2025 Annual Public Meeting of the Board of Directors
July 17, 2025 | 9-10:30am *(eastern)*

Transcript

Welcome & Call to Order

Richard L Schilsky, MD, FACP, FSCT, FASCO, Foundation Board Chair, Regan-Udall Foundation for the FDA

Dr. Richard Schilsky (00:00:33):

Welcome to the 2025 annual public board meeting of the Reagan-Udall Foundation for the FDA board of directors. My name is Rich Schilsky. I'm the current chair of the board. I'm a medical oncologist. Spend most of my career at the University of Chicago. Have been a board member for quite a few years now and have had the honor to serve as chair of the board these last three years. I see in the room and I know online we have a quorum of our board members present. So I will call this meeting to order. We're pleased that so many of you are here and able to join us in person today.

(00:01:08):

I understand from Susan, our CEO that we almost didn't have this venue because apparently the power was out in this building just a short time ago and remarkably it's all up and running. So I've known for many years we've had a remarkable CEO, but I didn't know she could actually get the power turned on in an hour's notice.

FDA Leadership Discussion

Martin Makary, MD, MPH, Commissioner of Food and Drugs, FDA
Jim Traficant, Chief of Staff, FDA
Lowell Zeta, JD, Deputy Commissioner for Strategic Initiatives and Special Counsel, FDA

Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA (Moderator)

Dr. Richard Schilsky (00:01:32):

It's my distinct pleasure to welcome FDA leadership to the stage, Commissioner Martin Makary is a fellow oncologist and academic who now serves as the 27th Commissioner of Food and Drugs. The next step in his very distinguished career as an author, researcher, and physician. Joining the commissioner this morning are Lowell Zeta, deputy commissioner for Strategic Initiatives and special counsel for FDA in the Office of the Chief Counsel. And Jim Traficant, the chief of staff for the commissioner.

(00:02:04):

So I'll now hand the microphone over and welcome to the stage our foundation CEO, Susan Winkler who will guide the conversation with our distinguished guests. Susan.

Susan Winkler (00:02:13):

All right. Well, good morning, everyone. Before we turn to the conversation, just I'll echo thanks to all who have joined us both in the room and virtually. And I will thank some of you provided questions before the session. I appreciate you doing that. I'll note that as in all of our meetings, we will not be

asking our panelists to address questions regarding any specific regulatory actions nor any specific company products. Many of you know that drill and could probably say that for me, but it's important to underscore.

(00:02:46):

So let's turn to the conversation. I'll say, Dr. Makary, it's just wonderful to have you here. We're pleased that your deputy commissioner, Lowell Zeta could join us and then as any good chief of staff at the FDA would do, Jim Traficant is stepping in because Deputy Commissioner Graham is under the weather today. So we'll have you on the slide by the time we post these so that you get full credit. But, Commissioner Makary, why don't we start with you. For those of us who watch the FDA direct videos right away, we caught your recap of the first a hundred days and then the even more comprehensive write-up on the website. I don't think we have the 49 minutes that we had for the podcast, but we do have some minutes. We'd love to hear what you would like to highlight for this group from those hundred days.

Commissioner Martin Makary (00:03:45):

Great. Thank you, Susan. It's great to be here and it's great to meet a bunch of you here and I'd love to meet everybody here. So thank you for what you do at the foundation. I've been looking forward to this meeting to connect because we have a lot of invitations that come in and a lot of things we'd love to do, but we have been really deeply focused on the operations at the agency. I came in just after a challenging time, and so we've been on the ground. We've not taken a lot of external meetings. It's not because we don't love people, it's because we've just been so present and essentially every day I've been there and we're meeting with folks. What do you need to do your job better?

(00:04:33):

So the initial period when I came in there, which was right after the reduction in force in early retirement, we had to do a rapid assessment, make sure we can keep the trains running on time and continue to grow and thrive with our reform agenda. And our reform agenda is very simply to modernize the FDA to enable more cures and meaningful treatments to reach Americans and to deliver healthier food for children with more options. And so we're interested not just in the drug side and device side, but we're very interested in addressing the childhood vaping epidemic.

(00:05:16):

We're very interested in the root causes of the diseases that we're treating. We're very interested in the lunches that we put in front of kids because we've got to start talking honestly about school lunch programs, not just putting every six-year-old on Ozempic that's overweight. We've got to start talking about chemicals that may be involved in GI cancers, which are increasing in the group under age-50, something that Richard and I have seen throughout our careers. And it's always a one-off. "Well, can you believe this happened? She's only 29." Well, at some point we have to get off this treadmill that we're on, this billing coding throughput treadmill where we're measured by our productivity and just stop and put our heads up and look around and say, "what's happening?"

(00:06:13):

40% of our nation's kids have a chronic disease. Sure, we can just medicate them at scale and we can incrementally improve the quality of the medications or the effectiveness. But we can both do that and ask why do 31% of kids now have insulin resistance or severe pre-diabetes? And we're very interested in that because the F in FDA stands for food. It doesn't stand for federal as somebody thought. And so that's a big area of focus for us. So I know we have a limited time. I can just talk and talk and talk, but let me stop there.

Susan Winkler (00:06:53):

Well, that's very helpful and I think similar, I mean, the foundation has the same range of responsibility as the agency in supporting what you do. So we too think through what's the food part and the drug part and then all of those other pieces, whether it's cosmetics, tobacco, and those other areas of importance. Maybe we turn Deputy Commissioner Zeta to you. Some of us track titles at FDA really, really closely, and yours is a new one at least for a couple decades. We haven't seen it. Maybe it's before that. I'm not an FDA historian, but this audience I know and our board in particular would welcome knowing what's your writ at the agency and how are you thinking about maybe those next hundred days in your work with the commissioner?

Deputy Commissioner Lowell Zeta (00:07:44):

Sure. Well, good to see everyone and thanks for having us. It's a new title for me and kind of evolving with the team. The role as I understood this was created a couple years back and was never filled. We shifted the remit a bit. Less of sort of a built-out office and is really... I've been focused on strategic initiatives from ideation to strategic planning to execution with the team in the commissioner's office certainly thinking about all kind of the tools that are needed from talent and resources to what can we do within the lanes of our regulatory paradigm, what changes might be necessary and making sure that we have the right subject matter expertise.

(00:08:44):

Certainly center program engagement from my first tour was something that I really came to appreciate and how to get things done, and then making sure we have milestones so that we can keep folks honest and make sure that we can update Jim and Dr. Makary as we're sort of checking the box along the way.

Susan Winkler (00:09:10):

Now, you're reminding me, I did see that announcement, but it wasn't ever filled. So glad to have you in that... filling it for the first time.

Commissioner Martin Makary (00:09:18):

By not changing the title, we saved $35.

Susan Winkler (00:09:22):

Brilliant. We've got it noted and we'll help with that tracking. But it is helpful to have someone who can be thinking about the strategy because so much of your work, and I'm going to turn to you Jim for this, so much of the agency's work can occasionally be caught in just firefighting and saying what is the issue of the day and those types of things. But maybe you're having a much better chief of staff experience, although mine was amazing. No offense, Commissioner Vanishibach. It was great. But tell us a little bit about what you've seen in your time at the agency.

Jim Traficant (00:10:00):

Sure. Thanks for having us again. Maybe just to give you a little background, I'm a technologist by training and then I was also a patient. I've had two liver transplants. First one my neighbor saved my life and in fact, Saturday will be the anniversary of that. The second one gave me my life back and I'd worked in the intelligence community in other markets and then could see that healthcare was lacking the same kind of decision-making support that I saw in other industries. And so created a couple of

businesses in order to bring that to light and had the good fortune of working across multiple countries, the National Health Service, the VA.

(00:10:39):

But the key was I went back to Hopkins where I had my first transplant and went to my doctors and said, "Hey, you saved my life. Maybe you could save my career." And we did the first ever joint venture where we brought technology out of the private sector and worked with medicine, took their clinical expertise to inform how we might approach delivering value for patients. And it was in that experience that I ran into Dr. Makary. He has helped our family and when I had the chance, this was towards the end of last year after he had been nominated, he got the call and I'd never served in government. I've been in industry my whole career, but worked alongside of government and have about 20 years in healthcare.

(00:11:23):

I went home and told my wife, Gwen, I said, "Craziest thing happened today. Marty called and asked about going into the FDA." And she said, "Well, what are you waiting for? What a great opportunity to serve somebody."

Susan Winkler (00:11:36):

That's a good answer.

Jim Traficant (00:11:38):

Well, the end of this is I knew that Dr. Makary was a great physician and what I didn't know was that he was also a great leader. And so coming in, we had a really good plan about priority things we wanted to get done in the early days of his term, but we didn't anticipate walking in with some of the challenges that we all were confronting. But we've been able to lead from there to a new place. And so I'm excited about... The people at FDA as all of are deeply committed. They're very passionate, they're very talented, and so we've been able to blend in and work alongside of them to harness the opportunity to shape the place differently than it was previously out of necessity and also to capture the opportunity.

Susan Winkler (00:12:25):

It's such a great story and perspective. We all come to these positions by very different pathways, but to come from the patient pathway is powerful and reminds us, I think of why we all get up and go to work every day.

Commissioner Martin Makary (00:12:45):

I want to say your life was saved by an FDA, one of the first Compassionate Use of authorizations on OKT3. I probably had four HIPAA violations there by December.

Jim Traficant (00:12:56):

Yeah. We'll talk about it on the way over. But honestly that did happen. I went into rejection after the first transplant and they couldn't stop it. And they said, "Well, we're going to give you a shot. We don't know if it'll cure you or kill you. We'll know in 20 minutes." And I'm also a business guy, so I said, "What's plan B?" And there wasn't one. But in the second episode, I was the first to take a drug. The FDA made it possible. Compassionate Use had just been passed and that drug saved my life.

(00:13:22):

And so to go from there, and I don't want to be dramatic here, but I had septic shock in between, which was much harder. I didn't know if I'd ever get to work again, let alone get to do this. So I'm extremely grateful and sometimes things you feel like are happening to you and they're actually happening for you. And it turns out in this case that was true.

Susan Winkler (00:13:42):

Yeah. Well, and now if you needed it, the foundation is one of the ways to expedite that request into the agency for the Compassionate Use.

Jim Traficant (00:13:53):

Thank you for that.

Susan Winkler (00:13:54):

Well, and trying to make sure that healthcare professionals even know about that avenue. That's been an interesting part is I've been on this side to there just are many who wouldn't know that you can in fact access investigational products in situations where it is indeed life-changing and so very important. So what are you thinking about? My guess is that you already have 1,200 plans for the next hundred days, but I did just make up that number. And so maybe it's us. How can the broader FDA ecosystem help with that? What's on your horizon for the next many days?

Commissioner Martin Makary (00:14:40):

Well, first of all, that Compassionate Use authorization assistance that the foundation helps with is huge. And I'm speaking from experience on the clinical side. It's not only that some physicians don't even know about these expanded access opportunities, but sometimes they don't even know about other FDA-approved opportunities out there for their patients because, look, we're just so busy. We are so busy. And so on the agenda at the FDA, we want to continue to harness the great ideas that live within the FDA among the scientists and inspectors, and law enforcement and policy staff and everybody else close to the actual trains coming in and leaving the station.

(00:15:33):

That is, we want people on the ground to talk to us. It's what I firmly believe in all of my work and patient safety. It was all about the relationship between management and the front lines. When that relationship is distant, then bad things happen in the hospital. And we studied that and that was a clear dose-dependent relationship, if you will. And so we have been doing meetings. Now, if you meet with 50 people with their boss in the room and say, "How's it going?" They're going to say, "Thanks to the leadership of my center director. Everything is going great."

(00:16:15):

Some people relate to this. So then if you get them one-on-one and you say, "Look, there are no repercussions. You can say anything freely. We're going to give you anonymity here. We are looking for ideas." And you let them talk and you give them time, they will talk. And so we hear about all kinds of stuff. So we've been very busy doing these one-on-one meetings. It's both part of figuring out this restructuring coming out of the healing of the changes that preceded us.

(00:16:50):

There were a lot of early retirements and so the vacancy rate that we normally have increased. We have posted hundreds and hundreds of new positions and we've got over a thousand applications so far. So

we are doing a lot on the operational side right now, but we want big ideas. And so we're not interested in, the stapler should go over here in the mail room instead of here, so it's closer.

(00:17:17):

We're interested in big ideas that allow us to maintain our mission to safeguard the public. And so we're hearing them. We are hearing about how to reduce idle time, increase efficiency. We, as you know, piloted a powerful AI tool for our entire, not just the reviewers, but our staff. And I hear there's interest in other health agencies to use our same tool. I don't know if this is public, but maybe that'll make some news, but not intentionally. But we want to deliver everything they want and need to do their job better and more creatively.

(00:17:53):

So we're going to keep doing that. We're going to keep exploring new pilot pathways and programs. We also want to make the campus just a great place to work. And so we have taken our cafeteria hours from a couple hours around lunch till people can get an early dinner there. We are having a farmer's market now twice a week, every week. Whatever they want. I mean, doing reviews is hard work. Doing inspection is hard work. And so we want to give them everything they need to do their job well. So we're going to continue to meet with them. We're going to continue to meet with stakeholders and industry. We've been doing this in the spirit of listening this national CEO listening tour. And I thought Jim is the one who really encouraged me to do it. He said, "You're all about listening and we're doing all these meetings to listen within the agency on people at the front door." He's like, "How about we meet with the CEOs and we can do it in the same format, closed door?"

(00:19:01):

Not for us. I mean, we believe in radical transparency, but for them, so they don't have to worry about what their shareholders are saying, and they can unload on us. They can tell us whatever their big ideas are. And we give them the same disclaimer you gave, which is no product. We don't want to discuss any products currently under review. Of course, within 10 minutes, somebody is talking about their product that cures cancer. Product that cures cancer and Lyme disease and ALS with one pill, and it's just waiting for one little thing at the FDA. And then you find out there are six manufacturing violations and the study shows it doesn't work and it's under review.

(00:19:43):

And you're like, "Okay, these are kind of the fun parts of the job." So we're going to continue to listen. The feedback from the CEO forum has been so formative. I had no idea it would be that specific and formative. I thought it was going to be like, "We don't hear from you," or we get these erratic decisions. It wasn't at all. It was not an unloading session. It was two 15-minute calls with the reviewers over the course of the review process could save us months of guesswork.

(00:20:20):

And nobody doesn't want to return a call. It's an idea that sounds reasonable to everybody, but as science has expanded and grown, and you have so many new drugs being submitted and so many new areas of healthcare, the agency has had to grow to accommodate this expanding scientific world and healthcare community. And so we just have to now realize sometimes things get big and we have to figure out how to reconnect with a good user interface.

(00:20:59):

And the other big piece is food. We're going to do a lot more on food. So we announced the removal of all nine petroleum based food dyes, and people said, "Oh, you can't do it. You don't have the full regulatory authority to do this this quickly with the timeframe you want. You have to go through all this

process and rulemaking." Well, here we are, maybe a matter of weeks after the announcement, and we've got almost half the industry that has pledged to remove all petroleum based food dyes in a timeframe as quick or quicker than we've asked for.

(00:21:36):

Kraft Heinz, General Mills. I just had some ice cream this week with the ice cream makers that decided they're going to a hundred percent abide by this new pledge. So these are the fun parts of the job. Wouldn't you agree? And there's some opportunities now we've never had before for post-market surveillance. We've never had big data and cloud storage. Andrew was in leadership. You didn't have these incredible server farms that had this capacity to store a hundred million electronic health records. And now we have the ability to create in silico controls that are as perfectly matched or better matched than in a randomized controlled trial.

(00:22:20):

We have the ability as a country to enroll people in clinical trials through the EHR. So I mean, there's some amazing opportunities right now. We got a great tech team that came in. I didn't think they'd want to come in because as you know, you can make a lot of money doing other stuff in tech. But they said, "Look, we want to be a part of this." Just like Jim stepped up and Lowell. Lowell was making $50 million a year. Something like that.

Susan Winkler (00:22:50):

Part of that transition into public service is that opportunity to have those levers or the big gears in working for commissioners who would refer to the big gears of government. That's what you have both in regulatory ability and from the podium to say, "These products, we'd be better served if they weren't available." That's a power that's helpful. And then, I think the promise there is really intriguing of saying, "How can we better use these technologies?" I sense, I can actually feel some of the anxiety from the broader ecosystem saying, "Tell us how." They want certainty while also pursuing new ideas. So, I imagine that might be a space too, just of helping industry understand how they might apply those technologies. But does that fall in... Lowell, what will you be working on now that you're in the government sector?

Lowell Zeta (00:23:53):

Sure. Well, I think on technology and infrastructure, certainly the rapid speed that we're working at as integrating into the systems will help folks on the industry side in terms of understanding what data should be submitted, in what capacity, in what manner as we're set up on the inside to receive or to access. So, I'm really excited to see more of that. Three things I'll touch on quickly. One is a big reason why I felt the calling is the work that we've done on infant formula. When I had a, now five-year-old, we were going through that crisis. We had the privilege of sourcing from European brands because nothing else was working or not well-ingested or taken or kept down. And our network of friends did the same. And so, we sort of left with what are we supposed to do and what's the rest of the world do?

(00:25:11):

So, the challenge to find more nutritious formulations, I think is noble. It's ambitious, and I'm excited to see what we do. A couple others in addition to the ramp-up through the 100 days and the deliverables, there's been a lot of work that is a bit more of a, I guess, slower boil where there's cross-functional teams working on domestic manufacturing. What regulatory incentives can we help to support on-shoring efforts and more broadly, to keep them here? And then, on the foreign inspection program, how can we establish parity? I think that all of the programs have nuanced challenges and so we're thinking

about the program holistically from resources to planning and prioritization and workflow, especially post-re-org, post changes over the last few weeks or months into even culture and messaging where the quantitative number of inspections is just one piece of what FDA does in terms of its mission for regulatory oversight. So, again, excited to see that move forward.

Susan Winkler (00:26:42):

Yeah. And really important, particularly on the infant formula side. I think where we are now is that there's not a problem of availability, but how do you keep that? That's not an accident, that there isn't a shortage.

Commissioner Martin Makary (00:26:58):

And nobody says, "thank you," for preventing an infant formula shortage.

Susan Winkler (00:27:01):

Yeah, we'll try, but we're probably the only ones. Someone once called us the FDA booster club, which is not quite right because we do try to provide incident and help, but we can at least take... What we absolutely see, that those things, there are many things that are done that the American public will never know. And really, the world benefits from the forward regulatory posture of the FDA and the things that you keep from happening.

Commissioner Martin Makary (00:27:34):

Yeah. And I think there are giant blind spots in the US healthcare system, issues that we're not talking about that we should be talking about. And it's not because anyone's diabolical or trying to conceal. It's that we tend to have group think in a lot of things in any profession. And it's because science is telling us new things. It is naturally by its nature, challenging deeply-held assumptions. We are learning that the microbiome may be one of the most central organs in the entire body. A garden of over a billion different bacteria, not total, different bacteria that live in the GI tract that makes 90% of your body's serotonin involved in mood, makes vitamins, it metabolizes estrogen, is involved in digestion. We don't understand why somebody changes their diet and exercises like crazy and can't lose weight. Well, maybe their microbiome has been altered. The study out of Mayo Clinic found that when kids take antibiotics in the first two years of life, which as we know sort of carpet bombs the microbiome, now, they also save lives that are necessary, but about half of outpatient antibiotics are unnecessary according to different studies.

(00:28:59):

And so, the presence of antibiotics in those first two years of life, which are the formative years of the microbiome, is associated with being overweight, diabetes, asthma, dermatitis, all the conditions that have become epidemic in our lifetime that were rare two generations ago. We're just beginning to understand some of this stuff. So, we need to think about new regulatory pathways. We have to think about how we manage AI as software. If a AI of an x-ray reads 200 different chest findings on an x-ray, are we requiring 200 different applications, one for each indication? So, we've got to modernize and think differently. And I do think, to build on what Lowell was saying, look, markets like predictability, investors like predictability. We need investors to advance drug development. Scientists, inventors, individuals, and academia like predictability with the regulatory process. So, that's why we have decided to go ahead and put the resources behind making the CR letters public. And that's why Lowell was a little late. He's been redacting them nonstop, and he hit a circuit button this morning to try to delay the conference a little bit so he could have more time to redact.

Susan Winkler (00:30:29):

Thank you. Thanks for flipping it back on. Excellent. Well, I know that you all had a limited amount of time. In fact, I was getting the chief of staff's signal that we're at that time. But any final thoughts? This has been very helpful just to help really the broader stakeholder community get that additional window into thinking and spark some ideas of how the foundation might be helpful, how the broader community can engage and what's important.

Commissioner Martin Makary (00:31:02):

I'll start off. Thank you for your support. The FDA is a national treasure. It's one of the greatest brands of the world. I'm continuing in a tradition of great leaders at the FDA as represented here by Susan and Andrew and others who have worked at the FDA who are here in the room. And so, the challenge that we have in the charge is a big one, but the FDA today is strong and it will continue to be strong. We're going to meet all our PDUFA targets. We're going to continue to do things to improve the culture. We're going to add more AI efficiencies and novel pathways and listen to people and talk and figure out what we can do to make sure all the core staff have all the resources that they need.

(00:31:52):

It's an exciting time. We have phenomenal talent that wants to come in and work at the FDA. And so, we're excited about making some new announcements in the next couple weeks of incredible talent with impeccable credentials that don't need to work in government and they're going to come in because they believe in this incredible tradition that has preceded us. So, I just want to say, "thank you," on that.

Susan Winkler (00:32:20):

All right, great. Thank our guests. Truly appreciate it.

Foundation Highlights

Richard L. Schilsky, MD, FACP, FSCT, FASCO, Foundation Board Chair, Reagan-Udall Foundation for the FDA

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

Susan Winkler (00:32:25):

Yeah, it is advised. Thank you. So, we'll then transition to the next part of our program and in that, I want to make sure first that we don't have any injuries on the way down. And so, we are going to do just a brief recap of some of the work that the foundation has been doing, and then, we're going to hear directly from the foundation's board of directors. This is a meeting that Congress requires that we hold every year, and so, it allows us to share what we're doing. I think perhaps it was... Congress didn't use the phrase, radical transparency, but we can assume that was what they were shooting for in asking us to have a meeting every year that we shared what's happening within the foundation. So, with that, Dr. Schilsky, I will turn the podium back to you.

Dr. Richard Schilsky (00:33:35):

Okay. I'm just looking for where I'm supposed to pick up here. Okay. Well, again, we want to thank FDA leadership for being here. Certainly, they've got a big job ahead of them. We all need to help them because if the FDA is successful, we're going to do a lot to improve the health of the American public and really by extension, people around the world because the FDA sets an example for so many other

regulatory agencies around the world. So, we appreciate their insights. Susan and I will now provide a few updates on the foundation's work, and we'll then be joined by some of my colleagues on the board for a more in-depth discussion on just a few focused areas.

(00:34:25):

Foundation's work as you know, helps advance the FDA's mission through an unwavering focus on innovation, transparency and efficiency in regulatory science. That is really our sweet spot is helping to advance regulatory science, which has to keep up with all of the scientific advances that are being made in every therapeutic area. Every initiative we undertake is grounded in a clear priority, which is the well-being of patients and consumers. After all, that's really what the primary responsibility of FDA is. Those voices, patients and consumer voices, are central to many of our projects. For example, as you heard about, in our work to build out the Expanded Access Navigator program, a critical resource that helps patients and healthcare providers find and access investigational treatments. Hearing from patients, hearing from providers about what they need in order to be more aware of expanded access and how to obtain drugs through that mechanism was very informative for the program that we've developed.

(00:35:32):

In 2024, the number of drug developers listing their resources in the navigator grew by nearly 25%. And the foundation facilitated the submission of more than 650 expedited access requests to FDA through the eRequest app. I can tell you from personal experience as an oncologist who has tried to get expanded access over the years for my patients, this is an extremely valuable resource because it's very hard to understand as a physician, what are the steps in the process, what paperwork needs to be filed when, how do you communicate with the FDA and so on.

(00:36:11):

Separately, through a series of 14 patient listening sessions on a wide range of conditions, the foundation helped the FDA staff gather valuable insights directly from those most affected by these conditions, sometimes rare disorders, and again, providing valuable insight. At the same time, we remain deeply committed to ensuring that Americans have access to safe and nutritious food. You heard from the commissioner, that's clearly a priority for FDA now. It's been an area that we've been working on for certainly some time already. It's a priority that's more important than ever amid a growing epidemic of chronic disease. With our expanded food portfolio, we brought together stakeholders from across the food supply chain to identify data gaps, discuss real-world challenges, to maintain efficiency and work collaboratively towards safer, healthier food systems. And we'll get into a little bit more about that in our more focused discussion. I would be remiss if I didn't also mention our Innovation in Medical Evidence and Development Surveillance program affectionately known as IMEDS, hopefully for obvious reasons, because that other long thing is a real mouthful.

(00:37:24):

IMEDS continues to be a powerful resource for post-market safety surveillance studies. By using FDA tools, we're able to better understand the frequency and severity of specific adverse events, identify the populations most at risk, and help FDA-regulated industry meet their commitments to monitor their products' effects. And I just want to emphasize that as more and more medical products are making it to market, oftentimes with smaller data sets to support the risk benefit assessment by FDA, gathering the post-market data on their safety is increasingly important because the numbers of patients represented in the clinical trials that lead to regulatory approval are far smaller, and oftentimes, not well representative of the population of people who are going to receive those treatments in real-world medical practice. So, IMEDS offers an opportunity to bridge that gap. We've also advanced real-world

evidence generation through public webinars and projects designed to strengthen data evaluation and the use of algorithms in regulatory science.

(00:38:35):

Now, turning to another subject, the rising toll of substance use disorder has also captured our attention. In 2024, we tackled complex questions around the online availability of controlled substances and convened meaningful discussions on the risks and benefits of drugs like ketamine and psychedelics. We also explored how digital tools can help support disease evaluation and management in mental health. Susan, I think you have a few more things you want to add to this list of 2024 highlights before we move into our board discussion. So, I'll turn it back to Susan for a few more remarks.

Susan Winkler (00:39:12):

Sounds great. Thanks. Thanks so much, Dr. Schilsky, and I'll empower the team in the room, you can go ahead and fix the room set for the panel while I'm talking because I don't mind if people are mildly distracted by something else in my space. So, one of the other things, I mentioned that this is a congressionally-required meeting. We also are required to issue an annual report. For those of you who are here in the room, you have that report on your chairs and we're dropping a link into the chat. It should now be available on our website. And I'll note that an important part of that report is providing visibility into our financing. So, in 2024, we continued to try to diversify our funding support, being good stewards of the funds invested by the American public in our work via the FDA, and enhancing those with support from non-government resources.

(00:40:10):

So, part of that good stewardship is the oversight that our board provides in that space. Among those congressional requirements in our authorizing statute is a provision that our board, which has seats designated for consumers, for healthcare professionals, for academia, and for regulated industry, oversee rules to assure that the foundation is independent. It is one of the least glamorous parts of their jobs for which we pay them nothing because they are board members on a non-profit. But one of the most important, and our board is made aware of all funding that comes to the foundation, and in fact improves all donations of more than $250. That process helps protect and assure the impartiality of our work and allows us to remain free from conflicts of interest or undue influence.

(00:41:03):

So, another important component is that the foundation, we control the work. So, funders including when that funding is from FDA, may provide input to our work, but the foundation controls the project and the output. Further, the foundation requires that any projects supported by regulated industry have support from more than one sponsor. So, we'll share a bit of our numbers. The foundation remained at a relatively consistent size according to revenue in 2024 at just over 8.3 million. But perhaps more important is the breakdown of that funding. So, if you think about how it is that we do our work, you'll see that about 44% of that is coming from the FDA directly. And then, the rest is made up of projects that are conducted in collaboration with the private sector as well as donations through our gala, which will be in December. And we're happy to talk to you about that later if you'd like.

(00:42:05):

What isn't shown in the dollars here is the way that so many individuals see the foundation and the engagement of all of you in our work, for which we are deeply appreciative. Most individuals see the foundation through our public meetings. And we had 13 of those last year, each of which is shared not only in the moment, but is available as an enduring resource via the recording transcript and slide deck on our website. Another work product is our reports, whether summaries of our meetings or the work

of expert panels. And those documents capture shared learnings. And because some conversations are more productive if they're not held on camera, we do host a number of listening sessions and closed-door round tables. But in the spirit of transparency, the results of those discussions are prepared under Chatham House Rules and shared with the public so that the public knows what indeed the insight is that has been provided to the agency.

(00:43:09):

But each of those, I should say, none of this could happen without each of you that individuals who are willing to share candidly, your expertise, your insight, your experience. We had a session where it was biosimilar developers who haven't had much experience with the FDA, and they invested in a series of five virtual conversations to say, "Here's what we could benefit from a regulatory science program." The developers were around the world, so many of the conversations were taking place at 11:00 at night, local time, or wherever they might be. And the companies showed up for every conversation. In this room, we've had individuals with experience with post-traumatic stress disorder or who are studying the impacts of ketamine or talking about how to make produce safer. And the foundation is merely the facilitator for the extraordinary insights that each of you provides.

Panel Discussion with Foundation Board Members

Edward John Allera, JD
Debra L. Ness, MS, Treasurer
Pietro Antonio Tataranni, MD
Andrew C. von Eschenbach, MD
Richard L. Schilsky, MD, FACP, FSCT, FASCO

Susan Winckler(00:44:08):

So, that's enough on the numbers discussion. I see the stage set is ready, and so we're going to hear just a panel discussion. Not just, it's going to be a great panel discussion with the members of our board of directors, many of them who are here in the room are going to join us up here. So, Dr. Schilsky, if you want to come on up, I will go park myself on the side there and we'll bring up our other directors for the conversation.

Dr. Richard Schilsky (00:44:41):

Okay. So, marching to the stage, Directors, Ed Allera, Debra Ness, Antonio Tataranni, and somewhere out there is former Commissioner von Eschenbach, who I think is sending off the current commissioner. So, we'll try to get Andy back in the room so we can get started. Can we see where Andy is? Yeah.

Susan Winkler (00:45:09):

He's on his-

Dr. Richard Schilsky (00:45:10):

He'll be back. He'll be back. Great. So, I'm going to maybe sit down.

Susan Winkler (00:45:22):

Should be ready to go.

Dr. Richard Schilsky (00:45:23):

Okay. Thank you all for being here. It's great to see you guys in person today. I know we have many of our other board members on the line. During the summer months, sometimes hard to get everybody to Washington on relatively short notice, but glad everybody's able to attend. I want to start with you, Ed. Ed who is an attorney, as I'm sure most of you know, reminds us frequently at our board meetings, that as he puts it, our product is our process. So, could you talk a little bit about what exactly you mean by that and maybe give an example?

Edward John Allera (00:46:00):

Sure. I mean, we have a unique capacity to bring together FDA and people whose voices aren't routinely heard. We have the passion to go out and find people who aren't routinely heard, whose views can be invaluable to the agency because as the Commissioner pointed out, science is going so rapidly. The reviewers, they haven't studied this, and we're trying to provide them with input as to how we can move forward so everyone benefits. It's a collegial atmosphere that we provide. The thing to remember is FDA is not a monolith. Every center's unique, every reviewing division's unique. So we have capacity to get these people to together and talk and learn. It's not in a product-by-product confrontational system. It's really looking at broad issues that we can all benefit from because realistically, when you're particularly for rare diseases, I think it's particularly important because as our dear colleague David Fajgenbaum and Grant Mitchell discovered, they brought together the clinicians, the top researchers in Castleman disease for a meeting.

(00:47:24):

And it was like a meeting of Mac users and PCs. They didn't speak the same language, and that doesn't even include the patient caregivers. So we're in a new era. We have to have these dialogues to really, particularly as you said, we don't have a lot of patients in many rare diseases. How can we learn how to provide the most meaningful clinical benefit to patients and their caregivers and create new tools? You can do hip replacement with a saw and a hammer. You can't use that for brain surgery. So we have to provide this way and remember as one-

Susan Winckler (00:48:04):

I don't think Dr. von Eschenbach did surgery that way.

Edward John Allera (00:48:06):

Oh, one never knows. But the other thing is not every drug is safe, not everything works and as one of Andy's predecessors, Mac Schmidt said, FDA is a large slow-moving target that bleeds easily and profusely. So you have to recognize the human nature of the people you're dealing with to give them the confidence that they won't miss things. And you come across in this way as an asset. You're not a friend, you're not a foe, and you're known. And that's just so valuable for the community because investors want to know what FDA thinks about your product, particularly for rare diseases.

Dr. Richard Schilsky (00:48:52):

Yeah, I think the rare disease example is really a good one because although obviously rare diseases is a collection of disorders, collectively rare diseases are not that uncommon across all of biomedicine and the paradigm for how to study rare diseases, for how to define them, how to understand their pathogenesis, for how to characterize them, for how to monitor treatment effectiveness, it extends across most of the rare disorders, regardless of what their specific clinical manifestations are. So being able to bring together a group of stakeholders and talk about that and use that information to help

inform FDA's thinking about how to address the issue of oversight of new therapeutics, new biomarkers. Many cases, developing a new therapeutic intervention for rare disease is also going to require developing a new biomarker. And then there's the whole issue of at what point do you have sufficient evidence to pull the trigger on a regulatory approval?

(00:50:07):

How do you continue to follow patients who get these novel interventions? Some of them are going to be children, some of them are going to need lifelong follow-up. These are all some of the types of conversations that we've had and that hopefully have been valuable to FDA. I want to turn to Antonio for a minute. Antonio, I think some of you'll know is the chief medical officer at PepsiCo, and obviously food and nutrition is a big part of American health and a big focus of the current administration. And we've done some work on food traceability, which of course we want to be sure that the food supply chain is safe. Maybe you want to talk a little bit about that.

Dr. Pietro Antonio Tataranni (00:50:50):

Yeah. Thank you, Rich. First of all, on the one-year anniversary, almost date to date of joining this board, let me tell you how humbled I am to be sitting on this panel with such illustrious colleagues and be part of the conversation. We have heard from Commissioner Makary that F in FDA stands for food and obviously as somebody who lives and breathes food in the food industry day in and day out, that's a very important statement to hear. And obviously you have heard that the industry has engaged already with the FDA to work on some of the issues that are pointed at as a way to improve the food system. But as somebody from the food industry, I think it's completely appropriate that I celebrate one of the accomplishments that it's very well described in the annual report here of the foundation, which is the role that you have played in facilitating an interesting and intense conversation on the food traceability final rule, and in a way that has led to a very concrete action then at the FDA.

(00:52:21):

So as you read in the report, three round tables were organized by the foundation, saw the participation of 34 actors in the value chain, a very, very rich set of conversations and recommendations and inputs that are captured in the final report that was presented to the agency and presented during a public meeting where the foundation was also able to collect further public input from 19 individuals. And all of this done in the spirit of improving a process that wants to see identification of foodborne illnesses as quickly as possible and implementation of recalls as efficiently as possible. And these are things that are in the news almost on a daily basis.

(00:53:26):

Now, I said there was action that was derived from all this consultation and that is that a common theme through the consultation was that the implementation of the rule to be well done strategically and practically required a little bit more time for actors to become familiar and perhaps pilot a little bit around the actual requirements of the rule. And so the final decision was that instead of launching the rule in early 2025 as originally planned, that the FDA extended the implementation of deadline to June 20, 2028. So I guess a great accomplishment in line with the feedback that was received.

Dr. Richard Schilsky (00:54:18):

Yeah, thanks for that, Antonio. I'm going to go off script a little bit for a minute just ask you a follow-up question. And this is really based on my own lack of knowledge in this area, and it relates to what level of evidence is necessary to trigger a product recall. How is that decision actually made?

Dr. Pietro Antonio Tataranni (00:54:42):

So I'm not an expert in the area, but is a level of evidence that is contributed by multiple actors into the space. And once that evidence is recognized, then it triggers a series of downstream actions which are aimed at protecting the public, as I said, as quickly as possible and as efficiently as possible.

Dr. Richard Schilsky (00:55:10):

Go ahead, Andy.

Susan Winckler (00:55:11):

There's one in your chair.

Dr. Andrew von Eschenbach (00:55:15):

I think there are two ways of thinking about it, Rich, just simply one is if you see a blip in what you might expect as a random occurrence, and also if you see a cluster, so if things are starting to break out in a particular domain, then you know that something unusual.

Dr. Richard Schilsky (00:55:33):

Got it. Got it.

Susan Winckler (00:55:34):

If I may, Rich, it's also a great place where we follow the science.

Dr. Pietro Antonio Tataranni (00:55:38):

That's right.

Susan Winckler (00:55:39):

And that sometimes you may believe that an illness is associated with a certain commodity and then upon further research you find out it's a different one. And I actually have one on my head, so I'm good. That's an important part of FDA being able to continue to conduct these tracebacks with industry's help so that we know which commodity was involved because it doesn't help anyone to have an action or a warning associated with the wrong thing. And you want to be able to get to the right thing quickly and protect consumer.

Dr. Richard Schilsky (00:56:18):

So speaking of consumers, I'm going to pivot to Debra. Debra, it's so great to have you on the board and to bring that consumer perspective from all of your years of work as a consumer advocate. I know you've also spent a good portion of your time on the board dealing with some of our food-related activities, particularly from the nutrition point of view, and obviously that the food producers can do all sorts of wonderful things to improve the nutrition value and the quality and the safety of food. But if we somehow don't get consumers to recognize those issues and make appropriate modifications to their behavior and their choices, we're never actually going to result in significant improvements in the healthy diet of the American public. And we've been trying to think a little bit about that. I wanted, Debra, if you could speak to some of those issues.

Debra Ness (00:57:20):

So thank you. I'm very excited about digging into this area. It's really a time when I think we're going to see a lot of focus on empowering consumers to make the right decisions to improve and protect their health. And I was really very excited to hear Commissioner Makary talk about the emphasis on food because food is something that affects all of us. We all eat, and there's a very long and complex chain, I have learned, between what happens on the farm as you're growing the food and it ultimately getting to our stomachs. And that's where we come in. And the foundation has now for a while been playing, I think, a very important role in providing the kind of information that consumers need to make those good decisions about their health. The Nutrition Communications Network that we have in place provides wonderful, easy-to-understand, easy-to-use messaging, and they have developed products that can be used for social media, that can be used in interactive ways online.

(00:58:51):

They've developed resources for educators, health educators, teachers to help children, patients understand better how to take care of their food and nutrition needs. And they have a wonderful, if you haven't checked it out, a wonderful toolkit on their website for dietary professionals. Their quarterly newsletter is really terrific. And if you're not part of that network, you should go online and sign up and get on board. And right now there're over 30 organizations that are making this information available to their audiences, but it isn't just about providing information, Rich. So if I can just say there's an extraordinary amount of work to be done to keep the food supply safe. So we can't just tell people to go out there and eat healthy. We have to make sure that there's healthy food out there and safe food for them to eat. And there's been a lot of emphasis on getting people to eat more fresh produce, fruits and vegetables.

(01:00:02):

And again, when you dig into that and you look at all the actors between the space of where the food gets grown and how it actually ends up on people's plates, it's a myriad of many different players. You've got the growers, but you've also got the buyers, and you've got the packagers and you've got the distributors. You've got the academic research community, you've got the extension professionals, and you've got consumers. And at every link in that chain of that complex web, you can have errors, but at every point, you could also have an effort to prevent error, an opportunity to reduce risk. And what the foundation does so well is bring all those different players together, and sometimes players who don't normally talk to each other, get them in the room to identify where their shared interest is. And that's exactly what they've done in their project.

(01:01:12):

And there's a soon-to-be-released report that's going to be called the Roadmap for Produce Safety. The end of this month, we should see that come out. And that is a report that's going to lay out a roadmap created by all these different players who have begun to talk to each other and say, we can't just do this in incremental ways and we can't do it in silos. We have to look at the whole, and we have to all take responsibility and step up. So I'm very excited about that report, and it's a great reflection of the work that the foundation does.

Susan Winckler (01:01:49):

Well, and eight working groups with 15 odd people in each working group. I mean, the investment of volunteer resources who said, we're willing to look at this difficult issue where in fact we don't agree, there's some trust to be built moving forward. But that's been a really fun one to be involved in.

Debra Ness (01:02:09):

And I think you had over 175 different organizations and a real commitment on the part of the private sector to step up and really lead in this area. It's not just government. We need the private sector to lead.

Dr. Pietro Antonio Tataranni (01:02:26):

And if I may for a second, Director Ness and I serve on the health and nutrition subcommittee of the foundation where many of these discussions take place, and to put a cap on the great things that Debra mentioned, obviously there is a central element in all of this discussion, which is well-intended regulatory actions, especially in the space of food and beverages, have to translate ultimately into consumer behavior. And how does that happen is a central tenet of improving the food system. And I wanted to acknowledge that in the committee, we often spend quite a bit of time thinking and discussing how to help the FDA to achieve that goal.

Dr. Richard Schilsky (01:03:28):

It's remarkable that there is some crossover in various areas of our work. We've been doing some work on preparedness for an avian influenza epidemic, if you will, but there you have a situation of an infection that affects primarily birds, but birds are part of the food supply. And we've seen the impact already on egg production and things of that sort, and even concerns about the safety of the food supply. And then I have to say, without being an alarmist, I mean, I have often wondered, we all lived through the COVID pandemic and obviously millions of people died in that horrible global pandemic, but how much worse might it have been if COVID was a foodborne illness instead of a respiratory illness?

(01:04:28):

I mean, how much more fear would there have been if people would've been afraid to even buy fresh food because of fear that it might transmit a disease like COVID? So these things all touch on each other, I think the way in which the foundation works, the capacity to bring together disparate groups of experts as Debra and Antonio have stressed to talk about really complex topics like this is really unique and valuable. Andy, I think you wanted to make-

Dr. Andrew von Eschenbach (01:05:03):

Well, I just want to amplify. I think we've picked up on a really critically important theme, and the idea of which is that science and technology is changing so rapidly, almost at exponential rate, that even when you think about food and food supply and how that has changed even with regard to how we grow it, how we process it, et cetera, that the FDA has to constantly stay in front of that. And the only way it can possibly do that is if there is a bridge between the FDA and the vast community that's engaged in these frontline activities, production, et cetera, et cetera. And that's you. That's you in the audience, and that's you beyond this room. And so your participation, your involvement to keep us at that cutting edge is so critically important. And the way the foundation is in place is to try to create that bridge between you and the FDA so that everything continues to stay current and timely.

(01:06:15):

And to the point of nutrition, I mean, just the changes that the Commissioner and I were talking about as I escorted him out, we're now thinking about nutrition at the molecular level. It's one thing for me to tell you to eat blueberries, but it's even more important for me to be able to know what it is exactly in that blueberry that is making the difference in your microbiome or in your brain cells, and then what we might be able to do with regard to formula once we know that. So you have to be a part of what the Reagan-Udall Foundation's about, and thank you when we reach out to you to join in on conferences or

calls, et cetera, because you're giving us the opportunity to work directly with the FDA so they serve you even better.

Edward John Allera (01:07:10):

What the Commissioner said, I thought was so profound was trying to bring the technology into FDA and new technologies across agencies and across industries, and as you said, Andy, nutrition to medicine, but the other technologies and manufacturer products, there's so many opportunities now that, as I said, people haven't studied yet, so we have to have you bring it to us so we can help educate them because we will all benefit.

Dr. Richard Schilsky (01:07:44):

So we spent a lot of time, excuse me, talking about food. Andy, while you've got the microphone, let me turn to you and let's maybe refocus a little bit on medical products, devices, therapeutics, biologics, I mean the range of areas that FDA now has to deal with on the medical product side. It continues to increase because the type of products continues to evolve. I mean, whoever would've thought we would be dealing with changing a person's immune system or modifying their genome in order to treat a medical problem? You were there at the beginning of the foundation. In fact, I think many people would say you created the vision for the foundation. And I wonder if you'd like to offer some comments as you've now observed, how the foundation has evolved over the years, how the foundation has conducted its work, interacted with FDA. Are we achieving the vision that you had so many years ago now when you really conjured up the idea of an FDA foundation?

Dr. Andrew von Eschenbach (01:08:58):

Well, I think probably more than a vision, I'd describe it as a wake-up call because those of you know I was the director of the National Cancer Institute for four years, and then I transitioned to become the commissioner of the Food and Drug Administration. And I did both jobs simultaneously for six months as we worked through that transition. And the contrast was really striking for me that when I was at NCI, I had more opportunities for input into our national cancer agenda, whether it was the National Cancer Advisory Board, Board of Scientific Advisers, advocacy groups, et cetera.

(01:09:40):

When I got to FDA, FDA was walled off. And it's very difficult for a regulatory agency to be in those intimate conversations because of the concerns that you're all aware of. So there needed to be a bridge, a way we could be able to have the opportunity to have those conversations, to get that kind of input, get that feedback, to create the dialogue while still maintaining our, if you will, integrity and firewalls.

(01:10:16):

And that became the genesis for the idea of Reagan-Udall Foundation. For the Reagan-Udall Foundation to be commissioned by Congress in law to serve the mission of the Food and Drug Administration and help it continue to promote and impact the public health. So what I've watched with tremendous amount of gratitude over the years that the foundation has been in place is that those of you who are here and those of you who are participating virtually have really brought that vision to full fruition. That we now have that opportunity to create that dialogue to provide those inputs. And to Richard's point, the challenge for the agency is to recognize that although we have been extraordinarily successful at regulating drugs, biologics, devices, food, as we look at the future, we're looking for solutions for problems of health. And those solutions are almost invariably going to involve the integrated interoperability of those components. And food is going to be just as much an important part of the prescription as perhaps the drugs that you're taking.

(01:11:40):

And Commissioner was talking about the microbiome, et cetera. So we need to be able to help the agency move forward with regard to not only continuing to be extraordinarily the world's gold standard at understanding and regulating components, but also being able to regulate integrated interoperability those components, combining diagnostic biomarkers with being able to know what exactly the right treatment is for a particular subset of lung cancer is the future. And the FDA needs to move forward with that. And that's one of the important dialogues that I think the foundation wants to continue to catalyze.

Dr. Richard Schilsky (01:12:27):

So again, I'm going to deviate a little bit. So as you know better than probably anybody in this room, what the org chart of the FDA looks like and its internal structure and how it functions. And we've seen in the last several years the reorganization of the way oncology works with the creation of the Oncology Center of Excellence. And that was driven in large part by Rick Pazdur's vision for just what you're talking about, an integrated approach, recognizing that the diagnosis of cancer, the assessment of cancer, its characterization, the selection of therapy, follow-up of patients who are receiving a novel cancer intervention is all driven increasingly by the interplay between diagnostics and therapeutics in order to appropriately select therapy and manage a cancer patient.

(01:13:29):

So that seems to be working pretty well in oncology. And I guess the question for you, Andy, is can you imagine other therapeutic areas taking on that more center approach? I mean, do we need a center for neurodegenerative disorders or a center for cardiovascular disorders? A center for metabolic disease? Antonio is an endocrinologist. I'm sure he has thoughts on that. Is that a future state for FDA that you think should be considered?

Dr. Andrew von Eschenbach (01:14:04):

Absolutely. There's no question in my mind about it. And I think your point, we already have the operative model. Look at our cancer center programs around the country. We're not going to get rid of surgeons, thank god. We're not going to get rid of medical oncologists as a discipline. We're not going to get rid of radiation therapy as a unique culture and way of thinking. But what we have done is create breast cancer programs, pancreatic cancer program. We've learned to become a matrix organization where we stay in our vertical disciplines but we function horizontally as an integrated team.

(01:14:45):

I don't see any reason why the FDA can't work the same way and include food, CIFSAN, as an integral part of that horizontal integration so that it's a part and parcel of the things we're learning and discovering about drugs and biologics and part and parcel of that. So it's exchange of knowledge. It's creating the opportunity to look holistically at products that were being developed. And we're seeing more and more, especially in areas like stem cell biology and general medicine, the integrated interoperability of components. Genetically modified cells that have to have the right growth factors, etc. etc. So yeah, I don't think there's any question that the challenges of doing that are significant, but they're not insurmountable.

Susan Winckler (01:15:39):

Well, and the rare disease innovation hub is a way, right, a way for the agency to think about doing that just a little bit differently and that you have a group specifically tasked with saying, "How do we work

across centers? And how do we make sure if we're learning something about a rare disease in one center, are we applying that learning across centers? Are we doing some of the learning collectively?" The foundation facilitated the public meeting that launched the innovation hub, and it was just fascinating to hear the forty-some contributors who said, "Here's where we think the hub could make a difference."

Dr. Andrew von Eschenbach (01:16:15):

Yeah, absolutely. And I don't want to dominate this, but to Rich's earlier point, I mean, we need to get that example, that pilot, that paradigm really well-developed, because you take a common disease like lung cancer, it's made up of a group of rare diseases depending upon which unique genetic modification you have. So what we learn about rare diseases in this hub needs to be extrapolated to all their other diseases as we learn more and more about them at the genetic and molecular level.

Susan Winckler (01:16:49):

Well, in the collective learning of the regulator, the researchers, the patients, and the caregivers in industry allow, and everyone can speak to their pain points because they've all looking out and seeing a different view out the windows and we need to help them. It's great to just have that time where they can come together and see where their common problems and potentially common solutions.

Dr. Richard Schilsky (01:17:15):

So our time is starting to wind down here, and maybe we could, as a last round of discussion, ask each of our board members here to give us some thoughts as to where do you see the FDA going in the next year or two, where do you think it needs to go, and what do you think our foundation can do, should do to further the priorities and goals of FDA? If anyone in particular wants to start, otherwise, I'll ask Ed, we'll just go down the line, if you want to start off.

Edward John Allera (01:17:53):

I think discussion, dialogue, and openness as today was evident. Tip O'Neill said, "All politics are local." What we discovered today is all healthcare is local. You look at that. So how can we get everybody's input to really help guide the future of FDA? Because you want new ideas, new cutting-edge things to help us move forward. Things are happening so rapidly in ways that people haven't studied. And I think getting that information to open-minded people inform where people are not confrontational. "You have to approve my drug because it's so important to my investors and my kids." to "Here's the issues we see, here's how it cuts across so many different things." But you have to do it in a way that is, everyone learns and everyone benefits. It's a collegial environment. Everything we can do to help that, we've done that. Susan's been fabulous at it and getting more and more voices heard, because every disease has its own group, but so many things transcend. So it's building that continuous dialogue.

Dr. Richard Schilsky (01:19:12):

Thanks. Debra?

Debra Ness (01:19:14):

So I was particularly excited to hear the commissioner talk about the extraordinary breakthroughs that we're experiencing now and that are promised ahead when it comes to understanding the role of the microbiome and the way in which that may unlock understanding of various diseases, behavioral illnesses. And Andy, your idea of what we learn in the food arena, cutting across all of the different

verticals within the FDA. I mean, it's extraordinary I think what we're on the cusp of right now. And I'm also struck by the focus on transparency, but I'm very aware that transparency by itself is not a goal. So the end goal is not radical transparency. We want radical transparency for a reason. We want it so that we can learn, so that we can listen, so that we can eventually act and behave differently. And then that takes me back to what the foundation is so good at. And I think we have to keep doing more of it and even better.

(01:20:40):

So the two-way communication, translating what the FDA is trying to convey to the public in ways that the public can understand and consume. Listening and bringing all those voices, especially the voice of the consumer, which wouldn't easily find a path into the FDA without the Reagan-Udall Foundation. And then taking that two-way communication and fostering the collaboration in a trusted place so that all the voices come together and eventually can see the shared threads and common agendas. So I think we have a really exciting future ahead of us.

Dr. Richard Schilsky (01:21:32):

Antonio.

Dr. Pietro Antonio Tataranni (01:21:33):

So Rich, listen, I was thinking what to add at this point. And I realize I'm just about in my 35-plus year of a career dedicated to understanding the relationship between nutrition and health. I've done that at the National Institutes of Health, initially as a hardcore researcher trying to understand mechanism of diseases. At that time, we didn't talk too much about the microbiome. It was most about the genetics of chronic metabolic diseases. I've done it for 15 years in the pharma industry trying being somewhat successful with other people, bringing medications for the treatment of chronic metabolic diseases to improve the lives of many patients with those diseases. And now, I've dedicated the last seven years of my career to food and beverage.

(01:22:32):

And in this journey, I have progressively convinced myself more and more that food and beverages to a certain extent belongs, is the low-tech, low-cost solution to that problem along the continuum of interventions, as Commissioner Makary was saying. So I rejoice in realizing that the FDA sees that as one of the opportunities to move what we often refer to here in this country as a sick health system to a real healthcare system, and move a little bit the needle towards prevention as opposed to intervention.

(01:23:23):

Everything has a place in that continuum, but this renewed emphasis on the F of FDA is very refreshing. I think it's very important. It calls all the actors, including us in the food and beverage industry to think and rethink our role in that continuum. And I think the foundation can really have an exciting role in continuing to keep that discussion with the actors in the space alive, well, engaging, interesting, full of feedback one way or another. So I'm really excited about what we can do going forward.

Dr. Richard Schilsky (01:24:06):

Great. Got me excited. Great. Andy?

Dr. Andrew von Eschenbach (01:24:10):

Yeah, I think that, and it's, what, now is almost 125 year history, FDA's facing one of the most transformational opportunities in its history. But one of the most incredible challenges in its history, and

I'll give you a little background. When I arrived at FDA and we were creating White Oak as its new home, it was only one building at the White Oak campus and it was Cedar. And they brought me up to Cedar to see the future of the FDA. And I asked the question, "Can you show me how it works when a drug application comes in to be reviewed?" Because every single drug that's ever going to be evaluated by the FDA is going to go through this building. They brought me down into the sub-basement and they opened up a vault. And in the vault, there was it seemed like a football field size room of filing cabinets that you turned a crank and it opened up. And on every shelf there were these huge paper files of applications. And I said, "Do you have any idea what the wealth of knowledge is in this room? How do we use it?" And the answer was, "We can't. We don't unless it's in someone's head that remembers."

(01:25:37):

So where am I going? The opportunity, as the Commissioner said, there were tools that weren't available at the time, so we couldn't. Those tools are now available where we can unlock that vault. We can capture that data. And it's not only everything that's been approved, it's the ones that didn't get approved. And so whether it's drugs, biologics, devices, there is no greater repository of knowledge data than exists within the FDA. The greatest challenge is figuring out how to understand how to unlock that vault. There are going to be social problems, there are going to be legal problems, there are going to be regulatory issues. We need you.

(01:26:21):

We need the community to come together and say, "Let's figure this out." We need the foundation to be that bridge so that we understand what the FDA needs and what they're capable of or what restrictions there may be and what you can provide. And I can obviously, from my tone of voice to understand how passionate I get about this, because this can be the opportunity to not do something wrong because we've already learned that before, but to do something right for those people who are suffering and dying out there, and they're not going to get any better until FDA says it's okay for them to have, whether it's the food or the drug or the biologic or the device.

Dr. Richard Schilsky (01:27:03):

And Andy, just to amplify in your last point, which the commissioner also mentioned. You know ...

Dr. Andrew von Eschenbach (01:27:12):

Do I mention artificial intelligence?

Dr. Richard Schilsky (01:27:13):

Well, I was just going to mention, 20 years or so ago, we saw the emerging concept of the learning healthcare system whereby we as a community have the opportunity to learn from the experience of every person who's receiving healthcare in this country. And we've never really been able to capitalize on that, because until the last 15 years or so, we didn't have robust electronic health records and we didn't have the tools of AI to basically examine those records in a very efficient manner.

(01:27:53):

When the commissioner said, we can access a hundred million EHRs and apply AI tools to learn from those, that is the promise of the future because there's only so much we can learn from the standard kinds of clinical trials that are necessary for drug approvals. There's only so much we can learn from post-market registries. We have to be able to learn from the experience of every one of us in this room who's receiving healthcare. But to do that requires that we have a set of guidelines and standards and data formats and so on. And I think the foundation has a unique opportunity to really help lead in that

discussion about how to develop and use real-world evidence so that we can really more rapidly learn about how to improve the health of all of us and people around the world.

Susan Winckler (01:28:47):

And with that Rich, I'll say, I've already picked up seven assignments in the meeting, and we are at the conclusion of our time.

Dr. Richard Schilsky (01:28:56):

I see that. So Susan, let me ask you if you have a last word, anything you want to reflect on about where the foundation's going in the coming months or years?

Susan Winckler (01:29:05):

Yeah. So to be that bridge between the stakeholder community, which has such extraordinary input and FDA which has input and needs to be that bridge is the best job in the world. And while I didn't turn the power back on today, I'm really glad that the power came back on. Thank you all for joining us today. And as chair, would you entertain a motion to adjourn?

Dr. Richard Schilsky (01:29:28):

Yes, of course. Before I do that, I do want to thank my fellow board members who are here today, and for your tantalizing thoughts and participation. I want to thank our fabulous CEO and the terrific staff that she works with day to day to do the work of the foundation. And thank all of you for participating in all of our activities and more to come. And with that, we will formally adjourn the meeting. Thank you.