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INNOVATION SAVES LIVES:
EVALUATING MEDICARE COVERAGE PATHWAYS
FOR INNOVATIVE DRUGS, MEDICAL DEVICES, AND TECHNOLOGY

TUESDAY, JULY 18, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:33 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Burgess, Latta, Griffith, Bilirakis, Johnson, Bucshon, Hudson, Carter, Dunn, Pence, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Obernolte, Rodgers (ex officio); Eshoo, Sarbanes, Cardenas, Ruiz,

Dingell, Kuster, Kelly, Barragan, Craig, Schrier, Trahan, Pallone (ex officio).

Staff Present: Alec Aramanda, Professional Staff Member, Health; Jolie Brochin, Clerk, Health; Sarah Burke, Deputy Staff Director; Sydney Greene, Director of Operations; Nate Hodson, Staff Director; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Lydia Abma, Minority Policy Analyst; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Saha Khaterzai, Minority Professional Staff Member; Una Lee, Minority Chief Health Counsel; Tristen Tellman, Minority Health Fellow; and Keegan Cardman, Minority Intern.

*Mr. Guthrie. The subcommittee will come to order, and I will recognize myself for five minutes for an opening statement.

Thank you, everybody, for being here today, and our goal today is to identify possible solutions to help address the financial sustainability of the Medicare program that also can help promote a greater quality of life and give way to a longer life expectancy for today's seniors and future seniors.

Over the past 50 years we have developed therapies to help treat and manage chronic conditions such as diabetes, and transformative diagnostic imaging technology such as MRI and CT scans and ultrasound technology to help diagnose other complex conditions that were once death sentences. Researchers are now racing against the clock to help diagnose and treat other diseases that reduce patients' overall quality of life and serve as a cost burden on our health care system. This includes the FDA's accelerated approval of an Alzheimer's disease drug two years ago, and the agency's recent traditional approval of another drug used to the same symptoms only two weeks ago.

Despite the historic advancement in treatments for

Alzheimer's disease, the Biden Administration has decided to limit access to these therapies through onerous coverage policies that require patients and their providers to take great lengths in order to administer and gain access to these drugs.

I remain extremely frustrated by the Biden Administration's restrictive approach to addressing this vicious disease. The costs associated with treating patients earlier in the disease might not only potentially save Medicare money, but, more importantly, it will also give these patients more time with their families until more effective treatments are developed.

The Biden Administration is also undermining our innovative ecosystem through actions taken to limit Medicare access to FDA-approved breakthrough medical devices and technologies. Instead of rewarding this innovation by providing a streamlined path to Medicare coverage for these novel products like the Trump-era Medicare coverage of innovative technologies rule would have gone down [sic].

The Biden Administration is reducing access to cures for patients -- policies through its proposed transitional coverage of innovative technologies rule. This significantly

narrows the number and type of products that can be used -- can use the breakthrough device program for streamlined Medicare coverage.

While I am pleased to see any action on this important issue from CMS, I believe this proposal misses the mark for patients and undermines the bipartisan work this committee did by creating the Breakthrough Devices Program in the 21st Century Cures Act.

I look forward to working with my colleagues on the subcommittee to address many of the proposal's shortcomings and to provide greater clarity for their patients, their doctors, and innovators by passing H.R. 1691, the Ensuring Patient Access to Critical Breakthrough Products Act. This would provide patients more predictable access to FDA-approved breakthrough devices if certain conditions are met.

Congress should also act to ensure patients are able to access these therapies by identifying reimbursement models that drive value. For example, the Medicare Advantage program could lead an adoption of value-based contracting for certain drugs or therapies. In addition to novel therapies, we now have diagnostic tools that can help us detect diseases sooner, such as multi-cancer screening diagnostics leading to

improved patient outcomes and savings to the health care system. These tools represent another opportunity to ensure our Medicare policies strike the appropriate balance of increasing access while driving higher quality care.

In closing, with a finite number of Medicare resources and an aging population, it is absolutely imperative for policy makers to ensure we are appropriately striking the balance of rewarding innovation while providing access to quality care in a way that doesn't bankrupt the system.

[The statement of Mr. Guthrie follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. That concludes my opening statement, and I yield back, and the chair will recognize the gentlelady from California for five minutes for an opening statement.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning, colleagues, and welcome to all of our witnesses.

The New York Times magazine last month declared the following: "It looks like we are in a golden age for medicine.'' Thanks to breakthroughs in mapping the human genome, advancing mRNA technology, and creating multi-cancer blood tests and other new diagnostics, we are on the cusp of seeing lifesaving innovations for some of the most intractable diseases.

This potential golden age is why I worked so hard with all of the members of this subcommittee to create the Advanced Research Projects Agency for Health, ARPA-H, which we got over the finish line last year, and that is designed to accelerate research and development to bring more cures to really the most intractable diseases, those diseases that, when someone is diagnosed, is essentially a death sentence.

However, the R&D pipeline doesn't end with a successful clinical trial or FDA approval. To bring cures from the benchtop to the bedside, patients need Medicare to cover new

drugs and devices. But the Medicare coverage determination process can be lengthy. According to the Stanford Byers Center for Biodesign, nationwide Medicare coverage for breakthrough medical technologies can take, on average, four to six years following FDA authorization. Medicare has tried to speed up coverage decisions through a pathway called Coverage with Evidence Development, or CED.

CED allows for Medicare to cover a new drug or device more quickly, while still collecting information about whether the new drug or device is reasonable and necessary for Medicare beneficiaries. In theory, CED sounds like a reasonable compromise. Medicare beneficiaries get timely access to new breakthroughs, while the Medicare program receives more information about how the treatments work in the real world. In practice, however, there has been a wide variability in the implementation of a CED.

Some therapies in a CED have had no data collection mechanisms. That means no one could actually receive coverage for the treatment. So that is a bust, in plain English. Other therapies have had registries to collect the patient data, but they were too costly or burdensome for the doctors, leading to inequities in coverage. This

unpredictability in CED requirements is partly why there was such a huge outcry over CMS announcing that it would require a CED for new Alzheimer's treatments. Patients weren't sure how they were going to get the care they need.

It is also unclear when a CED requirement will end. Out of the 26 treatments that have CEDs, only 4 have had their data collection requirements retired. For the CED process to be successful, CMS needs to issue clear policy and provide more predictable timelines.

CMS will also need resources and expert staff to make coverage decisions. That is why I was really horrified to see that the House Republicans released last week a draft fiscal year 2024 LHHS appropriations bill that cuts nearly $800 million from CMS, $800 million. That is a whopping amount of money that provides resources for what is necessary. These cuts are going to hurt seniors by making them face longer wait time for Medicare.

Industry can do its part by planning earlier for how to provide the evidence Medicare needs for coverage. More diverse clinical trials will help speed up CMS coverage decisions. And that is why my DEPICT Act that passed last year required drug and drug makers to plan to include more

diverse populations in their pivotal clinical trials.

With over 65 million Americans enrolled in Medicare, every coverage decision is fraught. Medicare beneficiaries deserve access to safe, effective, and affordable treatments. So I look forward to hearing from our witnesses today -- you are a panel of experts and -- on how Medicare can better achieve the balance that -- I have hopefully drawn out where the kinks are, and how we can do much better for them. They are counting on us to make sure this really does take place for them.

[The statement of Ms. Eshoo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. So thank you, Mr. Chairman, and I yield back the balance of my time.

*Mr. Guthrie. Thank you. The gentlelady yields back her time. The chair will now recognize the chair of the full committee, Chair Rodgers, for five minutes for an opening statement.

*The Chair. Thank you, Mr. Chairman, and good morning, everyone. I too am grateful to all who are here, those that will be testifying. And it is just great to see the committee room packed out for this hearing.

America is the global leader in medical innovation. It is truly an American success story. Today there is more than 160,000 clinical trials taking place around the country. That is more than the European Union, Australia, and South America combined. That means hope for patients with diseases like spinal muscular atrophy, Alzheimer's, ALS, and many others. It means hope that a treatment or cure is likely to be studied and approved in the U.S. first.

But it does not necessarily mean that patients in the U.S. will have access to these breakthroughs first. Today we will discuss how to remedy government policies standing in the way or slowing down patient access to treatments and

cures.

I think about how America was home to one of the first successful treatments for sickle cell disease and multiple sclerosis. In 2010 a woman named Jennifer Nsenjyire underwent a then-experimental procedure that changed the course of her life. For 10 years following her stem cell transplant her quality of life improved in ways she never imagined possible. She worked, walked miles a day, and had hope for the future. Tragically, Jennifer passed away from COVID-19 in 2022, but she left a legacy of advocating for other sickle cell patients in hope for a cure.

Imagine having sickle cell disease or other diseases, knowing there is a possible cure, and not being able to access it. Unfortunately, in 2016 CMS issued a national coverage determination, or NCD, that might prevent others from accessing the same treatment. And these decisions to limit coverage like the one for the new Alzheimer's treatments discourage innovation that could help patients and improve people's lives.

As our competitors like China continue to invest more money in biotechnology, it is crucial that we maintain our competitive edge so that people continue to look to the

United States of America for lifesaving medical products and treatments. As such, I remain extremely concerned about the impact of the so-called Inflation Reduction Act price controls on innovation and the $3 billion that was given to CMS.

I hope that Democrats heed the warnings of outside experts who see lost innovation happening in real time, and work with us to mitigate the damage before it is too late. Bipartisan concerns over CMS's heavy-handed coverage policies present us with an opportunity to work together to ensure seniors can access new and innovative treatments.

For example, I look forward to hearing from our witnesses about how we can strengthen the CMS TCET proposal. There appears to be some good in the notice, but I remain concerned about the uncertainty for patients and doctors created by CMS's lack of transparency, accountable timelines, and a predictable coverage pathway for FDA-approved technologies.

That said, I remain encouraged by the strong bipartisan support for key policies in the previous Administration's Medicare Coverage of Innovative Technology, the MCIT, rule. I believe it will help us come together to strengthen TCET

proposal for patients.

Predictability in these coverage pathways is also important for American leadership in cures and treatments. Predictability is compromised when a health care bureaucracy is tasked with determining whether a treatment is reasonable and necessary for Medicare patients.

Take the example of how Alzheimer's afflicts the Medicare population, namely millions of Americans over 65 and people with disabilities like Down syndrome. First-of-their-kind medicines were brought to the market, and CMS decided that these medicines and any future ones like them did not meet the reasonable and necessary standard for those that depend on Medicare for coverage.

This is unacceptable. Not only did CMS cut off access for the very population their medicines were intended to treat, but it also stopped innovation in the tracks by passing judgment on products that do not yet exist, or whose clinical outcomes were under review. In a self-fulfilling prophecy, by saying future products won't be covered CMS is ensuring investors will never take the risk necessary to bring them to market.

I want to provide hope -- all of us do -- hope to all

patients like those with sickle cell disease, MS, or Alzheimer's, that a cure or treatment is on the way. We want an innovation ecosystem that constantly seeks new cures, new treatments, and new ways to help people. That is the promise of America, where hope turns into real lifesaving breakthroughs. So again, thank you to the witnesses. I look forward to hearing your ideas as to how we can make these processes work better for patients.

[The statement of The Chair follows:]

**********COMMITTEE INSERT**********

*The Chair. I yield back.

*Mr. Guthrie. Thank you. The chair yields back. The chair will now recognize the ranking member of the full committee, the gentleman from New Jersey, Mr. Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman. And, you know, I just have to say that I do hear constantly from the other side, from the Republican side, criticism of CMS, FDA, and all these agencies that, in my opinion, are really the key to our success in innovation.

I mean, also at the same time, efforts on the Republican side to cut back on research dollars for these agencies like the CMS and FDA, I mean, we can't rely on pharma and the private sector to, you know, solely develop new drugs. I mean, they are driven by profit. They are driven by how much money they can make. And they are not -- you know, sure, they are worried about safety because they want to make sure that their drugs are safe, otherwise people won't buy them.

But we can't just constantly say CMS is bad, CMS shouldn't have any money, you know, and then say, okay, pharma and the industry is going to take care of everything. It doesn't work that way. They have to work together, and we

have to be monitoring both the Federal agencies as well as the private sector to make sure that they are well funded, and that they have -- that they are conscious of safety in their effort to bring drugs to market. And I think that -- you know, I don't want to constantly remind the other side, but you need to work hand in hand and not just say, you know, that the public sector is the bad guys.

In any case, let me just talk about the issue at hand here. The Centers for Medicare and Medicaid Services plays an important role in ensuring that Medicare beneficiaries can access innovative medical technologies and treatments in a timely manner. CMS does all this while maintaining appropriate safeguards that prioritize the health and well-being of our nation's seniors and the disabled. And this is particularly critical, since we have seen an acceleration of scientific breakthroughs over the last few decades.

We are extremely fortunate to live at a time when biomedical sciences have become so advanced and medical knowledge has progressed to allow the creation of cures and treatments to address and slow the progression of devastating diseases, including Alzheimer's. Today nearly 6.7 million Americans are living with Alzheimer's disease, and

unfortunately, that number is expected to increase by 214 million by 2060. And these numbers are sobering, and virtually no one in this country will be spared from the devastating impact of Alzheimer's.

So I was pleased to see Medicare provide broad coverage of Lecanemab following the FDA's decision to grant traditional approval. Medicare covers Lecanemab more broadly at this point than any other payor, while facilitating the collection of real-world evidence through a patient registry. And I am hopeful the drug will live up to its promise of slowing the progression of Alzheimer's disease for patients.

Because of the nature of clinical trials, the approval studies left important questions unanswered about how Medicare beneficiaries as a whole will do on this medication. Both the FDA and the neurology community have cautioned about safety in certain patient groups and the potential deadly side effects that drugs can cause. And as a result, CMS is asking doctors who prescribe the drug to provide clinical data through a free registry. This registry will allow doctors and patients access to all the information they need to make the right decisions about this treatment and others like it.

And I believe CMS has taken the right approach, leaving clinical decision-making between patients and doctors, while addressing current evidence gaps to better understand the benefits and side effects associated with the drug. And I look forward to hearing from our witnesses today about the proposed registry, as well as opportunities for improvement to ensure that it collects the right information at the right time, and does not hinder beneficiary access.

Now, CMS has also proposed a process for covering breakthrough devices in the Medicare program, while ensuring the collection of real-world evidence to fill any evidence gaps. And the collection and review of this evidence will also allow CMS to adjust coverage decisions based on new developments.

We must also recognize that treatments and cures only work when patients can afford them. Lecanemab costs $26,500 per year. That is nearly the annual income of the average Medicare beneficiary. And the pharmaceutical industry must stop putting profits over patients, and ensure seniors have access to effective treatments and medications that are affordable.

So I thank our witnesses for being here today. We look

forward to your testimony.

[The statement of Mr. Pallone follows:]

**********COMMITTEE INSERT**********

*Mr. Pallone. And with that, Mr. Chairman, I yield back.

*Mr. Guthrie. The ranking member yields back, so now we will move to witnesses' opening testimony.

I think most of you have testified before, but you know that you have five minutes for your opening statement. There is a lighting system. Four minutes into your opening statement you will see a yellow light, and it means you are approaching near the end, when you see the red light, to -- it is -- to wrap up if you are beyond that. But we appreciate you guys being here today.

So what I will do is introduce all of you, and then we will call on you one at a time to move forward. So the witnesses we have before us today is Dr. Natalia Rost, president-elect of the American Academy of Neurology; Dr. Thomas MacGillivray, president of the Society of Thoracic Surgeons -- I believe we have a thoracic surgeon on our committee, don't we, Dr. Bucshon?

[Laughter.]

*Mr. Guthrie. Yes, so he is your president now.

[Laughter.]

*Mr. Guthrie. Dr. Lishan Aklog, chairman and CEO of

PAVmed; Dr. Todd Brinton, corporate vice president and advanced technology chief scientific officer for Edwards Lifesciences; Ms. Sue Wronsky, Alzheimer's Association advocate; and Dr. Brian Miller, non-resident fellow at the American Enterprise Institute, and assistant professor of medicine at Johns Hopkins University School of Medicine.

So we will begin with Dr. Rost, and Dr. Rost, you are recognized for five minutes for your opening statement.

STATEMENT OF NATALIA ROST, M.D., PRESIDENT ELECT, AMERICAN ACADEMY OF NEUROLOGY; THOMAS MACGILLIVRAY, M.D., PRESIDENT, SOCIETY OF THORACIC SURGEONS; LISHAN AKLOG, M.D., CHAIRMAN AND CHIEF EXECUTIVE OFFICER, PAVMED; TODD BRINTON, M.D., CORPORATE VICE PRESIDENT, ADVANCED TECHNOLOGY CHIEF SCIENTIFIC OFFICER, EDWARDS LIFESCIENCES; SUE WRONSKY, ALZHEIMER'S ASSOCIATION ADVOCATE; AND BRIAN MILLER, M.D., NONRESIDENT FELLOW, AMERICAN ENTERPRISE INSTITUTE, ASSISTANT PROFESSOR OF MEDICINE, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

STATEMENT OF NATALIA ROST

*Dr. Rost. Good morning, everybody. First let me thank Chairman Rodgers -- Chairwoman Rodgers, Ranking Member Pallone, Chairman Guthrie, Ranking Member Eshoo, and the members of the subcommittee for the invitation to represent the American Academy of Neurology on this important topic.

My name is Dr. Natalia Rost. I am a vascular neurologist, chief of the stroke division at the Massachusetts General Hospital, and professor of neurology at Harvard Medical School. In addition to my roles at Harvard

and MGH, I am particularly proud of my career-long service to the American Academy of Neurology, or AAN, where I currently serve as president-elect and vice chair of the Committee on Public Engagement. The AAN is the world's largest neurology specialty society, representing more than 40,000 neurologists and clinical neuroscience professionals. Our priority is to provide the highest quality, patient-centric neurologic care for all in need.

For years, the disorders our profession treated such as stroke, epilepsy, dementia, MS, Parkinson's, ALS, traumatic brain injury, muscular dystrophy, and many others had little hope of a cure. Today science has progressed to the point where we have innovative therapies that can slow or stop the progress of many of the conditions we treat, giving new hope to our patients and their families.

One such area where we have been -- have seen innovation bring in potential hope is the development of monoclonal antibody treatments directed against amyloid for Alzheimer's disease. Our members know all too well the burden this disease places on our patients and their families. We fully understand the promise these new treatments hold, yet we remain concerned about the potential for dangerous side

effects and the need for additional data on their impact on certain patient populations.

Thus, we have been eager to provide our expertise to CMS as they have considered how to cover these new treatments. In fact, the AAN has been engaged with CMS on these new therapies for more than two years, with a goal of ensuring appropriate access to these treatments. We engaged with CMS as they made initial coverage determinations about Aducanumab, the first treatment to receive accelerated approval for this drug class, and many of our suggestions were included in the final coverage determination.

However, there are two key areas where we had concerns with CMS's final decision: first, given the first-in-class effect, where we were concerned that the initial coverage determination would apply to all drugs in the class without consideration of the potential clinical benefit they could demonstrate; second, we were concerned the coverage determination did not include a clear off-ramp for patients for whom questions of efficacy and safety have been clearly addressed.

It is because of these concerns that in February of 2023, following the publication of evidence relating to the

safety and efficacy of Lecanemab, that the AAN submitted a request to CMS that they would reconsider their current coverage determination for this class of drugs. Following that submission we engaged directly with the agency to refine our request and provide CMS with actionable recommendations. The result of those conversations was the amended formal reconsideration request we submitted to CMS on June 12 of this year.

There are two key asks in this amended reconsideration request: first, the AAN asks that the subset of patients for whom there is conclusive peer-reviewed evidence available demonstrating the safety and effectiveness of Lecanemab be removed from the CED requirements; second, we request that an off-ramp be clearly delineated to allow newly gathered evidence collected to be expeditiously taken into account so that the patients can be quickly removed from the study requirements as appropriate, based on the evidence.

We are grateful to CMS for engaging in a constructive dialogue with us throughout this process, and we hope it will result in positive changes for the benefit of our patients, their families, and their communities. We believe that our experience in providing feedback and working with

stakeholders throughout this process can shed light on lessons learned, opportunities for improvement to further promote appropriate patient access to innovative treatments.

While considering how the Medicare-eligible populations can access innovative treatments, the AAN hopes the committee will also consider additional factors that are likely to restrict patient access: among them the physician and, in this case, particularly neurology workforce shortage; increased use of utilization management tools by payers such as prior authorization and step therapy protocols; and the high out-of-pocket costs for these treatments will also create serious barriers to access.

I would like to reiterate the AAN's gratitude to the subcommittee for inviting me here today, and to CMS for their continued willingness to work with the Academy to find the best path forward to promote coverage of these new therapies to help our members deliver the best possible care to their patients in need. We look forward to continuing our engagement with the subcommittee on this important issue. Thank you.

[The statement of Dr. Rost follows:]

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*Mr. Guthrie. Thank you. The chair now recognizes Dr. MacGillivray for five minutes for your opening statement.

STATEMENT OF THOMAS MACGILLIVRAY

*Dr. MacGillivray. Good morning, Chair Guthrie, Ranking Member Eshoo, and members of the committee. Thank you for the opportunity to testify today on this very important topic. My name is Dr. Thomas MacGillivray. I am a heart surgeon, chair of the department of cardiac surgery at MedStar Washington Hospital Center, and president of the Society of Thoracic Surgeons, also known as the STS.

Founded in 1964, the STS is a professional medical association of almost 8,000 surgeons and allied health professionals who operate on and care for babies, children, and adults with cardiothoracic disease, from cradle to cane. The STS national database has become the gold standard of clinical registries. Established in 1989, our database now contains 9.4 million cardiothoracic surgery operations, including 98 percent of all cardiac surgeries performed in the United States by 4,000 surgeons. With this data, cardiothoracic surgeons can evaluate their own patient outcomes, measure their performance against national benchmarks, and implement changes for quality improvement.

You may ask, why are clinical registries like the STS

database important for coverage decisions? Well, let's look at the example of transcatheter aortic valve replacement, or TAVR, a less invasive therapy to treat aortic valve disease that otherwise has been managed by open heart surgery.

When TAVR was first approved by Medicare for coverage with evidence development in 2012, it was only for extremely high-risk patients. At that time the STS, collaborating with the American College of Cardiology, created the TVT Registry to monitor patient safety related to this new therapy. The TVT Registry was approved by CMS to meet the registry requirements outlined in the NCD.

The TAVR procedure is an exceptional example of how tying national coverage determination to coverage with evidence development requirements can both validate the effectiveness of emerging therapies, as well as expand access based on ongoing, real-world data. Over time, more and more patients were able to receive this new therapy based on the data collected in the TVT Registry.

Recently, the Administration issued the transitional coverage of emerging technologies notice that would create an alternative expedited pathway to payment coverage for emerging devices and diagnostics. It is important that

reforms strike a balance between providing access to innovative therapy while also ensuring that the collection of robust evidence is available to best inform these coverage decisions.

The STS believes that reforms to coverage of emerging therapies should include the following provisions: first, to prioritize the collection of real-world data, particularly for new, innovative medical devices; secondly, to permit early discussions and coordination between the FDA, CMS, and all relevant stakeholders to allow sufficient time for the appropriate design, application, and implementation of any CED requirements; we would also hope that it would provide flexibility for data collection mechanisms that can be adjusted based on new observations and developments in the evidence; and lastly, to provide registries with timely, affordable, and continuous access to Medicare claims data that facilitates longitudinal studies to show efficacy and value.

In the STS's experience with the TVT registry, it is shown that CED helps protect patients while offering timely access to innovative therapies. Randomized clinical trials are important, but these findings from small, pre-market

clinical trials with carefully selected patients at carefully selected sites do not always generalize to widespread application. Without ongoing, real-world evidence collection, the appropriateness, safety, and efficacy of innovative therapies will remain uncertain. And this uncertainty will not only impair physicians, but, more importantly, the ability for patients to make the best health care decisions.

Thank you very much for the privilege of being here.

[The statement of Dr. MacGillivray follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you, Dr. MacGillivray.

Next the chair will recognize Dr. Aklog for five minutes for your opening statement. Thank you.

STATEMENT OF LISHAN AKLOG

*Dr. Aklog. Chairman Guthrie and Ranking member Eshoo, I am honored to be here. My name is Dr. Lishan Aklog. I am also a heart surgeon, but I am an entrepreneur and small company chief executive. I also serve on the PAVmed board and chair its health equity committee.

Let me first thank you for leading with the title with the words "Innovation Saves Lives.'' This factual statement has defined my entire professional career. Although medical technology innovation has saved millions of lives, the arduous process of translating innovation into equitable access to lifesaving products lacks transparency and predictability.

As a first-generation American who fled political violence in Ethiopia as a young boy, I am proud that America remains the world's engine for medical technology innovation. Most of this innovation, fueled by our entrepreneurial spirit, occurs in small companies, where our ability to raise capital is predicated on a transparent and predictable process. Government, including Congress, must keep pace and adjust.

For example, thanks to improvements in the transparency and predictability of FDA processes, Europeans are no longer the first beneficiary of groundbreaking American medical technologies. We need similar improvements to Medicare coverage processes. Let me offer some concrete examples from my own experience.

Ten years ago I transitioned from heart surgeon to co-founder, chairman, and CEO of PAVmed, a now Nasdaq-listed diversified medical technology company with two subsidiaries and 130 employees. One subsidiary, Lucid Diagnostics, has commercialized groundbreaking cancer prevention technology developed by NCI investigators at Case Western Reserve University. NCI itself highlighted, as I quote, "one of the year's significant advances in cancer prevention'' in its 2020 report to Congress. NCI was right. Esoguard is the world's first and only molecular diagnostic test that can accurately detect early stage pre-cancer.

Before this hearing ends, two dozen or so Americans will receive a likely death sentence. Their executioner will be esophageal cancer, our second-most lethal cancer. Over 10,000 Medicare beneficiaries will succumb to it this year. Even stage one disease carries a 50 percent mortality. We

can prevent cancer and save lives by detecting esophageal pre-cancer before it progresses to cancer, consistent with the goals of the 21st Century Cures Act and the Cancer Moonshot. In two recent studies, Esoguard detected 100 percent of cancers and over 80 percent of pre-cancers. These unprecedented early cancer detection results demonstrate Esoguard's promises of widespread cancer detection tool, pre-cancer detection tool.

So here is a real-world example. An elderly gentleman, Steve, read a poster in his doctor's office and discovered he was at risk for esophageal pre-cancer. He requested an Esoguard test, which was positive. Further testing confirmed a very late stage pre-cancer. He completed curative treatment and, with monitoring, should remain cancer free. Steve said, "I am damn lucky. I think I saved my own life.'' He did. But without access to our innovative technology, he very likely would have progressed and died of esophageal cancer. So, you know, innovation saved Steve's life.

But his story illustrates some of our challenges. We have been working with CMS and the MAC which oversees molecular diagnostics for four years. We secured Medicare payment, a Medicare payment rate three years ago. The

coverage process, however, has dragged on through years of uncertainty and long stretches of total silence before recently starting to progress. Although Lucid has raised and deployed over $100 million of capital, this lack of transparency and predictability makes raising capital much more difficult than it should be for such promising technology.

It also leads to health inequities. Compared to Medicare, our path to commercial coverage is much more transparent and predictable. Sometime soon, a 64-year-old commercial -- a 64-year-old man with commercial insurance will likely have access to the technology that saved Steve's life. But his 66-year-old brother on Medicare will probably not.

The committee's work on H.R. 1691 and TCET can help establish a transparent and predictable path to transitional Medicare coverage to ensure equitable access to lifesaving technologies. Let me highlight three serious concerns over TCET.

TCET currently excludes diagnostics. There is really no justification for this. Molecular diagnostic testing is at the leading edge of innovation. Our experience is a

testament to the fact that the MAC-led coverage process for diagnostics is neither transparent nor predictable.

Number two, TCET set does not currently provide a viable plan to update the decades-old defined benefit category system to keep pace with new horizons of innovation such as digital health.

And number three, CMS anticipates a small, fixed number of TCET slots per year. This will not work. It effectively asks companies to buy a TCET lottery ticket and hope their number hits. This will wipe out any improvements in predictability, and lead to new inequities, favoring certain groups of patients over others.

So I would like to close by thanking the H.R. 1691 cosponsors. And I am grateful that this committee is strongly engaged on this issue on a bipartisan basis. Thank you.

[The statement of Dr. Aklog follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you. I appreciate your testimony.

The chair will now recognize Dr. Brinton for five minutes for your opening statement.

STATEMENT OF TODD BRINTON

*Dr. Brinton. Good morning, Chair Guthrie, Ranking Member Eshoo, and distinguished members of the committee. My name is Todd Brinton. I am the chief scientific officer and corporate vice president of advanced technology for Edwards Life Sciences.

Edwards is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. It is a privilege to be here on behalf of Edwards, and I would first applaud the committee for recognizing the need to provide patients with more timely access to lifesaving technologies.

I started my own career as a biomedical engineer and later attended medical school, eventually spending 14 years on faculty at Stanford University as a practicing interventional cardiologist and clinical professor of medicine. Combining my passion for patient care and innovation has taught me the critical need for cutting-edge technologies and how it can improve millions of lives. This continues today in my role at Edwards, where we are committed to delivering lifesaving innovations to patients.

We are passionate about helping patients like Jill Poole, who suffers from heart failure. Jill is a 66-year-old registered nurse who has worked for the VA for more than 30 years. She has always been active, but about five years ago she started experiencing symptoms that forced her to slow down. When she sought medical help, Jill was told there was no treatment options for her extremely common type of heart failure. Eventually, Jill was referred to Dr. Firas Zahr at Oregon Health Sciences University Hospital, who believed she might be a good candidate for an investigational device for heart failure sponsored by Edwards in an early feasibility trial. After careful consideration, Jill consented to join the trial.

Jill's story is not unique. Heart failure impacts more than six million Americans, and is the top cause of U.S. hospitalizations, costing the system billions of dollars.

In 2021, Jill underwent her procedure. And soon after, she walked in a parade to honor her late father, going from struggling to put on her own shoes to marching in the parade. She is back to gardening and taking care of her family and the veterans she helps at work.

For patients like Jill, streamlining the process to make

coverage of breakthrough medical technologies more transparent and efficient can help ensure the medical technology innovation ecosystem continues to deliver new lifesaving therapies.

At Edwards the innovation process is paired with our commitment to evidence development. Evidence helps us understand how therapies and procedures evolve over time and further improve patient outcomes. Medical device technology and pharmaceuticals are different. Simply stated, once drugs are developed and approved, they are in their final form. Conversely, for medical technology, like our transcatheter heart valve therapies, we are constantly learning how to improve the procedure and iterate the device.

Clinicians learn and improve their skills with medical technology over time. TAVR, an innovative procedure which enables replacement of a patient's aortic heart valve without open heart surgery, has provided us a unique perspective on coverage of innovative technologies. Edwards worked with FDA, CMS, the medical and patient communities, and others to ensure that it was used safely and appropriately. CMS recognized the need for a heart team to evaluate and treat patients, and implemented the coverage with evidence

development for us to work with providers to collect registry data, align with FDA's post-market requirements.

While we continue to be concerned about the large amount of registry information being collected creating a burden, we believe the TAVR experience is a great success story. The registry helps generate meaningful evidence to support continuous innovation and advancements in TAVR technology and expand patient access. While imperfect, the data collection has identified disparities in patient access to transcatheter heart interventions, particularly in rural and under-represented communities whose hospitals don't have the resources to meet the current NCD requirements.

We remain committed to ensure all patients have access to transcatheter heart procedures and high-quality care. We look forward to working with the committee to address the system-wide access disparities.

In a positive step, CMS issued a proposed guidance for transitional coverage for emerging technologies for FDA-designated breakthrough devices. A voluntary, timely, and predictable coverage process will allow CMS to achieve its goal of providing Medicare coverage for innovative technologies based on clinical evidence with appropriate

patient safeguards.

Edwards is encouraged by CMS's openness to incorporate robust, fit-for-purpose evidence development. However, the proposed guidance doesn't anticipate the TCET pathway will accept more than five candidates per year. Therefore, we urge CMS to establish specific criteria to select candidate technologies for TCT review. I am sorry, for TCET review.

To support this, we also believe CMS should be -- hire additional clinical and research experts from outside the agency. I urge Congress to work with CMS to improve and finalize the TCET guidance and consider additional legislative improvements. We must keep up the momentum, as further delay will prevent Medicare patients from timely access to lifesaving breakthrough medical innovations.

On behalf of Edwards Lifesciences, thank you so much for your time.

[The statement of Dr. Brinton follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you for your testimony.

The chair will now recognize Ms. Wronsky for five minutes for your opening statement.

STATEMENT OF SUE WRONSKY

*Ms. Wronsky. Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee, thank you for the opportunity to testify before you today to share my story about my experience caring for my mother who lived with Alzheimer's disease for 11 years.

My name is Sue Wronsky. I am from Potomac, Maryland, although I grew up in Syracuse, New York. I am here today on behalf of my late mother, Lynn, who died from Alzheimer's in 2002, and my late father, Marty, who cared for her from the beginning of her devastating diagnosis until the very end.

After several years of struggling with my mom's symptoms of early dementia, my parents finally received the unwelcome diagnosis of Alzheimer's in 1991, when she was just 63. She had what was called early or younger onset Alzheimer's. Back then, the diagnosis process was often longer than it is now, and she had been showing symptoms of the disease for a few years before finally diagnosed.

Once it became clear that Mom would no longer be able to be at home on her own, my dad retired from his teaching job earlier than planned to be a full-time caregiver. In fact,

our entire family became caregivers. Travel plans went by the wayside, and long-planned projects were put on the back burner. Thankfully, she was able to be cared for at home for the 11 years that she lived with the disease.

My dad was an incredible caregiver, and his Marine Corps training taught him that, if you are given a problem, you play the hand that you are dealt. But he was also very willing to accept help when it was offered. It was tough on him, and yet he was such a supportive spokesperson for other caregivers.

In addition to his full-time care of Mom, he became one of the Alzheimer's Association's central New York's chapter's most active advocates. And he eventually served on the board of directors there for several years. He wrote letters to the editor. He made visits to legislators. He took the bus to Albany with Mom in tow for the annual State Advocacy Day, and he joined me here in Washington one precious time for the Alzheimer's Impact Movement Advocacy Forum in 2006. He used to say, "If the caregiver crashes, everything falls apart.'' And sure enough, six weeks after my mom passed away, my father was having triple bypass surgery because he had been ignoring his own heart issues. Caregivers will often put

aside their own health issues to put loved ones first.

Scientific progress has been momentous in the fight against Alzheimer's. In 1991 there were no treatments available to my mom. But in the last year-and-a-half, we have seen two treatments be approved by the FDA. And even just this month, the FDA granted traditional approval for the first Alzheimer's treatment that changes the underlying cause of the disease. However, we as Alzheimer's advocates have had to raise our voices to ensure that Medicare covers these treatments. Under a 2022 policy by CMS, Alzheimer's drugs approved under the accelerated approval pathway were only available to individuals enrolled in randomized clinical trials. This translated into effectively no access throughout this period. Many people with Alzheimer's, some who I know very well, progressed even faster over this time than they might otherwise have because they were blocked from access to these treatments.

Now that the first drug in this class has received traditional approval, access is becoming possible through a registry, and I appreciate that CMS seems to have worked hard to ensure that this registry now poses as little of a barrier as possible. Nevertheless, such restrictions have -- no such

restrictions have ever been put in place for any other FDA-approved drug. With all of the evidence regarding these newer treatments, it is time for CMS to remove this policy.

The benefits of these treatments will only be realized if patients have access. For those individuals who receive a diagnosis early, evidence released just this week indicates that the delay in progression of this disease could be one or more years. Still, patients are losing precious time. For individuals living with Alzheimer's, the value of time, while independent, is much different than those living with other chronic conditions. With Alzheimer's, it is all about time, and the last thing we need is more roadblocks.

I am an advocate to honor both of my parents, but especially to carry the torch for my father, who wanted nothing more than for a breakthrough to be found during his lifetime. This wasn't to be as, sadly, we lost him in 2013. But I have got some time left on this Earth, and I would like nothing more during my lifetime than to witness the end to this horrible disease.

Thank you so much for the opportunity to testify here today, and I look forward to answering any questions that the subcommittee might have.

[The statement of Ms. Wronsky follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you for your powerful testimony. Sharing your parents' stories is how it affects the policy, so thank you for doing that.

You are also blessed with two wonderful parents. That is one of the life's great gifts. I thank you.

So it is tough to follow, Dr. Miller.

[Laughter.]

*Mr. Guthrie. But Dr. Miller, you are now recognized for five minutes.

STATEMENT OF BRIAN MILLER

*Dr. Miller. Chair Guthrie, Ranking Member Eshoo, and distinguished members of the Subcommittee on Health, thank you for allowing me to share my views on promoting access to innovation in the Medicare program. I am a practicing hospitalist at Hopkins, a non-resident fellow at AEI. I have worked at two of those much maligned bureaucracies, FDA and CMS, and I actually also served on the CMS Medicare Evidence Development and Coverage Advisory Committee for four years.

Today I am here in my personal capacity. My views are my own and don't necessarily represent those of Hopkins, AEI, or the Medicare Payment Advisory Commission, of which I am a commissioner. A few things I want to talk about today.

One is innovation is a real thing. It is a real thing for individuals and populations. It is not an abstract. And so some numbers I pulled: since 1950 FDA has approved over 1,200 new molecular entities. That is new drugs, completely new drugs. In 2022, last year, the FDA approved 22 pre-market approval applications for devices, and -- it is a pretty big number -- 3,194 510(k) clearances. Sort of nuts, right?

And then we are like, well, new paradigms also emerge. There are 521 AI and machine learning-enabled devices approved as of right now.

What does this mean for actual individual patients?

HIV, which was formerly a death sentence that disproportionately affected minority populations and LGBTQ+ populations, was a death sentence. Now the average life span after getting diagnosed is 40 years. That is partially because of the accelerated approval pathway.

Health care labor productivity in hospitals is in the toilet. It has been flat for 20 years. Health tech and AI offer an opportunity for us to make delivery more efficient and more patient-centered.

Thinking about Medicare's coverage policies, it really needs -- and I am glad we are doing this -- it needs your time and attention. The agency has a variety of tools, local coverage decisions, national coverage decisions, coverage with evidence development. The problem is that the coverage function at CMS has ossified and decayed. It was actually Nancy-Ann DeParle, who was the administrator under the Clinton Administration, who recognized that and improved that starting in 1999. That effort was continued during the Bush

Administration, and then over the past 10 years it has sort of decayed. I picked some numbers from before the pandemic because I realize the pandemic is atypical. There were two national coverage decisions each in 2018 and 2019. So we definitely have work to do.

MCIT and TCET, they are both trying to do the same thing for devices. They ignore this overall broken system. Congress needs to update the statutory timelines for the coverage process and force CMS to issue guidance about when it uses which tools, and also update and provide guidance on what a definition of -- for reasonable and necessary. You can't get coverage if you don't know what the standard is. It is hard to guess what the answer is.

I think another thing to think about is that we need to improve medical device regulation to better support Medicare coverage. The FDA is drowning in 510(k) applications. It is over 2,800 annually. And actually, during the pandemic two reviewers committed suicide due to the diagnostic review burden, and they were overworking 18 hours a day, and at home and isolated. So we need to tune up and support the third-party review program for 510(k) applications so that we can offload this burden from the FDA, and let the FDA figure out

how to best address high-risk applications. They are just not going to be able to hire another 1,000 doctors and biomedical engineers. We would like to think they can. It is probably not realistic.

We also need fit-for-purpose pathways that are voluntary and alternative pathways for health, tech, and AI. We are in a software-driven world. The FDA's regulatory process for devices is from the disco ball era.

The other thing which I wanted to mention is that we definitely should not be a stick in the mud when we think about paying for health tech and AI. We did that with telehealth, and now we are catching up after decades. We shouldn't be doing the same thing for technology. We shouldn't be worried about the precautionary principle. AI is one of the few things that can make medical care safer, more efficient, more effective, and easier for patients to access. And it is going to help the disadvantaged populations in Medicare the most.

Thank you, and I look forward to your questions.

[The statement of Dr. Miller follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you. That concludes our witnesses' opening statements. We appreciate that. We will now begin the questioning, and I will recognize myself for five minutes for questions.

So, Dr. Brinton, how long has it taken for your technology to get a coverage decision?

I am sorry. Dr. Brinton, yes. How long has it taken your --

*Dr. Brinton. So are speaking specifically about TAVR? It was a --

*Mr. Guthrie. Right.

*Dr. Brinton. -- relationship between the coverage decision that was between FDA approval that happened in 2011 and, actually, pretty quick. A requirement -- it was structured with CED. So it was a working relationship. It was really, you know, all the groups coming together between FDA, CMS, the medical communities, and patient advocacy groups that ultimately drafted what we felt was the best at the time, the data we had, the best approach to actually move forward with the technology, a lifesaving, disruptive technology that was going to have pretty dramatic effects on patients' lives.

We have seen now, actually, really as a result of the TVT Registry, and as required by CED -- we have learned from that. And there has been some confusion about this, the fact that the CED requirement and the TVT has provided a real knowledge and understanding about inequities in care that we are now aware of that were really an unintended consequence of -- really, the structure that we built.

So we moved very rapidly to get that approval, but we are learning. And I think earlier in my testimony I identified the fact that there is big differences between drugs and devices.

*Mr. Guthrie. Right.

*Dr. Brinton. Devices really require procedure. They are component of an entire therapy for patients. And so it is important to recognize that they are different than actual -- the drugs themselves. So they -- and the learning needs to go on. This gap we talk about, the valley of death we often identified as the valley of death for the company is really, in some ways, the valley of death for patients because we are getting FDA approval, we are getting something that is safe and effective, but we are not necessarily getting to the possibility of providing this therapy broadly

for patients in a meaningful way.

*Mr. Guthrie. Okay, thank --

*Dr. Brinton. So really, the proposal today is to provide that opportunity in the gap.

*Mr. Guthrie. Okay, thank you. I appreciate it. I appreciate your answer.

Dr. Aklog, in Dr. Miller's testimony he notes there were 166 devices. We just heard. There was a breakthrough designation in 2022 alone. In the TCET proposed rule, CMS indicates they could only accept five applicants for the TCET coverage pathway. Could you speak to how this would impact a company's decision to pursue that pathway?

*Dr. Aklog. Yes, as I said, it just won't work. I mean, just to be really, really blunt. It has a variety of problems. I think the lottery analogy is a bit, at least from a small company point of view, is a bit apt.

First of all, it assumes that the -- that progress is linear, that every year we will have five applications, and it sort of moves on at a steady pace. That is not the case. There may be some years where there is a, you know, a flow of innovations and others where -- to allocate five a year is just not enough. Five itself doesn't sound anywhere close to

being a sufficient number. And, you know, we suspect -- and I think they are sensing that that is related to questions around resources.

I also hinted at inequities. If there are only five, and it is a lottery, and CMS, you know, provides some hint as to how they will select those five, at the end of the day that is sort of, you know, pitting one patient group against the other. And if it is based on the size of the populations, then, you know, rare diseases and devices that target smaller populations will be left out. It just can't work.

I mean, it is a -- the analogy -- another analogy I would take is the FDA. Honestly, it would be the equivalent of the FDA saying, okay, this year we can only do 100 510(k)s, and we can do X number of PMAs, and, oops, sorry, you didn't make the cut this year, you will have to wait until next year. It really is equivalent to that, and it just can't work.

*Mr. Guthrie. All right, thank you. Thank you for your testimony.

And Dr. Miller, as we talk about accelerated approval drugs and high-cost medications with potential to cure a

life-threatening or otherwise debilitating condition, how important is -- will it be for CMS to leverage value-based contracting?

And what do you believe Congress should do to promote value-based contracting?

*Dr. Miller. Thank you. One is pass the MVP Act. I would say it is number one.

And then number two is look at the Medicaid drug rebate program, and potentially look at creating a statutory exception for value-based arrangements tied to clinical outcomes over time. Because right now the Medicare program can't do that because, if you have clinical outcomes that are priced, say, 0, 100,000, $200,000 at 6 months and different values at 12 and 18 months, if you get $0 for that outcome, that means the best price is 0 bucks. We need to fix that to allow for the Medicaid program to pay for value, and we should be doing the same in the Medicare program.

*Mr. Guthrie. Thank you.

And then, Dr. Brinton, the same kind of question I asked Dr. Aklog. From your perspective as a larger device manufacturer, can you talk about how the TCET proposal will affect breakthrough device pathway?

*Dr. Brinton. Yes. So I think the TCET pathway is a positive step. One of the things that was brought up is really an arbitrary number of five potential TCETs per year, suggesting it is linear, and the resources. It depends. And I think there needs to be prioritization deciding on what should actually be approached first. So lifesaving technologies, really significant impact technologies, unmet clinical needs, and technologies that actually satisfy disparities, those should be the prioritization as it comes to approaching which things go first when there is these resource limitations.

*Mr. Guthrie. Okay, thank you. Well, my time is -- I appreciate your answers, all of you. My time is expired, and I now recognize the ranking member, Ranking Member Eshoo, for five minutes.

*Ms. Eshoo. Thank you, Mr. Chairman. I want to thank each one of the witnesses. You have given really superb testimony to us this morning. And it is varied, but it speaks to all the different moving parts, the parts that aren't moving quickly enough, and then what the impacts are when the parts don't move very well. I wish I had time to spend with each one of you, but we have five minutes for

everyone. But your wealth of knowledge and experience, I think, has really enhanced and deepened, broadened our understanding of what is at hand.

I have the privilege of representing the Silicon Valley district in our country. So the word "innovation'' drives us every split second of the day. It is, I think, the innovation capital of our country, and we want to keep it that way.

To Dr. Brinton, thank you for your work at Stanford Byers Center for Biodesign. Brook Byers is a -- well, we are -- America is blessed by his leadership and his knowledge and the work that he has done. And you are a very important part of that. In your testimony you spoke about your company's experience with CED to cover TAVR, the TAVR device, and how you view it as a success story. We all view it as a success story. It is exciting to hear you describe it.

From others on the panel we heard your concerns about the potential barriers to coverage a CED might present. Now, based on your experience with CED, what do you think was in the success lane, what do you think should be done differently?

*Dr. Brinton. Well, Ranking Member Eshoo, thank you

very much for your question.

I think it is really clear that we need a predictable process. That does not mean certainty of outcome. It means a predictable process --

*Ms. Eshoo. Process, mm-hmm.

*Dr. Brinton. -- so we can all understand the risk versus benefit of going down this process of innovation.

*Ms. Eshoo. Well, the individuals, the innovators, they are the risk takers. So they understand risk.

*Dr. Brinton. Yes, but actually coming up with also timelines that are quite clear, anything that does that improves patient care.

*Ms. Eshoo. Okay.

*Dr. Brinton. It provides the benefit. Every day we wait is the potential that a patient dies because they haven't gotten to therapy that has been found to be safe and effective for patients.

But in addition to that, when it comes to CED specifically, there has been big benefits of things we have learned. I mentioned earlier about disparities of care. However, there is also the concern over least burdensome. And right now we know that actually the TVT Registry,

although it provides real benefit, is quite burdensome on the providers. It actually is an eight-page report that often they need to complete of data to collect when often it takes longer than the TAVR procedure itself.

*Ms. Eshoo. Wow.

*Dr. Brinton. And so that does not meet the criteria. We want to learn from continuous evidence, but this burden seems to be too much.

But taking a step further, it allows us to also think about the fact of what really is the limiting factor. And currently it is the NCD. The NCD is the limiting factor that chooses the number of sites and the operator's resources and training that needs to be done. And if we are going to address this, we need to actually address the NCD directly.

*Ms. Eshoo. Okay, thank you.

Ms. Wronsky, you are a magnificent daughter, really, a magnificent daughter. And thank you. Your testimony has touched everyone here.

Dr. Aklog, you have such a powerful story. And America is blessed by you. See what immigrants do for our country? Really. So thank you for that. You have such an inspiring life story of being a first generation American. And it is

always exciting for me to hear the stories. It reminds me of my own family's story. I am a first generation American, and you are now an entrepreneur. You have invented advanced diagnostic technologies that, as you spoke, you know, saving lives.

The CMS new rule on transitional coverage for emerging technologies excluded diagnostics for the new coverage pathway. Can you just speak briefly -- I don't have very much time left -- that this decision would have on patient access and innovation?

*Dr. Aklog. Sure. Thank you for your kind comments, Congresswoman.

You know, surgeons are pretty blunt, so I am known to be blunt. So I will be blunt again. There is just no justification for excluding diagnostics as part of this process.

*Ms. Eshoo. He is sitting next to me.

*Dr. Aklog. I know, I know.

[Laughter.]

*Mr. Bucshon. [Presiding] That is why we are laughing.

*Dr. Aklog. You know, a lot of the most cutting-edge -- I mean, we saw COVID, we see this revolution in cancer care

from screening to precision medicine to minimal residual disease and others. And these breakthroughs are staggering. So the need for this process to be predictable and transparent is as great with diagnostics than elsewhere.

And the MAC-led process that controls coverage right now and, therefore, access to these innovative diagnostics is complicated. It is sort of Byzantine. It is not transparent, it is not predictable. You have to deal with, you know, multiple different local coverage in MACs, with regard to their local coverage determinations that may not be where your laboratory is, and so forth. So it needs to be upgraded.

And I am looking forward to progress on the legislation, as well as improvements for TCET.

*Ms. Eshoo. Good. Thank you. I have gone over my time, and so I don't have any time to yield back. Thank you for your patience.

*Mr. Bucshon. The gentlelady yields. I now recognize the chairwoman of the full committee, Mrs. Rodgers, for her five minutes.

*The Chair. Dr. Rost, I was alarmed by the proposed Alzheimer's NCDs categorical exclusion of patients with Down

syndrome from any form of coverage. Yet despite CMS's removal of this blanket exclusion, patients with Down syndrome will continue to have extreme difficulty practically accessing these approved treatments.

What are neurologists and other doctors doing to help CMS swiftly recover its policy so that patients can more broadly access these treatments, and that patients with Down syndrome, in coordination with their other doctors, can develop more specialized ways to access these treatments?

*Dr. Rost. Thank you, Chairwoman, for asking this question. This is very important to us, as neurologists, and to the entire field of neuroscience professionals.

As you know, we are very strong advocates for inclusive care. We want to make sure that the competent care is delivered to every American in need. And we have been engaging with the CMS specifically, and also other agencies, and continue the advocacy on the Hill to make sure that we have processes in place that allow not only to gain access to appropriate care for those patients who fit the inclusion criteria of the original trials that bring the peer-reviewed evidence to us, but also create the opportunities for those criteria to be reviewed in a nimble and effective way, and

also have an opportunity for this two-pronged approach where off-ramp is offered to patients as they gain the level of evidence for efficacy and safety for them to be able to access the medications that they need.

*The Chair. Yes. For those with Down syndrome, you know, it wasn't that long ago their life expectancy was maybe 20 years, and now they are living longer -- 60 years -- as we give them a chance for life.

I wanted -- as a follow-up -- but they are developing Alzheimer's, so it just makes sense that they would be included, that we could learn from those with Down syndrome and others.

So even the most streamlined coverage with evidence development policy involves some extra burden on physician, patients, and even caregivers. Dr. Rost, is there clear guidance or consistency from CMS at which point they will end CED and transition to traditional coverage?

*Dr. Rost. At this time there are certain processes that have been already put in place. For example, there is a 24-month of the period of observation and data gathering that CMS put in place. But we are not entirely clear yet what the process will entail, and we continue to seek more

transparency in that space.

*The Chair. Okay, okay. Thank you.

Dr. Aklog and Dr. Brinton, Congress and the public currently have no insight into the request pending before CMS for national coverage determinations. I recently led a letter with my colleagues on this topic, and I am also concerned about the lack of dedicated coverage pathway for truly innovative medical products and the lack of commitment to predictable timelines in the process and the TCET proposed notice. So I have a couple of questions for each of you, and limited time. So quickly, please.

Would greater transparency into the coverage process overall, and NCD requests in particular, help you with your company's planning and ability to ultimately deliver these innovations to patients? And what specific information is helpful?

*Dr. Aklog. Thank you, Madam Chairman. Absolutely. I think I counted transparency and predictability in my opening remarks where I mentioned it a dozen times or so. And they are critical, and they go hand in hand. Without them, particularly as a small company, we are basically flying blind. You know, it is hard to plan, it is hard to operate,

it is hard to raise capital. It is really hard to know where we are going without some -- without transparency, having some level of communication, you know, with commercial payers.

You know, we have board meetings, we talk to medical directors, we have peer-to-peers during claims adjudication. There is an ongoing back-and-forth as to how -- you know, what we need to do to cross certain thresholds.

*The Chair. Okay.

*Dr. Aklog. With FDA we do the same, pre-sub meetings and so forth.

*The Chair. Okay.

*Dr. Aklog. And we need both. We really do need transparency --

*The Chair. Okay, thank you.

I am going to add on to this question before you get to answer, Dr. Brinton. Would you also mention one or two of the most important targeted policies or concepts that we need to maintain from the previous Medicare coverage of innovation technology rule and bipartisan-introduced legislation not included in the TCET proposed notice?

*Dr. Brinton. Yes, I think it is timely coverage. I

mean, earlier it was, obviously, immediate coverage within MCIT. And TCET currently has a six-month review. I think trying to pull that earlier as possible has benefit to patients. As I mentioned, every day that goes by, we are not providing, you know, evidence-based technologies that have been proven safe and effective for patients. So early -- pulling that earlier is clearly going to be a big benefit to patients overall.

The other thing is that TCET, I think, serves an opportunity as a setup to the NCD. I mentioned medical devices are different, the burden is different, reasonable and necessary. And so providing the opportunity for evidence to then meet that criteria prevents a gap in a sense to meet the need of what the requirements are for medical devices.

*The Chair. Okay. Thank you, everyone. I have run out of time.

I yield back.

*Mr. Bucshon. The gentlelady yields back. I recognize Mr. Sarbanes for five minutes.

*Mr. Sarbanes. Thank you very much, Mr. Chairman. Thanks to all of you. Obviously, much interest in this hearing today, and your testimony has been extremely helpful.

I just want to kind of restate some of the basic principles that we have recognized today, first that seniors deserve timely access to safe and effective treatments and medical technologies, especially, obviously, those with the most promise for generating real, meaningful improvement in health outcomes, which is what we are always striving for.

But we also know that they and their doctors deserve a clear understanding of the risks and benefits of innovative therapies so they can make the best-informed decisions about treatment options.

We have talked about how the current process can take up to five years for breakthrough devices to gain nationwide Medicare coverage, and we have talked about the proposed transitional coverage for emerging technologies and the notice that has gone out on this, which would provide a pathway for expedited coverage of emerging devices with the goal, obviously, of increasing the breakthrough device availability for Medicare beneficiaries.

Dr. Brinton, I wanted to focus a little bit on the clinical trial dimension of this. Typically, clinical trials for emerging therapies tend to be small, may not always be reflective of the broader Medicare population. Could you

discuss what types of evidence gaps can exist, and how this transitional coverage pathway -- and I gather it is collection of -- or proposed collection of real-world data -- can help address them and support Medicare coverage of breakthrough devices?

*Dr. Brinton. Yes, thank you very much for the question, Representative.

I think it is important to recognize that breakthrough technologies, that qualification, is really a first-in-line review. It is not a difference of the quality or the review process. This actually just moves it to the earlier place in the line to be reviewed more rapidly. And so with that, I think that safety and effectiveness is not in question.

The opportunity to potentially provide these therapies for patients early in the process is the opportunity to ultimately make big impact in patients lives. And so the therapies that we can potentially provide earlier in the process, and the things that we can do to actually impact those patients are going to have positive impact on outcomes. Innovation, potentially, is the solution here. It is not the problem. It is an opportunity to kind of turn this over and actually suggest that it is a way to drive benefit.

So we think of TAVR therapy, which I mentioned in my statement. TAVR therapy is the triple win. It is where we actually improve mortality, improve quality of life, and actually reduce costs. And if we compare it to some of the other predicates that are out there, it provides the benefit of ultimately, really, truly reducing costs and driving value, as well as delivering great care for patients.

*Mr. Sarbanes. Talk to me a little bit more, though, about what this concept of collecting real-world data means in the context of the clinical trial approach.

*Dr. Brinton. So I think that the fit-for-purpose component of TCETs, as has been suggested, provides the flexibility of not one size fits all. In a sense, it depends on the technology, it depends on the patient population. And so the idea of being able to use claims data potentially to actually have real-world data to actually make decisions versus some require a full registry, a detailed registry, and that depends on the technology that is at hand.

So I think evidence is the key, particularly, as I mentioned with the medical devices. We learn from the evidence, we change -- our skills change over time. The procedures change over time. So we need to collect that data

to make decisions about how to optimize and iterate our technologies. So I think that it will be a range of possibilities. I think fit-for-purpose needs to be better defined within TCET, but it provides the flexibility because it could be claims data, but it could be registry data, as well.

*Mr. Sarbanes. Okay, that is helpful.

Dr. MacGillivray, in your testimony you discussed the importance of collecting robust evidence to inform coverage decisions. Can you explain a little bit more why that is so critical?

I mean, it seems intuitively obvious, but why that can help inform coverage decisions and why, again, it is important to collect real-world evidence when we can do that for new and innovative medical devices.

*Dr. MacGillivray. Yes, thank you, Congressman, for the question.

As mentioned earlier, clinical trials are designed to answer specific questions. If you have confounding problems, it can confound your answer. So carefully selected patients at carefully selected institutions, which usually are small patient populations that don't have other risk factors, are

chosen. But even though there is narrow inclusion criteria, the application, the approval is broad for patients with those problems.

An example that we learned from our data registry on monitoring artificial heart technology, left ventricular assist devices, there are two devices on the market based on clinical trials that showed that they were equivalent. Unfortunately, what we saw from our data was that one of the devices over time had more incidents of stroke and death compared to the other device. Identifying that from that database, we were able to able to notify the FDA, and that device has been taken off the market. So even though they were equivalent in clinical trials, the registry showed they were different.

*Mr. Sarbanes. Thanks very much.

I yield back.

*Mr. Bucshon. The gentleman yields back. I now recognize Dr. Burgess for five minutes.

*Mr. Burgess. Thank you, Chairman.

Dr. Rost, did part of your answer to Chairwoman McMorris Rodgers's question -- can you give us any idea as to whether right-to-try, which this committee passed a little over five

years ago -- has right-to-try impacted the ability of a patient to access a therapy?

*Dr. Rost. Yes. This is a great question because this was the nature of our re-submission request for reconsideration to the -- to CMS with regard to the national coverage determination for this patient population. Basically, we are concerned that the increasing burden of real data -- real-world data collection over the time of administration of the drug for each individual patient will increase the burden on neurological practices that are already experiencing the burdens of taking care of a growing number of neurologic patients with multiple diagnoses, not only patients who suffer from Alzheimer's, dementia.

And so even though we appreciate CMS taking concrete steps to simplify the Web-based portal that they are proposing as part of the CED pathway, we still feel that there is a risk of increasing burden and by -- through that, decreasing access to treatment.

*Mr. Burgess. Sure. Dr. Miller, thank you so much for joining us today. It is always insightful when we get to hear you speak. Can you speak to the current regulatory challenges for FDA and CMS that exist for artificial

intelligence in digital and digital health?

*Dr. Miller. Thank you. I am not sure we have enough time to go through all of them. There is quite a long list.

CMS is not prepared to pay for new health technology and AI. You could ask the sort of snarky but appropriate question of should a tech company be a Part B provider as an example. We don't have a way of paying for automated service. We don't have a way of paying for augmented human-driven service. We don't have appropriate FDA regulatory tools for that. Like, the FDA has done a great job with the tools it has, it has the pre-determined change control guidance, which allows sort of a range of improvements to happen to a device. But the FDA doesn't want to review version 5.2.2 and version 5.2.3 of software.

So we really need to give the FDA fit-for-purpose, building block-driven regulatory pathways for medical software, and then we need to tie that to coverage.

*Mr. Burgess. So you anticipated one of my next questions. Is CMS prepared to classify and reimburse for artificial intelligence?

*Dr. Miller. Unfortunately not.

*Mr. Burgess. And, I mean, this is not just an academic

question. I have had visits from radiologists who legitimately have concerns about where they see their profession going and, yes, how reimbursement will happen from that.

I mean, many of us remember the experiences of 20, 25 years ago, when insurance companies began to incorporate some black box edits into their insurance payments. And in fact, it took a class action suit on the part of many state medical associations to get them to stop doing this.

But on the other hand, with the advent of AI, it seems like -- well, again, without the proper guardrails and controls, it may not work out well.

*Dr. Miller. Right. And I would add that the difference for regulating AI for regulating other sorts of medical devices is it is more regulated on performance. The details of the black box matter, but it is like the traction control on your car. We know it is there. We know it works. I don't know the details of how it works, but the regulator does. But the end user needs to know that it performs as expected.

*Mr. Burgess. Let me just ask, in the time I have got left, a couple of questions on CMMI. I have been frustrated

that CMMI was created, and it was created as an offset for costs in the Affordable Care Act. And yet -- our chairman of the Oversight Committee is here -- we never get any data back from CMMI as to what -- the models that they have entertained, what they actually save, what the deliverable from CMMI is. So do any of you have any thoughts or input on that, and direction that you can give the chairman of Oversight and Investigation?

Dr. Brinton, you are bound to have some idea.

*Dr. Miller. I was going to say that the problem with CMMI is that it usurps Congress's authority, so it is making payment policy decisions in -- and I worked at CMMI -- it is making decisions outside the purview of the public, and potentially mandating it out to an entire industry, be it physicians, hospitals, device companies, pharmaceutical product manufacturers. So there is -- it is something that should be put back into the hands of Congress.

*Mr. Burgess. Absolutely. I couldn't agree more.

Mr. Chairman, I hope you took that into consideration. I yield back.

*Mr. Bucshon. The gentleman yields back now. I now recognize Mr. Cardenas for five minutes.

*Mr. Cardenas. Thank you, Chairman Guthrie and Ranking Member Eshoo, for holding this hearing to discuss access to innovative treatment therapies.

I also want to thank our witnesses for joining us today and sharing their perspectives on existing pathways to bring lifesaving devices, drugs, and technologies to market.

For much of my time in Congress I have advocated for and supported the idea of transitional coverage for breakthrough devices. This Congress I am proud to co-lead the Ensuring Patient Access to Critical Breakthrough Products Act, along with my colleagues Representative DelBene, Wenstrup, Moore, Sewell, and my Energy and Commerce Committee colleagues, Chairman Guthrie, Ranking Member Eshoo, and Representative Bilirakis.

This bill would allow designated medical breakthrough devices that are approved through the FDA Breakthrough Devices Program to be temporarily covered under Medicare during a four-year transitional period. So my question to Dr. Brinton is, Dr. Brinton, you note in your testimony that "a well designated designed transitional coverage program could allow Medicare beneficiaries access to cutting-edge medical innovation while ensuring that those innovations are

used appropriately.'' What kind of impact do you expect something like this would have on patient access and patient care?

*Dr. Brinton. Thank you very much for your question.

I think along with TCET, obviously, this group, Congress weighing in on TCET, has an important role to play in impacting the possibility of actually creating and filling the gap I mentioned earlier, this gap between approval and, as had been researched by Stanford, the greater than five years it takes to get actual meaningful coverage to Medicare recipients for breakthrough technologies.

As you speak directly about legislation, I think any effort we can make to actually align the possibilities of bringing resources to recognize the fact of this important initiative for innovation for Medicare recipients is positive. This is an important component of what drives our innovation engine, which actually improves health of the entire American population.

So either of these, whether it is legislative or weighing in on, obviously, the TCET rule is beneficial.

*Mr. Cardenas. Okay. And how can we ensure that this type of access is enjoyed equitably?

*Dr. Brinton. Absolutely. It is a huge priority for this to be equitable. And I think that the way to establish that is data, right? We need to understand it.

I mentioned earlier when we actually drew up the first NCD and worked with CMS and FDA, we had best of intentions to actually, as I mentioned, for safe and appropriate care. But we have learned. We had unintentional consequences in the sense that we don't have equal access to care. We know that now from the TVT Registry. And that allows us to build strategies to address this directly.

So by building these strategies we can actually work with and we can actually approach the NCD, the NCD in a sense that limits resources to certain rural areas that don't have the same resources and capabilities to operator training, which is a major component of the ability to actually do enough cases, in a sense. We know that the complication rate is extremely low for TAVR, for instance, and so getting access for these technologies, as well.

But there is also the grassroots effort. So the National Urban League working with the Association of Black Cardiologists, and actually in the community making sure we recognize the access that they need to have the -- promote

the fact that this lifesaving therapy is available to Medicare recipients.

*Mr. Cardenas. Thank you. I also want to revisit an issue I raised in 2019 relating to racial disparities in access to transcatheter aortic valve replacement, otherwise known as TAVR, a treatment for aortic stenosis. As you mentioned in your testimony, CMS released a coverage decision that invoked the "coverage with evidence of development,'' or CED, pathway to allow you to collect necessary data aligned with the FDA post-market requirements.

Dr. Brinton, in your testimony you noted -- you note it is because of data collection through the CED requirements that you were able to identify disparities in patient access to TAVR. How can the TAVR Registry help ensure access to treatment for all patient populations?

*Dr. Brinton. I think it is much the same. The trade-off is the burdensome component of it. And so we have learned a lot from the TVT Registry, as mandated by CED. But the burdensome -- as I mentioned, the fact that it is an eight-page report that takes longer than the procedure itself, that is burdensome on the physicians, the care providers.

So we need to find the balance between collecting appropriate information that is going to help us make best decisions and, as we expand therapy, we are going to learn more. As we expand it is important we continue to get data to make good decisions about access so that we understand how these technologies are being provided, and actually try -- to actually have -- you know, to improve the inequities of access to care.

*Mr. Cardenas. What other lessons can we learn from the TAVR Registry?

*Dr. Brinton. I think we have learned a lot. I mean, we use the TVT Registry for us to understand how to improve our innovative process. We understand how we work side by side with physicians, and we have patient advocacy. We work with patient groups to actually understand their experiences, actually -- and what is going on with the procedure itself.

But particularly, it is how we innovate the next generation of devices. We learn where the limitations are, and we actually seek to improve upon them.

*Mr. Cardenas. Thank you, Mr. Chairman. My time having expired, I yield back. Thank you.

*Mr. Guthrie. [Presiding] The gentleman yields back.

The chair recognizes Mr. Latta for five minutes for questions.

*Mr. Latta. Thank you, Mr. Chairman, and thanks for holding today's hearing, and thanks to all of our witnesses for being with us today.

Earlier this month CMS finalized its maximum fair price, MFP, guidance that, unfortunately, failed to ensure a drug price negotiation framework that provides incentives for innovation. This could have been achieved if CMS had established the MFP at the ceiling price for products that are therapeutic advancements or that address unmet medical needs. In doing so, the agency could have ensured that incentives deployed during the drug price negotiations are clearly defined and achievable.

This system does not preserve incentives for investment into rare diseases. Along with fear that coverage and innovation would be stifled in the aftermath of the Inflation Reduction Act's passage into law, we are now seeing the consequences of this when it comes to Alzheimer's coverage and investments.

The IRA and the CMS national coverage determination for Alzheimer's treatments disproportionately restricts patient

access to new treatments in high-need areas. In contrast, Medicare has always covered FDA-approved drugs for those living with other conditions like cancer, heart disease, and HIV until now. The implications from the drug price control program reducing investment in treatments for Alzheimer's disease alone could be deeply impactful for patients and their caregivers, especially given the inherent suffering associated with the disease and the costs to the U.S. health system that total more than $1 trillion per year. Early indications suggest that U.S. biopharma industry will need to cut back on R&D into treatments due to these controls.

You know, if I could ask Ms. Wronsky -- am I pronouncing your name properly?

*Ms. Wronsky. Wronsky.

*Mr. Latta. Okay, I am sorry.

*Ms. Wronsky. It was pretty close.

*Mr. Latta. But first, you know, thank you for your testimony. You know, in my family, on both sides, we have had devastating effects because of Alzheimer's and dementia. And we also know, as -- what you in your testimony pointed out, for caregivers and what is out there. And it is something that is affecting more and more families across our

nation. And it is something that we need to be looking at because, again, this is an absolutely horrible disease, and it is one that we need -- as I mentioned, that -- how much, you know, just not only in human costs, but in dollars that are spent. And we need to find a cure.

With CMS's decision to restrict Alzheimer's patients' access to treatments through the agency's unprecedented decision, how might this impact America's seniors -- and not only just seniors, there is also younger people that are getting Alzheimer's that I know -- and their confidence in public health officials, given their hopes of witnessing the next generation of promising Alzheimer's treatments?

*Ms. Wronsky. A very good question, and thank you for the question, Representative Latta. So I can tell you two words that -- in the senior community and in the Alzheimer's community, and you are right. More and more younger people are experiencing Alzheimer's disease. Hope and frustration.

Back when I said in my testimony when my mother was diagnosed, there really was no hope for any kind of treatment for her. And for many years in my advocacy work I have been saying that, should I be diagnosed with Alzheimer's tomorrow, I am not much younger than my mom was when she was diagnosed

at 61. I turned 60 myself this year. There would have been no better treatment for me than there was for my mother 30 years ago. That is all changed now.

We are in the era of treatment now for Alzheimer's, and the hope is -- it has been very exciting for us the last couple of years. I can say that without doubt. But to have gotten this far, I have been advocating since 2004, and I have gotten to meet more and more people living in the early stages of Alzheimer's disease. People are, fortunately, getting diagnosed a little bit more quickly these days.

But to find out that there are treatments available, FDA-approved treatments available, and they are not able to access those treatments has been incredibly frustrating. We are very happy now that Leqembi has received traditional approval, that CMS has agreed to cover it.

The registries, however -- I am completely in favor of acquiring more information. I think it is an important tool in the process of living and dealing with Alzheimer's disease. We do see it as another roadblock. For those doctors who are not enrolled in registries, who are not utilizing registries for location or other reasons they might not be in it, a patient wouldn't have access to the

registries. Many roadblocks we feel have been put up to these new drugs, and it is -- there is a lot of frustration in the Alzheimer's community due to that.

*Mr. Latta. Well, thank you very much for your advocacy. And we -- again, for all those across this country that are suffering from that absolutely horrible disease of Alzheimer's that appreciate all that you are doing and your work.

*Ms. Wronsky. It is an honor --

*Mr. Latta. Mr. Chairman, my time is expired and I will submit my other questions after the hearing.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Latta. But thank you very much, Mr. Chairman, and I yield back.

*Mr. Guthrie. Thank you. The gentleman yields back and the chair recognizes the ranking member, Ranking Member Pallone, for five minutes.

*Mr. Pallone. Thank you, Mr. Chairman. I have some questions, but I have to first take a few moments to respond to the claims from my Republican colleagues about the Inflation Reduction Act, which for the first time empowers the Secretary of Health and Human Services to negotiate on behalf of Medicare to lower drug costs for America's seniors.

The law caps out-of-pocket costs at $2,000 annually for Medicare Part D, caps insulin at $35 a month in Medicare, and stops drug companies from unfairly raising their prices faster than the rate of inflation. And these are all wins for the American people, in my opinion.

And Republicans would have you believe that we must make a choice between reducing drug prices and bringing new and innovative drugs to market, but that is not true. I think these are scare taxes [sic], and I am just kind of tired of these old talking points on the other side that put forward -- also by the pharmaceutical industry, who are only

interested in remaining one of the most profitable industries in the world.

It is -- I think Republicans are saying they are protecting innovation, but they are at the same time pushing these multi-billion-dollar appropriation cuts to research at NIH, ARPA-H, and other HHS-funded programs.

So, you know, I believe that Democrats have delivered on lowering drug prices. We are going to continue to push to ensure that more Americans can take advantage of these savings from the Inflation Reduction Act by extending the negotiated prices to those outside of Medicare, as well. And we are going to continue to push for funding for research.

And, you know, there is no reason, as I said earlier in my opening statement, why this can't all go hand in hand. We need our Federal agencies. We need to take action to help people to deal with affordability. But at the same time, we can have innovation with the drug companies and innovation through our Federal research arms, as well. There is no reason why these can't all happen at the same time.

Now, let me just say I just wanted to ask a question. I wanted to mention clinical trials. I have to cut back on it because I only have three minutes here. But I think that

clinical trials may not always reflect the diversity of the patient population. And this is particularly true of Medicare beneficiaries, who can be under-represented in clinical trials.

And I also understand there is evidence gaps in specific patient populations not included in the clinical trial and important questions remaining on drug side effects. But let me just ask Dr. MacGillivray.

Can you briefly explain how the evidence development requirements on transcatheter aortic valve replacement, TAVR, helped expand access to previously under-treated patients, briefly?

*Dr. MacGillivray. Yes, thank you, Congressman.

So in the early trials of TAVR it involved 25 centers and about 700 patients. We now, through the TVT Registry, have 830 centers of the total 1,100 cardiac surgery programs in the country. We have 700,000 patients now involved in the TVT Registry. There is a TAVR Registry -- there is a TAVR center in every state in the United States now, and in major metropolitan centers around the country there are multiple TAVR centers.

So in the beginning it was limited access to selected

patients. It is not perfect now, but it is much better.

*Mr. Pallone. I appreciate that. And I am glad to see these additional patient groups have gained access to this therapy, thanks to the evidence generated by the TVT Registry.

But let me ask Dr. Rost -- I understand that AAN has proposed a two-pronged coverage for -- I can't pronounce it -- lecanemab. Can you briefly explain why it is important to collect real-world evidence for specific patient groups?

*Dr. Rost. Thank you for this question. We did propose a two-prong approach, one prong being the -- allowing patients who meet the criteria that have been fully supported through evidence to be meaningfully -- both clinical and statistical -- to be excused, so to speak, or excluded from the CED criteria.

We also suggested an off-ramp for those patients who have been included into the ongoing study to have a transparent and also clear process by which they would be able to exit that particular pathway.

But the real-world evidence could be very important. We could learn not only about the particular medication -- in this case Lecanemab -- but there is also an upcoming pipeline

of medical innovations that we are going to continue to learn how they apply to the real-world scenarios, and patients that may both benefit from the efficacy of those drugs, and also we will learn with regard to the safety profile.

*Mr. Pallone. Thank you so much.

Thank you, Mr. Chairman.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Mr. Griffith of Virginia for five minutes.

*Mr. Griffith. Thank you, Mr. Chairman. I greatly appreciate it. As far as old talking points go, the reason that we have old talking points is that my colleagues on the other side of the aisle aren't listening.

The negotiations that take place with the drug manufacturers that were included in the IRA and originally in H.R. 3 are such that the government comes in, they tell you we are going to negotiate, you can't talk about it if you are a drug manufacturer, and if you don't agree to the price that we are going to offer you, we are going to take 95 percent of your sales. That is not much of a negotiation, unless you are the Godfather.

Exclusivity is also a problem in the IRA because of the fact that with -- particularly with small molecule

treatments, the exclusivity period is so short that companies have told me they may take their trials overseas, and medicine may not be available as quickly in the United States.

All right, that said, back to my questioning. I understand that nearly -- Dr. Brinton, I understand that nearly a third of all products requiring coverage with evidence development since 2005 were for cardiovascular medical products. Furthermore, I understand that registry costs in the case of the transcatheter valve therapy registry are roughly 25,000. And as you have said -- you have talked about it as being burdensome, and the staff hours and resources are a real challenge for both providers and their patients, especially in rural areas.

So what do we do about the rural areas? How are the registries set up, funding-wise? Do they -- does the industry help rural areas get started? Is there a process to help the start-up?

*Dr. Brinton. So thank you very much, Congressman Griffith, for the question. This is, obviously, a major focus for us now, particularly with the fact that we have learned from the TVT Registry that we do have inequities in

care, particularly in rural areas. So we are making great efforts, I think, as I mentioned earlier.

I think one of the drivers of this is actually limitations that come as resource limitations within the NCD. So the NCD has listed a number of sites that can be involved in TAVR. That does not necessarily have anything to do with CED. We are learning the information from CED that tells us about the inequities in care. So we are trying to then develop strategies to address those. And one of those is the limitations that are provided, as I mentioned, from the NCD. So there are resources. The resources generally come from the guidance of the NCD. So that is one area that I think we can potentially suggest that we need to actually approach.

Other areas are the fact that we need, really, grassroots efforts to actually get those patients that are -- you know, racial disparities actually addressed directly. It is not just inequities in care in rural, but it is also we have -- within the inner cities we actually have racial disparities, as well. And we are learning that through the actual CED and the TVT Registry directly.

So you know, how do we do that? We need a strategy. And the strategy is that we need to think about, even if you

are in a large city -- and people suggest that -- as I mentioned earlier, we have TAVR centers in all states. And at the time that we came up with this strategy, we were really trying to roll out, as I mentioned, the safe and most appropriate way to bring this lifesaving therapy to patients. But that was at the time. We have learned now from that. And the ask is, can we bring access to more patients? That means bringing those technologies into the rural communities directly.

And right now, whether you are in the rural communities or in the inner city, sometimes it takes jumping on a bus for multiple hours to actually get to something that is 12 miles away. And so that is impossible for access for some actual providers and for some patients. And so we need to think about the fact that we have actually distributed actually these centers in a way that doesn't necessarily provide equal access. And so that is now what the TVT Registry has provided us.

And so then, once we have the ability to open further centers, we then have the ability to actually provide this care to the rural areas themselves.

*Mr. Griffith. Yes, I am concerned because Alzheimer's

affects us all. And I am just wondering, you know, are we doing enough in the rural areas?

And there -- and I am not against talking about the inner cities, as well, and I understand it may take a while because -- you know, sometimes we have a problem with people see -- look at a map and they say -- in my district they say, well, it looks like it is only this far apart. But what they don't know is there is two mountains in the way, and what might take -- you know, if you were just driving the mileage at 65 miles an hour, it might only take you 15 minutes. But to get around the mountain you are not going 65 miles an hour.

So I recognize your bus analogy, but I am really concerned about the rural areas that people are being -- are not being served, and I am particularly concerned with comments that Ms. Wronsky brought up that, you know, that they are not being served.

Ms. Wronsky, what do you think? What do we need to do in the rural areas?

*Ms. Wronsky. That is a great, great question.

*Mr. Griffith. Should we get rid of the registry for the people who are trying to do it in those rural areas, or

where they are under-served, whether it be inner city or rural?

I mean, I know the registry can help, but it can it prohibit health care --

*Ms. Wronsky. I think it can be prohibitive, absolutely. We do have a lot of issues with outreach in some rural states, where we only have one Alzheimer's chapter for resources alone. That is -- those are areas that aren't being touched by things like this. So we absolutely -- it can be prohibitive.

Again, I am very much in favor of continuing the process of learning more about these drugs. But I think where it is -- where a patient has proven that they have the disease, and they are in need of treatment, and the treatments are available, we believe that they should be -- have access to them.

*Mr. Griffith. Yes, I appreciate that.

Mr. Chairman, as you know, but maybe the folks back home or around the country and maybe our witnesses don't know, my district land mass is larger than nine states. I am east of the Mississippi. I am one of the largest, if not the largest east of the Mississippi. And I have a lot of rural people

who don't get health care.

I yield back.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Ms. Kuster for five minutes for questions.

*Ms. Kuster. Thank you, Mr. Chairman, and thank you to our witnesses for testifying today.

I want to thank you, Ms. Wronsky, for sharing your experience as a daughter of someone with Alzheimer's. My heart definitely goes out to you. My own mother, former state Senator Susan McLane, was in the public eye in New Hampshire when she was diagnosed with Alzheimer's. And we worked through her disease progression together, ending up co-writing a book about her experience called "The Last Dance.'' I appreciate you being here today to help educate us and the public on this important topic. So thank you for sharing your story.

Today's hearing is an opportunity to understand how Medicare serves as a conduit for innovation, not only through the millions of beneficiaries, but for the broader health care system. I am working with several colleagues on this committee to advance legislation that promotes program innovation, including my bipartisan bill with Representative

Miller-Meeks that would increase access to generics and biosimilar drugs for people with Medicare coverage. We need to prioritize policies that promote innovation, improve access to health care across the board.

I am going to turn to Dr. Miller.

Your testimony references the need to think differently about paying for health technology, including telehealth. I am a strong advocate of telehealth services, particularly in helping to reach Medicare beneficiaries in rural areas. We bought ourselves some time with the extension through 2024, but important conversations remain, and the clock is ticking. Can you briefly explain your recommendations on how to improve the payment system for telehealth and other considerations as this committee weighs the future of telehealth policies before the end of 2024?

*Dr. Miller. Thank you, an excellent question. It actually helps the inner city beneficiaries who have four busses to get to the doctor. It also helps the rural beneficiary who has to drive around two mountains in a blizzard, right, because you can access care either, you know --

*Ms. Kuster. And the busy working parent who doesn't

have access to --

*Dr. Miller. Who doesn't have time.

*Ms. Kuster. -- or time to --

*Dr. Miller. Right.

*Ms. Kuster. -- child care, grandparents taking care of kids now.

*Dr. Miller. Exactly. I mean, not everyone has half a day to take off, or an entire day to go take off and go to the doctor's office.

I think -- well, one is this payment parity for telehealth versus in-person, it is just not realistic. I know everyone, like lots of advocacy groups, want that. But it is just not realistic. It doesn't cost as much money.

A way to think about it is you could think about tiers of service, right? You could think about in-person, human-driven service. You could think about some degree of automated service. You could think about human capital-driven, like physician-driven, remote service, audio visual with, say, a Bluetooth-assisted remote exam. You could think about remote telehealth without the exam. You could think about audio-only.

You could think about text message-based or SMS text

messaging patient portal, and you could attach a modifier, and you could have that modifier have different values between zero and one for, say, everywhere on the physician fee schedule, and then put it appropriately for what -- you know, some services shouldn't be remote, should only be in person. Other services, you know, you might think that actually just sending a note is sufficient.

And so that would allow the Medicare program to customize the type of service and level of service for every individual beneficiary as needed.

*Ms. Kuster. Thank you very much. That sounds like an enormous task for us to complete in the next year, but it is good direction.

Another area of discussion today is how Congress is working with the Administration to support Medicare innovation and technology, particularly with the recent TCET framework release. Dr. Aklog, can you -- thank you for your moving testimony. Can you please describe how Congress can help improve the TCET proposal?

And what areas of the framework are companies like yours excited about?

*Dr. Aklog. Thank you, Congresswoman. I will start

with the second question.

We are just excited to be here. We are excited that Congress is engaged, and that this is bipartisan, and we all are looking for the same thing: to have patients have access to this -- these lifesaving care, lifesaving innovations. Both the H.R. 1691 and TCET, you know, are a step in the right direction, and we will work to improve the process.

Many of the areas for improvement have been covered here today, so I will just sort of rattle them off again, just to -- for completeness. As I think I have said already twice, the omission of diagnostics is really not -- is not reasonable. We need as much streamlining, we need as much transparency and predictability in that space. And the opportunities to have an impact are just as great.

One thing that is not in TCET that was in prior rules was automatic coverage. Without automatic coverage, the predictability aspects of the process get -- you know, get quite diminished. Going in, especially as a small company that is raising capital, going into a process knowing that you might fail, but knowing that if you are successful and you -- and the criteria are clear, that there is not uncertainty at the end of the road, so that is really

important.

We talked about the quotas and the resource allocations and the five -- you know, the five slots a year. That is, again, not workable. It doesn't follow the pace of innovation, and it pits patient groups against each other.

The defined benefit category, also an issue. You know, we have 21st century innovations, and we have a defined benefit category system that is many decades old. They have to be aligned.

*Ms. Kuster. Thank you very much.

My time went over. I apologize. I yield back.

*Mr. Guthrie. The gentlelady yields back. The chair now recognizes the gentleman from Florida, Mr. Bilirakis, for five minutes.

*Mr. Bilirakis. Thank you. Thank you, Mr. Chairman. I want to thank you again, and the ranking member, for holding this critical hearing on medical innovation and the need to ensure that Medicare beneficiaries have access to treatments and cures being developed for patients in need, particularly those who have debilitating, life-threatening diseases that no alternatives exist.

And while drugs have historically had a pathway forward,

devices too often get lost in bureaucracy. That is why I am proud to help lead the Ensuring Patient Access to Critical Breakthrough Products Act, H.R. 1691, with my bipartisan colleagues -- again, Representatives Cardenas, Wenstrup, DelBene, and, of course, our chair, Mr. Guthrie, and our Ranking Member, Ms. Eshoo.

Our bill will provide a statutory pathway for Medicaid, Medicare coverage for medical devices approved by the FDA under the Breakthrough Devices Program. We want to expand upon and strengthen the policies recently laid out by CMS in their proposed transitional coverage for emergency technologies, TCET, guidance recently released.

But I would be remiss if I didn't express disappointment that TCET doesn't go further, and only expands Medicare access to only a small number of innovative devices under the existing national coverage determination pathway compared to the now-repealed MCIT rule.

So my questions are -- let's see, Dr. Miller first. I understand that there are vastly different levels of expertise and staffing resources between FDA Device Review Group and the Medicare coverage group at CMS, which has a much smaller footprint of medical experts on staff. Can you

elaborate on the respective roles of the FDA and CMS, and whether CMS should develop a means to harness external expertise without overstepping its statutory role, such as unnecessarily requiring duplicative studies redundant to what the FDA has already required?

If you could answer that, I would appreciate it, sir.

*Dr. Miller. Thank you. So the FDA ensures that products are safe and effective. The CMS ensures that they are reasonable and necessary for the Medicare population.

So the FDA device might -- or the FDA-approved or cleared device may or may not be tested in a population that is exactly representative of the Medicare population. So that is one issue where the FDA and CMS working together could improve that. We have the parallel review program, which is a good effort, but, unfortunately, operationally hasn't really changed that.

I think that the problem is, as I said, CMS has a variety of tools and it doesn't use them. It has the Medicare evidence coverage, or Evidence Development Coverage Advisory Committee, which is 100 members. They haven't had many -- they had, I think, 14 meetings of that over the past 10 years, even though the charter says 2 to 4. And when it

was first set up in 2000, they had 6 meetings in that first year. So they have the external experts. They have recruited them, screened them. When I joined, I -- and I am no longer a member -- I did, I think, 263 pages of paperwork. So it is not exactly a low entry barrier. You have to undergo ethics screening.

So CMS has those tools, they just have chosen not to use them. That is why I think they need to have a statutory requirement for issuing guidance as to when they use which tool, when they are going to do an LCD, when they are going to do an NCD, guidance for when they convene an outside technical assessment, guidance for when they convene the MEDCAC, and then timelines for each of those.

*Mr. Bilirakis. Thank you. Along similar lines, in the policies being put in place by CMS with TCET there also bipartisan concerns surrounding the NCD for beta amyloid reduction treatments for Alzheimer's disease.

Ms. Wronsky, you mentioned in your testimony that the coverage with evidence development, CED determination, that CMS has decided for a fully FDA-approved drug has never been put in place before [sic]. Can you speak to the need for CMS to reconsider putting up these barriers and replace it with

the NCD that makes patient access as easy as possible when it is medically necessary?

I too have a loved one with the mid-stages of Alzheimer's and, of course, I have a lot of constituents that, unfortunately, were diagnosed with Alzheimer's. If you could answer, I would appreciate it.

*Ms. Wronsky. Thank you, Congressman, for the question, and we appreciate your support on the issues, as well.

I think I just need you to repeat the question one more time.

*Mr. Bilirakis. I am sorry.

*Ms. Wronsky. No, that is okay.

*Mr. Guthrie. We are past time. Mr. -- we are about to have 30 seconds over time. Can we pick it up --

*Mr. Bilirakis. All right. I will actually --

*Ms. Wronsky. Thank you, Congressman.

*Mr. Bilirakis. -- submit for the record.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Bilirakis. I appreciate it very much. I yield back.

*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Dr. Schrier for five minutes.

*Ms. Schrier. Thank you, Mr. Chairman. Thank you, Ranking Member Eshoo. Thank you to all of our witnesses for being here today.

Just heads up, Dr. Aklog, this question will be for you. Diabetes management technologies have seen some great advances in recent years with technologies like insulin pumps -- although I have been on one for, like, 30 years -- continuous glucose monitors, and closed loop systems that combine these technologies together. And CMS in recent years has worked to improve coverage for these devices, but has significantly lagged private insurance.

Now, looking forward, digital software-based technologies hold a great deal of promise in helping people to even better manage their diabetes. In fact, I use software, an app on my phone that connects my glucose -- continuous glucose monitor with a pump on my leg. And even if I am running between hearings and forget to take insulin, or my sugar goes low, it knows what to do. It will slow down

insulin, or it will bump it up.

And this is really the next frontier. Like, I think the next frontier is going to be that you don't necessarily buy a whole system that goes together, you buy the CGM that you like, and you buy the pump that you like, and what you are -- what you need next is the thing that links the two together, which is not a ,medication and it is not a device in the traditional sense.

But this sort of thing doesn't have a pathway through the FDA. But this is definitely kind of FDA-related, tangential, and certainly works with medications. So TCET, as proposed, really wouldn't have a benefit here. So I was wondering if you could just comment on how this might impact these type of technologies, and how quickly they can become available to people on the market and, you know, whether they are -- whether people are going to have to circumvent the FDA, which can sound a little Wild West and dangerous, or what needs to happen at the FDA to keep up with the next frontier of medicine.

*Dr. Aklog. That is such a great question, Dr. Schrier, and I thank you for asking it.

We are pretty far into this hearing, and, you know, we

have heard a lot about valve disease and other -- and Alzheimer's. It is great to hear about another scourge that we are dealing with, which is diabetes. And it is also a really important question because it goes to the heart of the issue of, you know, what -- you know, fitting square pegs in round holes.

You know, we have -- diabetes, as you said, has a lot of device technology, but also a lot of software technology and monitoring technology, all of which are coming together in very remarkable ways that are taking advantage of a host of technologic innovations. And we have a system that has defined benefit categories that are not really defined along those ways.

I think on the FDA side, I think there is hope. I think there has certainly been conversations and at least an acknowledgment that the digital health revolution is not just coming, it is here, and that FDA has to upgrade its approaches to how it addresses these things. So I think there is hope, and I think there is dialogue there that I see progress on.

I think on the coverage side, that is a problem because of the defined benefit category issue.

*Ms. Schrier. Well, that will get lots of letters from my office, probably with some co-signatures from a lot of my colleagues here.

But you bring up an interesting point. We have heard a lot about how overworked and overstretched the FDA is right now, how there are -- there already isn't enough staff to keep up with the demand, and this calls into question -- you are going to need a, like, whole new category of people, and a whole new sort of pathway for approval. Do you have an -- you know, this can go to you, this can go to Dr. Brinton. Just needing more research and clinical expertise, how do you think we are going to fill those roles, and where are we going to look for them?

*Dr. Brinton. Thank you for the question, Representative.

I think that, you know, as innovation drives forward, we are going to find all sorts of different platforms for technology, digital being one of them. But you think about material science, AI, there is going to be a whole plethora of different technology platforms that we need expertise within FDA, but also within CMS.

And so allowing them to be able to hire or recruit those

experts as advisors, to bring in that expertise, I think, is fundamental to the process. I think we have to have that expertise at the agencies to make good, informed decisions.

*Ms. Schrier. I think so, too, having that independent hiring authority.

Thank you, and with 15 seconds left I will yield back.

*Mr. Guthrie. The gentlelady yields back. The chair will recognize Dr. Bucshon for five minutes for questions.

*Mr. Bucshon. Thank you, Mr. Chairman. Thanks for holding today's hearing. And thanks to all the witnesses.

I really believe this is a great hearing because this is a critical issue. And I honestly think in the health care space this is one of the most important challenges that we are all going to face, and we are facing: how we address approval and payment for innovative products.

The United States possesses the most innovative pharmaceutical and medical device manufacturers in the world, and as a result the -- of the innovative treatments, therapies, cures, and devices, patients are able to live longer and healthier lives. And I am -- as a physician, I believe that we must ensure that Federal policies supporting -- support in maintaining this leadership, and that the

Federal Government doesn't inhibit innovation or unnecessarily restrict access for patients, and we have heard some of that today.

Unfortunately, the lack of a timely and appropriate pathway for reimbursement by CMS in the form of coverage decision plays an outsized role in whether or not patients can access a drug or device once it is approved by the FDA, as we have heard today. And it is even a factor in decisions about whether or not people will invest the capital in attempting to develop a drug or device due to the lack of predictability about reimbursement. We have also heard that today.

But I am going to focus on another issue with Dr. MacGillivray. And I know you mentioned this in more depth in your written testimony, but one of the key ingredients for innovative coverage pathways is data.

The STS database has been a gold standard of care for many years. I used it when I was in practice. I believe that clinician-led data registries like the STS database are the way to go as we determine what constitutes quality care. These clinician-led registries can even be even better with access to Medicare claims data to help better track patient

outcomes and assess the effectiveness of treatments and therapies.

Section 105(b) of MACRA, the Medicare and Chip Reauthorization Act, was passed to help provide access to this data, but CMS has refused, essentially, to provide meaningful access. This is why Dr. Schrier, who just spoke, and I introduced the Meaningful Access to Federal Health Data -- Federal Health Plans Claims Data in the last Congress.

Can you talk to that? Can you talk about why getting access to this data is so important for driving quality and better patient outcomes?

*Dr. MacGillivray. Thank you, Dr. Bucshon, for that question. You know, as the pioneer of quality improvement, Edwards Deming once said, "In God we trust; from everyone else we require data.'' And that -- the STS databases have really been very impactful at capturing data for cardiac surgery. With that risk-adjusted data we can help individual surgeons, programs, and the whole country make the quality of cardiac surgery care better.

But we are handcuffed by our registries only go to 30 days. We have over nine million patient records. If we had the ability to, in real time, cost efficiently and affordably

have access to claims data, we could demonstrate over time efficacy of the treatments and quality and value of care by lower cost.

*Mr. Bucshon. Do you have any indication of why this has been a challenge to get this data, even the -- from CMS?

I mean, they are not -- I mean, MACRA is requiring them to help with this -- why that is not working?

*Dr. MacGillivray. I wish I knew.

*Mr. Bucshon. Yes. It is the government. I could say that, I guess. Punt to that, right?

Dr. Rost, in recent guidance CMS provided to treating physicians, CMS stated that physicians will get the usual Medicare payment and cost sharing to administer Lecanemab -- is that how you pronounce that? And you may have already answered this, but when you submit a valid claim and information to help answer treatment questions in a qualifying study, as a physician who may interact with a quality net portal, what outstanding questions must CMS clarify to create confidence that the medicines and the necessary diagnostic and imaging tests will be covered by the Medicare program? Does that make sense?

*Dr. Rost. It does.

*Mr. Bucshon. Yes.

*Dr. Rost. You are referring to the CED pathway. That is the one that we have been submitting the request for reconsideration, particularly for the patients who already fit the inclusion criteria of what we consider to be peer-reviewed, evidence-driven --

*Mr. Bucshon. Right.

*Dr. Rost. -- evidence of benefit and safety.

And so we still have questions with regard to what the process is going to be, so we are asking for more transparency in terms of what the process will entail, and where does that actually end for those patients who accrue real-world data that addresses the questions of efficacy and safety with the passage of time. So that is the off-ramp.

*Mr. Bucshon. Right, right.

*Dr. Rost. That is another approach that we advocated for.

And we also wanted to make sure that this process is more nimble because, you know, for these patients, as we have heard so many times today already, we just don't have time for them to wait for the --

*Mr. Bucshon. Yes, thank you for that, and my time is

expired.

*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Dr. Ruiz for five minutes.

*Mr. Ruiz. Thank you, Mr. Chairman. Thank you for being here today. I would like to take some time to talk about not just how to ensure the Medicare program can operate more effectively, but also how it could be better structured to address the very real and present equity gaps in our health care system.

This year it is estimated that over a million Medicare beneficiaries will be diagnosed with cancer. Many of these will be late-stage cases, where the prospect of successful treatment is slim. There is a real unmet need when it comes to our ability to catch cancer sooner. That is the goal of cancer screening: catch it sooner. You are better able to remove it, to treat it so it doesn't get to the dangerous, life-threatening stages.

And as a doctor, and as an emergency physician especially, I have seen far too many cases that were detected much later than they should have been or they could have been. Late-stage cancer doesn't impact everyone equally. Studies show that Black and Latino and Latina patients are

far more likely to have their cancers detected at later stages, and thus have lower survival rates. And I have studied this ad nauseam throughout my medical school, public health education, residency training, et cetera.

I conducted some field research in my district prior to running for Congress, and a lot of those barriers include affordability, include lack of infrastructure or a provider shortage crisis, lack of transportation, lack of educational outreach, or health care literacy due to unfamiliarity with health protocols and treatments.

But for decades we have been stuck with limited cancer detection resources and virtually no means to detect some types of cancers such as pancreatic, liver, and stomach at an early stage. As powerful and lifesaving as they are, currently recommended screenings we do have available, such as mammograms and colonoscopies, are only able to detect five specific types of cancers. This is now changing.

Multi-cancer early detection screenings are blood tests with the potential to detect dozens of cancers at once. But for seniors in Medicare to benefit from these multi-cancer screening tools, first we need to act. Medicare currently is not able to cover tests like these in a timely manner, even

after they are approved by the FDA. Congress can fix this issue and make sure seniors are not left waiting.

Along with Representatives Hudson, Arrington, and Sewell, I have spearheaded a bipartisan bill known as the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act that would make the necessary changes to the law to strengthen Medicare so it can cover this technology.

So I urge this committee to give this bill priority and advance a popular bipartisan solution that addresses this pressing unmet need, Mr. Chairman. Our legislation has garnered broad support in just a few short months since it was reintroduced. In the previous Congress it had the support of 258 bipartisan House Members and 55 bipartisan Senate sponsors. And already this year we have the support of more than 160 Members across the House and the Senate and across the aisle, including over half of this committee.

So it is our duty and responsibility in Congress to ensure Medicare is there for those who have contributed to and rely on it. This includes ensuring Medicare patients are able to access the most innovative technologies and cancer detection. So Dr. Brinton, can you address the importance of

making sure that there are pathways for coverage of new innovative products and tests that will help reduce disparities in health outcomes?

*Dr. Brinton. So thank you for the question. I think you get from my earlier testimony we are very passionate about patients. We are very, very -- patients are at the center of what we do. And I mentioned Jill Poole as a patient whose life was completely changed by getting access to early therapy that was within the early feasibility trial stage at Edwards.

And so absolutely, the mechanism to not just apply the opportunity to be involved in clinical trials, but access to ultimately get to meaningful coverage is essential to, actually, the improvement of all Americans and Medicare recipients.

You know, not all things are equal. In a sense, I think the priority should be lifesaving therapy. I think it should be for not just incremental, but significant impact needs. They should be for unmet clinical needs and, particularly, as you mentioned, disparities in care. That should be the priority.

*Mr. Ruiz. Yes, and I think that legislation and

implementation should also -- should have equity in the forefront as a planning in order to implement it. Unfortunately, too often we implement laws and then react to the fact that they are not reaching those that need it the most. And then we have to reorganize and backtrack, but the damage has already been done.

So this is a clear opportunity where we can think through the process in implementing these new innovative technologies that do save lives in a way that ensures that the people that need them the most, those that suffer from high disparities due to these, get them in a -- with their fair opportunities, and that it is accessible to them.

And with that, I yield back.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Mr. Johnson for five minutes.

*Mr. Johnson. Thank you, Mr. Chairman, and good morning to our panelists. Thank you all for being here with us.

Today's topic is one that really hits home to me, as an IT professional and a patent holder myself. I know the pains that individual Americans and companies go through each day to try and bring their ideas to market. I mean, you think about what has grown the most powerful economy on the planet.

Where does innovation -- where does -- how does ingenuity fit with innovation in the American free enterprise system?

Ingenuity rests along that highway between innovation and investment. And for someone to have a great idea, and to have the mindset to pursue great ideas, ingenuity, they have got to have some certainty that there is going to be some payoff, some reward for their work.

And when innovation pulls investment -- you know, I think back, for example, to the invention of the airplane and the light bulb. Nobody asked for any Federal Government help, subsidies, incentives, any of that stuff. These were people that put their own money, their own reputation, their own time and energy on the line to make something happen because we had a free enterprise market that promised that, if they were successful, then investment dollars are going to follow.

But when investment pulls innovation rather than innovation pulling investment, when it is the opposite direction, when the Federal Government through either regulations or laws begins to influence what is invested in, innovation begins to die. And as a result, because of that uncertainty, so does ingenuity. We need to provide

businesses with the certainty that once a product is tested and proven safe, there is a reasonable process for getting it to market.

In recent years, numerous software products that treat serious diseases have received FDA clearance and approval. These products, Prescription Digital Therapeutics, or PDTs, put world-class care at patient's fingertips for afflictions ranging from opioid and substance use disorder to PTSD, ADHD, stroke, eye conditions, and more. While drugs and other products that complete FDA review are then reviewed by CMS for coverage determinations, PDTs do not fit in CMS's existing benefit categories, and the agency has been unable to consider them for reimbursement, thus jeopardizing the ability of patients to receive access to cutting-edge lifesaving treatment.

So, Dr. Aklog, American innovation has saved and improved the lives of millions of people, domestically and around the world. Would you agree that, in order for companies like yours to continue into the future, we must have a path to reimbursement for products completing the FDA review?

*Dr. Aklog. Thank you, Congressman, and I am sure you

are not surprised the answer is an absolute yes.

And thank you for highlighting the importance of individual innovators and entrepreneurs and how that ecosystem works, because it does require a level of predictability to get an investment, and it requires knowing what is at the end of the process. The process, as I said, might fail. But if you succeed you need to know that you have the ability to get that -- to get your products to benefit patients.

*Mr. Johnson. Okay. Well, I was pleased to see that CMS included a request for comments on digital therapeutics in the proposed calendar year 2024 Medicare physician fee schedule, including requests for comments on how digital therapeutics could be covered under existing coverage pathways.

Dr. Miller, in your opinion, how could CMS use existing benefit pathways for digital therapeutics which are already being used to pay for "software'' as a medical device to reimburse for those innovative and effective tools?

*Dr. Miller. Excellent question. A couple of answers. One is the chronic care condition management codes. CMS could use those to reimburse for software. I think the other

thing we need to think about is should software be allowed to compete within the Medicare program, right?

There are some things that we do not need human capital to -- we don't have enough doctors, we don't have enough nurses. We don't have enough licensed nurse practitioners. We just don't have enough human capital, and we can't fund enough human capital. So is there a way that we can allow technology into the Medicare fee-for-service program to augment human capital?

*Mr. Johnson. Okay. Well, thank you.

With that, Mr. Chairman, I yield back.

*Mr. Guthrie. The gentleman yields back. The chair recognizes Mrs. Trahan for five minutes for questions.

*Mrs. Trahan. Thank you, Mr. Chairman. I am grateful to you and the ranking member for holding this important hearing, and thank you to all the witnesses here today.

For decades, countless lives have been saved through medical innovation, and I appreciate the opportunity to be part of this conversation on how we can improve Medicare coverage pathways for innovative drugs, medical devices, and technologies. We are at a pivotal moment in the course of medical history. New therapies and treatments, including for

some conditions that were previously thought untreatable, are being developed and incorporated into commercial use as we speak.

However, in order to access this new, innovative care, patients need the correct diagnosis so that their providers have the most accurate picture of their disease. And in order to do that, particularly for Medicare beneficiaries, we must ensure that they have access to the best diagnostic tools, including PET scans. When providers have access to these devices that help them get an accurate diagnosis, it is not just patients and families that benefit. The Medicare program, as a whole, does too, because an accurate diagnosis means Medicare is paying for patients to receive the treatments that they actually need.

My home state of Massachusetts is a global leader in medical innovation, and that is especially true in the development of diagnostic radiopharmaceuticals that provide incredible images to diagnose disease. It is for that reason that I am working with 13 members of this subcommittee to advance the FIND Act, which will ensure that PET scans for Alzheimer's, prostate cancer, and other diseases are available and accessible to seniors.

Medicare pays for PET scans differently, depending on the setting in which the scan is provided. But the current system is far from perfect. Dr. Rost, how would more adequate payments for PET scans increase patients' access to care?

*Dr. Rost. Thank you so much, Congresswoman, for recognizing the state of innovation in my own state of Massachusetts. Coming from Massachusetts General Hospital, which is the number-one research hospital in the country, I can tell you confidently that many of the personalized diagnostics have been developed in that cradle of science, and I am very proud to be part of that.

Also, as a clinician scientist, I know that providing the tools that were developed through the research pipeline ultimately becoming the standard of -- or a state of art for diagnostic and clinical care is something that we need to make sure that it is nimble, dynamic, and, you know, evolving with the speed that matches the speed of the diseases that we are trying to diagnose with that. So we are very pleased to hear yesterday that the CMS retired the preexisting coverage determination for the amyloid path for Alzheimer's disease as of last night. And we are very proud that the American

Academy of Neurology to be in those dialogues with the CMS on that topic.

I would say, though, that almost 10 years of conversation in this space had gone by and, you know, this is not necessarily -- this is not necessary to be so, you know, so behind on advancing these treatments. So these diagnostics are critical. They need to be available to doctors who are taking care of patients in real world.

*Mrs. Trahan. Great. Thank you for that. I couldn't agree more on nimble and agile, and it is important to get the FIND Act across the finish line to address part of that issue.

Mr. Brinton, you have a unique perspective on medical device innovation. Based on your background, can you speak to the distinct challenges that smaller companies face when trying to get a product to market?

And in your opinion, what additional resources do both FDA and CMS need to help get lifesaving innovations to patients?

*Dr. Brinton. Yes, thank you very much for the question.

Prior to my life at Edwards I was an entrepreneur, and

worked at the Stanford Byers Center, training people in medical innovation. I think it comes back to the same things we talked about before, which is predictability of the process, that there is a predictable process for everyone, in a sense, a level playing field. That does not guarantee the certainty of the outcome. The fact that you actually know that there is a predictable process and a timeline that has been set up that is actually responsible that allows you to get the FDA approval and then approach a possible -- for actual, you know, real payment, meaningful payment that allows you to actually fund the technology -- because if you can't fund the technology, you can't get it to patients.

So ultimately, I think it is the same whether you are a large company or a small company. I really think it is about a predictable process.

*Mrs. Trahan. I appreciate that.

Lastly, I am sending a bipartisan letter to CMS urging the agency to address delays in a new benefit category for FDA-approved exoskeleton technology that works to ensure that wheelchair users suffering from a spinal cord injury can perform tasks in their everyday life. And certainly, proper coverage and payment for new technologies like exoskeletons

improve innovation, and they lead to more patient access and lifesaving technology.

Oh, I thought I had remaining time to yield to you, Ranking -- I am sorry.

*Mr. Guthrie. It goes too fast. We have so much -- it is such an interesting subject, and everybody is dedicated to this, so -- thank -- and good witnesses.

So, Dr. Dunn, you are now recognized for five minutes.

*Mr. Dunn. Thank you very much, Mr. Chair. And I, too, am excited to be joined by such an esteemed panel of witnesses to discuss the landscape of American innovation in the life sciences community.

Industry has certainly delivered next generation therapeutics and diagnostics at an impressive rate. But I hear frustrations every day about the inefficiencies and inability of CMS and FDA to keep up with the progress that the clinicians and the scientists are making.

I do want to thank my colleagues, Scott Peters and Mrs. Trahan, who just spoke, for working with me on one particular policy, and that is H.R. 1199, the FIND Act, which seeks to address the inefficient payment policy related to precision diagnostic radiopharmaceuticals.

I have seen the utility and potential of advanced diagnostic radiopharmaceuticals firsthand. These tools are important for early diagnosis, as well as treatment planning. Accurate diagnosis saves lives. For example, in the Alzheimer's space the IDEAS study demonstrated that scans utilizing diagnostic radiopharmaceuticals led to physicians to change their care management for patients in 60 percent of cases. Packaged payments for those important tools, unfortunately, currently limit their access for the Medicare population.

The FIND Act would improve that payment for diagnostic radiopharmaceuticals, incentivizing their use when appropriate.

And I would like to ask the chair to include the IDEAS study in the record.

*Mr. Guthrie. Any objection?

Seeing no objection --

*Mr. Dunn. Thank you very much.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Dunn. You know, we have been focusing on dementia in this example, but in my specialty, urology, the advances in CT, PET scanning, and cancer, both diagnostics and therapeutics, is perhaps even more dramatic. The wholesale imposition of prior authorizations, fail first step therapies, and inadequate reimbursements have been crippling our continued progress in our clinics.

My message to CMS would be simply this: Healthy patients save money, and they add to the sum total of human capital.

Another issue which I have engaged in CMS is the transitional pass-through payment. When CMS recognizes the value of some transformative technology, they reward such innovation with temporary add-on payments that incentivizes utilization and data collection about the impact of uptake. And I have heard from numerous companies who have received pass-through payments status, but then are placed in limbo when it comes to CMS setting their permanent payment levels.

So imagine, if you will, that instead of fighting layer upon layer of bureaucracy, these innovators actually had a cooperative relationship with CMS.

Dr. Rost, given your expertise in the Alzheimer's space,

would you support an improved payment for advanced diagnostic radiopharmaceuticals?

And can you speak to the different experience of patients who have access to advanced diagnostics, how their experience is different from those who don't?

*Dr. Rost. Thank you for this question.

There is no doubt that when doctors have access to diagnostics and management options that are applied to real patients in real world, we can do better informed, earlier, and more impactful decisions.

As a neurologist, we know that Alzheimer's disease is just one example of these neurologic disorders that are so important, but there are dozens of others. And, you know, the diagnostics that you have mentioned and others that are coming down the pipeline is something that we want to make sure that we have available and ready for these patients to benefit from.

Obviously, those individuals who are not able to receive the benefit of the diagnostic will not be able to get the advanced warnings of the disease. And as you mentioned, some of those conditions where you want to be able to highlight the variety of pathology -- you know, we are talking only

here about beta amyloid, but there are other types of pathology in the brain that can be diagnosed early on, and hopefully have ways for prevention.

*Mr. Dunn. I couldn't agree more. We are actually talking about curing metastatic prostate cancer now if we get it early enough, and treat extra prostatic sites.

Dr. Miller, in the remaining 20-something seconds, can you give me some of the practical challenges in facing innovative drug and device companies' recommendations to improve the CMS processes and decrease bureaucratic inefficiencies?

*Dr. Miller. I think the key is transparency of process and a guaranteed process. Right now it is a little bit of a crapshoot. You don't know what reasonable and necessary is. So if you don't know how you are being graded, how can you perform?

*Mr. Dunn. Well, I appreciate it, that was very succinct. Thank you, Dr. Miller.

[Laughter.]

*Mr. Dunn. Mr. Chairman, I yield back.

*Mr. Guthrie. The gentleman yields back. The chair recognizes Dr. Joyce.

We have a lot of physicians, as you can hear, the doctors.

Dr. Joyce.

*Mr. Joyce. Thank you for yielding, Mr. Chairman and Ranking Member, for convening such a hearing on an important topic: Innovation.

I have said, as a practicing physician, and continue to say as a member of this great legislative body that innovation is the cornerstone of American medicine. It is something that patients expect. And we need to make sure that government policy is not a barrier to access to the latest technology and therapies. Breakthroughs like in areas of gene therapy, the first-ever FDA-approved medication for Alzheimer's, and cutting-edge medical devices all need to be able to be in reach of patients for them to be ultimately effective.

With both TCET and NCD for Alzheimer's, the Biden Administration has created uncertainty and confusion about what might be reimbursed by Medicare and when. Recent decisions regarding IRA implementation have only added to this uncertainty, and will continue to stifle innovation.

Two years after withdrawing the Trump Administration's

MCIT regulation, I was pleased to finally see CMS release the proposed TCET guidance. This represents a first step towards establishing a more predictable and transparent coverage process for Medicare beneficiaries to access new medical devices. However, I am very disappointed that TCET, as proposed, may expand patient access to only a very small number of innovative breakthrough medical devices and technologies using the existing national coverage determination, or NCD, pathway.

Dr. Brinton and Dr. Aklog, can you speak on how this proposed -- this proposal differs from the previous MCIT proposal, including how it appears to apply to a smaller set of products seeking full national coverage determination, NCD, especially how the universe of potential products was narrowed to only a subset of breakthrough devices, despite CMS previously suggesting that they would look beyond the breakthrough designation after the repeal of MCIT?

Dr. Brinton, I will ask you to address first.

*Dr. Brinton. Yes, Dr. Joyce, thank you very much for the question.

I think that the differences between MCIT and TCET are significant. One of -- the biggest thing was, obviously, the

onset of the plan. So MCIT was immediate coverage. Obviously, TCET is actually delayed. It is delayed for six months. And as I said earlier, I think that every single day we wait there is patients that are suffering and not getting the therapies that have actually been proven to be safe and effective. It can be beneficial for the patient population.

As far as coverage and the breadth of coverage, I think one of the limitations is the arbitrary choice of five TCET candidates per year that allows to go through the process. That is an arbitrary number. As was mentioned earlier, it is not a linear process. You would imagine there is going to be certain amounts of new technology, new breakthrough technologies that come under review at certain points in time and less other times.

I am not sure where the limitation comes from, and it should be about, as I mentioned earlier, the criteria of being in fact -- lifesaving technology should be at the top of the list, in my opinion, things that actually -- really significant unmet clinical needs, things that actually address disparities of care. Those should ultimately be the actual criteria that actually is addressed first. And it is hard, with an arbitrary number of five, to actually address

that directly.

*Mr. Joyce. Dr. Aklog, would you agree with what Dr. Brinton just said?

*Dr. Aklog. Yes, I won't reiterate, but I do agree with every point he makes. And the fact that without a predictable path to automatic coverage, you know, these are breakthrough devices that have FDA -- will have received FDA clearance, have been deemed safe and effective.

*Mr. Joyce. I think that -- I think this entire committee and I think you, as witnesses, share in the concerns that certain medical technologies have been in coverage with evidence development, CED, limbo for over a decade.

I understand that it has also taken an average of 16 months for CMS to remove the CED requirements after requests have been made by manufacturers, if they are even removed at all.

Dr. Miller, understanding that different medical products will have different features, the different risk factors, patient populations, and bodies of evidence, should policy-makers consider a practical sunseting of CED after some period of time?

And would more clear criteria for termination of CED actually help increase access for patients?

*Dr. Miller. Absolutely. We have heard that registries, and trials, and having the continuation of that collection of data is incredibly burdensome and also inequitable for patients. So I think providing statutory guidance for CMS with timelines is what is needed. That is going to sort of unclog the bureaucratic machine.

*Mr. Joyce. And I think it is so necessary, as my time expires, that we need to be, as a body, unclogging that bureaucratic machine, unclogging access, allowing patients to innovation which truly is the cornerstone of American medicine.

Thank you, Mr. Chairman, and I yield.

*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Mr. Carter from Georgia for five minutes.

*Mr. Carter. Thank you, Mr. Chairman, and thank all of you for being here. I know it has been a long day, but we appreciate this. This is extremely important.

Folks, I am the oldest pharmacist in Congress. And the youngest one is sitting in front of me over here.

[Laughter.]

*Mr. Carter. But there are two of us, and both of us agree that drug prices are too high, and we know the problem. And I don't speak for my colleague, but I think she would agree that the problem is the middlemen, the PBMs, the Pharmacy Benefit Managers.

As you can tell, and I am not going to go into my usual spiel, but I am not a fan of PBMs. I am not a fan of any group that does not bring value to the health care system. And I don't believe they bring value to the health care system at all. I believe all they do is profit, and pocket those profits.

But nevertheless, one of the problems is the link between PBM compensation and the price of medicines. In fact, you are familiar with spread pricing. I suspect all of you are familiar with that, where they charge -- they pay one thing, and then they charge another price, a much higher price. In fact, the State of Ohio is now suing a PBM as a result of this spread pricing that took place in that state, and the attorney general described the PBMs as being gangsters, and they are. And, you know, I am sorry, that is just all there is to it.

But I want to tell you about a bill I have got. It is a bipartisan bill that Representative Lisa Blunt Rochester and I have introduced. It is called Protecting Patients Against PBM Abuses Act. And what it does is to delink the PBM compensation from medicine prices in Part D, and instead it implements just a flat fee-based model, which I think would work much better.

Dr. Miller, you are familiar with PBMs and the way that they -- I suspect, and the way that they practice. Do you believe or do you agree that the current PBM compensation model, including the use of spread pricing and public health programs, incentivizes PBMs to put higher-priced medicines on the formulary, potentially limiting access to lower cost medicines?

*Dr. Miller. Yes, it can definitely be problematic.

*Mr. Carter. Yes, it can, and it is problematic. And I appreciate you acknowledging that.

Does anyone else want to speak on that? Anyone else hate PBMs as much as I do?

[Laughter.]

*Mr. Carter. No, I doubt that. Yes, the other pharmacist does.

But nevertheless, well, again, this is extremely important. And I hope that -- I hope you will look at this bill, because this is one of the many ways that we feel like we can address this situation.

Now, very quickly, I want to switch my attention to Alzheimer's because this is another pet project of mine, if you will, and I have witnessed it firsthand in my family. I have witnessed it, obviously, as a health care professional in treating patients in my pharmacies. And I know what an awful, awful disease it is. And it impacts almost seven million Americans every year that are living with this heartbreaking disease.

I was encouraged to see recently that we have got some progress in the world of medicine, in the world of drugs that finally we got a new class of Alzheimer's treatments that will give families hope. And they need hope, God bless them, they need hope, not only those who are suffering from it, but the caretakers. Let's always keep them in mind. The caregivers are suffering just as much and -- well, they are suffering, as well. And that is something we have to be cognitive of.

They have hope that this will give them more quality

time with their loved ones before the disease takes hold, but that time will most likely not be extended if the CMS does not open the national coverage determination to ensure access to more patients. Dr. Rost, can you speak to how requiring provider and patient participation in a registry may impact people living with dementia, particularly those living in rural and underserved communities?

*Dr. Rost. Thank you, Congressman, for this question. As you know, we have submitted a request for reconsideration of the NCD criteria with the CMS, particularly as refers to the CED requirements.

Under the current pathway we -- there is two patient populations where some of the patients that we believe fit the well-established, evidence-based criteria for treatment should be excused from the CED pathway and allowed to receive the medication as appropriate. For other patients who will be undergoing the CED pathway, we believe that they should have an off-ramp procedure. As the evidence is gathered for those patient populations, they should have a determinate opportunity to receive treatment without the burden of data entering in the real world.

*Mr. Carter. Well, I couldn't agree with you more.

This is a bad-enough situation, and just an awful situation. And to have to deal with this on top of it is just something that I think is unnecessary. So thank you for that.

*Dr. Rost. And if you would allow me --

*Mr. Carter. Yes, please.

*Dr. Rost. I would also say with regard to the rural access to neurologists, I would say that, you know, one of the more pressing issues is actually shortage of physicians -- in this case, neurologists -- who are the specialists who are specifically trained to diagnose and treat this disorder. So anything that the American Academy of Neurology can do working with the Congress to improve our current situation with the workforce, particularly neurologists, we would be happy to engage.

*Mr. Carter. And of course, that also stresses the importance of telemedicine, as well. So thank you.

Thank you very much, and I yield back.

*Mr. Guthrie. Hey, thanks. The gentleman yields back. The chair now recognizes Mrs. Harshbarger for five minutes for questions.

*Mrs. Harshbarger. Thank you, Mr. Chairman. Thank you, panel, for being here. This has been -- I have taken a lot

of notes today.

Well, it is green. Is it on? Can you hear me? Maybe I need to put it toward my mouth. Okay. Thank you, Mr. Chairman.

Dr. Miller, I will start with you. Americans should not have to rely on a health bureaucracy and politicians to determine the value of innovation and whether or not to cover a medical product. Yet in Medicare that is exactly what happens. And we often hear that Medicare has to cover something before private insurers do so. And I see that in the pharmaceutical world, in a lot of cases.

But it shouldn't be necessarily true. Insurance companies should have incentives to cover products that either, one, reduce overall cost or make them more competitive by improving access to patients. Or, if a product meets this criteria for commercial payers, it seems to me that the same benefits should apply to Medicare.

So how would it improve the Medicare program if there were a mechanism to ensure access for treatments covered by a substantial portion of the commercial market?

*Dr. Miller. It would actually reduce bureaucratic barriers to entry, right, if the commercial market says that

for a certain population covering a drug device or service, even, makes sense. And CMS has a pathway to do that and decide that that is relevant for the Medicare population. It could increase access much faster, right? Because why redo the evaluation if it has already been done before?

*Mrs. Harshbarger. Yes, there is a lot of redundancies in a lot of these programs. I have come to that realization.

There is a section of the Social Security Act that prohibits the Secretary from covering items or services under Medicare parts A or B that are not reasonable and necessary for the diagnostics and treatment of illness. And it provides the Secretary the authority to determine whether or not something is reasonable or necessary.

So I guess this is my question. How do innovators and regulators interpret the reasonable and necessary definition, and does this reasonable and necessary definition need greater clarity?

And I will start with you, Dr. Brinton, because I think I know what your answer is going to be. I have written it down, like, 40 times.

*Dr. Brinton. Predictable process?

[Laughter.]

*Mrs. Harshbarger. Yes.

*Dr. Brinton. Let me say that again. Look, I think that the burden for the FDA's "safe and effective'' and for CMS's "reasonable and necessary'' are different. And what we have all really talked about here, TCET or a gap proposal, it provides the opportunity to actually generate data using CED to fulfill a requirement that is different than actually safe and effective.

So we think that data evidence is important. It has really guided the development of TAVR. You know, from first generation to where we are today, TAVR is not the same as it was when it came out in the United States 11 years ago. It has evolved tremendously, and that has been a result of the fact that we have been able to get data access.

And so, despite the fact that there are some limitations and it can be burdensome, it is trying to reduce the burden on that. So I think this provides the opportunity to actually provide coverage at the time that you can then gather data to meet the burden, actually, of reasonable and necessary.

*Mrs. Harshbarger. Exactly.

Dr. Aklog, you specifically say you want diagnostics,

and you think they should be covered, and I totally agree. For one, it is hard to plan. It is hard to raise capital. You can't do that. But how much money would we save in the long run if they put these innovations out there, and let the patient try them? Because honestly, do we have data on that?

*Dr. Aklog. I think you are touching on an important issue, which is that, once you have established safety --

*Mrs. Harshbarger. Yes.

*Dr. Aklog. -- particularly for an early stage tool that -- you know, there is an opportunity to offer it to patients while effectiveness data is being collected. And the key there is establishing safety.

In many diagnostics, including ours, you know, patients are not getting tested. And so they are failing -- you know, false positives and false negatives have a much lower risk because the alternative is to do nothing. So I think there is an opportunity to accelerate that process because patients are dying every year. If you have -- if it is a two or three-year path to get to that point of coverage, then, you know, thousands of patients would have died.

*Mrs. Harshbarger. Honestly, that is -- I see that all the time. So the very bureaucratic agency who requires all

this data and this evidence development process to protect the patient is the very agency who makes it -- the end user, who is the patient, suffer and wait an average of 11.5 years to get these products to market to where you could use them.

So how much -- I mean, it is unbelievable. I was talking to you, Dr. Brinton, before. It is -- give that patient, based on the unmet clinical needs because of the disparities of care -- you want a predictable process. If you know the rules of the game, you can get there a lot quicker, can't you? You can save money in the long run.

There sure are a lot of things need to be changed, and I think you are just the panel to help us do this.

So -- oh, my time is up. I had other questions, but I yield back my time, Mr. Chair.

*Mr. Guthrie. The gentlelady yields back. The chair recognizes Dr. Miller-Meeks for five minutes for questions.

*Mrs. Miller-Meeks. Thank you, Mr. Chair, and I thank all of our panel for being here.

Last year Republicans had a Healthy Future Task Force chaired by Representative Guthrie, and I was the chair of the modernization sub of that committee. We discussed artificial intelligence, innovative technology, wearable devices, and

how rapidly we could advance both better treatment options and also prevention in health care through both personification, or personalized drugs, medical devices, both internal and external, and would be able to prevent disease, save lives, and promote healthy behaviors.

An example of what you are talking about -- I am going to show my age and have a discussion of when I was in medical school. So I was a nurse prior to being in medical school. I was in the military 24 years. We had a discussion. One of our evening discussions one night was with a cardiologist and a cardiothoracic surgeon at the University of Texas discussing whether or not Medicare should approve CABGs, coronary artery bypass surgery, and if we should even be doing them.

The cardiothoracic surgeon said they extend life by one year, and better quality of life. The cardiologist said it is only one life, one year, we should not do it. Imagine. Imagine. I was asked as a medical student what I thought of that, and I said, "If we can extend life one year and increase productivity, we should absolutely do it, because it won't solely be for seniors. And think of all of the young people we have saved by coronary artery bypass surgery.''

That is what you all are talking about. That is the point you are trying to get across, that we can save lives, better treat chronic diseases, promote healthy behaviors, and prevent disease. So Congress needs to act to make sure Medicare beneficiaries have access to diagnostic tools, including those that detect cancer early.

Dr. Aklog, given that seniors are seven times more likely to get cancer than younger people, and whatever breakthroughs we have with seniors will also relate to younger people, what actions do you think Congress and CMS should consider to ensure seniors are getting their proper screenings?

*Dr. Aklog. Yes, I am glad again you focused on diagnostics because, as you note, being able to do -- we know that early detection works. We know that in other cancers, and we know that in cancers that are -- where we have new approaches using molecular diagnostics to do so.

So, you know, Congress and CMS just have to act and provide us with predictable pathways to take these really groundbreaking molecular diagnostic technologies and use them for this purpose.

*Mrs. Miller-Meeks. And Dr. Brinton, you know, having

been a trauma nurse and an operating room nurse, I have seen the advances. And when you talked about our transcatheter valve replacements, what an amazing thing. I have a brother who had open heart surgery at two years old for a patent foramen ovale.

When CMS repealed the MCIT rule, they indicated other devices outside of the breakthrough program may benefit from this TCET coverage pathway, but it appears that CMS ultimately narrowed the criteria more than the MCIT policy. How should policy-makers think about the breakthrough designation as a proxy for truly innovative devices and technologies?

And what other features or designations should Congress or CMS consider when providing a predictable coverage pathway to innovative technologies?

*Dr. Brinton. Thank you very much for the question. I hate to repeat myself, but I am going to.

I think that, you know, as a prioritization, you know, innovation overall, there is a lot of ways you can think about bringing new things, new products, new technologies to patients. But the prioritization needs to be lifesaving technologies, large, unmet, significant clinical needs. It

needs to be addressing, you know, not incremental needs, but very significant needs. And it needs to be addressing disparities of care.

Those should be the top priorities. And whether you call that breakthrough status, whether you call it emerging technologies, or you label it something, the reality is we need to actually move the resources to where we can have the biggest effect on patients. So my belief is that is in that order.

*Mrs. Miller-Meeks. I am going to thank you for that, and then I am going to have a sidebar in response to one of our colleagues' comments on how we use real-world evidence. And I will just give an example of that.

The Doctors Caucus sent a letter to the FDA last -- or in 2021 talking about the duration of time between the COVID-19 vaccines and how the time should be expanded based upon real-world evidence. So when we are talking about real-world evidence, we are talking about not just randomized controlled studies, but all of that information that comes after a drug has been approved, whether it is here in the United States or abroad.

Thank you so much for your testimonies.

Mr. Chair, I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair recognizes Mr. Crenshaw for five minutes for questions.

*Mr. Crenshaw. Thank you, Mr. Chairman.

You know, we talk about a lot of things in our health care system -- affordability, quality, accessibility -- and we often miss one crucial element, but it should stand out, which is innovation, and the United States proudly leads the world in this regard, offering innovative products and treatment options that truly save lives on a global scale.

Of course, this does seem to be despite the efforts of the FDA and CMS to quell that innovation. Luckily, our innovators continue on. They press on. They ask for more rounds of fundraising and investments for their small startups in order to get FDA approval. They keep trying, despite the obstacles.

And it is noteworthy that, you know, nearly half of all spending in health care occurs in the second half of our lives, when Americans are on Medicare. So older Americans must have access to the latest technologies.

You know, it has been talked about plenty, and I guess I

will just have to beat the dead horse. But on the diagnostics, prompt diagnosis not only saves lives, but also curtails health care spending. So it is baffling to see the recent rulemaking for transitional coverage for emerging technologies that diagnostic technologies were overlooked. It is astonishing that we are not expediting coverage as diagnosing illnesses is a fundamental aspect of health care.

Dr. Aklog, what would be the impact of not including diagnostic technology in this expedited coverage option?

*Dr. Aklog. I think it would be a big loss. Patients will suffer. We will have -- we won't have the ability to use these technologies to save lives. I will give one quick example, as you mentioned, as it relates to cost.

Early detection of esophageal pre-cancer, the cost of that relative to someone who presents with stage one or even more advanced cancers, is orders of magnitude greater. There is new data out that suggests that the cost of treating esophageal cancer is approaching seven figures per patient. So early detection definitely has an impact, and the only way to do that is to use these amazing tools that we have that molecular biology has provided to us.

*Mr. Crenshaw. You know, I want to go back to the FDA,

because you can't have a full conversation here if we don't talk about the FDA approval process. But the FDA is overloaded. It is easier to say no when you are a bureaucrat, let's be honest. And there are serious, unnecessary delays in a lot of approvals that I am seeing, you know, especially from companies in my own district. When they finally do get that green light, they have another uphill battle with CMS approval, as well.

Dr. Miller, you have talked about this in your testimony. Can you lay out some options that we might consider to improve the efficiency on the FDA approval side?

*Dr. Miller. Thank you, great question. Two things.

One is the 510(k) third-party review program. It is sort of neglected, living alone by itself in Silver Spring on campus. It is a way that you can offload simple applicant 510(k) applications to a recognized organization which reviews it and ships it back to the FDA. There are a series of things we can do to tune up that program, make it more efficient, so that way the FDA reviewers can focus on the complex applications and giving guidance to industry and more engagement to industry, who needs it for those applications.

The second thing is Dr. Schrier mentioned a digital

world, which is something that I support, and that is sort of the next stage of medical innovation, blending software and hardware. The FDA regulatory framework is completely inadequate to deal with that, partially because we haven't given them the tools. So they are using a risk-based regulatory framework dating back to 1976, and it is 2023. So no surprise it doesn't work.

One of the things that we could do is fit-for-purpose pathways, one for software as a medical device, another for those hardware-software combination products. I would call them integrated devices. You could have products that are broken down to components, they meet a consensus standard, they are tested in a third-party accredited lab, and they meet those standards. And then the actual FDA reviewer, the human capital, sits there and does a second-stage holistic review. That way you don't have a reviewer, the limited human capital that we have looking at all the components of a device.

So making it simple and saying what can meet a standard, and then what does the human capital need to do.

*Mr. Crenshaw. Yes, there is so many problems they are hard to list. I mean, I hear from innovators in Houston and

their dealings with the FDA, and it is a nightmare. This is a broken system. I mean, they have got reviewers who are an MD, but have never been a practicing physician, and they are making statements that are completely out of sync with what every other practicing physician would know to be true. I won't get into specifics, but I probably will bring it to the attention of the committee when we are ready.

I appreciate your testimony. I appreciate you laying out some solutions to a problem that is ultimately causing American lives, I mean, to be lost because when this -- when these innovations are not allowed out there, American lives are lost.

And I yield back. Thank you.

*Mr. Guthrie. The gentleman yields back, I thank the gentleman for yielding back. I thank all the witnesses for being here. That concludes everybody who has been present to ask questions.

The ranking member has asked to do a closing kind of -- make some closing comments, and I will just do that as unanimous consent. I assume there is no objection.

So you are recognized.

*Ms. Eshoo. Well, thank you, Mr. Chairman. I want to

once again thank the witnesses. I think that this has been an excellent hearing.

I have learned a great deal from you, and I think that that is really what hearings are for.

I appreciate my colleagues', you know, concerns about access to Alzheimer's treatments, but I want to highlight a major achievement in the Inflation Reduction Act that will make sure that seniors have access to these innovations.

You know, the word "innovation'' has dominated this hearing, legitimately so. And I think the state of innovation in the United States of America is at an all-time high. We don't have a problem there. But we want to make sure that it continues to be robust, and that it reaches people. But as policy-makers, the policy is central, obviously, to us because we are the ones that are shaping that. But you can have the best policies in the world, but if the product doesn't reach people because they can't afford it, then it is a collapse across the board.

And for Alzheimer's patients, we put in place the $2,000 cap on out-of-pocket costs. That is going to affect all of our constituents, whether they are Republicans, Democrats, independents, and that is going to save Alzheimer's patients

on the newly-approved Lecanemab by more than $3,000 annually when that is put into place. So I think that that is important to restate. It is not -- wasn't stated anywhere during the hearing.

And again, to each one of you, each one of you, thank you.

Dr. Miller, it seems to me that we have got to make sure that you meet with some of the key people in the agency. I don't know if they have considered the, you know, your responses to questions. You gave very practical things that -- to be put into place.

And I don't view these agencies as being groups of evil people. And most frankly, neither do my constituents or constituent companies. They are willing to work with the agencies, roll up their sleeves, and so often make important recommendations to them on how to do it better. So I wish we would stay away from this, you know, let's just smash them over the heads, these are bad people. They are -- I don't think we get anywhere with that. I don't think that is an intelligent approach to all of this. Let me just put it that way.

So I think that you have really advanced the case on

what else we need to do to make sure that these extraordinary innovations that are brought forward are to the benefit that every American -- and when America innovates, these innovations are for the betterment of humankind because what we do -- because we lead people around the world, become the beneficiaries of -- so thank you.

Thank you, Mr. Chairman, for allowing me a couple of minutes to say --

*Mr. Guthrie. Thank you. And if I have a couple of minutes to -- if there is no objection --

*Ms. Eshoo. Sure, I am happy to.

*Mr. Guthrie. Just to close, thank you all for being here, and what powerful stories we have -- so much policy comes from people coming and telling their family stories. We are all part of -- you know, Congress is a good reflection of the American people, and we have the same stories in our family. I am dealing with one myself. So thanks, thanks for doing that.

And just on the -- you know, the $2,000 out of pocket, I don't remember what the number we had in -- the original bill was bipartisan, and that I know it -- in a separate bill, so we both agreed on capping out-of-pocket costs through the

program. I know that it was in a different bill. We did agree to that. That is a fact. We did. I mean, you can do that, but it is true.

[Laughter.]

*Mr. Guthrie. And on the Inflation Reduction Act, I mean, we want affordable. We want it all affordable. We want it to be available. We have already had companies come to us and say that the nine-year launch -- they said that if we can -- we would like to launch early, and we have high capacity. And I won't to get into this since she touched on it in just closing. We have, like, you know, you launch early in stage four because that is where you can learn the most.

But then as you -- as the drugs improve, as you move forward, and if you -- somebody mentioned earlier they may launch in Europe first because they don't want to start the nine-year clock. And so we just want to make sure that we are hearing those kinds of things moving forward, and we need to have a more drawn-out hearing on that so we can bring that up. But since you brought it up, we are concerned about the innovation that is going to come because of that piece of legislation.

But thanks. Thanks so much for being here. This is important, and we all want innovation and see improvement. And I know you have it coming right out of the middle of your district at Stanford University, and we see it everywhere, and it is nice to have.

But I do ask unanimous consent to insert in the record the documents included on the staff hearing documents list.

Without objection --

*Ms. Eshoo. No objection.

*Mr. Guthrie. -- we will move forward with that. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. And then I want to remind members that they have 10 business days to submit questions to the record. So you can still receive questions for the record, and I ask that you respond promptly to those questions. And members should submit their questions by the close of business on August the first.

There is a vote on the floor for the full House, so we are going to probably run out of here, instead of I usually get a chance to shake your hand and thank you for being here. But we are going to go to the floor.

So without objection, the subcommittee is adjourned.

[Whereupon, at 1:30 p.m., the subcommittee was adjourned.]