S. HRG. 119–28

NOMINATION OF MARTIN MAKARY TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE NOMINATION OF MARTIN MAKARY, OF VIRGINIA, TO BE COMMISSIONER OF FOOD AND DRUGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

MARCH 6, 2025

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: *http://www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

59–570 PDF WASHINGTON : 2026

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C O N T E N T S

STATEMENTS

THURSDAY, MARCH 6, 2025

NOMINATION OF MARTIN MAKARY TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

Thursday, March 6, 2025

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room SD–562, Dirksen Senate Office Building, Hon. Bill Cassidy, presiding.

Present: Senators Cassidy [presiding], Paul, Collins, Murkowski, Hawley, Tuberville, Banks, Husted, Moody, Murray, Baldwin, Kaine, Hassan, Hickenlooper, Markey, Kim, Blunt Rochester, and Alsobrooks.

OPENING STATEMENT OF SENATOR CASSIDY

The CHAIRMAN. The Senate Committee on Health Education, Labor, and Pensions will please come to order. Thank you, Dr. Makary for appearing before the Committee.

The Food and Drug Administration is tasked with overseeing everything from drugs that treat debilitating diseases to safeguards in the U.S. food supply. Well, FDA has become a gold standard around the world in safeguarding public health, the agency faces significant challenges. The bureaucracy has led to delays in approving new medicines and devices, restricting patients' access to innovative treatments that can be lifesaving.

As the Trump administration looks to cut red tape across the Federal Government, the agency should look at innovative ways to address bottlenecks in the review process. This could include using artificial intelligence and other technologies to improve efficiency and accelerate drug discovery while ensuring these products are safe for Americans.

Another topic of interest is food safety. Americans deserve to know that the food they buy for their families is safe to eat. One place to start should be examining FDA's review process to ensure the safety of ingredients that go into foods. I know Dr. Makary is passionate about this issue. I look forward to working with him if he is confirmed.

The American people's trust in our public health and science agencies and the products they regulate must be restored. Rebuilding public confidence in medical products like vaccines is especially important as we respond to measles outbreaks and as FDA considers recommendations for vaccines for flu strains ahead of the

upcoming flu season. Dr. Makary with his experience as a surgeon and an effective health policy communicator, can help our public health agencies rebuild trust with the American people.

Thank you for appearing before the Committee and discussing your vision on how to make America healthy again. Senator Sanders is not here, so Dr. Makary, we will go to you for your opening statement.

STATEMENT OF DR. MARTIN MAKARY, ARLINGTON, VA

Dr. MAKARY. Thank you, Senator Dr. Cassidy, and Ranking Member Sanders and Members of the Committee. I'm humbled to be before you here.

I'd like to thank President Trump for his confidence in nominating me to lead the Food and Drug Administration. I'm joined today by my wife Jessica, my sister Maria, my brother Mark, Nora, Alexander Jacoby, and my very sacrificial mother and my career role model, my father. My father dedicated his life to the care of children with leukemia, lymphoma, hemophilia, sickle cell disease, and then turned his attention to adult hematology.

His father, my grandfather, was a pharmacist in a poor Egyptian community and believed in treating everybody equally, especially the most vulnerable among them—a philosophy I've tried to emulate in my career and research. Even from the African continent, my grandfather looked to the U.S. FDA for trusted guidance. That's because the FDA has a long history of using gold standard science to uphold public safety, and help us as clinicians take care of patients when they come to us for help.

As a kid, I vividly remember being in the grocery store in our small town with my dad, when somebody would stop him, break out in tears, and give him a long hug after what I would learn to be a decades long battle with lymphoma. It happened a few times, and each time it inspired me even more.

For 22 years now, I've had the privilege to walk into the Johns Hopkins Hospital to live out that mission. And each morning as I enter the front door, I pause and look at the nine-foot statue of Jesus that stands in the center of the hospital lobby. And I read the sacred text engraved at the base, "Come to me all ye who are heavy laden and I will give you rest."

I'm grateful to Johns Hopkins for allowing me to have a creative career, a dual career, as both a surgical oncologist and a healthcare public policy researcher. In addition to using FDA approved devices and medications, my research which has now spanned over 300 scientific peer reviewed articles in the medical literature, has focused on what's actually making a difference in helping people, and how healthcare has become too fragmented, too cold, and too corporate.

My research and subsequent book on price gouging and predatory billing in healthcare, turned into advocacy to demand more transparency in healthcare. President Trump heard the plea and invited me to the White House in his first Administration to enact the Nation's first executive order to bring down hospital and drug prices through greater transparency.

The reform was entirely bipartisan-just as President Trump and Secretary Kennedy's call to make America Healthy Again by finally addressing the root causes of our child chronic disease epidemic, a message that's resonated with moms across the country, regardless of their politics. A smarter FDA that works for all Americans should be a goal we can all agree on.

As a scientist who has spent a career evaluating medical interventions, I believe in the scientific process. In addition, I also believe, that we can use common sense, Dr. Cassidy, as I have been in the operating room, as you would relate, as a respected hematologist, it's hard to perform a long-sophisticated operation for liver cancer and not ask why are rates of liver cancer tripled in the United States. We now have a generational opportunity in American healthcare.

President Trump and Secretary Kennedy's focus on healthy foods has galvanized a grassroots movement in America. Childhood obesity is not a willpower problem, and the rise of early onset Alzheimer's is not a genetic cause. We should be and we will be addressing food, as it impacts our health.

Thanks to the courage of President Trump and Secretary Kennedy, we now have a generational opportunity to usher in radical transparency, to facilitate more cures, meaningful treatments, and diagnostics at the FDA to help people take care of their own health. My father told me to write down my observations and my experiences in healthcare and the research I delved into. Much of the research I did, focused on the fundamental question: is what we are doing working?

I wrote books to educate the public on medical science, and to empower them to live healthier lives. If confirmed, I hope to ensure the FDA holds to the gold standard of trusted science, transparency, and common sense to rebuild public trust and make America healthy again. Thank you, Mr. Chairman.

[The prepared statement Dr. Makary follows.]

PREPARED STATEMENT OF MARTIN MAKARY

Thank you and good morning, Chairman [Dr.] Cassidy, Ranking Member Sanders, and Members of the Committee.

I'm humbled to be here before you. I'd like to thank President Trump for his confidence in nominating me to lead the Food and Drug Administration. I am joined today by my wife, brother, and sister as well as my sacrificial mother and my career role model, my father. He dedicated his life to the care of children with leukemia, lymphoma, hemophilia, sickle cell disease, then turned his focus to adult hematology.

His father was a pharmacist in a poor Egyptian community, and believed in treating everyone in the community equally, especially the most vulnerable among them—a motto I've tried to live by in my career.

Even from the African continent, my grandfather looked to the FDA for trusted guidance. That's because the FDA has a long history using gold standard science to uphold public safety and help us take care of people when they come to us for help.

As a kid, I vividly remember being in a grocery store with my dad, when someone stopped to give him a hug after a long battle with lymphoma. It happened a few times, and each time it inspired me even more.

For 22 years now I've been privileged to walk into the Johns Hopkins Hospital to live out that mission, and each morning as I enter the front door, I pause to look at the 9-foot statue of Jesus that stands in the hospital lobby and read the sacred

text engraved at the base, "Come to me all who are heavily laden, and I will give you rest."

I'm grateful to Johns Hopkins for allowing me to have a dual career as both a surgical oncologist, and a health care researcher.

In addition to using FDA approved devices and medications, my research has focused on patient safety, the *Orphan Drug Act*, how the FDA evaluates devices, opioids, and how health care has become too fragmented, too cold, and too corporate. My research on price gouging and predatory billing turned into advocacy to call for price transparency in health care.

President Trump heard the plea and invited me to the White House to enact the Nation's first executive order to bring down hospital and drug prices through greater transparency.

The reform was entirely bipartisan—just as President Trump and Secretary Kennedy's call to Make America Health Again by finally addressing the root causes of our childhood chronic disease epidemic resonated with Republican, Democrat, and Independent moms across this country.

A smarter FDA that works for all Americans should be a goal we can all agree on. As a scientist who has spent a career evaluating medical interventions, I believe in the scientific process, but in addition to using trusted science, we can also use common sense. Dr. Cassidy is a highly respected hepatologist and can tell you: It's hard to perform a sophisticated long operation for liver cancer and not ask, "why have rates of liver cancer tripled in the U.S."?

We now have a generational opportunity in American health care. President Trump and Secretary Kennedy's focus on healthy foods has galvanized a grassroots movement in America. Childhood obesity is not a willpower problem, and the rise of early onset Alzheimer's is not genetic—we should be, and we will be, assessing the foods impacting our health.

Thanks to the courage of President Trump and Secretary Kennedy, we now have a generational opportunity to usher in radical transparency and to facilitate more cures, meaningful treatments, and diagnostics to empower people to take care of their health.

My father told me to write down my observations about my experiences in health care and the research I delved into. Much of the research I did research focused on the fundamental question: Is what we are doing working? I wrote books to educate people on medical science to empower them to live a healthy life. If confirmed, I hope to ensure the FDA holds to the gold standard of trusted science, transparency, and common sense to rebuild public trust and Make America Healthy Again.

The CHAIRMAN. Thank you, Dr. Makary. I'll start with questions. In 2021, a few months after President Biden took office, FDA announced it would no longer enforce the in-person dispensing requirement for Mifepristone, the drug, which obviously is an abortion.

Now, this is concerning to me. There is a case out of Louisiana, which is incredibly egregious, in which there was no recognition that the person requesting the drug was not the patient, but rather someone who was going to allegedly coerce the person into taking the medication, which would've been evident to a physician should she or he have seen the patient.

If confirmed, would you reinstate the in-person dispensing requirement as well as reporting requirements for adverse events and other complications associated with the drug?

Dr. MAKARY. Thank you, Senator. And to hear of someone being coerced to take Mifepristone is deeply disturbing and I might even suggest criminal. I have no preconceived plans on Mifepristone policy except to take a solid hard look at the data and to meet with the professional career scientists who have reviewed the data at the FDA, and to build an expert coalition to review the ongoing data, which is required to be collected as a part of the REMS pro-

gram, The Risk Evaluation and Mitigation Strategy. It is pursuant to the REMS. And so, if we're going to collect data, I believe we should look at it.

The CHAIRMAN. Last week the FDA announced it would cancel its annual Vaccines and Related Biologic Products Advisory Committee, which meets to select anticipated virus strains for next year's flu vaccines.

Now, I'm told by people who are familiar, that the FDA will make the recommendation and that they will come up with the right decision. But they also say what is lost is the transparency, because the open meeting allows a postmortem, if you will, as we say in medicine, a review of last year of what went right, what went wrong, and how to make it better.

I think one of the laudable things about Secretary Kennedy's positions is he wants more transparency in terms of how the Federal Government makes medical decisions as part of restoring that faith and so, frankly, this seems to kind of go backward on that. So how will you ensure that advisory committees remain objective, transparent, and still benefiting from the necessary expertise of external experts?

Dr. MAKARY. Senator, thank you for the question, and I was not involved in that decision. Certainly, we've confirmed once in office, you have my commitment to take a look at it. As you know, that VRBPAC committee takes a look at guidance and recommendations from international groups such as the GIP International Consortium. My understanding is, at least for the last seven or 8 years that I've been following that group, we have simply rubber stamped whatever the international GIP——

The CHAIRMAN. Can I stop you for a second? My understanding though, since these strains typically begin, like in Australia or China, it isn't so much as a rubber stamp, but as much as recognizing what are you seeing, because that's what's coming to us. So, I think it's more than quibbling to say that you're learning from them. Your thoughts?

Dr. MAKARY. Yes. So, the American public deserves confidence that scientists are looking at that data from the southern hemisphere. It's all reported into a registry, all the dominant strains, and then picking the most dominant strains that are lighting up in that registry is that process of really trying to estimate which strains are going to be dominant in the United States. It's not very precise, some years we don't get it very well, but it's the best we can do with the data we have available at the time.

For example, the International GIP group chose to no longer include the influenza B strains a couple years ago, sounded like a very reasonable decision, and VRBPAC also went along with that recommendation. But I think we're aligned in that the American public want to have some confidence that independent scientists are looking at these data.

The CHAIRMAN. Going back to the transparency again, it seems what's lost with the open meeting is the transparency. So how can you as FDA commissioner advocate for that transparency? Because

we want the American people to know, and obviously canceling the meeting will kind of shut that door a little bit.

Dr. MAKARY. Yes. So, Senator, I was not involved in that decision——

The CHAIRMAN. I accept that but we're voting for you. So how are you going to make it happen? I guess that's my question.

Dr. MAKARY. You have my commitment to review what the committees are doing, how they're being used—as you know, I was critical when that committee was not convened at all during one of the Covid booster guidance decisions by the FDA and leadership at the time argued that they are advisory, and we don't have to convene them, that was repeatedly throughout the Biden administration.

There may be some value if there's a step where the efficiencies can be made but I think with something that's important, something that's critical, something where we want expert opinion, it not only provides some of that wisdom, but it also increases the perception of confidence from the general public.

The CHAIRMAN. Thank you.

Senator Murray.

Senator MURRAY. Thank you very much. Thank you for, for being here today. Let me follow-up on that because last week I sent you a letter along with some of my colleagues asking you about the FDA's cancellation of that Vaccine Advisory Committee meeting.

For everybody's information, this is a meeting that takes place annually, for at least 30 years to make recommendations on which influenza strains should be included in the flu vaccines for the upcoming flu season. And for the first time in decades, FDA canceled that meeting with no explanation given, no new date chosen. That is, I believe, unprecedented and dangerous and you just referred to it, Dr. Makary.

In 2022, you raised concerns when the FDA was considering not holding a vaccine committee meeting to authorize Covid–19 boosters for kids 12 to 15, and at the time you said, "It was unconscionable and undermined the integrity of the FDA's standard process to not hold that committee meeting." So, if you are confirmed, will you commit to immediately reschedule that FDA Vaccine Advisory Committee meeting to get the expert views. We need to know those so we can have the correct vaccine for the upcoming flu season.

Dr. MAKARY. Thank you, Senator, for the question, and I appreciated our time together in meeting ahead of this hearing. I was not involved in that decision and what I would say is——

Senator MURRAY. I'm just asking you if you'll immediately reconvene it.

Dr. MAKARY. I will immediately reevaluate which sessions, the leadership of that center, which decisions, which topics, could benefit from——

Senator MURRAY. What goes into a reevaluation? This is done every year so we know what flu vaccine to have. What are you reevaluating?

Dr. MAKARY. First of all, for the last seven or 8 years that I've been following it, they simply adopt verbatim the recommendation

of the international GIP group. But I was not involved in that decision. I will say that in my opinion, there was a huge difference between requiring every 12-year-old girl in America to take an eighth Covid booster shot versus rubber stamping a recommendation from the international GIP group, which has done seven out of the last 7 years.

I'm not saying that the decision is something I was aware of or involved in, but it's certainly something I will look at, if confirmed.

Senator MURRAY. Okay. I'm very unclear because the FDA is the gold standard for all of us. And this committee hearing is what has always been what we look to, the FDA look to, the American people look to, to determine what the flu vaccine is. What are you going to look at to make a determination and figure something else out now decades into this, what are you re-looking at?

Dr. MAKARY. Senator, I was not involved in that decision, but the committee looks at——

Senator MURRAY. I understand that. I assumed you would say yes, I will reconfirm it immediately so we can let our public health experts and doctors know what flu to have next fall.

Dr. MAKARY. As I understand it, the committee members and the scientists at the FDA, the career professional scientists at the FDA, look at the recommendation of the international GIP group.

Senator MURRAY. I am just asking—you just told me that you were going to reevaluate it, and I want to know what you are reevaluating it on. What are you looking at to make a decision whether to reconvene it?

Dr. MAKARY. In conjunction with the Center Director of the Biologic Center, I would reevaluate which topics deserve a convening of the Advisory Committee members on VRBPAC and which may not require a convening, obviously during——

Senator MURRAY. What would we base our decision on?

Dr. MAKARY. Well, you can ask the Biden administration that chose not to convene the committee meeting for the Covid vaccine booster.

Senator MURRAY. I get that. I understand, but I'm asking you, how will we know what flu vaccine to take next year, if this committee doesn't reconvene and make their recommendation?

Dr. MAKARY. Senator, I was not involved in that decision not to convene that group.

Senator MURRAY. I just thought you would say yes, we're going to reconvene, who knows what's coming. Let me just ask you really quick, I am also following-up on a question and on mifepristone because FDA does play a really critical role in making sure we have safe and effective medications.

Contraception and medication abortion have been approved by the FDA for many, many decades based on mountains of high-quality evidence and expert scientific judgments. So, if you are confirmed, will you commit to upholding the science and evidence-based drug approvals for all FDA approved products, including contraception and medication abortion?

Dr. MAKARY. Thank you for the question, Senator Murray, you have my commitment to follow the independent scientific review process at the FDA, which is a tried-and-true process, and that has been around. And so that is my commitment to you, Senator.

Senator MURRAY. Okay, well, I want to be clear, there have been over a hundred high quality studies over more than two decades backing up the science and safety of mifepristone. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Paul.

Senator PAUL. Congratulations Dr. Makary, on your nomination.

Dr. MAKARY. Thank you.

Senator PAUL. I think one of the most important things we need in government are people who are open-minded. I think closed-mindedness, the idea that this is settled and no one will ever—If you see data as the FDA and you have to make a decision, are you willing to lead where the data and the facts take you as opposed to your preconceptions?

Dr. MAKARY. Absolutely, Senator Paul. I think it is part of being a scientist, we need more humility in the medical establishment. You have to be willing to evolve your position as new data comes in.

Senator PAUL. The people who aren't involved in science think that there's settled science, and this is, it's just all settled and we will all be quiet and submit to whatever settled science is. But you mentioned to me on the way in that yesterday you removed a gallbladder through the laparoscope.

I was in medical school and surgical training about the time where everybody made a four-or five-inch V incision to take the gallbladder out. And the older surgeons, the consensus, they ran the surgery departments, they were like, it's malpractice to use these tiny incisions and blow the air into the abdomen and do all this. But it took an overcoming of the consensus. Do you remember some of that, it might've been a little after your time, but you remember some of the trends from the larger incision, the small incision, and the resistance of the consensus?

[Laughter.]

Dr. MAKARY. Oh, yes. Senator, I can tell you some of the surgeons who trained me said things like, big surgeons used big incisions, and the bigger the incision the better. And without having a big open incision, you can't really see what you're doing. And I would point out that a laparoscope gives you 10 times the magnification, but there's a lot of medical dogma that has contaminated our field, and I think it's tied to a lack of humility.

Ultimately, what makes a great doctor, in my opinion, as I teach my residents, is not how much you know, it's your humility and your willingness to learn as you go from patients.

Senator PAUL. I think some people here also are not duly impressed enough by what it takes to do the kind of surgery that you do. Now, I'm an ophthalmologist and I do eye surgery, and we do really tiny incisions, but our surgery lasts between five and 20 minutes a lot of times to take the cataract. How long does it take

to do a—you've done Whipples, I imagine, which is a surgery on the liver. How long does a Whipple surgery take?

Dr. MAKARY. Yes, I've done a lot of Whipple operations and eyelet transplant procedures, and then pioneered a new type of procedure, which is a laparoscopic pancreas eyelet transplantation, with hopes that it can someday be used to cure diabetes. It was about 8 hours for that operation when we started. We've gotten it down to about four or 5 hours, and we've done some laparoscopic Whipples in 3 hours.

Senator PAUL. With regard to the vaccine committees, and they talk about whether they meet or they don't meet and things, there have been some questions, and one of the questions that I've been bringing forward is whether or not there could be a conflict of interest. And one of the things I've asked, and you would think it would be universally accepted by everyone without question, is you should have to reveal if you get royalties from drug companies.

If you're making a decision on a Pfizer vaccine or a Moderna vaccine, I would think the least of transparency should be that you reveal if you get royalties from those companies. Do you think we need to evaluate the people on the committees or see whether they get royalties or see whether or not there are conflict of interest for the people making these decisions?

Dr. MAKARY. Yes, I do, Senator. We need to review the ethics policy because people see things that appear to be a cozy relationship between industry and the regulators that are supposed to be regulating the products. Now, I want American companies to thrive. I want life sciences companies to thrive, but we need to call balls and strikes and to keep that independent scientific review process free of any conflicts. So, I do think it deserves a look.

Senator PAUL. Really, I think it would be an area that a lot of people, once again, think there's a consensus. Either take all the Covid vaccines or not. Most of Europe doesn't recommend a Covid vaccine for under age 12. Almost all the countries don't recommend it for under 12, some under 18. And it's because they've looked at the risk benefit for children of the vaccine and some of the possible complications of it. And it's different, frankly, for older people.

It's like, these are things that we should at least discuss and evaluate. Some of the most pro-vaccine people, when the policy came out to give boosters to your 6-month-old said they wouldn't even give it to their 24-year-old, a booster.

You remember one of the famous committee members, two committee members left the vaccine committee because the CDC under Biden politicized the process and overrode the vaccine committee. So, to insinuate that somehow there's some brand-new thing going on, these are longstanding controversies. And I think that the main thing, I'll go back to, is in the beginning, we need open-mindedness. And I appreciate your willingness to look at the facts, the data, and not be overwhelmed by preconceptions.

Dr. MAKARY. Thank you, Senator.

The CHAIRMAN. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. Welcome Dr. Makary. I want to go over a couple of topics that have already been

raised, and if we have time explore one that has not yet. But I want to understand your position on mifepristone. Because we had an opportunity to speak in my office and I thought that you were pretty clear with me during that meeting that you were aware of the overwhelming scientific conclusion about the safety of this medication and that you did not think politics should be involved in decisions moving forward. And I understood from our conversation that you intended to stand behind the FDA's longstanding determination.

But after our meeting I don't know if it was you or your minders, but they followed up with my staff and said they felt that you misunderstood my question and wanted to clarify your answer. Which by my read, implied that you are open to totally reexamining the scientific determination even with decades of evidence. So, I want to clearly understand your position as FDA commissioner. Will you maintain current access to mifepristone, yes, or no?

Dr. MAKARY. Senator, I'll be very clear about my position. My position is that of a scientist. As you know, part of the REMS, the Risk Evaluation Mitigation Strategy, that was put in initially by President Clinton in that Administration, and then modified under Obama, and then again under President Biden, requires ongoing data collection. So, I can't prejudge that data without looking at it.

Senator BALDWIN. You're going to—you said something about convening an ongoing panel.

Dr. MAKARY. I did not mention to——

Senator BALDWIN. A previous question just asked.

Dr. MAKARY. I did not mention a panel. I said I would convene the scientists, the professional career scientists at the FDA, who have reviewed the totality of data on this, and are also looking at ongoing data that is being collected. There could be, for example Senator, a drug-drug interaction that may show up on the ongoing data.

Senator BALDWIN. Okay. So, I want to ask if that's your approach to something that has been approved for now decades, are you going to do the same with Tylenol?

There are a lot of side effects for daily use, including liver damage. Will you be doing that for Tylenol?

Dr. MAKARY. As you may know Senator, Tylenol does not have a regulation requiring a REMS, a Risk Evaluation Mitigation Strategy.

Senator BALDWIN. I'm not asking whether it does or not. I'm asking, are you going to do ongoing surveillance of the possible side effects for that drug that was approved many years ago? How about asthma inhalers that have been associated with osteoporosis, opportunistic lung infections? Are you going to be doing that for those medications?

Dr. MAKARY. Senator, I will be following the law and the regulation requires an ongoing review.

Senator BALDWIN. You have a totally different approach to this. I want to get to that again, a little bit more about what we're talking about with the influenza vaccine and vaccines in general. As has been said in this hearing, the advisory committee annual meet-

ing was canceled for selection of what strain of influenza our vaccines for this next season would confront.

There have been additional reports that Secretary Kennedy wants to make significant changes to another Advisory Committee that makes recommendation and provides advice for vaccines. And I worry that this is merely a ploy to install vaccine skeptics on these critical panels. Our Advisory Committees must maintain scientific integrity and should not be changed for political purposes or to further an agenda.

Dr. Makary, do you intend to remove experts from the vaccine and related Biological Products Advisory Committee?

Dr. MAKARY. Senator, first of all, I'm not familiar with what you're referring to regarding Secretary Kennedy. Secretary Kennedy wants to make America healthy again. With regard to the Vaccine VRBPAC Committee, deciding on which flu strain to identify-I was not involved in that decision, but again, just as a reminder——

Senator BALDWIN. Are you planning if confirmed to remove any experts from the vaccine and related Biological Products Advisory Committee?

Dr. MAKARY. I have no preconceived plans to rearrange that committee or any committee, I will say on influenza that——

Senator BALDWIN. Do you commit to maintaining scientific integrity on advisory committees and receiving regular outside expertise if confirmed?

Dr. MAKARY. Of course.

Senator BALDWIN. Okay.

The CHAIRMAN. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. First of all, Doctor, I appreciate your willingness to serve and was impressed as a result of our conversation in my office. Let me ask you, you've had a lot of questions about the Vaccine Advisory Committee. Let me just ask you a simple, straightforward question, and that is, if you are confirmed, will you reinstate meetings of the committee?

Dr. MAKARY. The VRBPAC Committee will be meeting if confirmed and I'm commissioner. Yes.

Senator COLLINS. Thank you. In February, we learned that hundreds of probationary employees at FDA were dismissed. And this really concerns me because we need a flow of young new scientists and researchers, especially since we're seeing retirements and resignations. And ironically, more than half of the FDA employees are funded under various industry user fee agreements. So, there is revenue coming into the FDA to pay for these employees. If confirmed, will you, not an outside force, but you, have full authority over FDA staffing decisions?

Dr. MAKARY. Senator if confirmed as commissioner, you have my commitment that I will do an assessment of the staffing and personnel at the agency. I have not been involved in any of the decisions regarding any of the personnel changes recently, but if confirmed, you have my commitment that I will do an assessment.

Senator COLLINS. I just want to make sure that you are the one doing that assessment. I'm not saying that the staffing level is perfect, and I think it's helpful for a new commissioner to do an assessment, but I want that person to do it. And it sounds like you are committing to that. Is that correct?

Dr. MAKARY. I will do an assessment, I commit to that, yes, Senator.

Senator COLLINS. One of the best ways to lower the cost of prescription drugs is by promoting more market competition. And one way that we can do this is by making it easier for generic and biosimilar drugs to come to the market. As part of a broader bill that Senator Shaheen and I have introduced to help lower the cost of insulin, we've included a provision to create a new competitive biosimilar pathway and therapy designation to add FDA, under which eligible products for which there is inadequate biosimilar competition now, could achieve expedited review.

I worked with the FDA in the last Congress, to develop this provision, and I look forward to continuing to push this concept so that it becomes law. Do you support the concept of a new expedited pathway for biosimilars to compete, for example, with branded insulin?

Dr. MAKARY. First of all, Senator you've taken a strong interest in the FDA and I very much appreciate it, and I really enjoyed our time together. I've learned from you and thank you for your leadership on the Diabetes Caucus. It's something, of course, very close to my area of medicine.

I am a big believer that we need to figure out a way to get biosimilars approved quicker without cutting corners on the scientific review. And it is one of several strategies that the FDA can do to try to alleviate the problems of high drug prices in inadequate competition or underperformance of competition and the drug shortage in the United States.

Also, other strategies could include the way we look at generic drugs, moving medications to over the counter, does Naloxone really need to be a prescription only medication? Does an EpiPen need to be prescription only? If they can be over the counter and we can feel confident about public safety when with those products on the shelf at a pharmacy, it would force the companies to put a price on the shelf. And I do believe in price transparency, it will have an effect on the entire marketplace. So, thank you, Senator.

Senator COLLINS. Thank you. And let me just end by saying that I am delighted with your interest in Islet cell therapy for individuals with Type I. There are clinical trials underway, and I think that is such an exciting development. Thank you, Mr. Chairman.

Dr. MAKARY. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Collins.

Now Senator Hassan.

Senator HASSAN. Thank you, Mr. Chairman. And good morning, Doctor, and congratulations to you and your family on your nomination.

Dr. MAKARY. Good morning. Thank you, Senator.

Senator HASSAN. President Trump has promised to help lower costs, but prescription drug prices are once again skyrocketing for Granite Staters, and all Americans. In 2025, drug makers have increased the list prices of over 500 common medications. Dr. Makary, when we met, you and I discussed the importance of increasing generic drug competition. If confirmed, will you work with me to speed the approval of generic drugs at FDA to lower drug costs for patients?

Dr. MAKARY. Senator, first of all, I very much enjoyed our meeting together. The answer to your question is an emphatic yes, and I would add to that, that I would love to work with Congress to address the way that patent law has enabled patent thickening, which makes it more difficult for biosimilars and even some generics to come to market, because they got to navigate so many lawsuits and letter of the patent law.

Senator HASSAN. Well, and this is something that Senator Paul and I have actually been working on, and we have something, a bill called the *Increasing Transparency in Generic Drug Applications Act*, which would allow the FDA to communicate more transparently with generic drug manufacturers, in order to make more low-cost prescription drugs available for patients.

The bill would save taxpayers over a billion dollars and has bipartisan, bicameral agreement. So, I'm going to urge all my colleagues to look at it. I've enjoyed working with Senator Paul and his team on it.

Dr. Makary, you and I also discussed mifepristone when we met, a medication that has been used for decades in abortion care and miscarriage care. Now, during our meeting, you mentioned you weren't familiar with the drug, and I followed up by providing you with decades of the safety data and you said you're a data guy; you would review it. Have you reviewed the data, and do you agree that mifepristone is safe and effective?

Dr. MAKARY. Thank you, Senator, for sending me that homework to read. And I did read those articles, including—and what I was referring to when I said I'm not familiar with it is, I don't believe I said I was not familiar with it, what I said was, I have not reviewed the totality of the data. I am very familiar with mifepristone. And I did review those studies, including two surveys of patients inquiring about telemedicine, a 2018 National Academy of Medicine Review. I'm a member of the National Academy of Medicine, but was not involved in that particular review. But I did review that document.

Senator HASSAN. I shared with you that study from the National Academies where scientists looked at, just so people know, over a hundred studies of medication abortion, and found that the literature is clear that mifepristone is safe and effective.

Also, we've had the discussion about the REMS process for mifepristone. In 2021, the FDA looked again, based on a citizen petition asking them to review the safety of mifepristone. And I think—just so people get a sense, this is the report back from the FDA about their review and about their modification of the language in the REMS process. And their review again, was that it is safe and effective.

I think what you're hearing from a lot of us as we ask you questions about this, and just so the public can understand, there's lots and lots of data here that supports the safety and efficacy of mifepristone and supports its efficacy in, under current law, and its safety.

I think the concern you're hearing is not about whether you will follow an ongoing REMS process with any medication and look at the most current data. That's what the scientific process is about. The concern is whether you are going to unilaterally overrule the data that currently exists for political purposes, and for political reasons, and that's what we're looking for your reassurance on.

You have told us you are an independent scientist, I believe that. You have a very distinguished career as a physician. But we need to know that when you say you're an independent scientist, that's really what you mean. And then when the politics get heated around abortion, that you won't abandon that independence.

Dr. MAKARY. Senator, you have my commitment that once I'm in office, I will do a review of the data. I have no preconceived plans to make changes to the mifepristone policy. And I do plan to follow the law and the regulation of the REMS to look at ongoing data. It could be that there could be a drug-drug interaction that we could identify on ongoing data.

Senator HASSAN. I understand that. But what I am looking for is an understanding that the current state of science, in the process that you have been a participant in throughout your entire career, and that others up here have also participated in, that you will follow the science as it is currently developed and not unilaterally overrule scientists because you're under political pressure to do that.

Dr. MAKARY. Senator, if you look at my track record, I have never been afraid to speak my honest scientific opinion, and I have no preconceived plans to make changes on that medication.

Senator HASSAN. Well, I wish you were hedging a little bit less today. Thank you,

The CHAIRMAN. Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And I understand that the Senator from Alabama has an engagement that she needs to get off to. So, I'm going to defer my time to her and go afterwards.

The CHAIRMAN. The Florida, Alabama afterwards.

Senator MOODY. Florida Go Gators! But Katie Britt would want me to say, Roll Tide.

[Laughter.]

The CHAIRMAN. You'll lose your votes in Florida, but anyway, go ahead.

Senator MOODY. Thank you, Senator Murkowski, I'm so grateful. I'm very grateful as the rookie, to be able to question before these senior Senators. It's a big deal. So, I'm grateful to all of you. Thank you so much. I'm so honored.

I am so excited to see you here today, I was incredibly happy with this nomination. When confirmed, I know you're going to do

a great job. I have two issues I want to cover and they are relevant specifically to the two main roles in my life over the last 6 years: One as a mother and one as Attorney General of Florida.

First, I want to talk to you about what is going on with the FDA, and it's burying its head in the sand about illegal, chemically ridden, extraordinarily high amounts of nicotine, Chinese vapes that are flooding the United States market. In fact, two thirds of the export market here are Chinese vapes coming out of China. So, it's unbelievable. They are in flavors like strawberry, blow pop, watermelon sour berry, attracting children, addicting children.

We have so many thousands and thousands and thousands of pending applications, most of these things are illegal in the United States right now. But yet, somehow China has decided to flood our market with illegal vapes, the United States market with illegal vapes. And they're benefiting, in fact, in China, they banned flavored vapes. And so, all of the manufacturers there of these chemically ridden vapes, have now flooded our market, and now are addicting our children. Much like we're seeing this in many other ways in harmful substance coming from China and they're not doing much about it, fentanyl, ET cetera.

Whoever comes in as the head of FDA, this is one of your problems-you have to address immediately. I know there are a lot of things that you're going to get questioned about, but these things are all over the United States. In convenience stores, they are, readily available to children. If you walked in any one right now, you would be able to find them. And not only are the amounts of nicotine going up and up and up, we don't know what is in these things. And there has been little to nothing done to deal with our pending applications at the FDA or to enforce those that we know are illegal right now. How would you address this and what do you plan to do on day one?

Dr. MAKARY. Well, thank you, Senator. I appreciate your passion on this important issue, and I've appreciated your work as Attorney General in Florida on this issue, and maybe it's because you both believe in doing the right thing, and because you're a baseball mom that you're interested in this.

Senator MOODY. I first heard about this on the bleachers at a baseball game.

Dr. MAKARY. I think there are four new vaping stores that have popped up in my neighborhood, all in the last few years. I've not walked into one of them, although perhaps I should, to check it out. But you are absolutely right that we are being flooded with Chinese products. We have no idea what's in these products and public health is not even going to be able to study them because it takes so long for public health research to catch up.

But it's very concerning and it's not right that the products are banned in China, and yet they're manufacturing them and sending them into the United States. So, there are a few things the FDA can do to try to address this problem. First of all, the office of inspections and investigations has a lot of people with guns and they do enforcement and raids. And we need in collaboration with DOJ and other areas of law enforcement to try to address this problem of illegal products on our market.

Senator MOODY. There was an announcement during the last Administration, and I won't get into much—they were going to—once people finally convinced them that this is out of control and people are getting addicted by the day, there was this big announcement about task force, we're going to use all the tools available. That's great, and enforcement needs to be key.

Florida had to finally step up and do it ourselves because the Federal Government would do nothing. But the first key has to be, what do we do with our pending applications? How do you cleanup FDA's house first? You need to know what the law is before you can enforce it. Let's start there, please focus on that. And then we will also work with the enforcement measure.

I'd also like to just get a commitment from you as from the State of Florida citrus growers, orange growers, that's a big deal to us. There's a regulation in there, an arbitrary regulation, amount of sugar content. It needs to be examined with disease and greening, and all the things facing the citrus industry. That arbitrary regulation, the oranges aren't producing as much sugar, I can go into it, but do I have your commitment for them to look at that regulation? Things that are set sometimes we need to revisit on how it's affecting industries across the United States. So, do I have your commitment to look at that?

Dr. MAKARY. Senator, I had my cold press freshly squeezed orange juice this morning, and you do have my commitment to look at that.

Senator MOODY. Oh, our orange growers are going to be so happy to hear that. I will tell them. Thank you so much.

Dr. MAKARY. Thank you.

The CHAIRMAN. That was the great mother board that told you to drink the orange juice, do you know what I'm saying? That was really good.

Senator Kim.

[Laughter.]

Senator KIM. Thank you, Chairman. Doctor, thanks for coming on out. I was looking through your opening statement. At the very end, you talked about FDA being the gold standard, and you said gold standard of transparency, and I was glad to hear that. I wanted to ask you in terms of transparency, do you think it's important that we can ensure that there's public comments on actions of agencies and departments overseeing important aspects of our lives?

Dr. MAKARY. Senator, first of all, it was good to meet with you, and I enjoyed our conversation. I do believe in civil discourse and have been an advocate for civil discourse and coming out of an era of medical establishment censorship. So, I do believe in the principle. Now, there are laws and regulations around public comment periods, and in some situations, a public comment period is required by a regulation.

Senator KIM. I would just suggest here that this is really important, the public, very concerned you were talking about, we had a long conversation about how to restore trust. And I think a big part of that is about involving the public more, I think you saw some

of that in terms of the questions regarding VRBPAC, and just the need for that type of radical transparency as Secretary Kennedy talks about.

Recently, there was an effort addressing the Richardson waiver. I ask that you look into this if you're confirmed, but I do think it's important that we maintain public comments, something that so far, this HHS has not abided by, and something that has been longstanding practice.

Another aspect of this is about transparency and accountability. So, I guess I just wanted to ask you if we have this sense of nothing to hide, we want to root out waste, fraud, corruption, do you support the roles of Inspector Generals?

Dr. MAKARY. Senator, I believe in the law, and I believe in the process of having Inspector Generals.

Senator KIM. Okay. Well if you are confirmed, I just urge you to do everything you can to ensure that HHS has an Inspector General, has an ability for us to be able to oversee the accountability and to be able to root out some of the problems that I hope both of us can agree upon. So, I just want to ask for your commitment on that front that you would push to try to have an Inspector General there at HHS.

Dr. MAKARY. Thank you, Senator.

Senator KIM. When it comes to ethics, I heard you refer about just concerns, you want to have ethics review in terms of positions that people might be having, especially involving approval of drugs and other things. I guess I wanted to just ask you a little bit more on your end. It looked like I come across something that's saying that you were willing to divest from your own investments that were being perceived potentially as a conflict of interest if you are confirmed in this job, is that correct?

Dr. MAKARY. Senator, as you are aware, the Office of Government Ethics does a comprehensive review of basically everything I own, every stock, every equity, every share. I would describe it as a colonoscopy with a small bowel follow through.

[Laughter.]

Dr. MAKARY. It took about 4 weeks, and they gave me the option of resigning from some things, or maintaining a role, and I chose voluntarily to divest and resign from everything.

Senator KIM. I applaud that, and I think that should be the standard, especially for such important jobs. I guess I just wanted to ask you a little bit further here, would you agree to recuse yourself from matters involving your former clients and employers, if that comes before you at the FDA?

Dr. MAKARY. Senator, what I can promise you and commit to is, to abide by all the guidance of the Office of Government Ethics——

Senator KIM. I understand that, but you just talked about how you voluntarily took steps to be able to divest. That was not something you were required to do, though I do think you should have been. But I guess I would just ask you again, would you consider recusing yourself? Because I mean, if you're making decisions about a previous client of yours, you can see how the general public would react to that in terms of concern about whether or not you

are doing this for the best interest of the people or the best interest of people you know?

Dr. MAKARY. Senator, I have signed to agree to recusals as defined by the Office of Government Ethics in any area where they perceived a conflict could occur. And so, I have already agreed to the recusals required by the Office of Government Ethics.

Senator KIM. One last thing I just wanted to raise, and this is just something I just want to ask, what is you're feeling about these potential Medicaid cuts that are being reviewed right now in Congress?

Dr. MAKARY. Senator, the FDA is not involved in Medicaid or coverage decisions.

Senator KIM. I understand that, I guess the reason I raise it is that in your opening remarks you said—I thought it was really powerful—you said that your motto in life has been about treating everyone in the community equally, especially the most vulnerable amongst them.

I just urge you to just continue to press, you will have a seat at the table if you're confirmed on healthcare decisions across the Administration and Medicaid is essential for the most vulnerable amongst us. And treating everyone equally—your drugs, it's not just about the approval, you'd want to see that get into the hands of Americans, make sure that they can use and benefit from them. So, I do think that you have an interest in preserving Medicaid. Thank you.

The CHAIRMAN. Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. Doctor, welcome. It was a good conversation that we had, I appreciated that, I thank you for the encouragement to read that provision in your book. So, airplane reading for me.

Dr. MAKARY. Thank you, Senator.

Senator MURKOWSKI. I also want to thank you for the assurance that you gave to Senator Collins regarding the Vaccine Advisory Committee and ensuring that there would be meetings going forward. I think for several of us who had, I thought good substance conversations with Secretary Kennedy, we had received assurances about things like the vaccination committee. So, making sure, again, that kind of very important input goes forward, I think is important to many of us. So, I appreciate that.

I wanted to talk to you this morning about an issue that we discussed in my office, and that is with regards to ALS. The FDA's accelerated approval pathway has really been important, and I think very promising for treatments for ALS and some other rare diseases. You have advocated for using common sense alongside science in regulatory decisions. So, very briefly, how do we define common sense here as it applies to the regulatory decisions of FDA? How do we make sure that ALS patients who again, are looking at a very, very, very limited timeframe, they can't wait for the traditional approval process.

There are some emerging measures using digital technologies, is this in your realm of common sense? Give me a little bit of your

view here on how you would like to proceed on these accelerating approval pathways.

Dr. MAKARY. Thank you, Senator and I very much enjoyed our time together and talking through a bunch of these issues. We have to customize the regulatory process to the condition that we're trying to be able to offer hope for. So, if a condition affects 19 people in the world, as a partial triplication chromosome 15 disorder does, or a disease that affects 52 kids in the world, we cannot require two randomized controlled trials. We have to customize the regulatory process to what we're trying to do, if our goal is to try to provide safe and effective therapies.

I do believe firmly in that approach, and I think we can use some common sense to ask some big questions we've never asked before at the FDA. Why does it take 10 years for a drug to get approved? Why does a college student who suffers from chronic abdominal pain for years, and we have no idea what's going on, they go to Italy for a summer and they're suddenly cured of their abdominal pain. Why does a peanut allergy medication that's been safe with data for decades, get approved in Europe before the United States when nearly 10 percent of our population has a food allergy?

I do think there's a lot of areas where we can ask, does a drug need to be prescription when it could be over the counter? Why are we requiring continuous glucose monitors to have a doctor's prescription? When it's good for people to use these monitors and learn about what they're eating. We don't just want to limit continuous glucose monitoring to people with diabetes, we want to prevent diabetes when 30 percent of our Nation's children has diabetes or prediabetes, or some form of early insulin resistance. Why are we holding these tools to help people empower them with knowledge about their health, until after they're sick? Same with continuous blood pressure monitoring.

Senator MURKOWSKI. It's as you point out, why do we wait? Now, we want to make sure that there is that level of safety, that's the job there through the FDA. But again, being able to accelerate these in ways that are meaningful and to your point, that actually fit with the population that you're speaking to. So, know that I'm going to be pushing you on this as well as many other advocates out there.

Dr. MAKARY. Thank you.

Senator MURKOWSKI. I want to quickly ask you about food safety inspections. State and local governments conduct about 60 percent of food processing facility inspections, 90 percent of produce safety inspections, a hundred percent of retail food inspections. What has happened is we have seen in the Biden administration, FDA planning to cut funding for state and local food safety programs. This impacts us in the State of Alaska when it comes to our seafood industry and in other areas.

I'm looking for a commitment from you that under the Trump administration, the FDA is going to maintain funding for these contracts with state and local governments. They've proven that it's more cost effective, more efficient, and it also is what Congress has asked for. So, I'd like to know that you're going to be supportive in that regard with regards to state and local food.

Dr. MAKARY. I'm happy to look at that with you, Senator.

Senator MURKOWSKI. Very good. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Blunt Rochester.

Senator BLUNT ROCHESTER. Thank you, Mr. Chairman. And thank you so much Dr. Makary for taking time to meet with me. I've found that most parents would do anything to keep their children safe and healthy, which is why we probably see so much intense debate on the best ways to protect our children. And the FDA has historically been seen as the authority on reliable information about public health issues related to medical products, food, tobacco, cosmetics, dietary supplements. However, people are getting their information in many different ways now, in many different places.

We're faced with a growing challenge of opinions replacing scientific consensus and the proliferation of misinformation and disinformation. Parents need accurate science-based information to help make informed decisions for their children. How would you use your position as FDA commissioner, to compete with uninformed voices and to share evidence-based consensus-driven information that is free from political influence?

Dr. MAKARY. Well, thank you, Senator and I enjoyed our time meeting together. I believe very much in empowering people with good information, that's why I've written three bestselling books to try to educate people about health. And I do think you can explain to people with humility what we know and what we don't know, and then they're going to trust us more.

Trust in doctors and hospitals is at a crisis right now. It was 71 percent in 2019, 71 percent of the public trusted us in 2019, now it's down to 40 percent. That's a 31 point drop in my profession, that is a major problem. If we have the cure for pancreatic cancer, but only 40 percent of the public is going to come in and take it because the rest doesn't trust us, then that medication is only 40 percent effective.

I think we fight bad ideas with more ideas. I don't believe in censorship of scientific opinions. I think we need a civil discourse. Unfortunately, we have a sort of toxic discourse right now in the United States and the politicalization of immune cells in some cases.

Senator BLUNT ROCHESTER. One of my big concerns is who those voices are, and that they really are robust, scientifically trusted messengers as well. One of the other big issues that we're facing are drug shortages that have reached an all-time high, threatening access to products that we use every day, from IV bags to lifesaving drugs for cancer.

It's particularly concerning for children's hospitals because of pediatric drugs and supplies that must be formulated to accommodate children's unique needs. Do you agree, and this is kind of a yes or no, do you agree that the FDA should play a leading role in mitigating drug shortages?

Dr. MAKARY. I love yes and no questions.

Senator BLUNT ROCHESTER. Good. Can you, do it?

[Laughter.]

Dr. MAKARY. A leading role—they should take a role. I think the problem is much bigger than the FDA.

Senator BLUNT ROCHESTER. Yes or no, you're like not sure if it's a yes or no.

Dr. MAKARY. I would refer you to my article in JAMA on this topic.

Senator BLUNT ROCHESTER. I want to shift to clinical trials as well. You agreed, we talked about the importance of clinical trial diversity, but I want an assurance that you will stand up to any Trump administration actions that conflict with this. So, again, yes, or no, do you believe clinical trial diversity is critically important?

Senator BLUNT ROCHESTER. That's the easy one.

Dr. MAKARY. Well, if you're talking about a trial of sickle cell disease, are we saying that we need to have white people in a trial of sickle cell? I believe in common sense, and I believe in clinical trial diversity, both. And so, I believe if you're going to make results extrapolated to the general population, you should have results in those populations that you're making recommendations for.

Senator BLUNT ROCHESTER. That one was an easy one. Do you think it is acceptable for the Administration to remove congressionally mandated guidance documents on clinical trial diversity?

Dr. MAKARY. I'm not familiar with that.

Senator BLUNT ROCHESTER. Should you be confirmed, will you reinstate and finalize this document after you look at it as one of your first actions? Would you take a look at that? Could you commit to looking at that?

Dr. MAKARY. Yes, Senator.

Senator BLUNT ROCHESTER. Good answer.

[Laughter.]

Senator BLUNT ROCHESTER. Will you restore the Web site for the Office of Minority Health and Health Equity?

Dr. MAKARY. I'm not familiar with that Web site, Senator.

Senator BLUNT ROCHESTER. If there was one and you knew there was one, would you restore the Web site that would provide information to the American people?

Dr. MAKARY. I think you're asking me to make a decision on information that I don't have. So, you have my commitment to take a look at it.

Senator BLUNT ROCHESTER. If you got the opportunity to review the Web site, and then know that it would help to spread real information, science-based information, would you reinstate that Web site?

Dr. MAKARY. I would be happy to review it.

Senator BLUNT ROCHESTER. I have more questions that I will send for the record, but particularly, I'm concerned also about the Vaccines for Children program and making sure with the—you've heard our colleagues talk about the cancellation of the meeting. This is not just about cost for families, which is huge right now,

but it's also about coverage. And so, I yield back my time and I thank you so much, Doctor.

Dr. MAKARY. Thank you, Senator.

Senator HAWLEY. Thank you very much, Senator. Doctor, it's great to see you again, I enjoyed our conversation.

Dr. MAKARY. Good to see you.

Senator HAWLEY. Congratulations on your nomination and thank you for your willingness to take on this very important role. You've been asked about this several times already, but I just want to drill down a little bit further.

In 2000, President Clinton's FDA approved a chemical abortion regimen with the drugs mifepristone and also misoprostol. Now, the FDA concluded that mifepristone could not be safely used, I'm quoting the FDA there, safely used, could not be, without special measures, it's the FDA's language. And in particular, the FDA mandated that prescribers needed to be licensed physicians who were able to diagnose and treat ectopic pregnancies to accurately determine the gestational age of the baby.

The FDA further required that these drugs be administered and dispensed in person, that there be a day one in-person administration of the drug, a day three in-person administration of the second wave of the drug, a day 14 check-in for complications. And the FDA further emphasized that given the potential risks of these drugs, physicians needed to be able to provide ongoing care.

The FDA also said, "The percentage of women who considered any particular adverse event as severe ranged from two to 35 percent." And the FDA included what's called a black box warning, which you're very familiar with, which remains on the drug.

Now, those restrictions were largely in place until just a couple of years ago, when the Biden administration, after the U.S. Supreme Court took up the Dobbs decision, granted cert on it. At that point, the Biden administration decided to eliminate 20 years of in-person dispensing requirements for this drug that didn't cite any studies that they said were adequate. That the FDA acknowledged that the studies that they looked at did not take into account the new protocols that they were issuing. They just eliminated two decades of in-person dispensing requirements.

My question to you is, given the FDA's own findings on this drug over two decades, doesn't it make sense that the FDA returned to the pre political, before the political intervention of the Biden administration, the pre political protocol that requires in-person dispensing for chemical abortion drugs?

Dr. MAKARY. Senator, I appreciated our conversation prior to this hearing. I do think it makes sense to review the totality of data and ongoing data. I know personally of OB doctors who prefer to insist, even though they have the option to prescribe otherwise, but they choose to insist that mifepristone be taken, when necessary, in their office as they observe the person taking it. And I think their concern there is that if this drug is in the wrong hands, it could be used for coercion.

Senator HAWLEY. Of course, you're familiar with the fact that now it's not merely that there's no requirement that it be ingested

in the presence of a physician, there's no in-person dispensing requirement whatsoever. This is what the Biden administration—two decades of in-person dispensing requirements, the Biden administration eliminated those.

Now, you've said several times, you'll review the data. You are aware that in 2016, the Obama FDA eliminated the requirement that physicians report adverse events with regard to mifepristone, aren't you?

Dr. MAKARY. I believe they limited the data required to fatalities, but not adverse events.

Senator HAWLEY. Will you put back in place the full reporting requirements that you can have a full range of data to evaluate?

Dr. MAKARY. Senator, I'm happy to look at that. I do believe in data, and I don't believe in pre-judging data before somebody has taken a look at data, including future data.

Senator HAWLEY. Well, let me just say that, here's the deal. The FDA's rules were pretty consistent and pretty stable for 20 plus years, until suddenly the Dobbs decision appeared on the horizon. And when that happened, all of a sudden, we got massive changes in the dispensing requirements of this drug.

I'll just point out that over 60 percent of abortions in the United States are now carried out with chemical drugs, with these drugs. They're not done in clinics; they're not done in hospitals, they're done with these drugs, without any kind of physician supervision, without any physicians there.

If there's a serious adverse event—and I'll also just point out that if the Biden rules are allowed to stand, it doesn't matter what voters in the states, it doesn't matter what—this is a serious and very difficult moral issue, the case of life and abortion. And it won't matter what voters in the states say, because the Biden rules say now that bureaucrats can mail in abortion drugs to every single state, no in-person dispensing required. It doesn't matter what voters in the state have decided on the issue, it doesn't matter whatsoever.

Now, if that's allowed to stand, we may as well just go back to having the Supreme Court make all the decisions. Because right now, Washington bureaucrats are making all the decisions, doctors are not involved. They're not in person dispensing, state voters are not involved. And I just want to register this is extremely concerning to me. It ought to be concerning to everyone who's concerned about women's safety, and also about what I thought was the position of this Administration, which is that it ought to be voters in the states and the relevant localities that are deciding this decision.

I know you're familiar with this, doctor. I appreciate your commitment to the data. I hope that you'll look at the full range of data, and I hope we can count on you to protect women's health and the health of the unborn.

Dr. MAKARY. Thank you, Senator.

Senator HAWLEY. [Presiding.] Well, Senator Kaine, let the record reflect, even though I have the gavel, I'm going to stop right now and turn it over to you.

You're recognized, Senator.

Senator KAINE. Thank you, Senator Hawley. Senator Hawley and I share a unique perspective. There are two sets of Senators who went to the same high school. Chuck Schumer and Bernie Sanders went to James Madison High School in Brooklyn, New York and Josh and I went to Rockhurst High School in Kansas City, so I just wanted to put that on the record.

Dr. Makary, I loved the opportunity to visit with you and I know the answer to this question, but I just want to stress it again. You didn't have anything to do with the layoff of the thousand FDA employees that have been laid off in the last couple weeks, correct?

Dr. MAKARY. That's correct, Senator.

Senator KAINE. Do you know anything about the layoffs, for example, who made the decisions or what groups of people were laid off?

Dr. MAKARY. I do not, Senator.

Senator KAINE. You indicated that when you come into the office, you're going to do an assessment. And I suppose based on your experience, that if you look at this going forward, you think personnel policy, including layoffs, should be done strategically rather than just kind of willy nilly across the board randomly, correct?

Dr. MAKARY. I am open to ideas on making government more efficient.

Senator KAINE. Do you think willy nilly, random across the board, is a good idea or not a good idea?

Dr. MAKARY. Look, I'm a surgeon, so I'm going to give you a surgical answer.

Senator KAINE. Yes. Okay. That's good. It is a little bit puzzling; the Administration has high confidence in you. You've got this hearing right now, they expect you to be confirmed, probably will be based on practice of the notion that they would lay off a thousand people before you got there, is a little bit unusual. And what we're seeing in agencies, in the layoffs is that it is willy nilly random probationers get laid off because they can't fight back. Probationers are disproportionately veterans. I'm glad you will be a surgeon and act like a surgeon, should you be confirmed.

Second thing I want to ask is about user fees. And we chatted a little bit about this in the office. We agreed that despite the need for reforms at the FDA, that the FDA is sort of the gold standard. I asked you, is there another nation that does this better than us? And you said, no, there wasn't. Even though, again, you've got reforms you'd like to make.

Here is an issue that's pretty technical, but it's an important one. We talked about tracking adverse events after a drug or medical device is approved. And you indicated that the FDA can do a better job of identifying issues with problems that are already on the market. It's not all about approval and that it's about post-approval tracking.

There are many different user fee programs that outline the relationship between the FDA and industry. And for most of the user fee programs except medical device user fee, FDA can use the col-

lected user fee dollars to conduct post-marketing surveillance. But the medical device user fee program does not allow that use of the user fee dollars. Would you agree that the FDA should be able to use the user fees collected of medical devices to do post-approval surveillance?

Dr. MAKARY. Senator user fees are established by Congress, and I'm more than happy to be a part of the conversation about the best use of those dollars within the agencies. I very much enjoyed our conversation, and I'm committed to an FDA that delivers more cures for Americans and meaningful treatments, healthy food for children——

Senator KAINE. But can I just ask about this, do you think post-approval surveillance is something that's important?

Dr. MAKARY. I am a big believer, Okay, in the idea that we should not just turn a blind eye after the FDA approves something. If we do that, we get burned with a million lives lost from Oxycodone and OxyContin without——

Senator KAINE. That's my next topic. And I do agree with you that making that change would be on Congress's shoulders, but I do think it's odd that we don't allow the user fees to be used for post-approval surveillance on medical devices when we do in the other areas. And I'd love to work with you on that.

On OxyContin, I want to just close with this one. We're seeing some improvements: 24 percent decline in drug overdose for the 12-month period ending in September, 2024 compared to previous year. And just yesterday, the NIH released findings of an NIH funded study researching a new pathway to address pain issues. But 87,000 Americans died of overdose in the 12-month period. So, it's an improvement, but we got so much farther to go.

1 in 4 Virginians deal with chronic pain. And one of the issues you and I talked about is, can the FDA not just be in receive mode, to get the applications for approvals and approve? Can the FDA even be proactive in looking and saying, hmm, how come we don't have more non-opioid based pain management strategies? The FDA shouldn't be picking a winner among competitors, but to look at gaps and try to incentivize or encourage filling those gaps would be smart.

Could you share some of your ideas for how we might encourage appropriately, the development of innovative strategies to address chronic pain without using opioids?

Dr. MAKARY. Thank you, Senator. I do believe the FDA should not just be in receive mode, but also partner with industry and facilitate the process and ensure that the scientific review is independent, at the same time without cutting any corners on the independence of that review. The opioid pain problem can also be addressed by innovation, more localized treatments, and looking at post approval monitoring of devices.

Senator KAINE. Great and thank you. I look forward to more discussion.

Dr. MAKARY. Thanks, Senator.

The CHAIRMAN. [Presiding.] Senator Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman. Thank you, doctor, for being here.

Dr. MAKARY. Thank you, Coach.

Senator TUBERVILLE. Also for your willingness to do this. World War II, we had to find ways to feed our troops. We knew nothing about preservatives and canning foods and ever since then, our food's going downhill because we have put everything in the world, in our food, No. 1, to get kids addicted to it, which we have. We've lost probably a couple of generations because of the obesity and diabetes.

I have faith in this generation. I have two kids in this generation coming up, that they're looking at their health as a future. And they're fired up about nutrition being a good part of it.

Are you familiar with GRASS—generally recognize safe foods, the chemicals that go into our foods. What's your thoughts on that? What's your thoughts on you as FDA director having the ability to look at this and know we're not using this chemical in this food. What's your thoughts?

Dr. MAKARY. Well, first of all Senator Coach, I think you have had a perspective on this and been an advocate for healthy foods. And perhaps it's because of your unique position where you've worked with young people for so long. Half of our Nation's children are sick, and nobody has really been doing anything meaningful on this front until we have gotten new momentum and enthusiasm from Secretary Kennedy and President Trump to finally address the root causes of these diseases: General body inflammation and generalized insulin resistance, and food is a big part of it.

When we eat foods with a lot of molecules that do not appear in nature, these are chemicals. These are chemicals that the industry insists are safe, a subset of which are concerning. There's a body of research now that suggests concern with some of these ingredients. We have to look at those ingredients, and you have my commitment to do so if confirmed as FDA commissioner.

These chemicals are creating an inflammatory response in the gastrointestinal tract. And with an altered microbiome lining that GI tract, kids feel sick. It's not an acute inflammatory reaction, it's a chronic low-grade reaction, and they don't feel well. And what are we doing? We are drugging our Nation's children at scale. We have to reassess what we're doing because we're not on a good path right now.

Senator TUBERVILLE. I grew up in the South. I love fried foods. Okay. We fry everything, including snicker bars and Twinkies.

[Laughter.]

Senator TUBERVILLE. But let me ask you this, I hear a lot about seed oils and the good and the bad, your thoughts?

Dr. MAKARY. I think seed oils are a good example of where we could benefit from a consolidation of the scientific research. And I don't think it's any one ingredient in the food supply that's making our Nation's children sick with a 30 percent rate of insulin resistance and diabetes in American teenagers today. That's a massive signal in the data.

I think we have to look at the totality of every single thing in school lunch programs, in the diet of our Nation's children. When we're using tax dollars to make purchases of foods that we know make our Nation's children sick, we have to reexamine how we're spending those tax dollars.

One thing I would like to work on is a school lunch program, for some school districts, on a pilot basis to transition to healthier foods. A lot of school districts want to, but they don't know how, and they may not have the funds. So, I've been discussing this with Jay Bhattacharya and others in the Administration, and I hope that's something we can do.

Senator TUBERVILLE. Thank you. Just a few months ago, we had the former FDA director, and I asked him about red dye No. 3, and it was a pretty interesting conversation. Red dye No. 3, we've done studies on it, and we won't allow it in cosmetics, Okay? Because it causes cancer, but we are allowed to put it in our food and I'm a little bit confused.

I'm a football coach, but I'm not that stupid. Put it on your face and put in your stomach, there's no difference. But he made an interesting statement that we're 20 years behind Europe, because Europe doesn't allow it in anything. We're 20 years behind Europe on looking into red dye three and all the other dyes. What's your thoughts on dyes in this country?

Dr. MAKARY. I agree with you that we—it did not make sense that red dye No. 3 was banned in cosmetics, but allowed in the food supply. And so, with two business days left in the Biden administration, there was an announcement to ban red dye No. 3 in 2027 or 2028.

Senator TUBERVILLE. Why that long, we want to kill people for two more years. I mean, I would hope that you would, if you're confirmed, you go in and look at it very quickly and say, why do we want to put our people in harm's way? Thank you, Mr. Chairman.

Dr. MAKARY. Thank you, coach.

The CHAIRMAN. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chairman and thank you, Dr. Makary for your service. I finally got a chance to look over some of your three books, or you probably have more than that, but the three books that I was able to chase down, and they each one seemed provocative and full of answers. I will say, as a very, very slow reader, I'm a dyslexic, I do wish you had something like Cliff notes so that we could get 10 or 15 pages concise and get the essence out of that.

Dr. MAKARY. I'd be happy to personally summarize them for you Senator.

[Laughter.]

Senator HICKENLOOPER. I think we have witnesses that just heard that, I'm very excited. I appreciate your courage in taking on a lot of these traditional approaches and being so candid. Let me go through a couple of questions. In just a few weeks, roughly 10 percent of the FDA staff has been laid off. And most of these layoffs were inspectors who looked either at food supply, whether it was safety of medical devices and yet for the past several years, job va-

cancies, if you measure them as an indication of anything, but for FDA inspectors, job vacancies have been going up, not down. In other words, we have more unfilled spots, and now all of a sudden, we've laid off 10 percent of the people there.

That chaos and the understaffing is going to really present a serious morale issue, which I'm sure you're aware of. I don't know if you have any plans for that. And how are you going to be able to try and do the best you can to ensure the FDA's gold standard of science if we can't get enough inspectors?

Dr. MAKARY. Senator, thank you for the question and I enjoyed our time together in your office. I was not involved in any personnel decisions.

Senator HICKENLOOPER. That was not a criticism. I was just saying, once you get in the job, if your budget is suddenly diminished and you've got 10 percent fewer inspectors and you already didn't have enough by the existing measures, I'm not sure there's an answer for it. Maybe it's an unfair question.

Dr. MAKARY. Senator, if confirmed, you have my commitment that I will do an assessment within the Agency of personnel, and it will be an ongoing assessment to ensure that the scientists and food inspectors have all the resources they need to do their job.

Senator HICKENLOOPER. Great. Again, that's certainly the exact place to start. We have a bill, *Skinny Labels, Big Savings Act* that helps more generic drugs, more of that competition come into the market, lower drug costs.

Again, with so many of the FDA workers having been fired and laid off, will there be sufficient people at the agency to review generic drug applications? Because that often gets pushed to the bottom of the heap, and yet it has dramatic savings, especially for elderly and people on the lower parts, the people that don't have insurance. So, are you worried about a slowdown, again due to resources and personnel?

Dr. MAKARY. Senator, I want to make sure that the reviewers and the review process is done properly without cutting any corners on the scientific independence and done expeditiously. So, you do have my commitment that I will do my best to ensure that that's done as best as possible.

Just to put things in context, if I may. The FDA has almost 19,000 employees, just over 18,000. That represents a 100 percent increase since 2007. Now, I understand there were some layoffs recently, I understand some or many were hired back, but I just wanted to let you know that, to put things in context, we have seen a doubling of the agency in terms of number of employees since 2007.

Senator HICKENLOOPER. Fair point, I accept that and was aware of that, but it's a fair point. Lot of talk about measles. Secretary Kennedy recommended the use of cod liver oil as one of several things that people could do and left it to parental discretion as to whether they would get their kids vaccinated, which I think you've got—I agree with that.

I think the parents in the end have a right and a responsibility to make that decision for their kids. But it seemed to me that there

could be a stronger—those of us who looked adept and in detail at the facts, that this is really a very safe vaccination for 99.99 percent of kids. And it saves lives and it prevents huge levels of very sick kids. You think there should be more, or will you be willing to be a more enthusiastic supporter of vaccinations while at the same time recognizing that parents get the final say?

Dr. MAKARY. Senator vaccines save lives. And I do believe that any child who dies of a vaccine preventable illness is a tragedy in the modern era. The rare times in which a child dies of measles, it is often in the setting of a comorbid condition or severe malnutrition. And perhaps that is the rationale scientifically and physiologically as to why some supplementation in terms of nutrients may provide a benefit to children who are very sick and hospitalized with measles.

Senator HICKENLOOPER. Right. And I don't deny that. Thank you. But I'm getting gaveled.

Dr. MAKARY. Thank you, Senator.

Senator HICKENLOOPER. Thank you so much for your service.

Dr. MAKARY. Thank you, Senator.

The CHAIRMAN. Senator Husted.

Senator HUSTED. Thank you, Mr. Chairman. Great to have you before the Committee. I enjoyed Dr. Makary the conversation we had in my office. And I want to just give you a chance to share some thoughts kind of building on what I'm sure others have asked you.

I am deeply concerned about how much inflationary cost the healthcare system has created for the American public over the last decade in the 21st century. We talk about inflation around here, the most inflationary cost affecting consumers, businesses, the American public, the American taxpayer is healthcare costs. We seem to spend more, get worse outcomes.

You look at the fact that from the earliest stages we have children who are unhealthier, worse diets, more obesity, which lead to problems like diabetes, lower quality of life, lower productivity as they go through life, higher costs in the healthcare system, that continues to manifest through life on all those fronts. And then the government and the taxpayers end up paying for all of it through Medicare and Medicaid. It is driving us into bankruptcy in some levels and costing people and families the ability to afford to live. And so there are lots of ingredients to that.

How do we take cost out of the healthcare system, whether it is making people healthier and in making this whole system sustainable for the long run.

Dr. MAKARY. Well thank you Senator Husted, and it's good to see the Cavaliers doing great this year. I hope this is their year to win it all. I enjoyed our time in your office.

Senator HUSTED. We only have one championship in Cleveland. That was when LeBron was there.

[Laughter.]

Dr. MAKARY. First of all, you are a hundred percent correct, and this is something I'm very passionate about. Healthcare costs are

spiraling out of control, and its burdening everyday American businesses and families. It's getting more and more difficult to compete with businesses overseas because of healthcare costs. It outpaces inflation.

When we are spending money that we don't have as a country, it drives inflation and inflation is a backhanded dirty tax on the poor. It doesn't affect the wealthy; it affects the poor. And that's why we've got to address healthcare spending. We've heard of many different ideas out there, but the main root issue is the health of the population, and it is getting worse. 75 percent of adults have some comorbid condition or diabetes or pre-diabetes, or are overweight or obese. 3 in 10 teens now have insulin resistance, that's not good for our future as a country.

Thanks to President Trump and Secretary Kennedy for the first time, we're talking about root causes, both on a research basis and in terms of what we can do at every agency. And within the FDA, I do think there are things we can do to help empower people, by facilitating this independent scientific review of devices and other ways to prevent chronic diseases with continuous glucose monitoring, continuous blood pressure monitoring, and healthy foods for children.

If confirmed, my goals are very clear at the FDA, more cures, and meaningful treatments for Americans, including diagnostics, healthy food for children, and rebuilding the public trust.

Senator HUSTED. Great. I look forward to working with you on all those issues, as I'm sure many of the Members of this Committee do. One way that we can drive more efficiency and speed to market for things that can improve lives and hopefully lower costs is through technology. I know that I was involved with the Cleveland Clinic when they got the first quantum computer focused on healthcare research, and you use things like quantum and AI to drive discoveries, speed to market with these. Could you talk about how the FDA under your leadership would think about those things?

Dr. MAKARY. Thank you, Senator. I think there's a number of opportunities with AI right now that we have, that we've never had before. We have an incredible opportunity to use AI to help reviewers in the review process, not to replace the human reviews, but to aid them and assist them in the same way that EKGs are read by AI devices that tell us normal sinus rhythm at the bottom of the EKG. Now, we still look at the rhythm, but it aids and it may help the efficiency among the reviewers.

We can use AI also in drug design and drug development. Now, that's not something the FDA does, but the FDA can help provide data to help train machine learning models to help design AI systems that can predict toxicities, adverse events, and even cures for some conditions.

Finally, AI can be used to aid with data monitoring in a post-approval setting. So, we don't learn 5 years after Vioxx is approved that 38,000 Americans died from it. Thank you.

The CHAIRMAN. Thank you, Senator Husted.

Now Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman. I'm from Boston, the home of the World Champion, Boston Celtics. Good luck to the Cavaliers.

[Laughter.]

Senator MARKEY. But we'll have a little bet. You stated that you want to ensure that the FDA holds the gold standard of trusted science and transparency. In order for that to happen, the FDA commissioner must also uphold the gold standard for trusted science and transparency.

In your financial disclosures, you disclosed that you made over half a million dollars from Global Appropriateness Measures LLC. The client list for that company includes companies that are interested in making money off of the healthcare system, insurance companies, hospital chains, private equity backed companies. So, can you tell the Committee how much you made from those private equity and venture capital backed companies?

Dr. MAKARY. Senator, first of all, thank you for the question, and I enjoyed our conversation prior to this hearing. I'm very proud of my work at Global Appropriateness Measures. The purpose of the endeavor, was to lower healthcare costs for Americans by reducing unnecessary surgery and medications——

Senator MARKEY. I appreciate that. Just for the record, can you just tell us how much you made from the private equity and venture capital backed companies?

Dr. MAKARY. I have been a shareholder in Global Appropriateness Measures. I am fully divesting, I don't have the exact numbers at my fingertips, but they were all disclosed to the Office of Government Ethics, and they're all part of the disclosure system.

Senator MARKEY. Was it in the millions of dollars or less?

Dr. MAKARY. Over the course of what period of time?

Senator MARKEY. Over the period of time that you had a relationship with them.

Dr. MAKARY. There was revenue of that company in the millions of dollars. Yes. And I am one of the shareholders of that company, and I am very proud. The best way to lower drug prices in the United States are to stop taking drugs we don't need. So, I do believe in the appropriateness of care, and that endeavor was designed to create software, so we can monitor——

Senator MARKEY. I appreciate that. And we're just looking at the transparency issue, so I'm just trying to help you to be transparent here. So how much were you paid by insurance companies, including devoted health services and insurance company that primarily sells Medicare Advantage plans?

Dr. MAKARY. Yes, that figure is in the Office of Government Ethics Report. I don't have that exact number at my fingertips. And of course——

Senator MARKEY. Was that in the millions of dollars as well?

Dr. MAKARY. No, that was far less. And again, I'm one of the shareholders of that company.

Senator MARKEY. Well, I think the American people do deserve your full transparency about how you might be influenced by the

healthcare industry, insurance companies, private equity, and venture capital funds. And that's what I'm trying to get at here.

Dr. MAKARY. Yes, all of those reports will be public Senator.

Senator MARKEY. They will be public, they're not public at this point. So, I'm not in a position to ask you about them. And that's why I'm asking you if——

Dr. MAKARY. Office of Government Ethics releases it at a certain point of time.

Senator MARKEY. But it's not helpful for the confirmation hearing, which is essential in terms of the public understanding, all of the potential, not actual, but potential conflicts of interest that might show up. The FDA is responsible for approving medical devices or drugs that may impact how much insurance companies pay or what they cover. The same insurance companies that do overcharge Americans and undercover their care. It will impact hospital costs and private equity.

You're coming into this role with relationships preexisting, that have a profit interest in the decisions that you will be responsible for making. That's why I'm raising these issues. Will you commit today to not participating in any decisions that would have an impact on known clients of Global Appropriateness Measures during your tenure as FDA commissioner?

Dr. MAKARY. First of all, Senator, I appreciate your enthusiasm on this topic. I am one of the biggest advocates that was involved in the health insurance industry transparency of the secret negotiated rates. So, I'm a big—I'm with you. The recusals that I will be taking are a hundred percent in line with the Office of Government Ethics recommendations, which were not to resign from everything, but I chose to resign from everything to ensure no appearance of a conflict of interest.

Senator MARKEY. That's important for us to hear. And the same thing, will you commit today to not participating in any decisions that would have an impact on private equity and venture capital investors of those clients as well?

Dr. MAKARY. Senator, I commit to following the Office of Government Ethics Agreement.

Senator MARKEY. Well again, it's just so important for us to understand this going forward, because of obviously the increasing role that those sectors are now playing, and they will be attempting to influence FDA decisions. So that's the reason why I'm raising the questions and total transparency is absolutely necessary. Thank you, Mr. Chairman.

Dr. MAKARY. Thank you, Senator.

The CHAIRMAN. Thanks. And I'll note that as you mentioned that all your financial records have been with the Office of Governor Ethics.

Senator Banks.

Senator BANKS. Thank you, Mr. Chairman. On that note, doctor, you've been very transparent, right?

Dr. MAKARY. I believe so.

Senator BANKS. Talk about that process. I mean, how transparent you have to be to get to this point today.

[Laughter.]

Dr. MAKARY. Well, there was a massive disclosure of basically every single share of everything that I own. And that process took a number of weeks and I would describe it as a colonoscopy with a small bowel follow through. And everything is out there and basically, I will have essentially no privacy when the Office of Government Ethics chooses to release that form. But that's Okay. I'm proud of everything that I've done, and I'm more than happy to acknowledge that I've agreed to divest or resign from everything.

Again, I was given the option not to resign from everything, but I chose to resign from everything, because I want to ensure independence. This is not a job I'm taking to audition for my next job. This is a job I'm doing to serve the American public. I believe in more cures and meaningful treatments, healthy food for children, and rebuilding the public trust. So, Senator, I can commit to you that I am absolutely dedicated to that mission, and I am not there to audition for a future job.

Senator BANKS. I appreciate that, because this is so important. I mean, you've been nominated for this position because you're incredibly accomplished, your background perfectly fits the role that you're about to take, and you bring experiences and success to the table to be the new head of the FDA and change it.

Because you've talked about this, you mentioned in your testimony that healthcare has become too fragmented, too cold, and too corporate, right? I mean and you're going to go there to shake that up and change that. The Make America Healthy again movement, that was a big part of giving this President a giant mandate with Secretary Kennedy and others who are coming to the table, the role that you're going to play is really important to that, to disrupt it.

I think we all agree, that I think the American people agree, that the medical establishment is often condescending toward the American people, it is something that we have to disrupt and change. Can you talk about how you're going to do that at the FDA?

Dr. MAKARY. Thank you, Senator. And I do agree a hundred percent that for the first time ever, President Trump and Secretary Kennedy had moms that were Republican, Democrat, independent, come out and vote because they care deeply about the health of our Nation's children.

They want to see healthier food for children. They want to see an industry that has, they want to see an FDA that is independent of corporate influence, but at the same time working with partnerships around the country to facilitate, not just being a receive only mode. So, one of my goals is to ensure that the FDA maintains its scientific integrity and that we can do what we can to contribute to the Make America Healthy again spirit.

Senator BANKS. Very good. Clinical and nonclinical testing are both very important parts of FDA's drug approval process. How do we modernize that process? Modernize testing?

Dr. MAKARY. Well, first of all, there are steps in the regulatory process where we can take a look and ask, do we need to use the

same processes that we've been using? Infant formula, for example, has had the same recipe for the last 40 years. And so, with the exception of Selenium, which was added in 2015, for 40 years we're requiring infant formula companies to use a standard recipe that was developed back when the food pyramid was misleading Americans and basically government misinformation.

Can we take another look at that? Can we create other ways in which new products can be brought to market safely? Can we look at real world data from European products? The more competition, the more resiliency in the supply chain, and the lower the risk of a shortage in the future. So, does infant formula need to go through the same process as a new drug? Or can we look at real world data and work with the companies to figure out a smarter way that uses both trusted science and common sense, which is a theme I would like if confirmed.

Senator BANKS. I want to work with you on that. The FDA is starting to allow patients to choose whether they want prescription drug instructions on paper or digitally, seems like common sense. But medical device instructions are still required to be on paper. Would you support changing that requirement?

Dr. MAKARY. Senator, my understanding is that's a requirement set by Congress, and I would be more than happy to work with you and Members of Congress to take a look at that.

Senator BANKS. Do you have an opinion on it?

Dr. MAKARY. I've heard arguments on both sides. One thing that people have raised is that, on one hand it may be a waste of paper, it's a lot of paper. On the other hand, seniors may not go to a Web site to look at the information. So, I think there are arguments on both sides. I would welcome the opportunity to work with you on reforming.

Senator BANKS. Thank you. I yield back.

The CHAIRMAN. Senator Banks, thank you.

Senator Alsobrooks.

Senator ALSOBROOKS. Thank you so much, Mr. Chairman. Good morning, Dr. Makary.

Dr. MAKARY. Good morning.

Senator ALSOBROOKS. Good to see you here. I'm going to just feed off of something my colleague just mentioned, some words that I think are significant. He said the medical establishment is condescending to the American people. And I'd like to offer that, unfortunately because this Administration has been so reckless in the way that it has handled civil servants, I believe they've been very condescending to many of them as well. And they are for the most part, many of them are my constituents, who work in institutions like John Hopkins and who are serving the people. And many of the actions of this Administration have been quite chaotic and confusing.

I want to just draw you to a few things. The committee staff raised last week, a memo that was put out by OPM, and this memo directed agencies to dramatically reduce staff and then they reversed themselves and I'm not sure whether you've seen the latest guidance from OPM this week, which backtracked that directive to

fire employees, instead said they clarified by saying that decisions to fire should be left to individual agencies.

I'd like to just ask you, given this updated guidance, whether we have your assurance here today at this hearing, that you will not arbitrarily fire employees at FDA, given the new guidance.

Dr. MAKARY. First of all, Senator, good to see you and I enjoyed our conversation. And I'm very proud to work at Johns Hopkins in the State of Maryland. And I'm a big believer in the professional career staff at the FDA, which is also located by and large, most of the employees are in Maryland. And so, you have my promise that if confirmed, I will do my own independent assessment on personnel.

I welcome input on efficiencies at the agency, at the same time, I want to make sure that the scientists and food inspectors and staff central to the core mission of the agency, have all the resources they need to do their job well.

Senator ALSOBROOKS. Thank you. And as you mentioned, there are so many valuable members. FDA does a tremendous service for our Country. They handle, for example, drug safety. When we think about reviewing medical devices, and you mentioned infant formula, where the men and women who are designated as the people who would make sure that those items are safe, are the ones who've been terminated.

I would like to know whether you would commit then to rescinding the termination of scientists who were working, for example, to address the bird flu?

Dr. MAKARY. Senator, I was not involved in any of those personnel decisions, but if confirmed, I will certainly do an assessment.

Senator ALSOBROOKS. Okay. You'll go back and look at those terminations?

Dr. MAKARY. Happy to Senator.

Senator ALSOBROOKS. Okay. Thank you. As well as the termination of the individuals and FDA's food division, the people who keep our food safe. And so, you would commit then to going back and looking at those terminations to make an independent assessment?

Dr. MAKARY. Of course, happy to.

Senator ALSOBROOKS. Okay. And in the same vein, I wonder whether you realize that many of FDA's salaries, you may already know this, are paid in large, not by taxpayers, but by user fees. Are you familiar with that?

Dr. MAKARY. Yes, I am Senator.

Senator ALSOBROOKS. The concept that the reason to terminate these employees is to save taxpayer dollars is one that's based on a premise that is largely not true. Since we use the user fees for many of the salaries, and that being the case, I wonder whether you would commit them to rehiring their 100 employees who were fired from FDA's Tobacco Center, which is 100 percent funded by user fees. Will you commit to going back and looking to rehire the 100 who were terminated?

Dr. MAKARY. Senator, if an employee has not logged onto their VPN in 2 years, then I don't want to rehire that individual. But if there are people that deserve a look, of course, I'm happy to look at that.

Senator ALSOBROOKS. Right? We're talking about, again, there's a big lie out there that says, these civil servants are lazy, they are shiftless, they don't show up. That is by and large, not true. So, asking you if you would go back and look at the ones who have been summarily terminated without cause, and your answer to that has been, yes, you will go back and make your own independent assessment.

Dr. MAKARY. I will do an assessment if confirmed, Senator. Thank you.

Senator ALSOBROOKS. Okay. Thank you. And finally on Tuesday, DOGE made the GSA release a list of over 400 government buildings that they want to dispose of. And many of these are in White Oak Campus, which is in Maryland. One of them is in a building called Building Number One. And I wonder whether you're familiar with building Number One?

Dr. MAKARY. I'm not familiar with the numbering of the building, Senator. I'm sorry.

Senator ALSOBROOKS. Well, that's where your office would be. And that's one of the buildings that the DOGE has put on the list to close shutter and close up. And so, again, just pointing out that many of these decisions are arbitrary, that they harm the work that we do and harm the American people. And just wanted to ask you if you would be committed to making decisions that make sense and that do not eliminate the FDA.

Dr. MAKARY. I believe in common sense and trusted science. And if confirmed, you have my commitment to do an assessment of personnel, to look at efficiencies. I welcome the input of any organization, of any individual Member of Congress, from the Administration, and the DOGE team as well, to figure out how the government can be more efficient.

Senator ALSOBROOKS. Thank you so much, doctor.

Dr. MAKARY. Thank you, Senator.

The CHAIRMAN. Thank you, Dr. Makary.

I'd like to submit for the record a Washington Post article referenced by a HELP Committee witness, an abortion survivor, Melissa Ohden, regarding a woman who took mifepristone twice, including once obtaining it online and taken outside the FDA's 10-week indication window. She still delivered her baby. While FDA has conducted safety studies on the product, I'm not aware that they've studied any safety outcomes related to a child who might still be born.

As a physician, sending women abortion pills without a complete evaluation of the gestation of her pregnancy or checking for an ectopic pregnancy is clearly a safety issue. And that's why I would urge Dr. Makary to return the REMS policy in place during the first Trump administration, requiring an in-person visit.

[The following information can be found on page 38 in Additional Material:]

The CHAIRMAN. With that, this concludes our hearing. And I'll just say that I know your family's incredibly proud of you, and I just thank them for being here as well. Believe me, you're on for a ride. So, thank you for volunteering. For any Senators who wish to ask additional questions, questions for the record will be due tomorrow at 5 p.m. This concludes the hearing.

ADDITIONAL MATERIAL

Evelyn, 25, holds a stuffed bear that weighs the same as her daughter, Olivia, at birth.

Story by Amber Ferguson

Photography by Callaghan O'Hare

April 6 at 6:05 a.m.

Listen Share Comment Save

HOUSTON — It had been nearly a year since Evelyn had seen Olivia in person, and she had grown nervous about a planned reunion.

When she finally arrived at the three-story townhouse where a party for the baby she placed for adoption was being held, she was greeted by Carolyn Whiteman, the 44-year-old woman Evelyn had chosen to raise her child. Whiteman held bright-eyed Olivia in the doorway.

“I can’t believe she’s gotten so big. She’s so cute,” Evelyn, 25, said, beaming with tears in her eyes.

Deep reads

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For hours, Evelyn’s and Whiteman’s families marveled at Olivia’s eight teeth and how she crawled and grabbed their pant legs to pull herself up on her feet.

"It's so crazy being here and looking at Olivia," Evelyn's dad told Whiteman. "She crawls just the way Evelyn did when she was a baby." His gaze locked on the infant as her tiny toes gripped the hardwood floors.

But Evelyn's dad, a retired military veteran, resisted the urge to hold the infant, rebuffing Evelyn's encouragement until the end of the party. He was confident in his daughter's choice but didn't want to become attached to a grandchild he couldn't help raise.

▶ How her failed abortions fulfilled another woman's dreams
7:38

Evelyn's repeated attempts to have an abortion were thwarted by Texas's six-week ban. This is how she gave a home to her baby. (Amber Ferguson, Drea Cornejo and Reshma Kirpalani/The Washington Post)

A year earlier, Evelyn had been consumed by guilt, depression and hopelessness, she recalled in months of interviews. Her world had shattered when two lines appeared on a home pregnancy test.

She lied and hid the pregnancy from her parents for 34 weeks and traveled to two states to try to end it. She detached herself from the baby growing inside her, ignoring the flutters of movement in her expanding stomach.

Her repeated attempts to have an abortion were thwarted by Texas's six-week ban and a pregnancy clock that worked against her. She and her immediate family spoke to The Washington Post on the condition that their last name would be withheld to protect her privacy.

Now, here she was with a woman she barely knew, visiting the child she birthed despite all of her plans.

The women, Evelyn and Whiteman, couldn't be more different.

Evelyn, half-Native American and half-Black, with curly, sandy brown hair, felt internally broken as the weight of unmet expectations and the fear of the unknown seemed to overtake her when she accidentally became pregnant. While Evelyn struggled academically, Whiteman had degrees, a community of friends, and a supportive, boisterous Grenadian family. But after struggling to find a Black sperm donor, she would stand in the entryway of the empty guest bedroom in her newly constructed home, praying and longing for a baby.

Now Evelyn and Whiteman were bound together, by a child.

Evelyn, 25, gets ready for a reunion with her daughter, Olivia, who was adopted by Carolyn Whiteman.

Evelyn spent most of 2022 terrified.

After graduating from high school, she enrolled in a San Antonio community college. But she says she wasn't motivated, sometimes skipping classes and hanging out with people she knew weren't the best for her. By January of that year, she was on academic dismissal — for the third time — after her grade-point average dropped below 2.0. This time, she would have to sit out an entire academic year.

Evelyn began talking to a guy she met on social media. They dated for a few weeks and had casual sex.

A few weeks later, in February, the air in her body seemed to disappear as she stared at the positive pregnancy test on her bathroom counter.

A single thought swirled through her head: *I can't have a child. I can't have a child. I can't have a child.*

Her relationship, brief and tumultuous, went downhill swiftly and ended after she told him about the pregnancy. She immediately began making plans to have an abortion.

She decided not to tell her parents. Her mom (a nurse) and her dad (a former pilot) were retired military veterans who had struggled to conceive. They were in their mid-40s when they adopted Evelyn at 3 weeks old.

Although Evelyn had always felt close to them, she was petrified to tell them about the pregnancy.

"My parents are in their early 70s. I didn't have a job or any money. I didn't want to put it on them to raise the baby," Evelyn remembers thinking. She felt ashamed.

A friend, Bianca Hernandez, accompanied her to Alamo Women's Reproductive Services, in San Antonio three days after the positive pregnancy test. Around 8 a.m., Hernandez says she watched Evelyn walk past screaming protesters holding antiabortion signs and into the clinic.

Evelyn knew about the new law. A few months before she entered the clinic, Texas had become the first state in history to ban abortions beyond six weeks of pregnancy. It was one of the most restrictive abortion laws to take effect in the United States in nearly 50 years.

Abortion clinics were bombarded with calls from women rushing to get appointments to terminate their pregnancies. Evelyn was one of them.

When it was her turn, she reclined on the exam table and crossed her fingers, hoping she wasn't too far along.

"You're six weeks and four days pregnant," she recalls the doctors saying.

"So it's too late?" she asked.

Yes, she was told.

The clinic's staff advised her to go to Oklahoma before that state adopted an abortion ban, too.

Evelyn texted Hernandez, who was waiting outside: "It's not good." Back in the car, she started to weep. "I have to go to Oklahoma," Hernandez remembers her saying.

It was time to tell her parents, Hernandez told her. Evelyn refused.

Her appointment at Tulsa Women's Reproductive Services wasn't until mid-April — nearly four weeks later. She didn't want to make the six-hour journey alone, so she called her birth mother, Tamela, who lived near the Oklahoma border.

Her birth mother was a teenager when she became pregnant with Evelyn. With the encouragement of her adoptive mom, Evelyn had found her on Facebook in 2016. They stayed in touch. Evelyn hoped she would be able to understand her predicament.

Tamela says she was surprised by Evelyn's call but immediately understood her fear. "You don't think it's going to happen to you, that you're going to get pregnant so young. And it's scary. It's very scary because it happened to me," Tamela remembers thinking.

During the hours-long car ride to Oklahoma, Evelyn says they sat mostly silent while listening to music. Evelyn thanked her birth mother for accompanying her and keeping the secret from her adoptive parents. She remembers Tamela

telling her that she was making a good decision and that ending the pregnancy would be best for her future.

They checked into a DoubleTree hotel, and Evelyn spotted the clinic through the window.

Early the next morning Tamela watched as Evelyn maneuvered past yelling antiabortion protesters and entered the clinic. At the time, the Tulsa clinic's caseload had tripled to 500 cases per month, says Andrea Gallegos, the executive administrator at the Texas and Oklahoma clinics Evelyn went to. Most of the patients were from Texas.

The clinic's doctor estimated that she was nine, possibly 10 weeks along and handed her a prescription for mifepristone, Evelyn says. She should dissolve the pills under her tongue to start a medication abortion, according to the prescription she received from the clinic. She was told to take the remaining four pills, misoprostol, "orally" at home within 48 hours.

Back in the car, Tamela says Evelyn showed her the paperwork from the clinic and appeared relieved and happy. "They made me feel welcomed and were really supportive in there," Evelyn told her birth mother.

She didn't take the second dose until she returned to her home in San Antonio, nearly two days later. She wanted to be at home where she would have more privacy, Evelyn says. Her stomach had started to cramp. Then she saw the blood clots in the toilet. She bled for hours and had spotting for a couple of weeks.

Confident it had worked, she says she didn't bother to make the follow-up doctor's appointment the clinic had strongly recommended.

Evelyn found out she was pregnant in February 2022 and chose to give up her child for adoption after she was unable to get an abortion.

May and June passed. Evelyn started working as a fulfillment associate at Macy's. But she still hadn't gotten her menstrual cycle. She took another pregnancy test and was stunned when it came back positive.

A family friend, Yvette, a registered nurse, says she arranged for Evelyn to get bloodwork done at a hospital. At the hospital, a midwife, Monica, also measured Evelyn's uterus and conducted an ultrasound. Both women spoke on the condition that their last names be withheld because they were not authorized to speak by their employer.

Evelyn fainted when she saw that there was a heartbeat, and was in and out of consciousness for about five minutes, the midwife recalled in an interview. She was obviously in denial, Monica said. Perhaps it's time to consider adoption, the midwife told her.

"No, no, no, I can't go through with the pregnancy," Evelyn responded.

Evelyn says she didn't know the pills sometimes didn't work. It is a rare occurrence, but she later learned that 3 percent of medication abortions fail when gestation reaches 70 days, or 10 weeks, according to the American College of Obstetricians and Gynecologists. The odds of failure increase if the patient waits longer than prescribed to take the second dose of the medication, several medical experts said.

The Oklahoma clinic has since closed, and Gallegos said she doesn't have access to Evelyn's medical records. Failure is uncommon, but the clinic advises all patients to make follow-up appointments and receive an ultrasound, she said. "Have we had patients who have failed pills? Yes. Is it the norm? No," Gallegos told The Post. "We would try to schedule every patient to come back for a follow-up and ultrasound to make sure that everything was completed. Sometimes patients made it to those appointments, sometimes they didn't."

Desperate, Evelyn found a website, Aid Access, that shipped abortion medication across the country. After speaking with a doctor by phone and paying $150, she waited for pills that were being mailed from India.

Evelyn had told the doctor she wasn't sure the date of her last period. At the time, Aid Access prescribed medication abortion pills for patients who were up to 10 weeks pregnant, taking into account the two-week shipping time. "Aid Access trusts women to tell the truth about their situation," Rebecca Gomperts, the company's director, told The Post in a statement.

It may already have been too late for the medication to be effective, Evelyn says she told herself. But she was convinced that she didn't have any other choice.

When the pills arrived, she ripped open the package and read the instructions over and over. She said she wanted to do it right this time.

For a couple of hours she had cramps but no bleeding. She emailed the company. They advised her to take the additional pills they sent, according to

the email. Still, Evelyn says, nothing happened.

She was nervous, she wrote the company in another email reviewed by The Post. "I've been through this before and started bleeding within two hours," she told them of her previous experience with a medication abortion.

In the email exchange, the company offered to send more medication to a pharmacy near Evelyn, but she remembered the warning of Yvette, the registered nurse: At this stage, nearly five months into her pregnancy, an abortion was becoming risky to her health. She refused the offer of more medication.

Evelyn spent August and September in an emotional haze, pretending that life was normal around the house she shared with her parents but researching states that offered abortions later in pregnancy. She was still hanging out with friends, most of whom were oblivious to her pregnancy. During family dinners, she and her parents would chat about the latest movies, and they would stress the importance of her returning to school.

She found a clinic in Albuquerque that offered second-trimester abortions. She was past the halfway point in her pregnancy and approaching the third trimester, but she still had time, Evelyn told herself.

The clinic staff warned about the health risks of having a surgical abortion so late in her pregnancy but helped connect her to two abortion organizations that covered the cost of her plane ticket, hotel, food and the $12,000 procedure.

"There are no circumstances surrounding your pregnancy that will make you more or less deserving of assistance," the New Mexico Religious Coalition for Reproductive Choice wrote Evelyn in an email confirming she was approved for assistance. The organization doesn't keep abortion seekers' information, said Janeth Orozco, spokeswoman for the nonprofit group. Evelyn's travel documents to New Mexico list the coalition as the payee.

At the beginning of October 2022, Evelyn told her parents she was going to visit a friend across town but instead boarded a plane to Albuquerque. She called the midwife who had conducted her ultrasound while waiting to take off. Evelyn needed her bloodwork and lab results. She sounded desperate, the midwife says.

Behind the reporting

Washington Post senior video journalist Amber Ferguson has written extensively about women's health issues. In 2022, she explored the shortage of Black sperm donors and the difficulties it creates for some Black women who want to have children.

The next morning, Evelyn found herself staring up at fluorescent light panels. A nurse moved the curved ultrasound wand across her belly and tickled the long dark line that had emerged in the center of her stomach as the baby grew.

"I'm so sorry," Evelyn remembers the nurse telling her, looking at the screen. "You are too far along, 32 weeks pregnant," she said, pausing before adding, "We can't help you." The clinic's doctors aren't trained to perform abortions after 24 weeks, according to Southwestern Women's Options.

Evelyn burst into tears.

Suddenly out of options for ending the pregnancy, Evelyn began to consider a future that had once seemed impossible. She would be giving birth.

Her parents were already upset she had been kicked out of school. The weight of disappointing them further and having them find out she had unprotected sex was something she had not wanted to face.

She hadn't seriously considered adoption until now, despite being adopted herself. But now that seemed to be the only option.

Evelyn says she knew adoption could be positive. Her parents had given her an ideal childhood. There were trips to Argentina and France. She played soccer

and basketball before falling in love with volleyball.

She was grateful for her family but sometimes had questions. *What was her birth mother like? Did she have any biological siblings?*

When she returned home to San Antonio, she called the Gladney Center for Adoption, in Fort Worth, the agency her parents had used.

After concealing her growing belly from her parents for months, it was time to stop lying. She was starting to show.

One day, before heading to the movies for a family outing, she asked her mother to join her in her bedroom. By the time she had the courage to tell her mother, Evelyn was more than seven months pregnant. The words spilled out through tears — the abortion attempt, her fear.

Her mom, she learned, had been suspicious of the big robe she had been wearing around the house. But Evelyn was still too terrified to tell her father about her pregnancy. So her mother did.

His head dropped in disbelief, Evelyn's mom recalled. "Go talk to her. She needs you," she told him.

Her dad gave Evelyn a long hug in the kitchen. He was shocked, disappointed

and hurt. She should have come to them sooner for help, he told her.

Her parents assured her they would support any decision she made, including placing the baby up for adoption.

Two weeks later, on Nov. 10, her mom began timing Evelyn's contractions. Evelyn had initially mistaken the throbbing for gallbladder pain. She quickly packed a hospital bag. Six hours later, she gave birth.

Carolyn Whiteman, 44, struggled to find a Black sperm donor and was denied by two adoption agencies because she was single.

Two hours east, in Houston, Carolyn Whiteman, a human resources executive for a chemical company, had been struggling with becoming a mother for years.

In 2020, she had tested positive for BRCA2, a hereditary gene that puts her at increased risk of developing ovarian and breast cancer. Her OB/GYN told her

she would need to have her ovaries and uterus removed in her mid-40s.

She had always seen herself as a career-oriented Black woman who should have been married with kids in her mid-30s.

Now she was out of time and couldn't wait any longer if she wanted to be a mom.

At 41, Whiteman underwent two cycles of egg freezing, in 2021. She froze 24 eggs and felt "pretty lucky."

For three months, she says she meticulously searched cryobank websites daily for at least an hour. She joined Facebook groups for women looking for donors. There, she read posts from other Black women expressing the same struggle: There were hardly any Black sperm donors.

[America has a Black sperm donor shortage. Black women are paying the price.]

A few months after Whiteman ended her sperm donor search, her younger sister, Anika, sent her an Essence magazine article about a single woman who had adopted a baby at 49 after she too froze her eggs. Whiteman began researching private open domestic adoption, an increasingly common choice for keeping birth parents involved in the child's life.

Whiteman met the income requirements and had good references. She confidently called two adoption agencies in early 2022 but was rejected because she wasn't married.

She was devastated but contacted three other adoption agencies. They couldn't help her either. They already had long waitlists and weren't accepting applications from new prospective parents, they told her. Another door is closed, Whiteman remembers thinking.

Then a co-worker referred her to another agency, Gladney, which accepted her application. There was a need for more Black adoptive parents and it would

make her an attractive applicant to many birth parents, she was told. It was expensive — $50,000 — and took months as she went through various interviews and trainings. But she finally had hope.

Her profile went live on the agency's website in October 2022. "I will ensure you always hold an honored place in your child's life," Whiteman wrote in her letter to prospective parents. She prepared for a lengthy wait that she was told could last two years.

Olivia at the hospital (Courtesy of Evelyn)

Evelyn had not had any prenatal care and didn't know the gender of her baby until she delivered. But the baby, a girl, was healthy.

It felt like whiplash. She had tried for months not to have the child she was silently cradling. And she says she quickly discovered she was in love.

She took selfie videos, with playful social media filters, holding her daughter. Her photo album quickly filled with videos of Evelyn bottle-feeding, learning to swaddle and admiring the baby's fussy sounds.

She named her Kaya, the same name Evelyn had been given at birth — before she was adopted.

She was becoming attached but knew the decision she wanted to make.

The next day, Evelyn chose five prospective families to interview. But after reading Whiteman's profile four or five times, she gravitated toward the woman's warmth. Evelyn admired all of the pictures of Whiteman's family and friends and how she talked about traveling, working out and spoiling her goddaughters. To Evelyn, she seemed like someone who was "ready to give a child everything."

When they met over Zoom, the women say they talked of spirituality, faith and the importance of family time.

Whiteman mentioned that she was on the local board of Girls Inc., a nonprofit that encourages young girls to become leaders. Evelyn smiled. "I was part of Girls Inc. when I was younger," she told Whiteman.

Eight hours later, Whiteman received a call from the adoption agency.

She was about to become a mom.

She hung up, went online and signed up for an infant CPR class scheduled for 8 a.m. the next day.

The next 10 days were chaotic.

Whiteman hired a nanny and started shopping. She tested strollers and bought a formula maker.

Evelyn and her mom picked out a fluffy, light-pink dress from a children's store for the baby to wear on adoption day. They went to a craft store and bought soft fabric with rainbows on it. Evelyn knit the fabric into a baby blanket.

Adoption on the rise

The Post spoke with 10 adoption agencies in states that have recently restricted abortion. Eight reported experiencing an increase in the number of children placed for adoption over 2023, which they said correlated with the rise in abortion restrictions.

The night before Evelyn was to turn her baby over, on Nov. 29, 2022, the women traveled to Fort Worth and met in person for the first time over a chicken quesadilla dinner. Whiteman had grown nervous that Evelyn would change her mind but learned she had already signed the relinquishment papers.

The soon-to-be mom told Evelyn she had always loved the name Olivia.

"In honor of you, I want to keep the name that you had for her. So I will name her Olivia Kaya-Simone," Whiteman told her.

Evelyn hadn't taken Olivia home when she left the hospital, worried it would be too hard to parent her while the adoption was finalized.

In the moments before officially handing Olivia over to Whiteman, Evelyn sat alone with Olivia in a Gladney office and whispered: "I love you, I love you, I love you." She kissed Olivia's forehead and promised she would have a great life with Whiteman.

Eventually, when she was ready, Evelyn walked into a room as her parents followed her. Nearly all of Whiteman's family was there recording the moment and taking pictures. Face red with tears, Evelyn handed her child to her new mom. The two women sat and held hands for two hours.

Their case workers allowed them some time alone. Before they left, Evelyn says she wanted to explain to Whiteman how she had become pregnant and tell her about her abortion attempts.

"I really hope you won't judge me," she told her.

Evelyn, left, moments after she handed her daughter to her adoptive mother, Carolyn Whiteman, on Nov. 29, 2022. (Anika Whiteman)

In the weeks after the adoption, Evelyn says she barely left home. She cried every day and slept with Olivia's hospital clothes next to her for comfort. Her mother held her and said it would be okay.

She was sad but confident about her decisions, including her failed abortion attempts. A therapist helped her make peace with the guilt.

Olivia was in a good place, and Evelyn would get to watch her grow up, her therapist assured her.

As she grappled with her feelings, she watched the abortion landscape that had tripped up her decision to end her pregnancy continue to tighten. Twenty states had enacted laws limiting abortion access. The clinic in San Antonio she initially went to for an abortion closed, and the Oklahoma clinic that gave her medication abortion pills relocated to Illinois.

Other women should have the same choices she had, Evelyn remembers thinking, including an abortion.

PHOTO GALLERY

Carolyn and Olivia at home

+4

Click or tap an image to see all the photos.

Slowly, Evelyn's fog began to lift. In January 2023, her academic dismissal period ended, and she enrolled in classes at a community college. To return, she was required to submit a letter to the dean and wrote about her unplanned pregnancy and how much restarting her education meant to her.

She attended every lecture, went to tutoring and turned in her assignments on time. She passed all of her classes and, for the first time, earned straight A's.

“I’m going to use everything I went through to motivate me,” Evelyn remembers telling her mom. “I want Olivia to grow up and be proud of me.”

In the summer, she applied to a four-year historically Black college near Houston. “So pleased to hear you are back on track to continue your higher education,” the acceptance letter said.

(The Washington Post)

Eleven months after giving birth, Evelyn poured buttermilk pancake mix onto a hot pan, a late breakfast for herself and her new roommate before class. She had moved into an off-campus apartment, her first time living away from her parents, and was basking in life as a college student.

She goes to the gym four days per week, attends a midweek Bible study meeting on campus and is looking for a criminal justice internship. She goes out with her friends on the weekends and hopes to try out for the club volleyball team next year.

But she and her roommate were still getting to know each other, and Evelyn hadn't told her about her pregnancy yet.

Instead, her roommate watched as Evelyn giggled in excitement about a birthday party planned for a new friend on campus the next night. She reviewed the contents of her overstuffed closet, looking for an outfit and pulling out different crop top options.

"I'm trying to shop my closet. I don't want to spend money on a new outfit," Evelyn told her.

But the evidence of Olivia is everywhere. Evelyn sleeps with a gray 6-pound, 11-ounce teddy bear — Olivia's birth weight — that her Gladney caseworker gave her after she relinquished custody.

In the morning, she fluffs her hair and swipes through videos of Olivia on her phone.

She watches clips of the 1-year-old sitting in a highchair and stuffing cereal into her mouth. In another, Olivia is having her ears pierced.

Receiving Whiteman's photos and videos of Olivia over the months had comforted Evelyn, but seeing her for the first time in a year, holding her, would be different.

She had longed for this planned reunion for months — circling the date in her spiral planner, buying a small gift.

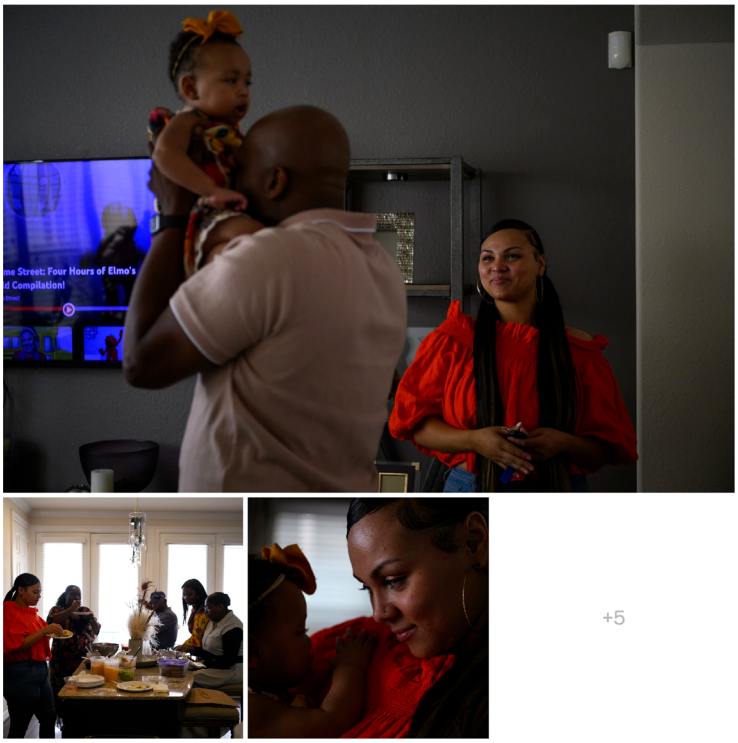
Whiteman had bought matching mommy-and-daughter multi-print dresses for herself and Olivia. She asked Evelyn to wear a bright-orange top so that they would all coordinate.

On a sunny fall afternoon, Evelyn drove 45 minutes to the townhouse where Whiteman had said they would reunite. Her parents traveled two hours to join

her. Evelyn again laid eyes on the baby she had given birth to.

PHOTO GALLERY

A family reunion



+5

Click or tap an image to see all the photos.

In the kitchen, Whiteman gave her updates about Olivia, telling her about the baby's love of Elmo, Ms. Rachel videos on YouTube and the more than 90 bows

she had collected to coordinate with her outfits. “Bows are the new barrettes,” Whiteman joked.

While sitting next to Whiteman on the couch, Evelyn rolled up the left pant leg of her skinny jeans and showed her a small tattoo on her ankle — a heart inside a triangle.

“The three points represent the birth mother, the adoptive mother and baby,” Evelyn said. “The heart represents the love they all share.”

It was a tattoo she had gotten years earlier to represent her own adoption, but it had taken on new meaning.

Whiteman watched as Evelyn studied Olivia’s every feature, took Snapchat pictures, and bounced her up and down in a corner of the living room.

“The more people who love Olivia, the better,” Whiteman said as she watched the two play.

As the sun began to set, Evelyn and her parents prepared to leave. She caressed Olivia’s soft curls and gently kissed her on the forehead.

She left a children’s book written by Gabrielle Union and Dwyane Wade on the dining room table. On the inside cover, she wrote: “Olivia, With this book, I hope you will grow to love reading. I love you forever! — Evelyn.”

Leaving the reunion, Evelyn felt a flush of calm. Olivia was happy.

On the car ride home, she received a text from Whiteman. It contained details about a garden brunch. Evelyn and her parents were invited to Olivia’s first birthday party the next month, where they would play Olivia Trivia.

There was no doubt, Evelyn knew. She would be there.

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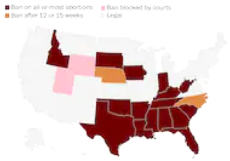

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Amber Ferguson

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[Whereupon, at 11:47 a.m., the hearing was adjourned.]

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