assuring equitable access to innovative technologies to all Americans, especially to Medicare beneficiaries. I proudly serve on the Executive Committee of the Board of Directors of AdvaMed, the Medtech Association, and chair its newly launched committee which focuses on health equity. Lack of equitable access to new lifesaving technologies, which we are tackling, spans different demographic dimensions and various underserved communities. A stark example is found in Los Angeles. Wealthy Cedars-Sinai Medical Center, where Hollywood elite receive their care, had access to cutting edge transcatheter heart valve replacement technology, which obviates the need for open heart surgery, immediately upon FDA approval. Such wealthy medical centers often offer such newly introduced innovative technologies as a loss leader while the coverage process catches up. However, a few miles away, MLK Community Healthcare Hospital apparently still struggles to offer its disadvantaged community this life-saving technology—fifteen years after it launched!

I am highly confident that the important legislation before this Committee has the ability to ensure health equity by bringing predictability to the Medicare coverage process for innovative medical technologies such as EsoGuard. The legislation H.R. 1691 and the proposed CMS Transitional Coverage for Emerging Technologies Rule have laid the foundation. The underlying principle is clear:

To fulfill the promise of innovation saving lives, emerging technologies with demonstrated safety and baseline evidence that they are medically reasonable and necessary in Medicare beneficiaries must have a streamlined initial path to transitional Medicare coverage while additional evidence is being

collected as part of a predictable final path to full coverage. Various stakeholders, including AdvaMed, will be providing detailed formal comments on how TCET can be improved and continue to provide input on H.R. 1691. So let me close by highlighting three key concerns that I hope can be addressed by Congress and CMS.

1. The proposed TCET rule excludes diagnostic lab tests such as EsoGuard. There is no justification for this. Molecular diagnostic testing is at the leading edge of innovation. We saw this with Covid, and we see it even more prominently in cancer testing, where innovative screening, precision oncology, and surveillance diagnostic tests are revolutionizing the care of cancer patients. The experience I described in trying to secure Medicare coverage for a molecular diagnostic test is a testament to the fact that the MAC process for diagnostics is neither streamlined nor predictable.
2. The process of updating Medicare benefit category determination has historically been slow and in its current form is unlikely to keep up with the pace of innovation. Forcing some new innovative technologies, such as cutting-edge digital health tools, into what are often decades-old benefit categories could seriously undermine or even neuter these initiatives.
3. Many of us are concerned that insufficient CMS resources will in fact limit the number of TCET candidates to five per year across all technologies and conditions, as CMS projects. Such a cap could gut any improvements in the predictably of the process since a given company cannot determine whether its emerging technology will win the lottery and secure one of those coveted slots. The only way to assure predictability, which is the most important criteria for any such program, is to provide clear prospective criteria and provide CMS the resources to handle all live-saving emerging technologies which fulfill them.

Let me close by reiterating how grateful and excited I am that this Committee is strongly engaged on this issue on a bipartisan basis. I would like to personally thank the many H.R. 1691 co-sponsors for their commitment to assuring equitable access to innovative technologies. I do so not just a surgeon, entrepreneur and medtech executive but as a son of an 87 year-young Medicare beneficiary mother, who would not be alive today if were not for the miracle of multiple innovative medical technologies, which themselves were emerging technologies in the not-too-distant past.