Annual Public Meeting of the Board of Directors

July 21, 2026 | 2:30pm (*eastern*)

Transcript

Welcome & Call to Order

Adrian F. Hernandez, MD, MHS, Board Chair, Reagan-Udall Foundation for the FDA

Adrian F. Hernandez:
Okay. Good afternoon everyone and welcome to the 2026 annual public meeting of the Reagan-Udall Foundation for the FDA's board of directors. My name is Adrian Hernandez and I have the pleasure of serving as a chair of the foundation board. We have officially a quorum of our board directors [00:00:30] present, so I'll call this meeting to order. We are so pleased that so many of you are joining us in person as well as online virtually. And we have really a great meeting agenda where we'll highlight what the foundation has accomplished as well as having a mix of other things that we'll hear about the priorities of the FDA as well as understanding the current impact of the foundation and the finances for the past year. As you can see on our agenda, we will hear from the [00:01:00] Chief Scientist, Steven Kozlowski, as well as a deputy commissioner and among other roles, Lowell Zeta. And then closing our meeting with remarks from the acting commissioner Kyle Diamantas.

So over the last year, the Reagan-Udall Foundation has accomplished a lot. You can see in our agenda, we'll go through the details here. The Reagan-Udall Foundation is an independent 501 [00:01:30] organization created through a bipartisan act of Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. We execute on that charge by advancing regulatory science with a strong emphasis on innovation, transparency, and efficiency. Across every effort, our work begins with one central priority, protecting, improving the health of patients [00:02:00] and consumers around the US. Our role as a bridge between the FDA and the people who use the products it regulates was particularly relevant to the agency as it faced a transition in 2025. So our next slide will show our work, for example, in controlled substances, where we expanded our work in 2025 as we focus on ensuring that medication used to treat pain and substance use disorders are available and safely prescribed [00:02:30] and enhancing protection against the risk of counterfeit drugs and unintentional consequences through the programs like the Online Controlled Substance Summit.

On our next slide, you'll see we partnered with CDER to review the forecasting techniques and data sources used by government agencies, the private sector, and academic researchers, to help inform improvements in predicting demand for controlled substances. And as [00:03:00] we continue on, importantly, understand the current use of ketamine for emerging areas of therapeutic interest, we dug deep in the science behind ketamine pharmacology as well as its emerging therapeutic application, safety considerations, and growing online access. And then on the next slide, you can see how we've been approaching real world evidence through IMEDS. IMEDS is our real world data front, our flagship

innovation [00:03:30] called Medical Evidence and Development Surveillance Program. It's published multiple journal articles over the last year advancing several FDA-required post-market safety studies of approved medical products.

And then on the next slide, you can also see where we have also helped address issues emerging around transforming animal health. Animal and human health are closely intertwined, as we've seen in 2025. And the foundation continues to grow our work by identifying [00:04:00] approaches that cross veterinary medicine, agriculture, and public health. This report provide 38 recommendations here on transforming animal health in US for the 21st century and provided help to regulators and stakeholders with a more robust and agile regulatory framework. Just last month, FDA's Center for Veterinary Medicine incorporates some of these recommendations in its blueprint for success, a three-year strategic plan to modernize and expand [00:04:30] the minor use and minor species program. And then on the next slide, you can see how we've addressed cross-sectional health issues. In another report addressing cross-sectional health issues that resulted from work across local, state, federal, public health, agriculture, and regulatory systems. We helped identify actionable opportunities to bolster integration and preparedness in advance of the next animal to human health crisis.

And, of course, this is just a few examples [00:05:00] of our accomplishment over the last year in 2025 and its impact. And through these convenings and research projects that we've also gathered expertise and experience to help inform FDA's work in rare diseases and improving clinical trials and more. And if you go to the next slide, you can see that we have a great board of directors that represent different constituencies across the US. And it's through this board of [00:05:30] directors that we build partnerships and collaborations, govern the foundation's operations, and make the impact we do throughout our mission. We're fortunate to have these colleagues that provide that invaluable insight, guidance, and leadership, as we continue to expand the breadth and the impact of the foundation.

And then also have to say that, and you'll hear more, but we have staff that are very nimble and passionate about their work and their commitment to the quality [00:06:00] of the work that the foundation does. You can learn more as we go to the next slide through our annual report. For those who are attending in person, you already received that or can pick it up outside. And those who are online, you can go to our website and get the report downloaded through a virtual link. And so with that, you can really explore everything that the foundation has done over 2025 and also see the breadth of activities and the impact [00:06:30] that we've had. And in just a few more minutes, you'll also hear a little more in depth about the impact of our work through the experience of different board members and their expertise.

So I'll go next and turn it over to Susan Winckler, our CEO of the foundation, to discuss the operational details of the past year. Susan? Thanks.

Year In Review
Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler:
Thanks so much, Adrian. It's great for me when I [00:07:00] don't have to open the meeting. So I appreciate that. So one of the reasons that we have this annual meeting and that we issue an annual report is because Congress told us to. It is in our authorizing statute and is essential to providing transparency about how the organization operates. So I will provide some of the information about the foundation's finances and a bit of an update as things are moving forward. So in 2025, we continued our efforts [00:07:30] to broaden our funding base to responsibly steward the public investment that FDA makes and complimenting that with non-government sources. That stewardship is reinforced by board oversight. Dr. Hernandez, serving as our chair, and all of the members of our board, serve an important function under our authorizing statute where they review all of our financial arrangements, including every donation over $250. [00:08:00] Our board is constructed, also according to the statute, with designated seats for consumers, health professionals, regulated industry, and academia.

Another important safeguard is that the foundation maintains control of its work as an organization. So while any of our funders, including FDA, provide input to what we do, the foundation retains control of the final work product. We also require that any project [00:08:30] supported by an individual member of regulated industry has to include more than one funder. With that context, here's the numbers. In 2025, the foundation remained relatively the same size with just about $8.8 million. Unfortunately, the expenses outpaced our revenue resulting in a negative 232,000 change in our net assets. A significant contributor to that is that we had a gap in our [00:09:00] cooperative agreements with FDA to discharge projects for them. Our initial five-year agreement ended October 31st and we have a new agreement, but that one was put in place in late May. So we had some time-lapse there. So the detailed financial and funder reporting is on pages 26 and 27 of our annual report if you want to review the details.

Our funding mix can also be instructive. This is a common question that I get. [00:09:30] But this shows the balance between government and private sector support, including the share of private sector funding that is provided by the studies that we help industry perform to meet their post-approval study commitments. So that's the quick tour of the finances for the year. And another way to look at our work is through the outputs. Many people encounter the foundation through our convenings. And so this just captures a [00:10:00] bit. While Dr. Hernandez shared some of the programmatic piece, this is more through the lens of the numbers. And so we had more than 5,000 people register for seven public meetings and there are recordings and transcripts of each of those meetings.

We also hold a number of discussions away from the camera. And so they're not on stage. They may be in this room, but not on stage. And so we conducted 27 round tables, 15 work group [00:10:30] and expert panel meetings, and conducted 39 patient and stakeholder listening sessions. All of that activity led to 14 public reports. In addition to other learnings, sometimes we share the results through slide decks or presentations, and all of that material is available on our website.

And one other piece, as we mentioned earlier, in late October, we closed out our first five-year agreement with FDA. And in that five years, we discharged [00:11:00] 74 projects and issued 38 reports in collaboration with the agency across nearly all of the agency's product centers. So we worked with CBER, CDER, CDRH, CVM and the Human Foods Program, and of course the Office of the Commissioner.

But that takes me through all the numbers that we had to share. If you were worried that we were going to get deep into spreadsheets, we are not. That is the coverage of the [00:11:30] numbers that we wanted to make sure that you had exposure to.

The Year Ahead: Strategic & Scientific Priorities

Steven Kozlowski, MD, Chief Scientist, U.S. Food and Drug Administration
Lowell Zeta, JD, Acting Chief of Staff, Deputy Commissioner for Strategic Initiatives, and Special Counsel, U.S. Food and Drug Administration

Susan C. Winckler:
And with that, I think we can transition to talking with two of our FDA leaders who have joined us today because I know one's in the room and I'm told the other is outside the room and about to walk in. So let's bring two distinguished leaders from FDA into the room. And so joining me for a conversation, come up on stage, Dr. Steven Kozlowski, who is [00:12:00] Chief Scientist for the FDA, and Lowell Zeta. Lowell, I have all of your titles ready to go. Are you ready? Deputy ... There you go. Yeah. So Lowell is Deputy Commissioner for Strategic Initiatives, Special Counsel in Office of Chief Counsel, and Acting Chief of Staff. Do you have business cards for all?

Lowell M. Zeta:
I don't.

Susan C. Winckler:
[00:12:30] Okay.

Lowell M. Zeta:
I should get them.

Steven Kozlowski:
Now they're electronic.

Susan C. Winckler:
That's true. We don't need the paper anymore. So thank you both for joining me for a conversation to talk about some of the priorities and all that is happening at the agency. It's been a lot, a busy time. I will remind our guests, both virtual and in person, that we do not ask our speakers to address questions regarding any pending regulatory actions or specific company [00:13:00] products.

So let me first turn to the multi-titled Deputy Commissioner Zeta. The agency has generated a lot of work product in the past year. When you think about it, what would you highlight as key steps toward strengthening the FDA and its role? When you reflect, what comes to mind for you?

Lowell M. Zeta:
I have a few topics to cover progress-wise in terms [00:13:30] of deliverables and things, highlights. But as I reflect now, I just want to add, I mean, it's the resilience of the staff, the career staff. I mean, it's pretty astounding in terms of executing on obligations, approvals, but also being dynamic and resilient, starting in April of last [00:14:00] year, and still coming, showing up every day, committed to the mission. I think that is ultimately the key to it. Some areas that we've made a tremendous progress that I wanted to touch on that I think we cover less.

Susan C. Winckler:
Yes.

Lowell M. Zeta:
One is some great progress on inspections. I think that [00:14:30] that program across the agency following last year through April and really before that with reorg and changes to the decision making, I guess. And I think that also impacted visibility of data and planning. It impacted planning. But through last year, 17,000 inspections, domestic and foreign, 75 [00:15:00] million import lines, distinct products, 25,000 samples pulled for this sort of field work. So just tremendous work to continue to carry on compliance and field work.

Great progress in terms of biosimilars. The guidance that we issued last year, there's been some great progress in product development. Just last year, I think it was 25 or 26 approvals on the biosimilar side, seven [00:15:30] total this year. And that was the evolving how we think and our expectations in terms of comparative efficacy in the human trials and streamlining PK studies. So that's been great progress to see and ultimately access to patients, that innovative products that in theory are more accessible and affordable. On the screwworm front.

Susan C. Winckler:
[00:16:00] New World screwworm-

Lowell M. Zeta:
New World screwworm.

Susan C. Winckler: Yes.

Lowell M. Zeta: Yeah. NWS.

Susan C. Winckler:
I know what that means. So the flies.

Lowell M. Zeta:
Maybe I'll let Steve jump in here if he-

Steven Kozlowski:
No, no, no. I think you're covering it well and I think it's pretty well-known.

Lowell M. Zeta:
Yeah.

Susan C. Winckler:
It is. Yes. So, yes.

Lowell M. Zeta:
It can be pretty devastating.

Susan C. Winckler:
Absolutely.

Lowell M. Zeta:
I mean, in terms of livestock. But the work that CVM has done in terms of preparedness, [00:16:30] no drama, no frills, really less probably attention in the media. But when I joined last April, their discussion was, "Oh my gosh, are we ready? What's next?" To date, including through last week, 15 drugs or treatments and also prophylactic for prevention products that are conditionally approved or through UA, including ivermectin liquid last week. And [00:17:00] it's a smaller shop. They have a tremendous lift and not just with products coming through CVM, but also continued coordination with USDA, with CDC, with state partners, that have some strong opinions on what should be happening, especially, for example, in Texas.

Susan C. Winckler:
If I can pull that thread?

Lowell M. Zeta:
Sure.

Susan C. Winckler:
CVM's smallest center at FDA still, [00:17:30] I think.

Lowell M. Zeta:
That sounds right.

Susan C. Winckl...:
Yeah. And yet responsible for the most species. We happened to have done a report with CVM last year, two different ones, but one was just about the breadth of their work and how to navigate it. And it's fascinating and a really interesting opportunity. And then there's the intersection probably on a daily basis with USDA and other [00:18:00] inter-agency groups and state level.

Lowell M. Zeta:
Right. Right. A lot of cooks. And it's not easy.

Susan C. Winckler:
Indeed.

Lowell M. Zeta:
It's an art. And then lastly, touch on hiring and recruitment progress that we're making. About 220 FTEs approved for FY26. That's in addition to about a thousand that Dr. Makary had mentioned [00:18:30] last June. So in total, about 3,200 that we have approval to hire. We're tracking against good progress. Just under, I think it's about 870 candidates that are going through the clearance process. The NEO classes every other week, including this week, are full. I think it was 53 this week and the majority are new to government. So we're making good progress, but it ain't easy [00:19:00] and it's not quick. And we're also mindful of finding the right talent for the moment where it's expertise in drug product development, but also AI digital health-literate. And finding the talent can be tough.

Susan C. Winckler:
Yes. And navigating that process.

Lowell M. Zeta:
Yeah.

Susan C. Winckler:
Yeah, yeah. That is a lot [00:19:30] going on with all of that. So really appreciate that review. So let me turn, Dr. Kozlowski. We've talked about things. Science can move at a different pace and often less in the limelight or at least a little less public awareness. What would you highlight as leadership in that scientific portfolio?

Steven Kozlowski:
So I would first say you mentioned different paces. So we know you look back historically, [00:20:00] 10 years is probably not that unusual of a time for drug development from discovery through marketing. And yet when you look daily, there are scientific discoveries in the press. We've made so much progress in terms of protein folding, systems biology, in vitro complex methods. And so even to the public, there's probably a question, what is all this technology going to do for me? And I think that's true of patient groups and there's a high expectation [00:20:30] on that. So the agency really does try to leverage all these things. Starting in 2005, we had two guidances on use of AI, one about devices and the other in drug development.

Susan C. Winckler:
So wait a minute, 2005?

Steven Kozlowski: Yep, but I'm about to move forward, right?

Susan C. Winckler:
Well, no, but I'm not sure I would've said AI in '05.

Steven Kozlowski:
Right.

Susan C. Winckler:
Right. Forward-thinking.

Steven Kozlowski:
Well, I think, well, ChatGPT started I think in November [00:21:00] of 2022 being public. So it really ... which has advanced incredibly rapidly when you think less than four years from something just released to something which is almost ubiquitous in how everybody thinks about things. And again, the speed of that compared to the speed of drug development really raises the issue of how we adapt. And this year we've had guidances on using software in making clinical decisions, just sort of setting some ground rules from CDRH, [00:21:30] but we've also had guidance of use of NAMs to really try and use these new approach methodologies to both reduce animal use and speed drug development. And very recently we had an ICH-finalized guidance on model-informed drug development. Again, trying to leverage this huge amount of information.

Concurrent with that, there is a draft guidance on using quantitative systems pharmacology, sort of a unique blend of systems biology [00:22:00] and pharmacology, to set first doses in human studies, which again, can save animals and could potentially speed development. So we are trying to figure out how to give you standards to leverage these technologies, but it is a tricky problem. And Clayton Christensen decades ago talked about disruptive innovation and made the case that it's not just the idea and it's not just the technology, but you need both business models and systems to work in, [00:22:30] but especially you need regulatory standards. And so it really sits upon the agency to think about how to have standards which both assure safety, quality, and efficacy when appropriate for the FDA regulated product, and at the same time, really minimize burdens in leveraging those technologies.

So in looking forward to how we do that, I will mention that the last report we had publicly focusing on areas of regulatory [00:23:00] science was also in 2022, and it was actually a couple of months before ChatGPT became public. NIDA didn't talk about machine learning, right? But that's a long time. And I think one of the things we really want to do is to revisit that report and to really consider both in the context of how science and technology has exploded over the last years and also in terms of agency direction, really as we set forward priorities [00:23:30] for the agency, how to really create a plan that pushes regulatory science investment in a way that really drives us forward.

And there's this ... We should be talking about soccer now, not about hockey, but the famous Wayne Gretzky quote about you need to be where the puck is going, not where the puck is now. I think that's really the demand on regulatory science. Policy changes so quickly. Biosimilars, right? [00:24:00] Just a few years ago we were talking about the science we needed to deal with interchangeability requirements. So many things move fast and so many different types of information inform policy that regulatory science really needs to be focused on what will be most helpful. And because it needs to be predictive, means sometimes it will fail. Another sports analogy, if you score every time you shot on goal, then you're not shooting enough. And so I think [00:24:30] there needs to be courageous investment in the science, the regulatory science, that will bring this general science into play to benefit patients.

Susan C. Winckler:
Mm-hmm. So I'm struck in kind of the advancements in policy and operations and having the people and then the authorities to do it right and then tracking and moving with the science. That's what we expect from FDA, is a science-based regulatory agency that can keep

[00:25:00] pace with things. But I know that's not easy and you both know that's not always easy.

So let's then think, too, about the future. You mentioned looking at new focus areas of regulatory science or refreshing that, but what's percolating around White Oak and College Park? Well, I know there's crises that you're dealing with that are taking time and distracting, [00:25:30] but what do you think for the FDAers who are working around the country and around the world, what are they looking to in the future as you're thinking next steps? Yeah.

Steven Kozlowski:
So I would start with one. So we've talked about AI. So the FDA upgraded its Elsa internal AI. It's working on a halo system that will really integrate a lot of different data into a shared space. I think FDA [00:26:00] staff are using AI much more. The agency is thinking about the right guardrails because we need to use it responsibly and carefully and make sure there's a human in the loop when there needs to be. So all these things are growing. And my sense in the next year that we will further leverage this. We will probably move more of our data into a shared space where it is available for more analytics and staff will become more comfortable in leveraging AI to help do their jobs.

Susan C. Winckler:
[00:26:30] And some of the new talent being brought in may help with some of that acceleration, just having experience outside the agency with some of these tools.

Lowell M. Zeta:
And we recently, I mean, to kind of build on those modernization and reform of where the puck is going, we launched our public health pillars. And the thinking there is that our work streams initiatives, our plan forward, is [00:27:00] anchored around these pillars that are innovation and global competition. So to the issue that we've had a lot of discussion about competition that we are being outpaced in terms of clinical trials with China, what can we do? Realizing that this is not sort of an anti-China initiative, but what can we do within FDA's remit, with [00:27:30] discussions with HHS more broadly or USG more broadly, to make the US the place to invest? And so last month we saw the launch of Operation TrialBlazer. I still initially want to say Trailblazer.

Susan C. Winckler:
Well, most of the press reports got it wrong first.

Lowell M. Zeta:
Okay. So in good company.

Susan C. Winckler:
I guess that's applicable to many things, but not always, but, yes, TrialBlazer.

Lowell M. Zeta:
And we're excited with the RFI [00:28:00] comments already coming in on what we can do to sort of upskill, leverage private industry third parties to working with sponsors in terms of that pre-IND ecosystem. I think it was 300 or so days on average and finding, sort of eliminating the white space. And then also more discreetly, already updating FDA's expectations for

CMC on the CDER side in CBER for first in human, [00:28:30] where, loud and clear from sponsors and trying to do the right thing, sometimes providing more than necessary to initiate. So that precision or effort, I think, has been well received already.

Advancing national health security. So that's number two. And similar in terms of our reliance on manufacturers abroad. Specifically going back to China, over [00:29:00] 70% of supply of heparin comes from China, antibiotics, essential vitamins. And so some of the work that we have been focused on, FDA pre-check to help facilitate on-shoring and streamline that process, we announced seven participants that were selected into the pilot program. So we're excited to see that get started. Separately, there was a pilot for generic manufacturers [00:29:30] that meet certain criteria that are coming abroad or supplies is domestic, prioritizing that review process.

And then recently another one to flag is that we recently rolled out the proposed rule for distributed manufacturing, realizing that CMOs, the manufacturing infrastructure is quite complicated. And so this is sort of to recognize that there can be sort [00:30:00] of a centralized quality unit and how would we go about reviewing and inspecting that type of a model? So we're looking forward to seeing how that is received in comments. The third is really more cures in terms of affordability access where there's an unmet need, we're continuing and honoring our commitments with CNPV, that pilot, more programmatically. We had the meeting in June. We're working [00:30:30] really hard to review the comments to think about what have we learned, what worked, what didn't, how do we evolve? I think the aim of 40, 50 days for review for a drug that will be administered to kids for sickle cell with no unmet need is a good aim, but figuring out how we integrate a sustainable program is key and not easy and requires a lot of engagement across the agency.

[00:31:00] And then the last is more on addressing the root causes of chronic disease. So acting commissioner and the HFP team have made tremendous progress on the food side from food safety to food standards to transparency and we're continuing to work on closing the GRAS loophole, but also within that falls the work that RUF [00:31:30] has been focused on as well on GeroScience. And I know Steve participated in that, but how do we address the problem of or the lifespan of Americans are, I think on average, it's 80 years, but in the context of healthy living, it's about 60. So how do we address that? And I know ARPA-H is doing great work, that part of the conference [00:32:00] or workshop that you all had. And so it's a topic that's been around, but it sort of feels like this is the moment. From an FDA perspective, we're working really hard to think about endpoints.

Susan C. Winckler:
Right. How do you measure that?

Lowell M. Zeta:
How do we evolve that? How do we measure that so we can get to a place of a prevention pathway? Is that possible? I got to think that it is. So that's a really wide scope, but under and sort of anchored on those four pillars.

Susan C. Winckler:
[00:32:30] Right, right. And certainly within that fourth pillar, a lot in thinking about, as you

said, the GRAS loophole, but also nutrition and the food safety is a core responsibility every day, but assuring that we know more about nutrition and have a safe and nutritious supply.

Lowell M. Zeta:
Yeah. And we're excited to roll this out. This will be an agency-wide engagement. We will be speaking with everyone about [00:33:00] initiatives, work streams, and not just sort of the guidance and the rulemaking, but a big focus on regulatory science. What more do we need to do in terms of research?

Susan C. Winckler:
Right. So thinking about the regulatory science in each of those four pillars.

Lowell M. Zeta:
Right.

Susan C. Winckler:
Yeah. Yeah.

Steven Kozlowski:
And I would comment that, obviously, new approach methodologies can be leveraged a lot more. They're not just about replacing animals, although that's potentially a role, but they're about speeding drug development and biomarkers, [00:33:30] a space where really there's huge opportunity, certainly in accelerating cures and in chronic disease and nutrition and the role of the microbiome. So I think that a well-targeted regulatory science and general scientific programs to deal with this will really enable progress in those pillars.

Susan C. Winckler:
Well, I'm pretty sure that neither one of you ever sleeps based on all that you are leading at the agency. One day. Yes. But [00:34:00] thank you both for sharing your insights today. I know we're going to hear from Acting Commissioner Diamantas in a bit. And right now, at least someone in the room is like, "She's mispronounced his name twice." I have not. Right. Correct.

Lowell M. Zeta:
You got it. I got it.

Susan C. Winckler:
So the entire ecosystem has been mispronouncing the acting commissioner's name and we're all going to get it right from now on. We'll practice it a couple of times in this room. But to Steve, to Lowell, thank you so much-

Lowell M. Zeta:
Thank you.

Susan C. Winckler:
... for what [00:34:30] you do every day in sharing your time here.

Steven Kozlowsk...:
Thank you.

Susan C. Winckler:
Yeah. I can't stand up, but that's okay. I'm going to stay.

Exploring the Foundation's Impact:
A discussion with members of the Foundation's Board of Directors

David C. Fajgenbaum, MD, MBA, MSc, FCPP
Adrian F. Hernandez, MD, MHS
Phuong Khanh (PK) Morrow, MD
Pietro Antonio Tataranni, MD

Susan C. Winckler:
So with that, I will thank our first FDA speakers and invite members of our board up to the panel. They are going to share some thoughts, help us think about the [00:35:00] year. We'll do a little stage-setting as we get here. The up and down always takes more time than we think, right? And slightly more coordination than we would imagine. So thank you to each of our directors who is joining us on stage. We have other directors who are here in the room. Thank you for being here as well. And I was thinking [00:35:30] about what we wanted to talk about today and it brought me back to last week in the congressional hearing where the foundation testified, and I think we're going to cover about as many subjects as they did in that hearing, but that was a great opportunity for the foundation. We don't advocate, so we weren't at the hearing to advocate, but rather to share what we've heard from the community as ideas to pursue.

So as board chair, I get to start with you, Dr. Hernandez. So [00:36:00] you joined the board in 2020 and then you stepped up from vice chair to chair at the beginning of this year. But you were a primary driver in the work that we did on early stage drug development, which was the primary topic for last week's hearing. Tell us a little bit more about that.

Adrian F. Hernandez:
Yeah. So I think as we've learned over the years, [inaudible 00:36:23], science is exploding, especially over the last several years in the US. We have [00:36:30] every day output that's coming from a variety of sources and the speed of science accelerating. Yet our infrastructure, in terms of during that early phase research, is not actually matching. As we heard from Deputy Commissioner Zeta that the US has not been as competitive on the global stage for early phase research. And so it was really great to see that the foundation hosted a convening to learn from the various [00:37:00] stakeholders, those who are leading cutting edge scientific discoveries, those who are translating those scientific discoveries in terms of targets and early phase research, and then how that speeds along in terms of actually getting eventually to patients or people to improve their health.

And it's at the very beginning stages where small steps can matter a lot. So the change between the concept of doing something within [00:37:30] weeks as opposed to years is great, to seeing how the process can speed up in terms of pre-IND process. And so those are themes that came out of that convening and report. And then also what's it going to take next

to have the community in the US respond to be more competitive? And so I'm really proud to see that the foundation helped spark and accelerate that conversation.

Susan C. Winckler:
[00:38:00] Yeah, that's great. It was a fascinating conversation to listen to and then think about how we might do better. Now, some folks may have looked at our agenda beforehand and they were expecting to see our colleague, Esther Krofah sitting on the stage. She's not here. She had a last minute conflict and she and I were going to talk a little bit about the work we've done with the Milken Institute on trying to address the problems in drug development that affect women [00:38:30] exclusively, disproportionately, or differently. We had a great collaboration with Milken to do that and Esther would've loved to talk about it, but she's not here so we won't. But what we do, I have to say for the second time, our colleague director Antonio Tataranni has stepped to the stage to say, "Sure, I'm happy to talk about things."

Pietro Antonio Tataranni:
Coming off the bench.

Susan C. Winckler:
I think you're first string now. Yeah. That's right.

Adrian F. Hernandez:
The one that [00:39:00] scores a goal.

Susan C. Winckler:
Yeah, yeah, there you go. It works well. So you are such a help to the foundation as we're thinking about what we can do to help the agency in the food space, whether it's relating to food safety or nutrition. What would you reflect on as some of the things that the foundation has been doing in the last year?

Pietro Antonio Tataranni:
So thank you for having, again, the unexpected opportunity to talk about our [00:39:30] role in advancing the discussion on nutrition and health in collaboration with the FDA. As we have said multiple times, the first letter in the agency name is food. And it's an important part of how the system can deliver really prevention at scale. And so it's a very important discussion to continue. And I want to express my kudos, obviously a little bit [00:40:00] self-serving since we serve with Deborah and others on the nutrition and health subcommittee of the board, but the direct emphasis that the foundation continues to apply to this topic. And the report illustrates very, very well. There are four pages. I don't know if it's a record in there, but all the activities that have been accomplished [00:40:30] this year.

I want to point to two directions that in my opinion are very, very important. Food safety, which is very foundational. It's a tough business food safety. It's a shared responsibility across the entire value chain of the food system from agriculture all the way to putting a product on the shelf. And when that system fails, everybody loses. The consumer loses confidence and everybody [00:41:00] has to reset or readjust. But it is a robust system in the first place and it's very worthwhile to engage multiple stakeholders in conversations to make it even more robust, even more resilient. And I want to point in the annual report to the two convenings that the foundation has done on fresh produce on one extreme and infant formula on the

other extreme as [00:41:30] an example of the range of food safety issues that have to be addressed by that process. That's one.

And the second one, which is very important, very briefly, is this ever-expanding discussion on nutrition and health, which is a very, very important discussion to be had, compounded by multiple external events, a pandemic, the advent of the GLP-1 drugs, very confusing discussion on processing of food [00:42:00] and Make America Healthy Again, which is bringing that conversation at the street level. And it's important that it's happening. So the convening on the healthy rule I think was a major contribution to a rule that was approved in April of 2025, I believe, and it has a compliance date of 2028. So still some room to make an impact and improvements. And [00:42:30] the other whole space that we are exploring on nutrition and education with the looming impending role of digitization and perhaps we can discuss that a little bit later, a little bit more.

Susan C. Winckler:
Yeah. The healthy rule discussions were so interesting from the perspective of a manufacturer, thinking about the labeling that's quite enduring versus the retailer and how they might use labeling on shelves. [00:43:00] Then as you noted to the digital side where you can change even more quickly and the different dynamics there. So you mentioned our convening and that's one of the common things we do is hold meetings in this space and virtually, often to do what we call shared learning so that the researchers, the regulators, industry, patient community can learn more about a topic. And I'll turn, Dr. Fajgenbaum, to you. You're [00:43:30] going to come back to this stage in a few weeks, don't forget, for our meeting on drug repurposing. But you also have reflected a bit on the impact of some of that shared learning. Could you share some thoughts about that?

David C. Fajgenbaum:
Yeah, absolutely, Susan. And just to start, thank you so much for your leadership of the Reagan-Udall Foundation and the work you're doing. It's so special as a board member to be able to see this great work. And one of those areas that such great work is being done in are in the convenings that Susan mentioned, those workshops, [00:44:00] the gatherings that you heard happen throughout the year. One in particular that stands out for me was the convening around biomarkers for rare diseases. Dr. Kozlowski mentioned earlier just how critical biomarkers are for rare diseases. There's a few that we're working on, separate role from Reagan-Udall Foundation, where specific rare diseases where that biomarker gives you both the confidence that this drug is working in these patients and also regulatory paths forward to getting them to many more patients. So the work is so critical.

And what Reagan-Udall Foundation did [00:44:30] was they focused on one particular biomarker, heparan sulfate. And what I think is so important about these convenings is sometimes convenings in Washington DC can be very hypothetical, theoretical, and hard to get to what exactly are we doing here? Susan does such a great job getting to the specifics of exactly where we can move forward. In this case, one particular biomarker as a model for many other conditions and many other biomarkers. And I was so proud because just this past year, one of my colleagues from a nonprofit I work [00:45:00] with told me, "David, that convening on biomarkers for rare diseases actually contributed to an approval for a drug," that they're working out of their company. And so these convenings have real world impact and it's really such a pleasure and an honor to see the work that Susan's doing.

And the last thing I'll mention, just because Susan mentioned drug repurposing, is not only will I be here, but I hope you all will come back for the session on drug repurposing. Drug repurposing has quickly become a priority within the federal [00:45:30] FDA, but also across government. And it's such a great opportunity to help patients in need.

Susan C. Winckler:
Mm-hmm, mm-hmm. And what's intriguing about it, the foundation model is we're above product, but it's an opportunity for everyone to learn and say what might we need to know more in certain space to test something out. So thank you.

Let me turn now to Dr. PK Morrow. And you just became chair of our research committee, [00:46:00] so thank you for that. And that committee spends a lot of time thinking about our work in real world data and how to apply it when we want to turn it into real world evidence. What do you think about from the last year?

Phuong Khanh Morrow:
Well, first of all, when Carla asked me to become chair, it was a no-brainer to me because it was so exciting to be involved in this research. I'll start with maybe two points. One is the fact that the work that Reagan-Udall is doing in terms of IMEDS, which for many [00:46:30] of you who may not know that's innovations and medical evidence and development surveillance, but what it really does is this specific private-public partnership which really leverages FDA Sentinel program and its capabilities has been really amazing in terms of bringing forth and really leveraging data across more than 150 million patients with 10 different partners across academia, across health outcomes, experts, across epidemiologists, and of course [00:47:00] industry, to really answer important questions. And the questions that they've answered I think have been ...

So when I think about myself as a drug developer, I really want to bring therapies to patients. But the other side of it is I really want to make sure that those are effective in the real world. And this database is what's really answering those important questions, whether it be pregnancy outcome questions for patients who are on certain drugs, whether it be helping for industry partners to really answer [00:47:30] important post-marketing commitments, or finally, honestly, really helping us to better understand how treatment practices and safety profiles change and maybe improved as FDA produces greater guidelines and more important insights. So all of those are really being answered through IMEDS. And I think I really look forward to the next 13 years to seeing what else is going to be produced.

The other element, if you can permit me to say a few words-

Susan C. Winckler:
Sure.

Phuong Khanh Morrow:
... is the Real-World Evidence Consortium [00:48:00] for Sickle Cell Disease. And for myself as a physician who treated a lot of patients with sickle cell disease and saw really the arduous complications that they went through. And we all understand and know about sickle cell disease, but I don't think we really understand the outcomes and the factors that really affect those patient outcomes. And as a physician who also helped to develop a gene therapy for

sickle cell disease, I think there's no more important time to better understand [00:48:30] this and really bring this forward to improve the efficacy of therapies and also potentially really implement better therapies for patients.

Susan C. Winckler:
And what you remind me as you're sharing that, and thank you for the work that you've done in this space, but even though when we think perhaps we have something that's fairly well characterized, that we're all like, "Yes, we understand," to varying levels, sickle cell disease. The data can be messy in electronic health records [00:49:00] and in trying to figure out, well, what exactly has happened? And then we think about use of that data in broader technologies with AI, machine learning, and the digitization, and I think there's just more opportunity for us to think about how to improve that data environment to better generate real world evidence and maybe improve that data environment in the nutrition space, yes, so that we have better [00:49:30] information for consumers.

I wanted to touch on one other piece just because it's a core part of what the foundation does. Dr. Fajgenbaum, could you recap a little bit of the pipeline that we provide between physicians and critically ill patients and the FDA for expanded access?

David C. Fajgenbaum:
Absolutely. The Expanded Access Navigator is such an incredible tool that Reagan-Udall Foundation provides and [00:50:00] another reason why I'm really proud to be part of this board. We were just looking at the numbers recently for last year. Over 30,000 individuals viewed this Expanded Access Navigator tool online on the website. And over 500 requests went in through this tool to basically look for expanded access or compassionate use of a medicine that was not yet approved.

I can actually share as a [00:50:30] patient myself, I received compassionate use for medicine back in 2010. It was rapidly given to me for a rare disease that I was battling and that drug didn't end up saving my life, but I ended up getting other medicines that did save my life. And when you're in the world of compassionate use, every hour counts. Literally every single hour counts. And the fact that Reagan-Udall Foundation has this tool that helps to compress time, speed up the time between I'm interested in maybe getting a drug through expanded access and actually [00:51:00] getting it into the tool, into FDA and to drug companies, it literally saves lives.

And so I'm just so proud of the work that they're doing. The numbers are impressive. There's actually, I think, a 20% increase in the number of companies that are listing their products on the website. Hopefully that number will rise even further. We want every patient who can benefit from medicine to make sure that they can actually get it through this tool.

Susan C. Winckler:
Thank you. And how do we say [00:51:30] glad that you were able to navigate the expanded access system and I'm sorry that you had to. I guess that's the way we should phrase that.

Adrian F. Hernandez:
I think he had to do it before the tool.

Susan C. Winckler:
That's true. Now it would at least be somewhat more efficient in that you can find the policies and then submit the request directly to FDA. So it's hard to capture all that we've done in 12 months, but I want to give [00:52:00] you each another about two minutes a piece if there's something that you think, yes, this is when I think about what happened in the last year and what I would want to make sure folks know the foundation, what was pursuing, what that would be. Dr. Tataranni, do you want to go first in that?

Pietro Antonio Tataranni:
I will do it with an eye on the future and expressing a wish for not only what we have done in the past 12 months, but perhaps what we are commit to do ourselves [00:52:30] in the foreseeable future. And there are two aspects of this experience that to me resonate hugely. With the premise that food and nutrition is a space that lends itself to very complicated discussions mixed with culture, personal experience, and all of that, lends itself to opinion-based recommendations, which is very dangerous in this space, and [00:53:00] a lot of snake oil selling out there.

Susan C. Winckler:
Snake oil's not good for us, right?

Pietro Antonio Tataranni:
No, no.

Susan C. Winckler:
Okay.

Pietro Antonio Tataranni:
I definitely would not recommend.

Adrian F. Hernandez:
Unproven.

Susan C. Winckler:
Unproven, yes.

Pietro Antonio Tataranni:
It's unproven. So what I wish for is that we recommit ourselves as a foundation to work with people like Dr. Kozlowski and others like him in the agency to be really driven by science, a good quality science, because that's another issue in nutrition. Most [00:53:30] of the assumptions are based on observational studies, which you can talk your way around every which way. And conducting randomized controlled clinical trials to prove cause and effect is incredibly demanding and hopefully we still have institutions like NIH and others that can dig us out of those holes when we have very, very difficult questions to answer. And so science-driven, hard science-driven.

And [00:54:00] the second one, which we have started to explore this year, but I think we should dig our heels very, very deep into this, is the advent of digitization. Steven, you have already mentioned it in the context of drug development, but there is an element of this that

is of huge importance to food and health and specifically to nutrition health, which has been delivered, I would say pretty unsuccessfully so far, [00:54:30] through learned intermediaries, the experts. But now this thing is about to get completely democratized by digital tools. Everybody can use one of these handheld devices and this proven/unproven applications that suggest food choices. Who's looking after this? Who's saying is right, wrong. But even deeper, everybody, and we are seeing it in our [00:55:00] own industry, can go on ChatGPT and say, "Is this food good for me?" And whether we like it or not, they get an answer, which can be very wrong. So who's looking after the quality of that answer? So that could be magnificent. It could be the promise of nutrition education that has been unfulfilled for decades. Now it can happen, but it has to happen in the right way. And if it doesn't happen in the right way, it can be pretty disastrous.

Susan C. Winckler:
Yeah. [00:55:30] So that strikes me as similar to the other spaces where we want to make sure that the systems we're building and how we're generating information is based on solid data and that we have some awareness and opportunity to improve the quality of that data. Yeah. Great. Should we go in order?

Adrian F. Hernandez:
Sure.

Susan C. Winckler:
All right, go ahead.

Adrian F. Hernandez:
Quickly, because I know we have someone else who may be nearby, but there are two things that come to mind. So there's been a lot of discussion about the opiate crisis. And so one of approaches could be, [00:56:00] well, we're just going to shut everything down, limit opiates. But then there are a lot of people who would suffer from that.

And so one of the things that I was really proud to see the foundation do is how to bring people together to understand so-called ... How do you develop precision approaches to make sure that there's a right amount of opiates that are available for patients in appropriate settings to use with not having too much so that there could be risk for misuse. And so that's a Goldilocks issue that you have to have not [00:56:30] too much, not too little, but just the right amount. So the foundation bringing all the different groups together to help understand those issues there.

The second thing, which I have to say, this is the interesting thing, part, of the FDA and the foundation, is the breadth of territory they cover. So I'll be honest, I never heard of a new screw room?

Susan C. Winckler:
New World screw worm.

Adrian F. Hernandez:
Yeah.

Susan C. Winckler:
I had to practice.

Adrian F. Hernandez:
And to learn about this parasitic fly that can infect the animals [00:57:00] and cows in open wounds and how that is dangerous to the whole food supply, et cetera, is really remarkable. And when you see there's not a lot of attention to some of the animal health issues there, how do we help bring attention, bring those groups together and facilitate what are the key issues that help accelerate issues or accelerate development for treating those problems is really important. So that's an example where I see [00:57:30] like, hey, the breadth is really amazing. But you have to go deep to get to the solutions for that.

Susan C. Winckler:
Mm-hmm. PK.

Phuong Khanh Morrow:
Well, I will also try to stay short and high level, but I think that Reagan-Udall is so special because it stays at that really critical intersection between food and medicine innovation, regulatory policy, and, truly, technology, which continues to accelerate every day. And what you've been hearing today is the fact that Reagan-Udall has the potential to be and has [00:58:00] been both a facilitator as well as a generator of evidence. So what I look forward to for the next 13 years or more is to continue to generate that evidence because, David, as you mentioned, patients are waiting. So ultimately we keep that all in mind as we proceed and try to act with urgency to help patients.

Susan C. Winckler:
Yeah.

David C. Fajgenbaum:
Yeah. I agree with everything that PK and my other colleagues shared. I may add that in addition to being really focused on scientific evidence, underlying [00:58:30] the principles of the FDA and Reagan-Udall Foundation, I think also this real focus on patient impact is something that I've been really proud of within the foundation. And then over the last year, leaning further into artificial intelligence and the role that it'll play in regulatory processes are just a few of the ways that I've been proud as I look back on 2025.

And then I'll make another plug as we are in 2026 around drug repurposing. And I'm just thrilled that the Reagan-Udall Foundation's leaning into putting together this convening on August 5th alongside [00:59:00] colleagues from FDA to gain better understanding into the drugs that already exist, those 4,000 FDA approved drugs. What are the other diseases that they can treat? What are the paths forward when those drugs already have good mechanistic data, they need clinical data, maybe even cases where there's already even good clinical data, but there aren't incentives for companies to get those medicines to patients. Let's think holistically from all those 4,000 drugs for all the diseases they can possibly treat. So just so proud to be a board member along with these great colleagues and thankful for the work you do, Susan.

Susan C. Winckler:
[00:59:30] Oh, wonderful. Let's thank our board members.

Remarks from the Acting Commissioner

Kyle Diamantas, JD, Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration

Susan C. Winckler:
It's easy to see why I love my job because I get to learn from folks like our board members throughout the year. So Acting Commissioner Diamantas, come on up. We did have a little practice session. Everyone now knows how to pronounce your name.

Kyle Diamantas:
[inaudible 00:59:59]-

Susan C. Winckler:
You did [01:00:00] know, but thanks for joining us and I'll turn the podium over to you.

Kyle Diamantas:
All right. Thanks, Susan. Good afternoon, everyone. Really great to be here. It's my pleasure to join the annual public meeting, the board of directors. I want to start and extend a real special personal thank you to the entire foundation team for the incredible patience and flexibility. I know we had to move this around. Susan and I joked about this last night. We had to reschedule this event a couple of times, I think at least once on my account. So apologies for that. But I know [01:00:30] I'm truly grateful that you worked so closely with us and to find a mutually agreeable date and time so we could make this happen. I also do want to recognize Susan's contributions as a former FDA chief of staff. You understand as well as anyone the challenges that we face on a daily basis and I appreciate your leadership and partnership in navigating the challenges of FDA and supporting us in our mission to protect and promote the health of the American public. So thanks, Susan.

Reagan-Udall has long played an essential, [01:01:00] and I might add, often unsung role in the work we do at FDA. Like the FDA itself, the foundation prioritizes the value of science and rigorous data to solve the challenges of public health. I think it's important to remember that the foundation was actually created by Congress as an independent 501(c)(3) organization specifically, and I'll quote, "To advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate [01:01:30] innovation, and enhance product safety." And through our unique partnership, that's precisely what you all have done. Supporting our work to meet the continued and often extraordinary challenges we face, both involving the remarkable advances in science that we embrace and the limits of our time and resources that we manage. The foundation helps fill gaps in our ability to meet the demands placed on us by building a community of stakeholders that leverage health data to inform regulatory decisions, [01:02:00] advance medical innovation, and improve care for patients.

Over the years, the foundation has provided the agency with crucial analysis and linkages across the health ecosystem on topics such as rare disease treatments, post-market research, tobacco, substance use, food data, including infant formula. Your work allows us to use our

resources more efficiently and effectively to apply regulatory science in new and creative ways and to better focus on what we should be doing, data-driven decision- [01:02:30] making. In short, our joint efforts help Americans build their trust in us at the FDA. That's why I'm so pleased that earlier this year we renewed our cooperative agreement with the foundation, which will ensure that our centers and offices continue to work with the foundation on important issues and activities. This is critical because we have a lot on our plate and a lot we want to accomplish and the foundation will need to continue to play a key role in that work. I truly believe that.

In the coming year, if the coming year, [01:03:00] excuse me, is anything like the extraordinarily productive year we just accomplished, then I would say let's hold on tight. And allow me to just give a few quick summaries of the past year's highlights from across our vast array of responsibilities. In the food sector, we worked to approve several new natural food colors and continue to support companies in transitioning the food supply from the use of petroleum-based colors. We renewed our focus on removing chemicals in the food supply by standing up a post-market framework and putting out a process for post- [01:03:30] market review that engages stakeholders. We advanced efforts on GRAS reform, issued new dietary guidelines in coordination with HHS and USDA. We initiated the removal of outdated orange juice regulations and commenced and reviewed obsolete food standards of identity that no longer benefited consumers.

I'm really proud of the work in our medical product space, including cutting red tape to accelerate the production and approval of biosimilars, taking action to modernize and eliminate unnecessary [01:04:00] animal testing, boosting domestic pharmaceutical manufacturing with the introduction of our recently released pre-check program, removing restrictions on laboratory-developed tests, expanding warnings about the use of ADHD treatment in young children, began fixing opioid medication safety labeling, launched a framework for accelerated development of individualized therapies for ultra-rare diseases, and took action against telehealth companies for illegal marketing of GLP-1s. [01:04:30] And of course, we continue to review and approve a range of promising pharmaceutical products. Just to mention a few, the first blood test diagnostic for Alzheimer's disease, the first gene therapy for young children with sickle cell disease. I don't think that's me, right? No, that's somebody ... Okay. Sorry. The first treatment for patients with cerebral folate transport deficiency, and a first of its kind device to treat pancreatic cancer.

We also regularly [01:05:00] respond to public health crisis and as everyone in this room knows, most recently among them, screw worm and cyclospora. And again, this list really just skims the surface of the work that we've accomplished and have ongoing, but it really does underscore two things. First, every day at FDA is exciting, fulfilling, and incredibly beneficial to the American public. And second, we have an extraordinary staff that does extraordinary work each and every day, but we can expect the road ahead [01:05:30] to be even busier at FDA. We're working toward building a faster agency that's more streamlined and more nimble. We want to put in place regulatory flexibilities that will work, excuse me, that will allow us to support the development and approval of more treatments more quickly. But we want to do this without sacrificing safety or reliability. No short-changing our high standards of review. And we can and will do both at FDA. We are committed to ensuring that the FDA maintains its role as the global [01:06:00] gold standard of scientific review.

I want to underscore that the reason we have led the world is thanks to the expertise, the judgment, and dedication of our workforce who uphold the scientific integrity and public trust of which our agency's success ultimately depends. As this nation marks our 250th anniversary, the FDA is also celebrating an important milestone, its 120th anniversary. I think this juxtaposition speaks volumes because it makes clear that the [01:06:30] American people for nearly half of our country's existence have relied on the FDA or its predecessor agencies to protect them from the dangers of health. That history is filled with stories of courage and creativity and countless groundbreaking achievements where we have helped translate scientific discovery into real world benefits for the American people.

Over those 120 years, we've seen enormous changes in science, technology, industry, and many other areas. [01:07:00] And thinking about this history and looking forward, to me, one thing is abundantly clear. The FDA's mission is more vital today than it's ever been. We are part of an innovation renaissance involving science and technological advances that will allow us to transform medicine, food, and public health, in ways previously unimaginable, delivering profound benefits for patients and consumers. That's why we've developed an exciting new framework, the FDA Public Health Pillars to help guide us. [01:07:30] We announced those pillars just last week and they represent a strong new foundation for our agency that reflects our commitment to modernization, scientific excellence, and a more proactive approach to protecting and promoting public health. The pillars are focused on broad concepts with specific action items, ensuring that we are the global leader in innovation and the best place in the world to innovate, strengthening America's health security, helping Americans gain faster access [01:08:00] to safe, effective, and more affordable medical products, and continuing to promote wellness and build a healthier America. Together, these pillars offer a bold and comprehensive vision for the FDA's future, one that empowers informed decision making, supports American innovation, and delivers better health outcomes for all Americans.

Let me give you one example of how we're putting that into practice at FDA relating to the first pillar, making America the leader in biomedical innovation. Some of you may [01:08:30] already be familiar with operation TrialBlazer and it is TrialBlazer, not Trailblazer. I know, I get them confused, too. And that is our roadmap to accelerate and modernize clinical research across the full continuum of drug development from the investigational new drug phase to late stage pivotal trials. It's designed to help maintain US leadership in biomedical research and pharmaceutical innovation, and reverse the unfortunate trend of clinical research moving overseas to combat the competitiveness [01:09:00] pressure we face. We think this can make a real difference, but Operation TrialBlazer is just one piece of a broader coordinated effort to advance our competitiveness and help ensure that Americans have reliable access to safe, quality medicines by strengthening domestic pharmaceutical manufacturing and ensuring that regulatory frameworks keep pace with innovation.

As you can tell, we've got a full plate before us. More than ever, the FDA is called upon to protect the public health and to empower consumers to make healthy choices [01:09:30] that they can have confidence in. We will continue to take our responsibilities to the American public very seriously, embracing our role not only as a trusted regulator, but also as a great scientific institution that does not stop learning, improving and earning the public's trust each and every day. The FDA will continue to lead the way, preserving a reliable and dependable

regulatory model, letting the data drive our decisions, and maintaining our commitment to gold standard science.

The foundation's [01:10:00] work and ability to adapt to a complex, rapidly-changing health landscape bolsters our ability to accomplish this, and so let me again extend my gratitude to the Reagan-Udall Foundation for everything they do as a partner to the FDA. You all allow us to maintain our unwavering commitment to scientific integrity, regulatory standards, public health, and patient safety. Thank you.

Can I [01:10:30] sit?

Susan C. Winckler:
You actually can go ahead. I'm going to thank you so much Commissioner Diamantas. Diamantas. I did it wrong again. I got it the second time. We'll do that. I'm going to ask our board members to go ahead and step out of the room because we do have another part of our meeting. For the rest of you, we're going to practice Diamantas. It's actually Diamantas. I am going to get it right and so will the rest of the world.

[01:11:00] So I do want to just say thank you so much for joining us today, whether it was in person or virtually. We are looking forward to continuing to work with FDA to help them continue to be a science-based regulatory agency that makes not only the US, but candidly, the world, a better place. So thank you for joining our 2026 public meeting of our board of directors. That annual public meeting is now adjourned. Have a great rest of your day.

Adjourn