SPEAKER:
And thank you to all of you for being so engaged and asking questions. Now we turn to the final session of the annual meeting. You can all clap for that too. I'm just being facetious. The Presidents Forum, which is gonna be entitled Revolutionizing Women's Health Envisioning a New ERA of Progress, Policy, and Research, led by and moderated by Dr Victor Dzau and I will now welcome Victor and the panelists to the stage. Thank you all very much.

VICTOR J DZAU:
So now we're in the homestretch. We'll have drinks for you afterwards and dinner. But I think this is gonna be the highlight of my opinion or everyone is a highlight. Let me just simply say the following. When I think about this meeting on women's health cells to society, I think you really met all the goals, because my feeling is you're able to touch on every aspect from the biology, to social issues to care issues, research, you name it. So it's been a great success. So again, thank you, Karen. Yeah. So when we think about where we are today, there's a lot to be thankful for. But also we know we have lots of challenges. The idea of getting this panel together are individuals with great leadership, in leadership positions, expertise, decision-makers, and policymakers. So the whole idea is how to bring all this together. We heard a whole variety of issues, from biology to internal external factors, the understanding of sex versus gender, the participation of women in clinical studies, and, of course, importantly, considering biological, social, and environmental life course issues.

We also know it's very clear there's a long way to go. Certainly, we've seen many, many challenges in research, we'll talk about, in clinical care and many other issues. There are lots of disparities, as we heard, in access affordability to innovation and to care, but also the whole issue of equity. And of course, we also heard that some of the legislative judicial actions, legal actions have also negative implications on women's health in terms of safe care access, workforce, and of course, suicide as a whole. So we're wrapping up this meeting with this wonderful panel who's gonna be talking about with me what's in the future. What do we need to do based on all these things that we have learned today and you already know. And so let me introduce the panel first. With me to my left is Monica Bertagnolli. Many of you know her. She's director of the National Cancer Institute. Welcome, Monica. And then Iffath Hoskins, the Immediate Past President of the American College of Obstetrics Gynecology, professor, vice chair of the department of OB-GYN and Montefiore Medical Center.

And then, of course, there's Mark McClellan, professor of medicine, business and policy and director of the Duke-Margolis Center for Health Policy at Duke. We're so glad that Representative Underwood can be with us. She's a member of US House of Representatives representing Illinois 14th district. And then there's my old friend Rob Califf, the FDA commissioner, and of course, Nicole Shanahan. Great to have you, founder and president of the Bia-Echo Foundation. I thought what I would do is ask each one of them, no slides to think a little one question, then I'm gonna go around the question for them and maybe a second round. Then we'll open for discussion from the audience. So I think if you look at being leaders, experts, policymakers, if you look forward based on where we are to the next five years, what is the most important or important issues that you feel that we have to address in women's health? Monica, can I start with you?

MONICA BERTAGNOLLI:
Yeah. Thank you, Victor. Can you hear me?

VICTOR J DZAU:
Nope.

MONICA BERTAGNOLLI:
Nope. Oh, if I can make this. There we go. OK, well, I'll pick one. Actually, I'll pick two. Let me start. We need more women in leading roles in research. I'm gonna confine my comments to research specifically. First, let me start by saying that the recent Nobel Laureate Prize announcements certainly affirm the value that women bring to biomedical research and to Dr Kariko, who shares this year's Nobel Prize in Medicine with Dr Weissman. Congratulations and welcome to the National Academy of Medicine membership.

VICTOR J DZAU:
She was inducted on Saturday, and we had a thunderous applause for her.

MONICA BERTAGNOLLI:
Exactly. So some issues women remain under-represented. Although there's been great progress in women entering the field of biomedical research, right now, today, women make up half, actually, maybe even a little more than half of those receiving doctoral degrees in life sciences. More than half. However, here's a sobering fact. Only about one-third of those applying for research project grant award funding at the NIH are women. Now, when women do apply, they're funded at exactly the same rate as men, but they don't apply as often. And why? What is preventing younger women from taking... younger and mid-career women from taking this critical step toward academic research advancement? This issue is undoubtedly multifactorial. We know that women still spend more time than men when it comes to childcare, during a part of life that is critical to academic development. We also now have data showing that within institutional settings, women spend more time in service roles, more administrative, serving on more administrative committees, teaching and women actually spend more time mentoring.

These are critical activities, but they must be balanced for women with enough time for their own academic advancement. Unconscious bias is still very much with us, with women not considered as displaying qualities of leadership as often as men. The good news is that when we address this issue deliberately and consistently, we see real improvement. More women are assuming leadership roles than ever before. Today, I'm really proud to say that 12 of the 27 directors of NIH institutes and centers are women. An all-time high. And this fact changes society's notion of what a leader should be. OK, next. We clearly need a more comprehensive approach to women's health research overall. Sex must be a biological variable considered throughout all biomedical research. That's clear. This has been a policy of NIH since 2016, but it's still incompletely implemented. We have seen research successes for women. We heard in the last panel about the great contributions of the Women's Health Initiative. In the field of oncology, more women than ever before are living long and full, and active lives after a breast cancer diagnosis.

And we actually have the chance within our lifetime to completely eradicate a lethal cancer, cervical cancer if we just implement worldwide HPV vaccination. So these are tremendous advances for women. So we can't say that there haven't been great accomplishments for women. There certainly have. But both of these success stories are still marred by disparities in access and inclusion. For some, particularly black women, those of low socioeconomic status worldwide, we see great disparities in access to care and even some very common cancers, lung cancer, for example, women are underrepresented in research. Why? We still do not routinely report sex-specific findings in clinical research, or consider sex

as a variable in all research, including fundamental science and this is critical. Another issue, we need to understand sex and gender issues in the uptake and adoption of evidence-based care. So we have a lot to do across the entire waterfront of research. Let me just close by saying that society is changing, but not fast enough.

Biomedical research must accelerate efforts to achieve inclusion at all levels, not just by counting numbers, but correcting knowledge gaps, supporting those in research with unfair challenges so that their talents can be realized, and ensuring that our research results apply to everyone. I really believe that success will lead to more success. So let's point to the successes we have now and get going to make sure that we expand them greatly. Thank you.

VICTOR J DZAU:
Wonderful.

AUDIENCE:
(APPLAUSE)

VICTOR J DZAU:
Thank you for kicking us off just in the right way. And in fact, if you think about the panel, I thought about Monica. Of course, she can do a lot of things, but I'm talking about research and Iffath should talk about education and training, and Mark to talk about maybe payment and of course, Representative Underwood and the things you do in Congress. And Rob Califf, of course, thinking about the FDA regulation and then Nicole representing, in fact, the more private-public perspective, particularly since you are a major funder of those areas. So perfect start. Iffath.

IFFATH A HOSKINS:
Thank you. Victor, can you hear me?

AUDIENCE:
Yes.

IFFATH A HOSKINS:
My daughter always says that I speak in capital letters anyway. So first of all, I am honored to be here. Raised in Pakistan and Nigeria. Worked in Oman. Came to Washington, DC, did psychiatry at Saint Elizabeth's Hospital. Trained in the military, Navy, Bethesda, and Walter Reed. Worked at NIH, then in New York. So here I am today. It's like that Carnival Cruise jingle. If my friends could see me now, I won't sing because then everybody would leave. But thank you so much for the questions challenges. I would put them... like Dr Monica. I would put them in two categories. And one of them is education and the other one is access. And these are the challenges of education. You've heard it throughout today's discussion. We have gaps in education, not only in terms of what we ourselves don't know or don't give importance to. We obviously also have gaps in education in terms of what we try to share with our patients, how we do patient education, teaching them when and where they should seek medical care.

And I will toggle back and forth with access as well, because there are many, many examples. And I will share some from my own clinical world where there is the ability to access care or there are restrictions on access to care, and it all comes under the whole umbrella of clinical care. So under education, for example, we know that as clinicians we are supposed to be guiding our patients towards whatever it is that is necessary for their care. And many times we ourselves don't know what is needed or when it is

needed. In my clinical practice, I'm a maternal-fetal medicine specialist, but I do see women who are in the age groups of 40s and 50s. Even sometimes, we've all done gynecological care. I personally just came from the wake of a close friend, a nurse. Theoretically had access, she worked with me at NYU when I was there, but she never got colon cancer screening, passed away at the age of 62. So the education is her clinician who's a colleague of ours, OB-GYN doctor did not send her for colon cancer screening, did the pap smears, did the mammograms, did the GYN care, the vaccines, etcetera, but did not do the overarching care, access and education towards this individual.

I have a life where I had a practice in the Wall Street area. They were the masters of the universe. You may recall. They had access to money, access to education, access to all kinds of resources that many of us cannot even imagine, including company-given chauffeur-driven cars. They were underserved in terms of time, so they did not access the medical care, missed pap smears for years, missed other screenings, etc. And again, it's a mixture of what did they not know that they needed? What did their clinicians providers not tell them that they needed? Was it siloed towards the traditional women's health care topics or not? So these are examples. And my final example to talk about the challenges is I have a 27-year career in the US military, in the active and reserves. When I was with the Marines in the reserves, the highest-ranking physician in the reserve section, planning resources, supplies deployments in across the globe. I was trying to teach my partners and colleagues on that planning table in the conference room about women's needs, and I have many examples where they would choose when they were sending the supplies in the field, whether it was actual war or at a military base overseas or stateside.

They were sending ammunition, food, clothing, maps, training. But they were not sending contraception. They were not sending women's health care needs, whether they were sanitary products, etc. And you can see that these had major impacts and effects on the individual themselves. How could they do the mission if they didn't have the things they need? When their birth control pills were not available, and I would get a call at headquarters, at marine headquarters, and I would say to those enlisted and junior officers, "You didn't put in the Depo-Provera, the birth control pills." They would say, "Ma'am, I have finite space. Why would I put boxes of sanitary products or birth control pills or even Depo-Provera, which needs refrigeration when I can put that much more ammunition or other aspects of military life?" So you can see that in my experience, being civilian and military, being overseas and in the United States area, the two things that I have seen which remain as challenges are education not only for the patient, but also for me, the clinician, and also the access.

Because even if I tell a person that she needs something and that it's in her community, will she be able to access it? I need the education to know about her circumstances as well, in terms of what she would need, when she would need it. Not to mention what I've already said the overall overarching medical needs of any patient. So I have to learn it. I have to teach my clinician colleagues what are the needs? There are examples where pregnant women are punished, so to speak, because they are pregnant. They're not getting the imaging even though they needed that. They're not getting a certain vaccine. We had so many examples during the Covid time where we were struggling for our pregnant patients. They were excluded from research funding at completely just because they were pregnant. They were excluded from receiving vaccination just because they were pregnant. We had to teach our colleagues and ourselves that that was not a punishment. That was not an obstacle. That was not a challenge.

It was not a barrier. She, the pregnant mother, needed it. The final comment I would share with you today is we must always remember that in obstetrics, although it is a small window of a woman's life and we heard many examples today, but it is a major milestone in her life, and we have to acknowledge that this is one field where there are two patients. Two patients, and we, the obstetricians, have to manage both. Again, the gap in education, the gap in accessibility targets that as well. What do I mean by education? I have a list of things that my pregnant patient needs. I know that I can share it with my patient, but I also need to be educated about patient-centered care, shared decision-making. I know that that mother will decide on her care, even if it's at a detriment on her care, based on what her perceived needs are for her fetus, for her unborn baby. I need to learn that in order for me to be able to serve my patient the best that I can, I need to teach my colleagues in the emergency room, in radiology, in internal medicine, in family medicine, the needs, the medical needs of a pregnant woman, of a GYN situation, an adolescent girl in this regard.

So those are my challenges, gaps in education, and gaps in care in terms of access.

VICTOR J DZAU:
Thank you.

AUDIENCE:
(APPLAUSE)

VICTOR J DZAU:
I think you set up the conversation really well, and with your vast experience, it's really helpful to hear this. So, Mark, previous administrator of CMS and former commissioner of FDA. Broad experience in government. And now you run policy and medicine at Duke-Margolis Center. So what's your thinking?

MARK MCCLELLAN:
Well, just first of all, thanks, Victor, for putting this together. You, the National Academy of Medicine team, deserve a whole lot of credit. And all of our speakers today, and all of you who have stuck with it for the whole day, it's definitely been a worthwhile experience. I'm gonna leave... I would like to start by saying we need better evidence, especially on impact of sex differences. I'm gonna leave that to maybe you Rob to talk about more, since he's a current commissioner and a little bit more up-to-date on those issues. But I'd like to come back to that topic. These are for many of these issues we've talked about today, impact of drugs and people who are pregnant or lactating, preventing preterm birth, etc. It's really hard to set up clinical trials because of concerns that people have about potential harms. That said, for a lot of the other topics we've talked about today impact of chronic diseases or combinations of chronic diseases and so on, there is a lot of opportunity available through innovative approaches to clinical trials.

So I hope we can come back to those topics. I want to talk, since you introduced me and talking about payment, about tying in policy to all of this, especially picking up on something that Paula said this morning. Is that the evidence we do have, we're not using, and does it really matter if we haven't figured out ways to translate it into practice? And I know that the citation that's 17 years. It doesn't have to be that long. And we heard a lot today from organizations that are taking lots of different pieces of evidence, whether it's on how to manage chronic, diagnose and manage chronic diseases more effectively in women, and especially women who come from disadvantaged backgrounds, or how to address the social factors and underlying stresses that are so important for long term health or how to address loneliness. You know, those are things that our health care systems traditionally haven't paid

much, if anything, for under so-called fee-for-service payment systems, which really disadvantage women and people who are likely to have more serious issues in these areas.

But I think the good news is that we're starting to see that change. And I have to tell a story, too. You might think like this guy, what lived experiences he have for the topics today, but I got it by osmosis. So I grew up in a family with three brothers, still not much-lived experience, and a single mom who decided that when we were still in elementary school, she needed to do something to change policy because the way that they were managing the school wasn't addressing some of the education needs and so forth. And she went to a school board meeting. The male school board, all male, told her, you know, thanks very much, ma'am. We'll try to take that into account because they didn't do anything. So she decided Victor to run for president of the school board, got out there, went all across Austin, Texas, and let's go. Exactly. Got elected for that and then went on to be mayor of Austin. And there are two things that she said all along during her career. One was tell it like it is, and the other was to go in and make the changes.

So I was talking to her when I went from FDA to CMS. This was when the Medicare Modernization Act passed. How should I introduce myself to the agencies? We've got really a chance to change policy here and some new programs being implemented as well. Tell it like it is. And so my first talk as CMS administrator was to our staff at CMS, we a bunch of really dedicated professionals whose job keeps getting harder and harder. And thanks to Congress, bigger and bigger.

SPEAKER:
We do our best.

MARK MCCLELLAN:
And so I started out the talk by saying, you are the nation's largest public health agency. No offense to my friends at FDA, but, you know, CMS then was spending about $800 billion a year. Now it's up to about 1.3 trillion with the expansions and the ACA and the expansions in Medicare drug coverage that went along with the Inflation Reduction Act. And I remember seeing people look around a little bit. And when I went off the stage, my chief of staff pulled me over and said, Mark, you know, you're at CMS now, which is under the Social Security Act, not the Public Health Service Act. You know, you're not at a public health agency. But that was kind of the point. How we pay in health care matters. If you think about all of the examples you heard today of organizations that are trying really hard, as (UNKNOWN) said, it's not people, it's systems. I want to modify that a little bit. It is people. There are a lot of very well-intended health professionals, community health workers, others who are trying, and my mom said, to make a difference in people's lives.

But it's not easy to do the right thing with a lot of our payments and regulations in place today, if you want to set up a program that does longitudinal care for individuals, coverage is really important. So the ACA expansions of coverage, the more recent expansions of coverage for continuous Medicaid coverage for a year after birth, those are all important steps. But as we've seen, that hasn't been enough to reverse these trends towards increasing maternal mortality, declining life expectancy differences affecting racial and ethnic groups within populations of women. What has started to make a difference is combining using the evidence on what drugs can work, what diagnostic tests can work, with building out longitudinal care models that also ask about what's really...

SPEAKER:
Getting in the way of people fulfilling their health, and that's very often social factors, community factors where those kinds of actions to address social drivers of poor health matter, that's very hard to do under fee for service payments. And so most of these organizations that are starting to succeed are moving away from that. They're getting paid more on a person basis for longitudinal care. It really comes down to intentionality. As my friend Mandy Cohen, who was secretary of HHS in North Carolina and now at CDC says, we should be paying for health. It's a team sport, not just paying for the traditional medical services. And that is especially important, I think, for women. So we have more steps to do to get there. We haven't figured out how to make these programs work. Hopefully we can come back to talk about how. But I do wanna reinforce one more point that was made earlier today, and that's about misinformation and trust. There has been a significant decline in trust in many national institutions, public health institutions, et cetera.

There has not been much of a decline in trust in people's trust with a health professional with whom they have an ongoing relationship. It could be a doctor. It could be a nurse, they know at the hospital or clinic where they get care. It could be a pharmacist. But reinforcing those relationships to help deal with misinformation is something that goes along with these changes in payment and development of better care models that can really be accountable and intentional for improving women's health outcomes. And we're just in the early days, I think, of developing evidence on how to do this right. It's now the exception, not the rule. But the good news is, Victor, it is happening more and more around the country. And in terms of telling it like it is and making the right thing to do, the easy thing to do, more reforms in this direction, I think, can help accomplish the goals that we've set out from today's discussions.

VICTOR:
Thank you, Mark. It's terrific. And (INAUDIBLE) come back to some examples of some ideas that you have that put forward in terms of payment. We'll come back to this. Representative Underwood, you were trained as a nurse. You serve as adviser at HHS. You work for Medicaid managed care company, and now you serve in Congress. Now, obviously, all of these experiences have great influence on the way you think. And we're so thankful for what you do, because in what you've done in Congress and we continue to do, we're really appreciative. After all, I think you're bringing a really unique human perspective to these policymaking, and we thank you for your thoughtful and sane voice in this crazy Congress right now.

LAUREN UNDERWOOD:
Thank you, Dr Zhao, and thank you so much for the invitation to be with you all today. It's so good to see you. I'm Lauren Underwood, I'm the co-founder and co-chair of the Black Maternal Health Caucus, and I work with my colleague, Congresswoman Alma Adams, to run one of the largest bipartisan caucuses on Capitol Hill. We are exclusively focused on ending our nation's maternal health crisis. We know that a lot of the deaths that we see, over 80% of the deaths that we see domestically are preventable and we are so fortunate to have great partners in the Biden-Harris administration as we continue forward on our quest to get a piece of legislation called the Black Maternal Health Momnibus act signed into law. We have been working so closely, in particular with Vice President Harris. I just have to acknowledge her leadership on this issue. She's talking about it nearly every day, you know, traveling around the country and making sure that we're advancing this conversation. And we've had some big wins, right?

This 12 month postpartum Medicaid expansion is significant. We know that if we could only do one thing, that's the one thing that we needed to do. We need it to be mandatory and our caucus is pushing hard to make that happen. However, we know that maternal mortality and severe morbidity is not a phenomenon limited to low income Americans. And so we need to be advancing comprehensive legislation to address every clinical and non-clinical factor contributing to maternal death in this country. So we gathered together, many of you, we have lots of friends in this room to advise us and pull together an evidence based package. It's up to 13 bills to address this issue, and that's on top of the legislation we've already passed and gotten signed into law. That's on top of the significant funding increases. We cannot neglect appropriations and the power of federal funding to help solve some of these problems. And we've enacted policy changes, you know, pushed our friends, our regulatory friends to do more with their agencies and their current executive powers to make sure that we are pushing on every policymaking lever.

And I share that with you, because so often the voices of the leading researchers, academics and providers are not that comprehensive, right? Most of the folks in this kind of academic and research space are focused on one bill at a time, and we will never be successful. And if I'm gonna be candid, most folks are neglecting the political side of this. We are in an environment where one party treats facts as opinion, right, and are not necessarily motivated to follow the evidence. If we neglect having conversations in that context, we will never be successful in solving so many of these persistent, preventable medical challenges. And I'm in the business of trying to solve problems, and I just had to say it. I hope it doesn't make folks uncomfortable, but let's talk about tell it like it is. That's how it is. OK. So we've seen data year after year after year. We're now looking at CDC reporting over the last three, four years an 89% increase in maternal death in this country. It's unacceptable.

And we have an opportunity to drive forward change. This is a crisis that is getting worse. It's not remaining stagnant, right? And it's not even variable necessarily year after year. It is just unequivocally getting worse on our watch. And I think we can take immediate action. The solution is the momnibus and I think, you know, we have to be really clear. A lot of my colleagues, just saying, are really excited to pass what we call study bills. Let us examine what's going on. Let's study it. Let's have a GAO report and let's circle back in five years. Absolutely not. We know what's happening and we need to be courageous enough to pass the legislation that will solve the problem. Every minute we wait, moms are dying. So I'm happy to say more about our legislation and our successes. But really, when we think about large challenges over the next five to ten years, this is the horizon that we have to solve a persistent problem that's faced our country. And I'm really excited to have you all as partners in this work.

VICTOR:
Terrific. Thank you. We definitely wanna hear some more and (INAUDIBLE), especially. And of course there's things on climate. We'll come back to that. Now, Rob, as I said the other day, I've known Rob for a long time. But Rob was the founder and creator of DCRI, which is one of the largest academic clinical research organization and he was a vice chancellor at Duke when I had the chance of working with him. Mark, I say, tell us as it is, that's the way Rob is, right? Tell it as it is, and certainly willing to make changes. And now, with your current job, I certainly feel very good about our opportunity of friendship to do things together. So, Rob, tell us what you think.

ROBERT CALIFF:
Sure. Thanks, Victor. I was gonna say it's so great to be with Representative Underwood when she's not

raking me over the coals (LAUGHTER). But you notice she couldn't resist turning and saying (CROSSTALK) step it up. So I'll just note that. But I'll mention two things that are squarely within the FDA swimlane and then another. None of these will be a surprise to those of you who know me. I think there are two very specific issues within the FDA swimlane that I'm quite concerned about. We need very specific studies of pregnant and lactating women so that we understand the right doses of drugs, which treatments are effective and we need to develop products in those areas. So that's a sphere where we just don't have what we need. I was amazed my first term as FDA commissioner, they had just fixed the labeling of drugs for pregnant women and there's a nice little spot there for all the information about that's known and it's blank for the most part. And here I have to mention, I think the major problem that we have is the liability issue, which no one wants to talk about or deal with.

That's not in the FDA lane. But what we're hearing from developers is it's too risky for us to develop new products in this area. I hear from academic medical centers like the one you used to run, Victor. It's too risky to do those studies to get the information.

VICTOR:
I never said that.

ROBERT CALIFF:
But if you look at the time we're in with imaging and informatics where it is, this is the time to figure out the maternal fetal interactions in which treatments are effective and then implement those in practice. Premature labor and infant mortality, a lot of it does have to do with access and social issues. But what effective treatments do we have? Some of it is biologic and the pipeline is empty. So we've got to do something about that. The second area has to do with the fact, you know, I always feel obligated to point this out, but several have done it already today. Women are living six years longer than men on average, and the difference is widening now. What does that mean for the aging population? And I'll just point to nursing homes as a place where I think National Academies has done some great work. But I have a mother in law who's in extended care. And I'll tell you, you go in. It's almost all women. What do we know about the right care for people that are in this situation?

And it's millions of people. Does anyone know the right dose of any drug for someone who's over 80 years old, for example? I would say the answer is no. So we've got to very specifically do studies in these two areas and develop effective treatments, use the same evidence generation techniques we use. And I just wanna point out, the NIH has made tremendous progress in the gap in sex and Roman and clinical trials. We're about to put out a paper that shows basically, on average, it's 50/50 at this point. That's tremendous progress compared to where we were. But we've got to get to the next step and look at these special populations where just enrolling them in regular clinical trials is not gonna answer the questions need to be answered about them. Then the third area that really is in this hand off, I've always likened it to a baton handoff. We have spectacular biotechnology in play now that could do wonders for women and for men, but I'm very worried that what we're seeing is very much reflected.

I refer to the Washington Post yesterday. I think it should be required reading the three articles from last week. We are seeing a decline in life expectancy it's been referred to, but I'm not sure we're absorbing the magnitude of this decline. Are the difference that it is compared to other countries in our same economic sphere? We're at 76 years now and going down. I was in Singapore with John Huang, who was the co-author of the Healthy Longevity Report last week. 85, next year, will be their average life span. We've got to pay attention to this, and what are the factors. They're the old disparities that we all know

and need to keep working on. But we have this really devastating new thing happening. How many people in the audience here don't have at least a BA degree? Is there anyone with less than a BA degree? If you had less, you probably wouldn't raise your hand because of the way that we deal with this. So if you look at education and wealth, the case Deaton report that was in The Economist last week, if you don't have a BA, your life expectancy is eight and a half years shorter.

This is affecting women who are dealing with families and this whole life span that we're talking about in a major way. If we continue with this difference, according to wealth and education, we're in big trouble. And so now we have spectacular treatment for obesity and diabetes. Who's getting that treatment? Wealthy, highly educated people. They're sopping up so much of it. The manufacturer or whoever heard you make an 80% profit margin once you're on the market, they can't make enough, but it's all being bought up by highly educated, wealthy people and the people who need it the most are not getting it. Now we'll see about the Alzheimer's drugs. I'm more positive on them than maybe some other people, but if they're as good as I think they are, we've got exactly the same problem. So we've got to really, and I just refer here in closing, Victor, to your five year plan. I paid a lot of attention to it. Like I told you, you're probably gonna get accused of boiling the ocean. But I basically say that five year plan is what we need to do.

So much of it has to do with implementation, dealing with disparities, dealing with unfairness in our society, which is causing these huge problems.

VICTOR:
Thank you, Rob. Outstanding. Tell it as it is. But if I don't boil the ocean, the ocean will overtake us with the rising ocean. So, Nicole, great to have you. You are entrepreneur, investor. You're from Silicon Valley and a philanthropist. I've known you for a while, and certainly I remember the day when I met you and you talked about intellectual property as a lawyer, right? Fighting to be sure that people have access to innovation. (INAUDIBLE) recently you got really involved, you know, with women's health and particularly in reproductive longevity, right? And so you have a whole variety of perspective that you can bring to this group of discussion. So give us a little bit of (INAUDIBLE) idea of what you're thinking about.

NICOLE SHANAHAN:
Well, first I just wanna say...

VICTOR:
By the way, you're the founding of Bia-Echo Foundation, right?

NICOLE SHANAHAN:
Yes. First, I'm so grateful to be here with all of you today, to be with this incredible panel of individuals. My jaw is just on the ground with your body of work and how far you've come in each of your careers and what you've contributed to this community. So it's really, I have a funny story. It was actually here that I changed my commitment from a $10 million commitment to $100 million commitment to reproductive longevity and it occurred over dinner in about a five minute conversation I had with an international group of heads of health agencies, and they were all men, and I was pitching them on the idea of reproductive longevity as a field of science. And I thought I was doing a really good job because I saw some nods and I saw some aha's. And then I finished and the table was quiet. The first comment that came up was from a gentleman from Taiwan and he says, what about sperm? And I was like, oh,

dear, OK. And so I stood up and I, you had asked me to announce this commitment and in that moment, I changed the commitment from $10 million to $100 million, 'cause clearly we have a ways to go.

So thank you for organizing that. You know, I have a few comments to make on what I've seen and what we've been funding. Jennifer Garrison's here, who leads the global consortium at the Buck Institute. And, you know, I think I'll work backwards. But Singapore, Singapore has come up a few times today. Singapore is the only government that has matched my funds to create a center for reproductive longevity inequality. The only government and they matched it dollar for dollar. So, you know, I think this is an indication that governments that understand that lifespan really starts with the mom and really starts with healthy reproductive health. They're investing also correctly, they are investing in basic fundamental research into, you know, ovarian, really fundamental ovarian science. And when I say fundamental, you'll say, well, don't we have that completed in our corpus of science? No, we don't. We actually do not. And so when I have been hearing about the stats related to maternal deaths increasing, when I hear about breast cancer rates increasing, when I hear about infertility rates increasing, when I hear about autism rates increasing, I really have to, you know, rewind and look at what is in the corpus.

And, you know, I started as a patent researcher thinking about what people are publishing and how it's overlapping with different areas of health care. And when I looked into the patent corpus and PubMed and I really wanted to understand the fundamentals of reproductive science within women, I realized that there was such a short fall of tangible, actionable science. And no wonder you have an empty pipeline at the FDA. No wonder. So my hope is that more governments will match funds for reproductive longevity research. Reproductive longevity research I have to define right now does not include IVF, does not include artificial wombs, does not include creating stem cells that we can turn in to, or skin stem cells that we can turn into gametes. It involves studying healthy women and studying how to keep healthy women healthy longer, how to heal chronically sick women, how to bring in a generation of children with decreasing chronic illness, not increasing chronic illness. And, you know, Dr Zhao, you had mentioned that this meeting you were really trying to figure out, should we make it about climate change or should we make it about women's reproductive health?

They're the same thing. They are the same thing. The science is starting to tell us, and if we fund it correctly, it will tell us more that what is bad for the planet and climate is bad for health, is bad for women's health, is bad for children's health, is bad for lifetime health. And I hope that as a community, we can begin to make that a global narrative. Thank you.

VICTOR:
Thank you very much. Perfect comment. So I'm gonna ask one round of questions for each. Although anybody can jump in if you feel that that's also part of what you wanna talk about. And let's see how much time we've got, 'cause I'm sure the audience has lots of questions. This is your chance. They're the guys who are movers and shakers. I wanna make sure they do the right thing. So Monica, first question, of course. Being NCI director and a leading women's health researcher (INAUDIBLE) cancer, you said about maybe insufficient women's leader and researchers. But also we heard throughout the day about possibly that perhaps the understanding of women's health research and the funding is not quite there yet. Now, we had Janine Clayton, who did a great job talking about the Office of Women's Health Research, but it's not a funding (INAUDIBLE), right, institute. And when you start looking at where's women research going. For gynecologists is an NICHD child development, right? So there's a lot of push now to say maybe we should do things differently, right?

We have been asked in National Academies by Congress to take a look at women health research at NIH. They still working on it. I don't know what the committee is thinking, but we'd love to hear what you think as a leader in this area.

MONICA:
So thank you, Victor. You know, there's two ways. One way is to say we are going to create a very large and funded institute purely to serve the needs of women. Another approach is to say women are critical to NCIs research, NHLBIs research, the Genome Institute research, the knowledge base in the National Library of Medicine. Women's research belongs everywhere. So it doesn't mean a big institute can't be charged with, you know, not being a silo. It doesn't mean, but no matter what is, first of all, you know, more research, more robust work into all of the issues that are important to women and that, let me just throw that in there, because I really believe that our research has to be what is important and critical to those we serve and that means what's important and critical to women in all their diversities and varieties. So number one, focus on the women. Not necessarily that you wanted me to think differently, you know. Focus on the women, not necessarily the, well, we have this.

Let's see if it applies. Do you see what I mean? Focus on what women need and then focus on making sure that it comprehensively permeates everything that the agency does. And I don't have the best model. I think we could work with either one, but no matter what, it cannot create yet another silo because it's some named entity that sits aside.

VICTOR:
So what's interesting is actually this afternoon, I look at NIH website and look at how much funding is going to women's research. Really difficult to find out. For women's research alone,250 million. I said, wow, that's so small. But then it's embedded everywhere. That's what you're saying. But we need better accounting, better accountability, right?

MONICA:
We need better accountability for how we are addressing the needs of the people we serve at all levels. You know, women's health is one aspect of that. But, you know, we can go up and count the, you know, count the beans. This much for breast cancer, this much for cervical cancer, this much for maternal fetal health, this much for mental health issues of women. You know, we can do that and it's definitely worth doing. Again, the focus should be on what are we spending that really addresses what people need.

VICTOR:
Rob, you wanna say something. He looks as he's ready to jump in.

ROBERT CALIFF:
Well, you know me. But I mean, one suggestion I have Monica is right now, the clinical trials website is only updated every third year, and it's a shame because you're actually doing a great job. I find myself crawling your website to write good papers about what a great job the NIH is doing.

DR ROBERT CALIFF:
And you look at it over the years, it gets better and better. I think if that data was more available, people will sort of get off the old narrative and get to the next phase where there's a lot to do. But just more women in clinical trials is not the current issue. You're doing a great job with that. Well, there's a whole lot more to do beyond that. Like relevant to the diseases, the age ranges, all that needs to be dealt with.

REPRESENTATIVE UNDERWOOD:
But if I could just add, absent an institute, it's very difficult for Congress to increase funding for women's health research. It's very difficult for us to help grow the pipeline of researchers. Absent a place to directly fund. It's very difficult as someone who wants to do that. And so we have to have an entity to fund. And, you know, it's hard to divert dollars to science right now, and especially for an unspecific target.

DR MONICA BERTAGNOLLI:
Understood totally. But funding an institute, making sure that it permeates everything is what we have to figure out how to do. And that's also how we have to be accountable. So it's tricky.

DR VICTOR DZAU:
Yeah. I mean that clearly is the issue, isn't it? Right? You do want to have total emphasis in this area. But when you start thinking about, you know, different diseases, different health areas, you want it to be also within all those spaces as well, alongside also studying total health and men's health. So how do you do that? Well, you guys got the big job to do.

DR MONICA BERTAGNOLLI:
Well we look forward to the advice that the Academy will bring us.

DR VICTOR DZAU:
OK. We do our best.

DR MONICA BERTAGNOLLI:
Yeah. Thank you.

DR IFFATH HOSKINS:
If I may add something for Doctor Monica, you know, funding, women's research, et cetera, I agree, but again, in my day job of being maternal fetal medicine, to put in a research program for a pregnant woman is a whole different set of hoops and obstacles and clarifications that are needed. Rightly so, there are implications of our trials, of our research, etcetera. So that's one other area that currently is lacking that we don't have that much in the field of obstetrics as a subset of women's health. And we need to have a little bit of focus there and even guidance of how do we create an application, how do we create an idea and move it forward where it is including a pregnant woman through whatever medical issue or some other study, whether it's a PCORI type thing or where you're looking at community, whatever it may be, but that's a subset that needs a little bit more tweaking.

DR VICTOR DZAU:
I agree with you. I think sex as a important biological variable should be in all research, but there may be special conditions where you need to focus more, and that's going to be maybe the nature of some emphasis within the area. So I want to ask you, I'm going to come back to you, Rob, on this issue, but I want to ask you about education. To begin with, you know, I mean, most of the care are given by primary care givers, internists, geriatricians, you name it, and the question is, are they well, actually instructed and trained in this area? After all, you heard earlier discussion that when you look at curriculum, when you look at training, you know, it's mainly focused on the information on men, right? So what do we need to do in this area? And I have a second question for you.

DR IFFATH HOSKINS:
Whoops. So in terms of training there's, I'm going to answer it in two components. And one is, first let's train ourselves the Ob-Gyn specialists serving women's health care and then the additional parts of the team. Because actually women do see their Ob-Gyn doctor, but there are many, many touch points like the emergency room, like internal medicine, like family medicine, even the pediatrician, a person may go in there with when she is taking their child and they may say, I have a medical issue et cetera, et cetera. But when we focus on the Ob-Gyn aspect, our training is from years ago, so we have not been able to catch up or maintain. There's so much more information, there's so much more complexity in our patients. Simple, simplistic examples like a mother is older when she might be having her first child. Therefore she has more comorbidities et cetera. They may have other comorbidities like the cancers et cetera and they are also coming for gyn-care or they are pregnant et cetera.

Our training is been the traditional model of approximately 18 months or 20 months of obstetrical care and equivalent in gyn-care when you correct for a lot of other factors which take away time. The knowledge and the complexity has gone so fast and advanced that we cannot provide the scope and breadth of that kind of training for this small window of time. We also know from workforce studies that many of our graduates, in terms of Ob-Gyn, do not go into general Ob-Gyn, many of them choose to subspecialize in one area or the other, yet we are using up the foundational months to give them the overall scope of the field. There are many advantages to that, but the disadvantage is that they're getting less time, less experience within that particular future or current chosen area they will be. So now the thing is, how many years of training should we have and what should we stick into those years? It clearly is different across the world. In Sweden, it's like five years or six years, United Kingdom up to seven years.

We have four years of training in the United States for ob-gyn, not even for the other ancillary people who also provide women's health care. So in those four years, we are not able to give them the training they need that's even outside of the legal ramifications and obstacles that we are facing currently. So we do need to come up with ways that in that window of time, they would be able to get the scope and breadth of that training in the areas of surgical expertise, in the area of clinical and didactic expertise. Very quickly, the other part is, we are lacking in telling a teaching the concept of the whole patient, shared decision making, patient centered care, ethics, legal, it's all coming together as one whole and by the time we finish teaching the surgical procedures, which we are not able to get the desired numbers anyway, while we are teaching all those other things, we are not able to do everything in all aspects of it. Having said that, this is in Ob-Gyn. Now you look at internal medicine, emergency medicine, radiology, other fields that also touch on women's health.

They have to learn their own areas as well. Plus we have to teach them the importance of women health care needs. So I think that ultimately we would have to over educate and spread our education through simulation, through 3D modeling, through other very, very innovative areas where they can, and different people learn differently. So that's a whole other discussion. But overall training right now has many gaps, has many needs. We are not fulfilling any one of the aspects well, we're trying to do a lot of things for a lot of aspects of women's health care. And sometimes we get good enough for government work and some sometimes we miss.

DR VICTOR DZAU:
Iffath, I do have to ask you this question. State restricted abortion is really changing the workforce in a

big way, right? Both in terms of the practice, right? Now we're talking about state from state to state fragmentation, the concern about legal actions, but also the trends of the match. You're getting fewer and fewer people entering Ob-Gyn and more and more people leaving the trigger states. So just a short answer.

DR IFFATH HOSKINS:
OK. First of all, I'll give you some facts. Approximately 43 to 45% of our trainees currently are being trained in areas that already have restrictions on the aspects of reproductive health care. So if you just take that one simple area, they're getting trained in various aspects of women's health care, except an essential aspect of women's health care, which is abortion training, contraception, reproductive health care. So they, if they stay within the community where they are, clearly they're going to be gaps and inabilities to practice that and therefore to provide for their patients. If they move somewhere else, they will not be adequately trained to be able to provide what the patients need. These are raw numbers, and they're real numbers. In terms of people choosing where they will try to get their training in terms of the match, they are looking at aspects of reproductive health care, in making their choices, in terms of being present in a location which we call a trigger state, where there is restriction on reproductive health care, restriction for abortion, etcetera, they are saying as soon as I finish, I'm out of here.

And one thing we need to consider is, it's not only OB-Gyn, it's not only abortion care. I, in my capacity last year as president of ACOG, would get calls from dermatology saying, "I can't give my patients methotrexate." I would get calls from individuals who were taking care of arthritis, saying, "I can't give my patients these medications because of the restrictions of the drugs." Et cetera, et cetera. The general surgery, people were saying, "we can't manage these patients who are coming into the ER, especially in rural areas, because there's these restrictions about the heartbeat and the fetus." Et cetera. So the problem is in terms of training, that it is making tectonic shifts within our work force. And on top of it all, is what you've heard today about the mental health aspects. I am fully trained in Ob-Gyn, I have the right to provide all aspects of Ob-Gyn care to every person who seeks Ob-Gyn care from me. If I am restricted, when I know that's what they need and I'm not able to give it, that's a burden on me emotionally as well.

I have talked to clinicians who have PTSD, I have talked to clinicians who are heartbroken because they they say, "I know my patient needs this." Very quickly, one quick story. A colleague calls me and says, "18 weeks ruptured membranes, there's a heartbeat, I can't intervene. When I do the ultrasound there's no more chest cavity. It's gone. It's all reabsorbed. But I have to continue this pregnancy." So there's concern on all sides.

DR VICTOR DZAU:
These stories are now getting better and I didn't known. I think the whole issue about solutions, which I think may be very difficult to discuss in a short time, but certainly I do think that people have to be aware of this big problem. And as a profession, we need to really take a position on this.

DR IFFATH HOSKINS:
I think we have a concept called 'Document the Harm'. Tell the stories.

DR VICTOR DZAU:
Exactly. So that's actually later about data. Mark, so you actually have a proposed payment reform, right? An alternative payment for perinatal care.

MARK MCCLELLAN:
Well I don't think it's going to solve the problem that you were just discussing.

DR VICTOR DZAU:
But tell us about some of the payment models, particularly what you did in North Carolina with Mandy and others. Yeah.

MARK MCCLELLAN:
Well, so I mean, this picks up on things that we've talked about all day long, and maybe we can come back to this very difficult issue where I don't I don't see an easy solution, differences in values that I mean, we're seeing this in North Carolina as one of the yellow states on the kind of the KFF map earlier. But where there is some more common bipartisan ground, kind of many of the areas that your bill is focusing on, we heard earlier today about a number of collaborative efforts around the country, like the California Maternal Quality Care Collaborative, there's others like it. Your bill would or your set of bills would help advance those efforts that combine the attention to more high quality longitudinal care for pregnancy and what comes after pregnancy, which remember a lot we heard about earlier today. A lot of the maternal mortality is not within, you know, the first week or even the first 60 days, but you know, after the first year. So, that are moving in the direction, well, how do we support and make those kinds of models, you know, the right thing, the evidence based thing, the easy thing to do?

So there are a number of states, including Connecticut, Pennsylvania, others that have implemented in Medicaid, payment reforms that that try to put together funding, that organizations that that are willing to take on more accountability for the, for the new moms whole prenatal and postnatal care experience, including the perinatal care, in a more coordinated way that gives them a way to sustain that approach. That the early versions of these approaches, not just Medicaid plans, but many employer plans, focused on things like quality improvement that could also lower costs, like, why do we see, and we do respect the Ob-Gyns, you know, 50-100% variations in C-section rates from state to state and community to community. They now are focusing much more on the deeper issues that really affect health outcomes as well. Like for women who are having difficulty accessing prenatal care and finding ways to go out and engage them, we talked earlier today about how community participation is really critical for making sure that lived experiences are incorporated in care models, and especially for people who don't have regular connections to care, which is, you know, half of women under 65 who don't have a diagnosed chronic condition, don't have a regular longitudinal primary care relationship.

40% who even have a chronic disease don't either. So how do you get out in the community and support all of that? Well, it takes resources. It takes a team-based approach to care. It takes a really knowledgeable Ob-Gyn helping at the center, but also community health workers, data systems that match up information that states might know about someone having difficulty with housing or having difficulty with interpersonal violence, ten times more likely in women, that we just haven't had systems in place to support people doing the right thing and delivering care in these models. And so these are still Victor, early on in implementation, but are showing signs of doing things like better job of screening for and then dealing with risk factors during pregnancy, dealing with social needs like food insecurity, housing insecurity, interpersonal violence. And this is something that I think has a lot of potential for bipartisan support. North Carolina just expanded Medicaid with actually more Republicans voting for it than than Democrats.

That came about because a big part of the presentation of the coverage expansion was that this is about, you know, more continuous coverage the year after childbirth and more continuous coverage for women and families generally. But it's really about making progress on things like those maternal health outcome trends that are really worrisome, as well as the risk factors during pregnancies that are not well addressed, sort of mortality, they are not well addressed in our traditional kinds of models. So North Carolina and the Trump administration got some underlying reforms approved, like a healthy opportunities program that involves setting up statewide networks that connect community based organizations to health care organizations. The health care organizations have the relationship and the trust to often screen people for needs, but don't have by themselves the ability to do something about it. Set up a program called Integrated Care for kids, which is working with the communities in a way that hopefully is building trust.

There is a lot of distrust out there, bringing together data from schools, from social service programs, from juvenile justice to help identify kids and families who are at risk and connect them with supports and bring in some accountability, frankly, for the pediatricians and the Ob-Gyn to make sure these problems are getting addressed as a team. We're still in early days of implementing it, but I have to say one of the big selling points for the Medicaid expansion was, look, we'll be able to bring in the mom and the whole family, not just dealing with this as a kids only problem and expanding these efforts. So early days, Victor, but I think there are a lot of opportunity to make this kind of approach to care the norm, not the exception, and make it much easier for everyone here who is trying so hard to address these underlying health inequity issues, to do something about it. And by the way, these health systems that are tracking patients longitudinally are a great place to do, not to not to add on to the NIH oversight hearing here, but a great place to do practical clinical trials in real world community settings where we can actually collect reliably the data that you need, and you have the trust and ability to enroll patients in closing, some of these evidence gaps.

DR VICTOR DZAU:
Well, you know, earlier, Paula Johnson's optimism. That certainly sounds very encouraging. Thank you. And so, Representative Underwood, you started telling us about that 13 bills.

REPRESENTATIVE UNDERWOOD:
Yes.

DR VICTOR DZAU:
Right? Now we want to hear how much momentum and what are your main goals.

REPRESENTATIVE UNDERWOOD:
OK.

DR VICTOR DZAU:
And I do want you to say a word about climate because you have them on your goals.

REPRESENTATIVE UNDERWOOD:
Yes. So let me just start out by saying that ending our nation's maternal health crisis is not a partisan issue. We can call it bipartisan if that makes you feel better, but it speaks to a core American value, which is that in 2023, we should be able to keep moms alive during and after pregnancy. And that, you know, that should not be just a privilege of the few in this country. Right? And it doesn't matter what side of

the aisle you sit on, most of us can come to that place and affirm that we want to be a place where moms can survive pregnancy and childbirth. OK. And so, (APPLAUSE) I think what you've heard is that we have so many examples across the states of models that work. What the barrier has been is funding in many examples. And so the first thing that you raised was California's Perinatal Quality Collaborative, that is funded through an existing authorization to CDC. And so what we've been doing is every year just increasing that amount a little bit over time. Why? Because it takes $1 million for a state to set up a PQC.

So why don't we just get them $50 million so we can get it in 50 states. Right? We are working on that every day. But we don't have some lobby out there pushing my colleagues forward. Right? And so we are small but mighty doing this work. But it's not a mystery on what the solutions are. We know that there's great models in the States for Medicaid plans to be able to do more to serve the families that they touch. We have a bill, Impact to Save Moms that Jan Schakowsky leads to scale up CMS's ability to more robustly fund and do this work for the state Medicaid programs. That's in the Momnibus. We have the Social Determinants for Moms Act, which addresses housing and nutrition and transportation factors that are contributing to preventable maternal death in this country. We pulled out the weak expansion, which we want to expand with to six, right now, six months for mom, 12 months for baby to 24 months for both. Why? Because no one should be going hungry in this postpartum period in the United States.

Now, the split screen is we're having a fight over the farm bill. We're having a fight over the ag FDA bill, right? Which they want to cut. They, you know who they is by 30% or more. Right? But what we're trying to do is get folks the food that they need to thrive. That's it. In the omnibus, we have the Protecting Moms and Babies Against Climate Change Act. Why? Because in June of 2020, in phase one COVID, OK? JAMA, some of y'all smart folks out here, JAMA put out this article that Bruce Bekkar and his colleagues wrote talking about the impacts of extreme heat and air pollution that contribute to negative maternal and infant birth outcomes. And we realized, oh my God, we miss climate change in the first Momnibus. So we wrote another bill and we added it into the package. So when I say it's comprehensive, we are reading what you were publishing, and we are turning that into legislation, and we are asking for your help to talk to my colleagues on the other side of the aisle in the United States Senate, so that we can get this package that costs $1.3 billion over ten years funded to do the work that he was just talking about in the States, we are funding community based organizations who, for many of them, have never been able to access federal funds.

Surprise. That requires a new authorization, right? Because many of these agencies HRSa, CDC, CMS can't necessarily just fund that excellent community based group in Philadelphia or that incredible rural group in Arkansas that's focused and trusted and leading in this community based effort. We want to unlock the possibilities of federal funding to touch the American people and save lives. We cannot do it on our own. So Dr Dzau, thank you for this opportunity to give my commercial pitch, but I want you all to hear me when I say I need your help. You are from all 50 states. You have one representative and two senators, and they need to hear from you on this priority. This women's health priority. We can get it done. It is dealmaking season in the Congress. It is. And we want this attached. Thank you.

DR VICTOR DZAU:
We got your message. (APPLAUSE) So, Rob, so much to talk about. I'm not even sure I can start because you did mention pregnant and lactating women. You did have a draft guidance, but nothing's happened, I think. And the question is, what's next? But I have a few more important questions to ask you. Even, I mean, this one is important. You know, you mentioned about the pipeline, and I'm going to ask Nicole

that question as well. But I think you also mentioned the fact that the pipeline is driven to a large extent by having a market to a more wealthy clientele. Did I get it right? Right. So we have just released a report about a framework for equitable innovation, which argues that equity should be in every part of an ecosystem of innovation, in which one would argue that when you write a grant or when you go to FDA, just like you ask for diversity in clinical trials, you can make that kind of a condition to look at consideration. Talk to me a little bit about how you think.

DR ROBERT CALIFF:
OK. How do I say this nicely? I'm full of bravado, when I go around the world representing the FDA, the US is number one in innovation, creativity, developing new technologies, we're doing our job at FDA. What's wrong with you McClellan. Inequity is built into our payment system.

DR VICTOR DZAU:
Yeah.

DR ROBERT CALIFF:
Why is development occurring in cancer drugs? Well, the science is there, but you make money. If you can do a net present value calculation, you don't even need an MBA to be able to do that by the way, it's pretty easy to do. You know, why certain areas are invested in and others are not. What's our pipeline in mental health? We had this great story of ketamine yesterday. But you know, the need in mental health is staggering right now. There's almost nothing happening in this field, relatively speaking. People are going in the US to where the money is, and so we can do the best job in the world that the FDA. But unless when we hand it over the transom to other people, something differently is done about where the money is. These gaps that we're seeing, I mean, who would have thought we'd be at 76 years and going down in the United States in life expectancy? And that the biggest determinants are becoming now what your education is and how much money you have. So something's got to be done about this.

It's not the FDA's swim lane. There is an intermediate step that both Mark and Monica are involved in, we do, one way to look at it is, well, here's the way I say it...

ROBERT CALIFF:
Most people around the world, and you know, I've done multinational clinical trials my whole career. They just say, "If you just had a primary care system in the US like we have, you'd be fine. It's not fancy." You know, UK, by the way, doesn't have great health records, despite what people say. They do put things together, but they're unlike their ninth iteration and they're going to pay. You know, I don't know, Peter Thiel, some huge amount of money to try to fix it, but we're so much worse because we don't have a primary care system. But US would never do it the easy way. So, what we've got to do, and this comes out in article two of the Washington Post, where it compares policies of states beautifully. If we do trials that show what works and then we implement what works, people actually live longer and have better lives. As simple as that sounds, that's basically the story. That's not what we're doing. We don't have a system geared to where the needs are. We have a system geared to where the money currently is to add more money to those places.

And it's devastating to this country right now. I hope I'm clear enough about that.

MARK MCCLELLAN:
Can I put a little bit more optimistic spin on this maybe.

VICTOR DZAU:
OK, go ahead.

MARK MCCLELLAN:
So, first of all, back to your question about pregnancy and lactation testing. FDA is making more progress on that. At Duke-Margolis, we had a meeting with FDA several weeks ago over two days, encouraged people to to Google it online, where FDA presented a framework that is building on that draft guidance for how to develop better evidence. It's hard to do the clinical trials, and it doesn't get to the liability issues if you did have some kind of protection.

ROBERT CALIFF:
(UNKNOWN). I really appreciate the comment about you got to go through 15 extra things and there's liability. So, we actually have to address those things. But...

MARK MCCLELLAN:
Yeah. But there are some good ideas out there for doing that and for using real world evidence and some of the kind of clinical trials that Rob was just talking about. But again, not very many people want to be randomized and want to try out new drugs if they don't know they're safe in this particular setting.

ROBERT CALIFF:
I think, that's wrong. Well, I think, people don't want to do the studies. Almost everyone, if they're approached by their doctor and says, "I think, it's a good thing to be in this study." The vast majority of people will do it.

MARK MCCLELLAN:
Maybe both and, but back to the drug access issues, where right now, look, we've got a situation where prices are really high and utilization is pretty limited. And unfortunately, I think, we are kind of building that into our public health policies. This isn't only a women's health issue, but if you look at, say, the current CDC recommendations and pricing related to COVID boosters, the new RSV vaccine, the RSV monoclonal treatments for newborns. In all those cases, CDC has said, you know, for widespread use. So, essentially for the COVID vaccines, you know, 300 million plus Americans. Well, the price is about an average of $120 per dose. It's not hard to do the math and say like, "Well, if everybody who was recommended to get it was getting it, that's $36 billion." But the manufacturers know, Rob, they're not going to get anywhere near that. Why? Because we have a delivery system that's not really good at getting the right treatment to the right patient. There is a deal to be...

ROBERT CALIFF:
We're spending $4.3 trillion dollars. (CROSSTALK).

VICTOR DZAU:
I'm going to let Monica jump in.

MONICA BERTAGNOLLI:
OK, I'm going to jump in because I think I have something that all three of us agree on. Our ability today to gather the evidence that we need, tied to outcomes that matter to patients is one-tenth or less of what should be.

MARK MCCLELLAN:
And deliver that reliably.

MONICA BERTAGNOLLI:
And deliver that. And it's not only the evidence that we need to understand what works, it's the evidence that we need to understand how to deliver it to this diverse population that we serve. And we can do this, but it will take coordination and cooperation...

ROBERT CALIFF:
Come on Congress. We need an NIH director.

MONICA BERTAGNOLLI:
Right?

LAUREN UNDERWOOD:
That's the Senate. That's not the House. We're working on a speaker in the House. (LAUGHS)

VICTOR DZAU:
OK, so... (LAUGH)

MONICA BERTAGNOLLI:
Awesome.

ROBERT CALIFF:
Let me just say, I love arguing with Mark, but he is an eternal optimist and I'm very grateful that we have an eternal optimist.

VICTOR DZAU:
But I do have a dream. I talked about this today that, in fact, we start having a culture of equity in the entire ecosystem of innovation.

MONICA BERTAGNOLLI:
There you go.

VICTOR DZAU:
Starting with the way we do research, designed clinical trial, going to NIH grant evaluation, as well as going to technology transfer and hopefully to get our partners in the private sector to come along with this. I mean, at least, I have a dream. I'm working on this. So, anyway, I do want to ask Rob a quick question, but very short answer. All the legal actions that's targeted to you at the FDA, right, and my friend Preston and others, how do you actually see this and how do you address this?

ROBERT CALIFF:
Well, FDA, as you know, is full of people who follow rules and so, all we can do is do our job according to the statute as it exists or (UNKNOWN) Preston. Full-time civil servants with no conflict of interest, evaluated the data, came to a conclusion. We re-evaluated, came to the conclusion again, that's our conclusion. We can't control the courts, but we do have to follow orders from the courts, legally. That doesn't mean that there aren't administration strategies which I can't discuss, as you well know, to deal with all this.

VICTOR DZAU:
I do want to thank you for the first over-the-counter birth control in the United States. (APPLAUSE)

ROBERT CALIFF:
It's in the FDA mission that people should have access to therapies that are shown to be safe and effective for a given indication.

VICTOR DZAU:
So, Nicole, perfect Segway to you. First of all, we talked about pipeline, right? We talked about equitable access, equal access to new innovation that can help reproductive health and then Representative Underwood talked about climate which is an environmental factor, right? So, say a few words about how you see the whole industry bringing more people into this research, creating more equity and make products as really affordable.

NICOLE SHANAHAN:
I have a happy statistic to share. So, the Buck Institute has been underway since 2020, and they implemented, under Jennifer's guidance, a new institutional and gender bias removal process. So, they taken out anything that would indicate institution or gender from any application. The results were pretty interesting. Total for all grants awarded 34 women, 17 men, 67% were women. So, I think, that's pretty great.

VICTOR DZAU:
Yeah.

NICOLE SHANAHAN:
Yeah. And it was thorough, I mean, it went through several layers of peer review and you know, I think, what we have right now is a field that is growing. And it's an interdisciplinary field. It's not just people who identify as longevity scientists, it's, or women's health scientists or reproductive scientists. We've brought in scientists from cellular biology, biochemistry, neuroscience, physiology, stem cell biology, microbiology, developmental biology, evolutionary biology and systems biology. So, that, I think, you know, small win, but maybe this is something that, you know, private sector we kind of, you know, put it out there, hoped it would work and it seems to be working. So, the other thing I wanted to mention about research and funding is it is a lonely place to be a funder right now in fundamental science and to have no conflicts. You know, I got a divorce. I have less conflicts now. So yay for me. But... (LAUGHS) I had to throw out a joke. OK, so, there are so many private foundations that have so many conflicts.

And so, it makes, you know, financing these clinical trials and financing these targets and drugs a little bit, in my opinion, untrustworthy. So, what I would like to do and try out is funding clinical trials that truly are for interventions that cost no money. And one of those is sunlight. I'm not sure that there has been a really thorough, like mitochondrial respiration study on the effects of two hours of morning sunlight on reproductive health. I would love to fund something like that. (LAUGH) Yeah, yeah, let's do it. So, you know, interventions that really actually truly cost no money, you know, an employer benefit of, you know, two hours out of the workday to be outside under the direct sunlight. I just have an intuition that could be interesting and maybe work and help. I don't know, you tell me, you guys are the experts.

VICTOR DZAU:
No, but I think, the story that you have certainly taught me is as we talk about climate and environment,

all these things matter. If you spend more research on those areas, you could improve reproductive health and other areas without the need for high expensive drugs. So, we need to do the research to find the evidence.

NICOLE SHANAHAN:
And just one last thing. There's a new movie out called Common Ground. It's the sequel to Kiss the Ground. It was a documentary about regenerative agriculture and the impacts on human health. It seems to me that agriculture is kind of our triple win in medicine. You get nutrition, you get increased maternal success, you get childhood nutrition issues addressed, and climate because soil sequesters carbon. So, one thing is out there.

SPEAKER:
Exactly, exactly. So, now we have a little time for questions from the audience. I see Ravi over there first.

RAVI THADANI:
Thank you, Victor. So, Representative Underwood, I just want to highlight that your sphere of influence is actually larger than you might think. My name is Ravi Thadani. I'm from Emory and my colleague and I, Ananth Karumanchi developed the test for pre-eclampsia that was approved in May. And we could not be more thankful because of people like you and pushed from Paula and others that we did this. So, (INAUDIBLE), what is my issue here? Because I should be celebrating. We made the discoveries for these markers 20 years ago and 15 years ago. We thought, fantastic, we would actually go to industry and develop these markers. Industry told us that the studies to do were too expensive, the return on investment was too low, and in fact, obstetrics is one of the most highly litigious environments there is. It wasn't until about four or five years ago where we were more senior enough, and we're in senior positions that we decided after much frustration that we would actually go to the FDA ourselves, meaning from academia.

So, you can actually pat Rob on the back because we went to the FDA and we said from academia, we want to fund the study, we want to conduct the study, we want to finish the study, we want to collect the samples. And we then want to share the samples with five industry partners because they didn't want to do the study. And the FDA said, "Go ahead." They looked at our study and they said, "Complete the study and give it to five companies and let them get this test approved." We finished the study actually during the pandemic, and we published it in one of the New England Journal online journals. And again, we're celebrating and we went to the five companies. And the five companies said, "Fantastic, you completed the study. We didn't have to put a penny into getting the study completed, but it's too risky." Obstetrics is one of the most highly litigious environments that there is. It wasn't until one company stepped up and working with the FDA and ratcheting a number of, or including a number of risk mitigation strategies that one company decided that it was going to take the risk.

It took us 15 years to get to this point. What we don't want to do is take us another 15 years to get to a therapy. Help us. You ask for what you can do. That's where we need help.

LAUREN UNDERWOOD:
Well, Dr Ravi, thank you for your persistence and your dedication. I know that there are so many moms and so many families around the country who neither of us have met, who are going to be celebrating the opportunity to get the information brought about by your Science and discovery. So, thank you. We have a bill called Tech to Save Moms. It is bipartisan in the Senate and now the House. And we are

working very hard to get that across the finish line. It is not about making improvements to the FDA. But it's about once there is a technology that's brought to market, making sure that we are not limiting the access to only the wealthy, well-connected and people who can afford on their own. And so, we'd love to be able to share that information with you. I don't have a team today, but I can see you after the panel to make sure you get the information about that legislation.

VICTOR DZAU:
Thank you, Ravi. Gill?

GILBERT OMENN:
So, it's been a great day and congratulations to this panel. I, despite the (UNKNOWN), I just want to lay a seed on a topic that has not come up today, which surely contributes to our large numbers of people with extended lifespan. And that is millions of people in chronic pain and dementia and other conditions in ten states, through the efforts of Death with Dignity and Compassion and Dying, there are legal structures for assisted dying. But in the rest of the country, it's apparently an unspeakable subject and certainly, it seems in Washington DC. Does anyone think that's a subject worth discussing at some future meeting?

VICTOR DZAU:
Well, thank you for raising this. I don't suppose anyone respond?

ROBERT CALIFF:
Anyone who hasn't been in a nursing home lately or extended care facilities should go and stay there for a while and it would be hard to say you should, we shouldn't be discussing it.

VICTOR DZAU:
Yeah. Thank you, Gill. Excellent. Question.

JOIA PERRY:
Yeah, I'll just be quick. So, to Rob, the, I was at LSU in medical school and residency when we got preeclampsia preterm labor and antibiotics. So, it was so exciting to get 30, 20 something years ago to have antibiotics as a treatment for preterm labor. And yet that was like the last big innovation and people fight about that now. So, to your point, we are mis looking at risk. So, we believe the current system, the risk is if we do something, we'll be sued for malpractice. And we have a large thing when it comes to malpractice, the money would just move. So, if there is a risk from doing studies on pregnant people, you would just move those lawsuits from the current way they're currently being litigated, because we're killing people with our current way that we're administering care to actually being sued over people participating in studies. So, when you talk to your colleagues at Duke and other places, just remind them that we are still misaddressing risk. And we're holding on to data from 30 years ago when they were excited to have some information, and they're not doing that anymore.

So that is my statement.

ROBERT CALIFF:
You know, I almost had Senator Murray in 2016 with a bill to create a safe haven for research in pregnancy for just this reason. I'm glad it's come up like three or four times already. Victor, I think, this is a great thing that National Academy could tackle. It's hard for me at FDA to talk about anything that would limit liability, but if you could objectively, I think, you'd find almost everybody in the field would

say whether it's liability and developing even a diagnostic test. But then you go to do a clinical trial and if something goes wrong and then people say, "I don't want to take that risk." And then you're stuck with the same old practices.

VICTOR DZAU:
Yep.

LAUREN UNDERWOOD:
If I can add. In August, there was just a new drug that was approved by the FDA to treat postpartum depression and it's a pill. It had been an infusion, and the access was limited because there's so few inpatient infusion sites around the country that are willing to take someone for postpartum depression, that it's just an asymmetric financial proposition. And so, this can revolutionize care. And the CEO came in to talk with me about it, because in this country, the leading cause of maternal death is the combination of suicide and overdose, substance use disorders. And while this is explicitly, I think, only approved for postpartum depression, that could be a major advancement in halting the quick acceleration to suicide ideation and suicide completion. And so, while the landscape is bleak, I just think that we should celebrate this small advancement of a, you may listen, I give Dr Califf a hard time sometimes on these things.

ROBERT CALIFF:
Oh, really?

LAUREN UNDERWOOD:
Yes, he knows it because, you know, I sit on the subcommittee that funds his agency. But this is one area that's very exciting and I just think it's great that we were able to get it to market. And you know, maybe they can have a competitor and maybe, you know, we can have some robust innovation in postpartum mental health. Because this is what's taking our moms right now in the United States across race and ethnicity.

MARK MCCLELLAN:
That's right. And OUD are huge issue. And getting access to OUD treatment and pregnancy care is really, really hard. CMS has a new initiative on that. The maternal opioid misuse program that not many states have taken up yet. But I just say one thing, one of the best things about being at FDA, hopefully you feel the same way too, is that you go into your office every day knowing that no matter what you do, you're going to be criticized. (LAUGHS) So, you may as well do the right thing. And the serious side of this, though, is that FDA's authority, which is really important for predictability about doing clinical trials. And not just doing the trials, but then putting the drug on the market, having it out there and used by diverse populations is that it's facing pressures on two sides. You mentioned the mifepristone approach, where people who don't like the conclusion are directly questioning the FDA's authority and you know, I know the judges are, you know, they're well-intentioned. They know a lot, I guess, and, but they don't have the whole infrastructure and support and experience and expertise that the FDA has.

We have one institution like that on the entire planet, and that's the FDA. On the flip side, remember, the flip side challenge is civil liability, where basically what's behind all of these product liability cases is saying that the FDA wasn't regulating properly. In other words, the company should have been doing something more above and beyond what was on the label to assure that safe and effective use of their product. Both of those are real threats to predictable, reliable drug development. There is a better

solution, which I think, actually, Rob, would be more resources. More support for the FDA to handle all of these issues effectively in return for some protection for on-label uses from liability and also for the clinical process.

ROBERT CALIFF:
You know, I can't advocate for funding. I was going to comment to the congresswoman, though. Our budget is right here and the Agriculture Department is way up here.

LAUREN UNDERWOOD:
That's true. But we give you equal attention, sir. Yes.

VICTOR DZAU:
Well, you know, you guys can go for a drink and both of you are from Duke like me. We can get together and chat about this. Question.

TAMERA LYNN:
My question is actually follows on what you all were just talking about and a little bit different from what we've been talking today. It's an issue that's directly impacting women in my. Given the problem that generic medications have faced, valsartan and lower statin are the ones I was thinking of specifically. What steps is the FDA taking to ensure domestic supplies of generic medication is safe when it contains the right amount of medications for each of these products?

VICTOR DZAU:
Why don't I do this? I'll take a number of questions so that we can answer this way real time. I think next is Carlos. Carlos, make it short.

CARLOS DEL RIO:
I don't have specific question. Just to mention that last year, the National Academy of Science Engineering Medicine issued a report. I was part of the committee, and that was requested by Congress on improving representation of women and minorities in clinical trials. And a lot of the things that we're talking about, how to increase representation of women, including pregnant women, are in that report. So, I would encourage Congress to read it because they're very clear things that can be done.

VICTOR DZAU:
Actually, for correction, the pregnant piece needs much further work from the report and in fact, HMD is having workshops on this. Yeah. Is that what you're going to talk about, Monica? Just say quickly then.

MONICA FEIT:
Yeah, I was just going to say we've conducted... The Health and Medicine Division has conducted a workshop on this issue, and we have a consensus study underway right now that's looking at a legal framework to address some of these issues. So, stay tuned.

VICTOR DZAU:
Excellent, OK. So, let's take another question and then we can answer both of them.

SPEAKER:
Sure. Just a quick comment and question. In many states, the leading cause of pregnancy associated deaths has now been labeled specifically as drug overdose. In addition, state level policies and at the local level are specifically punitive towards women of reproductive age affected by substance use

disorders. I'm a clinician and I work in a safety net setting. Our total budget is extremely low and it's dependent upon soft money. Specifically, federal government policies are not designed to affect state level policies because they've specifically been designed to leave states with discretion of how they affect these women at that individual level and community level. My question really is, is how do we look at child welfare policies and how they affect these patients? And have we looked at the research that's been specifically recently released that deters these women from seeking prenatal care and substance use disorder treatment, and how it actually leaves them unhoused, without, you know, community of support and unwilling to come into our health care systems to receive care.

VICTOR DZAU:
Thank you. Yeah, terrific. So, Rob, anyone want to address both those questions? Yes, Representative Underwood.

ROBERT CALIFF:
You are you talking about which question?

LAUREN UNDERWOOD:
The drug, the safety of the FDA.

VICTOR DZAU:
The first question is a generic.

ROBERT CALIFF:
Generic drug safety. I personally take valsartan and generic drugs are safe. I'd refer you to my, not my, the FDA's website, where we recently put up a whole tutorial on drug safety. I'm much more concerned about the drug supply. We're having real serious supply chain issues in the generic drug industry. And so, anyway, it would be a long discussion to go through the whole thing.

LAUREN UNDERWOOD:
And I support a public health approach to addiction and substance use disorder. We need to remain firm, even in the face of really tragic stories where it's easy for people to get wound up and try to just, as they say, lock them up. This is not the way to keep families together and build strong, healthy communities. Separately, I would direct you, I'm sure you've read it ma'am, an article in the New Yorker from this spring around postpartum psychosis and the really unique challenges there. And this is why I believe we have to be intentional about growing and diversifying our workforce. And when we have these trained clinicians who are experts in postpartum mental health disorders beyond depression, right, which in many cases primarily care can manage, they have to be willing to practice everywhere, including in our rural areas. And I recognize there are systems level problems to getting these kind of specialists into these communities. But the absence of providers is also a tremendous driver in the overcriminalization, particularly for new moms.

We got to be able to get people in care or else they end up in jail.

VICTOR DZAU:
Sorry.

SPEAKER:
Yeah, thanks.

VICTOR DZAU:
No, I was...

IFFATH HOSKINS:
I was going to answer the substance use. That's fine.

VICTOR DZAU:
Can you be very short?

IFFATH HOSKINS:
Yeah, I'll try.

VICTOR DZAU:
OK. (LAUGHS)

IFFATH HOSKINS:
So, the substance use. I just want to remind us that the place where the patients touch the health system is usually the emergency room or with the internist, which you were talking about, Dr Dzau, that, you know, what about training? What about education? It is very rare that a postpartum mother or a pregnant mother will access an OB-GYN regarding substance use. It is preventable. It's the leading cause of preventable maternal death. So, if we can do the training for the emergency room and or internist, but mainly emergency room is where the touch points are for substance use disorders.

VICTOR DZAU:
Thank you.

MARK MCCLELLAN:
An exception, not the rule, but there are a few programs that are integrating OUD support with pregnancy care. And there are some examples, CMS programs and a few states that are implementing them.

VICTOR DZAU:
Now, don't you think this panel's outstanding? (LAUGHS) You're putting trust in their hands.