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NOMINATION OF MONICA BERTAGNOLLI TO BE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE NOMINATION OF MONICA BERTAGNOLLI TO BE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH

OCTOBER 18, 2023

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C O N T E N T S

STATEMENTS

WEDNESDAY, OCTOBER 18, 2023

NOMINATION OF MONICA BERTAGNOLLI TO BE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH

Wednesday, October 18, 2023

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

The Committee met, pursuant to notice, at 10 a.m., in room 430, Dirksen Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Murray, Casey, Baldwin, Kaine, Hassan, Smith, Luján, Hickenlooper, Markey, Cassidy, Collins, Murkowski, Braun, Marshall, Romney, Tuberville, Budd, and Barrasso.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. All right. Let's go. Okay. Thank you all for being here and the Senate Committee on Health, Education, Labor, and Pensions will come to order. This morning, we will be considering the nomination of Dr. Monica Bertagnolli to serve as the Director of the U.S. National Institutes of Health.

Let me begin by welcoming Dr. Bertagnolli to our Committee. We look forward to hearing from you and we thank you for being here today. And I see you have brought along a fellow Wyomian—or is that what it is? We welcome Senator Barrasso as well.

The NIH, with a budget of more than $47 billion, is the largest funder of medical research in the world. This research has led to new treatments and prescription drugs that have significantly improved the lives of Americans and people throughout the entire world, and I think all of us, every single American should be very proud of those accomplishments.

But having said that, let me say a few words about my concerns. I don't have to tell any American that the health care system in our Country is broken and it is failing. We spend almost twice as much per capita on health care as any other industrialized nation, yet we have 85 million people who are uninsured or underinsured.

We don't have enough doctors, nurses, dentists, mental health specialists. Our life expectancy is lower than other major countries and is actually in decline today. And very relevant to the hearing that we are conducting right now, we spend as a nation the highest prices, we pay the highest prices in the world for prescription drugs, in some cases 10 times more than the people in other nations, while the largest drug companies made over $112 billion in

profits last year and pay their CEOs exorbitant compensation packages.

One out of four Americans cannot afford to pay for the medicine they need, and thousands of families face financial ruin as they pay prices that they cannot afford for the prescription drugs that keep them alive.

Think about it for one second. Millions of people get sick. They go to the doctor. Doctor writes out a prescription. They cannot afford to fill the prescription the doctors write. How insane is that? But it is not just the high cost of prescription drugs impacting individuals.

In the largest hospital in my State of Vermont, and I don't think it's terribly different elsewhere, the high cost of prescription drugs account for 20 percent of the overall budget for the hospital, and that drives insurance costs up as well. Prescription drugs impact hospital costs big time. In other words, the outrageously high cost of prescription drugs in America is a crisis and it must be addressed.

Adding insult to injury, not only has the Federal Government not effectively regulated the price of prescription drugs, but the taxpayers of this country have over the years provided hundreds of billions of dollars in research and development into new prescription drugs that have provided enormous benefits, financial benefits to some of the most profitable pharmaceutical companies in the country.

For example, in America today, the median cost of new cancer drugs has gone up by more than 300 percent over the past decade, even though 85 percent of the initial foundational cancer research was funded by the U.S. taxpayer.

We are putting money, rightfully so, into research to deal with cancer, and yet we pay outrageously high prices. In June, this Committee released a report that found that the average price of new treatments that NIH scientists helped invent over the past 20 years is $111,000. In virtually all cases, American taxpayers are paying far more than people in other countries for the exact same medicine that the NIH and taxpayers helped develop.

Here are just a few examples from this report. Astellas and Pfizer charge Americans with prostate cancer over $165,000 for XTANDI, while the exact same drug can be purchased in Japan for just $20,000. This is a drug developed by American taxpayer dollars. Johnson and Johnson charges Americans with HIV $56,000 for SYMTUZA, while the same exact treatment can be purchased in the UK for just $10,000—a product developed with U.S. tax dollars.

Gilead charges Americans with non-Hodgkin's lymphoma $424,000 for Yescarta, or the exact same therapy can be purchased in Japan for just $212,000. And the list goes on, and on, and on. We pay for the research, drug companies develop the drug, they make billions, and then they charge us the highest prices in the world for the product. One last example.

After receiving $12 billion from the Federal Government, Moderna has quadrupled the price of the COVID vaccine, a vaccine

that was literally co-invented by NIH scientists, to $128, while the exact same medicine—same vaccine will be available in Europe for as little as $26. Really? Anybody here think that vaguely makes sense?

We developed the research. We pay for it. We pay the highest prices of the world, how people can't afford it—doesn't make sense to me. In my view, at this very difficult moment for American health care, and we are in a crisis situation, we need a NIH Director who is prepared to take on the greed of the pharmaceutical industry and use every tool at his or her disposal to substantially lower the outrageous cost of prescription drugs.

The 1,800 well-paid lobbyists from the pharmaceutical industry who are all over this place may not be happy about that thought, but that is precisely what the American people want. The status quo is not working. We need fundamental changes in the way that the NIH addresses the crisis of prescription drugs.

We need NIH directors prepared to reinstate and expand the reasonable pricing clause, make sure the pharmaceutical companies set reasonable prices for new prescription drugs developed with taxpayers, etcetera, etcetera. The whole lot of things the NIH can do. Now, is the NIH alone going to solve the problem?

Of course not. Other agencies, the Administration has got to be active as well. You know, the media describes what goes on in Congress as we are a very divided nation. Well, we are. But I will tell you this, whether you are a Conservative Republican, a Progressive, a Democrat, or an Independent, you know what we all agree on?

Every poll tells us that. And that is they want—the American people want Congress to deal with the outrageously high cost of prescription drugs. That is what we have got to do. Senator Cassidy, you are recognized for your opening remarks.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Chair Sanders. Today, the Committee considers the nomination of Dr. Monica Bertagnolli to be the next Director of the National Institute of Health. And Dr. Bertagnolli, thanks for being here.

Thanks for taking on this job and going through this Committee, which I know must be stressful, but again, very pleased to have you. You have an incredibly impressive resume, and I say that as a physician who formerly was in academics but has no resume that compares with yours and is reflected by the support that you have from the scientific community.

There is no questions regarding scientific qualifications, but there are people that will ask questions regarding your overall ability to lead the NIH in the next phase, and this is what my remaining remarks will be about.

Everybody knows the NIH's role in strengthening America's biomedical research and supporting public health, especially during a crisis. Unfortunately, it became a lightning rod for partisan debates during the COVID–19 pandemic, and that eroded the trust between the NIH and the public.

First and foremost, you will be tasked to rebuild the relationship with Congress and the public, being a leader that represents the interests of all Americans and not just of the scientific community.

This means making the agency more transparent and accountable to Congress while also advancing cutting edge science, effectively communicating to the American people, and rebuilding trust between public health officials and the biomedical research community.

The NIH Director must also protect and strengthen the valuable public, private partnerships that make up our biomedical research enterprise. And sometimes our public, private partnership was underestimated, but clearly, the private and the public partnership has been what has made the United States a leader in innovative drugs.

Last month, I issued a request for information from stakeholders on modernizing the NIH, and this will include buy in from all. I look forward to hearing from you about your vision for the agency and how you shall achieve. Now, during our meeting, we spoke about bioethical issues, including fetal tissue and embryonic stem cell research, and the use of hormones and other gender transition interventions on children.

Frankly, at times you avoided getting into specifics, citing a lack of expertise. But as the Director, you will have to have this expertise. You will need to be prepared to weigh in on topics that are not in your research specialty, but across the entire enterprise, making the policy decisions that will shape the direction of biomedical research.

While you will consult with experts and take input from your institute directors, you are ultimately the person who decides. I point out that this hearing is apparently happening today, it was not going to otherwise, because of a publicly acknowledged deal the Biden administration cut with Chair Sanders to implement partisan drug pricing policies in exchange for advancing your nomination.

Biden administration officials told us in a hearing earlier this year that policies similar to those in the deal that have been reported could risk future partnerships between the Government and the private sector. By the way, future partnerships critical to generating the cures important for cancer and Alzheimer's and for the next pandemic.

The partnerships that are the foundation of the U.S. biomedical research enterprise, which, by the way, leads the world in developing these cures. It is concerning that the Administration would jeopardize the long term success of this enterprise for the short term goal of advancing your nomination.

Last week, I asked President Biden and Secretary Becerra for a full accounting of any deals cut with Members of Congress relative to advancing your nomination. At 5.43 p.m. last night—this is kind of the problem. At 5.43 p.m. last night, I received basically a form letter that provided no information and intentionally ignored the request it was supposedly responding to. The Administration was

not forthcoming about any deals with Members of Congress, even though some of those details have been reported in the press.

Now, Senators expected to vote in your confirmation should be aware of any such deal prior to the nomination. That is not you, it is the process. And we speak about the breakdown of trust is like rhetoric, inflammatory rhetoric, which is true, true, true, but not related, is driving a process by the Administration on something that we should know about, but we are not being told.

Another example, in June, Senator Tuberville and I sent the Acting NIH Director a letter about NIH funded projects that resulted in the death of two adolescents. We didn't get a response to that letter till September 15th, a week after the Biden administration struck the deal to move your nomination. I believe you when you say that you are committed to transparency and rebuilding the NIH's relationship with Congress.

I appreciate that commitment, but I have concerns given the Administration's history of failing to respond to congressional oversight requests, particularly from Members of this Committee who are responsible for that oversight.

Rebuilding NIH's relationship with Congress will require a strong Director who can overcome partisan divisions, overcome the Administration's deliberate stonewalling of requests from Members of this Committee for that information pertinent to the work of this Committee, and work with both Republicans and Democrats to improve trust in our Federal health institutions.

That means being open and responsive to this Committee, which will directly oversee your work as NIH Director, if you are confirmed. I look forward to hearing how you shall fulfill these parts of the job and move the NIH forward. I thank you, and with that, I yield.

The CHAIR. Thank you, Senator Cassidy. And now, I would like to welcome our nominee, Dr. Monica Bertagnolli has served as the Director of the National Cancer Institute since October 2022.

Prior to that role, Dr. Bertagnolli was a surgeon at Brigham and Women's Hospital and the Richard E. Wilson Professor of Surgery of the Field of Surgical Oncology at Harvard Medical School. Dr. Bertagnolli is a longtime member of the American Society of Clinical Oncology, where she has served as both President and a member of the Board of Directors.

I thank her for being here today, and I now turn it over to Senator John Barrasso to introduce her.

Senator BARRASSO. Well, thanks so much, Mr. Chairman. And I am pleased to welcome to the Senate and to the Committee Dr. Monica Bertagnolli, who is a fellow physician and a Wyoming native.

President Biden has nominated her to be the Director of the National Institutes of Health, and it is certainly not every day that one of Wyoming's very own is nominated for such a high position in our Nation. Dr. Bertagnolli has devoted her entire life to medicine and medical research.

She earned a Bachelor's degree in Engineering from Princeton University, graduated from the University of Utah's Medical

School, and completed her surgical residency training at Brigham and Women's Hospital in Boston.

She then went on to be a research fellow in tumor immunology at the Dana-Farber Cancer Institute in Boston, and she later served as the Chief of Surgical Oncology for over a decade. She has continued caring for patients at Brigham and Women's Hospital while being a renowned cancer researcher.

She has also served as a Professor in Surgical Oncology at Harvard Medical School. She has trained not only the next generation of doctors, but also cancer researchers. And this makes her a perfect fit to serve as our current Director of the National Cancer Institute.

While many may know that she is a well-respected physician and researcher that she is, Wyoming knows her as part of a multi-generation ranching family, and I am proud to say that she has never forgotten where she came from.

As I have traveled and met with folks across Wyoming, in the Mountain West, I have heard of her great work, not only as a doctor, but also on the ranch. So that includes the ranch neighbors. If you want to know about somebody, you talk to their neighbors and their ranching neighbors.

They speak of her grit, her endurance, and her determination. Her commitment to the land and the livestock speaks volumes about her character and her courage. She understands the needs of rural health and of frontier medicine.

She has used her background, medical as well as the values that she learned growing up, to improve health care for all Americans. She serves as an adviser to the Huntsman Cancer Institute in Salt Lake City, Utah, which is a designated cancer institute for Wyoming.

She also advised Huntsman on how to reach patients in rural areas. She focused on reducing burdens on patients by using local cancer treatment clinics. One is in the Sweetwater Regional Cancer Center in her hometown of Rock Springs, Wyoming. Her firsthand experience in accessing health care in rural America gives her a perspective that is often lacking in Washington.

She has an extensive track record of cultivating private, public partnerships to push medical innovation forward. I know this background will serve her well as the Director of the National Institutes of Health. I have tremendous appreciation and admiration and respect for Dr. Bertagnolli.

With that being said, Mr. Chairman, I do have serious concerns about the way this Administration has handled the COVID pandemic, has politicized Government agencies such as the NIH, has attacked health innovation through the Inflation Reduction Act.

I think it is important that this position be filled with someone with a critical and an open mind, ready to tackle the important challenges ahead. And for all these reasons, Mr. Chairman, I support the nomination of Dr. Monica Bertagnolli to serve as the Director of the National Institutes of Health.

Thank you, Mr. Chairman.

The CHAIR. Thank you, Senator Barrasso.

Senator CASSIDY. Mr. Chairman, can I ask a quick question. Do you have to be Italian to be from Wyoming? You know what I am saying? I am just thinking that.

[Laughter.]

Senator BARRASSO. Well, in a bipartisan way——

[Technical problems.]

Senator BARRASSO. Well, Mike Enzi, Republican. There was a former Congressman, Tito Ron Calio, who is also from Rock Springs, Wyoming. So, it helps.

[Laughter.]

The CHAIR. Okay. With that introduction, Dr. Bertagnolli, the stage is yours, please. Welcome. Turn the mic on, please.

STATEMENT OF MONICA BERTAGNOLLI TO BE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. BERTAGNOLLI. There we go. Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for considering my nomination to be Director of the National Institutes of Health. It is an honor to appear before you today to share my vision for the NIH.

I want to thank President Biden for trusting me with this nomination, and Senator Barrasso for the very kind introduction. I also want to thank my husband, Alex, and my two children for their unwavering support and unqualified love. I grew up on a ranch in Southwestern Wyoming.

My early inspiration was my uncle. He was a primary care physician whose practice included traveling across the entire state, it is a big state, to provide expert care to veterans, and it was his devotion to his patients that inspired me to pursue medicine. Like millions of Americans, when my father had cancer, the care he needed was hundreds of miles away.

I have seen firsthand what it means to deliver care to those living in rural communities. I have spent my entire professional life working to improve cancer prevention and treatment. I have done this as a surgical oncologist, researcher, as a professor of surgery helping to train the next generation of doctors and scientists.

As a physician scientist, I have run major clinical trials, helped to advance innovative research, and pushed hospitals and institutions to make sure that the most effective treatments are available to all patients.

For the past year, I have had the tremendous privilege of serving as the Director of the National Cancer Institute and working toward the President's Cancer Moonshot goal to end cancer as we know it. My experience has given me great appreciation for the inner workings of NIH and for what more is possible.

Recently, though, I found myself in a different position, as a patient when I was diagnosed with breast cancer. I was fortunate to have my cancer diagnosed very early. I have completed my treatment. My prognosis is excellent. I also had access to outstanding care, knowing full well that not every patient has that same chance.

Most importantly, every treatment I received was supported by NIH funded research. I am grateful beyond words to the patients who joined the clinical trials before me, the doctors, and researchers who were able to use that information to make the best decisions. There is so much that excites me about the possibility of leading the extraordinary team at NIH, if confirmed.

First, there has never been more potential for progress than what we have today. We just need to harness it. NIH can and must support research that is equitable and accessible to all populations, and this includes dramatically increasing clinical trials that reflect the full diversity of Americans, because we know that is what yields the best results. We should capitalize on new innovations in uncovering fundamental biology, in health information technology, and in exciting new data analytics.

We must interrogate the broad range of behavioral and social science challenges we face today, while laying the foundation to address new issues that will arise in the future. Second, we have an unprecedented opportunity to embrace and increase access to innovation.

As a physician researcher for more than 30 years, I have seen the transformative power of NIH research to produce results that save lives. But I have also seen the patients whose prospects were compromised by preventable factors.

We should be able to guarantee that the American people are getting a return on their investment by ensuring that health care innovations are available and affordable for everyone. Finally, we must restore faith and trust in our Nation's top scientists.

I am committed to ensuring that NIH continues to be the steward of our Nation's medical research and a force of innovation and discovery. But we must also continue to support education in all fields of biomedical research and to inspire young people to become doctors and scientists so that our critically important work will continue for generations. None of this NIH can do alone.

I look forward to partnering with Congress and many others to advance discovery and apply the results of our research to better the lives of every American. Again, I want to thank you for the opportunity to appear before you today, and I look forward to your questions.

[The prepared statement of Dr. Bertagnolli follows.]

PREPARED STATEMENT OF MONICA BERTAGNOLLI

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for considering my nomination to be Director of the National Institutes of Health (NIH). It's an honor to appear before you to share my vision for the NIH.

I want to thank President Biden for trusting me with this nomination and Senator Barrasso for the kind introduction. I also want to thank my husband, Alex, and my two children for their unwavering support and unqualified love.

I grew up on a ranch in southwestern Wyoming. My early inspiration was my uncle, a primary care physician whose practice included traveling across the state to provide expert care to veterans—and it was his devotion to his patients that inspired me to pursue medicine. Like millions of Americans, when my father had cancer, the care he needed was hundreds of miles away, and prohibitively expensive, so I have seen firsthand what it means to deliver care to those living in rural communities.

I have spent my entire professional life working to improve cancer prevention and treatment. I have done this as a surgical oncologist, researcher, and as a professor of surgery helping train the next generation of doctors and scientists. As a physician-scientist, I have run major clinical trials, helped to advance innovative research, and pushed hospitals and institutions to make sure the most effective treatments were available to *all* patients.

For the past year I have had the tremendous privilege of serving as the director of the National Cancer Institute and working toward the President's Cancer Moonshot goal to end cancer as we know it. My experience has given me new appreciation for the innerworkings of NIH, and what more is possible.

More recently though, I found myself in a different position: as a patient, when I was diagnosed with breast cancer. My prognosis is very favorable. I was fortunate to have my cancer detected early. I also had access to excellent care, knowing full well that not every patient has that same chance. Most importantly, every treatment I have received was supported by NIH-funded research. I am grateful beyond words to the patients who joined clinical trials before me and the doctors and researchers who were able to use that information to make the best decisions.

My fidelity to ensuring that high-quality, affordable care is available to everyone is informed by my own life experiences. If confirmed, I will work every day to enhance health, lengthen life, and reduce illness for *all* Americans—and in so doing, fulfill the mission of the NIH.

There is so much that excites me about the possibility of leading the extraordinary team at NIH.

First, there has never been more potential for progress than we have today—we just need to harness it. NIH can and must support research that is equitable and accessible to all populations regardless of income or zip code—that includes dramatically increasing clinical trials that reflect the diversity of Americans because we know that's what yields the best results. We should also improve the experience of people and communities whose health depends on the knowledge that cutting-edge research brings. We should capitalize on new innovations in uncovering fundamental biology, in health information technology, and in exciting new data analytics. And we must interrogate the broad range of behavioral and social science challenges we face today while laying the foundation to address new issues in the future.

Second, we have an unprecedented opportunity to embrace and increase access to innovation. As a physician-researcher for more than 30 years, I have seen the transformative power of research to produce results that save lives, but I've also seen the patients whose prospects were compromised by preventable factors. As we work to bring innovation to patients, we must ensure that we deploy NIH's research further, and wider, and that we deliver results that work for everyone. Throughout all this, we should be able to guarantee that the American people are getting a return on their investment by ensuring healthcare innovations are available and affordable for everyone.

Finally, we must restore faith and trust in our Nation's top scientists. NIH is the steward of our Nation's medical research, and I am committed to ensuring that NIH continues to be a force of innovation and discovery. To do that, we need to make science accessible to all communities and inspire young people to become doctors and scientists, to continue this critically important work for generations.

None of this NIH can do alone. I look forward to partnering with Congress, and many others, to bring research into every community and apply the results to better the lives of every American.

Again, I want to thank you for the opportunity to appear before you today. I look forward to your questions.

The CHAIR. Dr. Bertagnolli, thank you so much for being with us. Let me begin the questioning by picking up on a point you just made, and you put in your written remarks as well. You said, and I quote—and it goes without saying that everybody here wishes you the very best in your struggle with breast cancer.

Dr. BERTAGNOLLI. Thank you.

The CHAIR. You said, and I quote, "every treatment I have received was supported by NIH funded research," correct?

Dr. BERTAGNOLLI. Correct.

The CHAIR. Can you give us some idea, based on your expertise, about how much treatment for breast cancer costs in this country today? Somebody has breast cancer over a period of years, how much is it going to cost?

Dr. BERTAGNOLLI. Chairman Sanders, that is a widely variable result. I truly could not give you an estimate because breast cancer is incredibly complicated and can range anything from a simple surgery to years and years and years of very extensive——

The CHAIR. Would I be wrong in saying that for some individuals, it will cost hundreds of thousands of dollars for treatment?

Dr. BERTAGNOLLI. I believe that is correct.

The CHAIR. What do you say, as a physician yourself, to somebody who was undergoing treatment for a drug or treatment that was developed by taxpayer dollars that they can't afford or are going to go deeply in debt to pay for?

What does one say to a person to say thank you for your tax dollars developing the drug, but I am sorry you can't afford the treatment you need to save your life. How does one respond to that person?

Dr. BERTAGNOLLI. Yes. Chairman Sanders, I have to tell you that I have sat in a clinic next to patients of my own who, for one reason or another, could not afford their treatment. It is a tragedy.

I sincerely appreciate you championing the cause of affordable and accessible care for all Americans. And if confirmed, I will work with you to the fullest extent of my abilities to also ensure that is the case.

The CHAIR. Well, thank you for your thoughts. Let me be rather specific. If you are confirmed to be the next NIH Director, will you commit to reinstating and expanding the reasonable pricing clause in NIH contracts?

In other words, if the Federal Government puts money into the research and development of a drug, will you insist that the price that drug is charged in America is not higher than it is charged in other countries around the world given the fact that we paid for the research and development?

Dr. BERTAGNOLLI. Chairman Sanders, I can say that I myself believe that the American people deserve a fair return on the investment that Congress has placed within the National Institutes of Health and the research that we do.

I will commit to working to make sure that the benefits of our research are affordable and available to all the American people. I cannot give further specifics at this time about the execution of that plan.

The CHAIR. You are not prepared to tell us that when taxpayers spend billions on a drug, they will not be asked to pay the highest prices in the world for what they paid for?

Dr. BERTAGNOLLI. Chairman Sanders, I am more than prepared to say that I will do whatever I am able to bring—make sure that affordable and accessible care is available for everyone who needs it.

The CHAIR. Doctor, Astellas and Pfizer are charging Americans with prostate cancer over $165,000 for XTANDI, while the exact same drug can be purchased in Japan for just $20,000. $165,000, $20,000 in Japan.

This is a drug that was developed by NIH funded scientists at UCLA. Do you think the price of XTANDI is reasonable? Should we be paying eight times more for a drug that taxpayer dollars developed than the people in Japan?

Dr. BERTAGNOLLI. Chairman Sanders, my focus is on making sure that the American people have access, and availability, and can afford the health care that can save lives, and that is what I will make a commitment to.

The CHAIR. Right now, we pay by far the highest prices in the world for prescription drugs. The results are higher insurance premiums, higher hospital costs, then millions of people not able to get the drugs they desperately need.

Will you commit to us that you will work to make sure that Americans do not pay higher prices for prescription drugs in this country than people around the world?

Dr. BERTAGNOLLI. Chairman Sanders, it would be a great honor to be able to work with you to make sure that the American people have access to the care that they need to live long and healthy lives.

The CHAIR. Okay. My time is up.

Senator Cassidy.

Senator CASSIDY. I defer to Senator Collins.

Senator COLLINS. Thank you very much, Senator Cassidy. Welcome, doctor. The National Cancer Institute that you currently lead has the largest budget and research program of the 27 institutes and centers at the NIH.

Cancer research is vitally important, and I strongly support it. I am interested in how you will balance NI—NCI priorities while making any NIH wide budget decisions. For example, President Biden's budget request proposes a substantial increase for the NCI, but it flat funds research for Alzheimer's disease and diabetes, which collectively affect more than 40 million Americans.

If confirmed, how will you balance your background in cancer research and your leadership at NCI with the need to be fair in evaluating agency wide priorities?

Dr. BERTAGNOLLI. I will thank you for that question, Senator Collins. And I will say that, first of all, if confirmed, my commitment as NIH Director is to the health and vitality of every single American.

But I can give you some specifics to address your specific question. How does a cancer surgeon really lead an organization that deals with the huge spectrum of conditions that the American people face? I have two answers to that.

First, as a cancer doctor, I took care of patients of all ages, all walks of life, all different health states. I am very familiar to working with colleagues in cardiology, in mental health, in opioid use disorder, in kidney disease to take care of my patients with cancer.

I feel very comfortable engaging with the broadest possible team of researchers focused on bringing health to people. But second, one of the things that to me is the most exciting about the opportunity to lead the organization is the fact that so many of the diseases that we are working on, individual diseases in our relative silos, really have many common elements.

The need to access—to have care access to every community, but even down to the biology. So, what I want to—my field of research was in inflammation and how inflammation causes cancer. Well, guess what? Inflammation is one of the major inciting factors behind Alzheimer's disease, behind autoimmune disease, behind long COVID, behind arthritis. So many things.

Both on a scientific level and on the taking care of human beings level, I am really excited for this opportunity to lead NIH.

Senator COLLINS. As you know from our discussion in my office, I would like to see NIH fund more projects and more research looking at the role of inflammation in Alzheimer's disease, for example, instead of just funding amyloid plaque, important though that is, research. We have had that discussion.

My time is growing short, so let me switch to diabetes. Along with Senator Murray and Senator Shaheen, I had the honor of cohosting again this year at the JDRF Children's Congress this summer, and the NIDDK Director, Dr. Griffin Rogers said that with continued research, it is possible to imagine that people could lead a life free of the burden of type 1 diabetes and its complications, which is very exciting.

We have, as you know, a special diabetes program that is up for renewal, and this Committee has overwhelmingly approved its reauthorization. I want to make certain that you understand that program is intended to supplement and not supplant the regular appropriations. Part of the program goes for type 1 diabetes.

Part of that program goes for type 2 diabetes, with a special focus on Native Americans and Alaskan Americans. So, I would like to hear your reassurance that you do understand that is additional funding.

Dr. BERTAGNOLLI. Oh, thank you, Senator. I will just say that the researchers and team at the NIH are deeply grateful for the resources we get from Congress that allow us to serve people and embrace with the greatest enthusiasm particular communities and efforts that focus on serving people. So, thank you.

Senator COLLINS. Thank you.

The CHAIR. Senator Murray.

Senator MURRAY. Thank you very much. Welcome, Dr. Bertagnolli. Really nice to see you. And thank you so much for your willingness to take on this position at a really critical time, because, as you know, NIH has an absolutely critical mission supporting medical research and making groundbreaking discoveries that really help everyone stay healthy and keep our Nation competitive and give patients hope for the future.

Really appreciate your being here and your willingness to go through this process and lead this agency. The agency also does really critical work, in coordination with a lot of other agencies, to

protect public health and prepare for—our Nation for pandemics and a lot more.

Again, thank you. Let me start by asking you, I know at the National Cancer Institute you have done a lot to address cancer related disparities for women. So, in that vein, I wanted to ask you today, across NIH programs and initiatives, do you plan to strengthen research to specifically improve women's health inequities, including women's midlife health—outcomes?

Dr. BERTAGNOLLI. Thank you for that question, Senator. It is very clear that there are many health issues in women that are understudied, that really lack knowledge and deserve to have spotlight shine on them and renewed efforts to be able to provide data to support women's health.

I can give you a couple of examples that are really top of mind for me. We have a maternal health, I think it is fair to say, crisis. We had 750 women die either during childbirth or for 1 year after childbirth in 2019. In 2021, it was 1,200. Why? We have to understand that.

That is like—that is kind of an immediate need that rises to the top. But there are many other things. The whole life cycle of women's health, from childhood all the way through senior adulthood.

That we know women are different. They react to diseases different. And we know that we lack the data to know how to best care for them. So, you raise a commitment that—something I can easily commit to and say it is very important to me.

Senator MURRAY. Good. Thank you. And I am working with a number of other women Senators on some midlife health outcomes, so I will follow-up with you on that. I think that is really critical that we look at as well.

But let me focus on something you just said, and that is the maternal health crisis. That is something I spent a lot of time on. It is a huge issue facing women, as you just mentioned, especially since the Dobbs decision.

I wanted to ask you, what can NIH do to improve maternal health outcomes, specifically talk about that for especially Black and Native American women who face some of the highest mortality, maternal mortality rates in our Nation? Can you talk a little bit more about that?

Dr. BERTAGNOLLI. Yes, thank you very much. So, I think this raises the issue—it is a twofold issue. It is an issue of understanding how to care for women during the time of childbirth and immediately afterwards make sure that their health is optimal. But it also raises an issue of disparities in access to care and in engaging with people as physicians and caregivers, being able to listen to them, to understand them and to relate to them.

I think that the maternal health crisis raises not only important biological and medical care issues, it raises really important social issues. We need to understand people and their social makeup if we are going to help them best.

Senator MURRAY. Okay, great. And we will work with following you up on that as well. But let me ask you about the fentanyl crisis

and the opioid epidemic. Communities are really, as you know, hit hard by that.

The Lummi nation lost five members of their tribe to fentanyl overdoses in just one week. And King County has seen a record number of fentanyl overdose deaths this year. So, I wanted to ask you, if confirmed, how will you work to support research that addresses inequities in access to quality mental health care and treatment for substance use disorders through NIH programs and support those underserved communities that are really harmed by the national mental health crisis and the rising rate of opioid overdose deaths?

Dr. BERTAGNOLLI. Yes. Thank you very much for your championing this issue. I myself have lost patients to the opioid crisis, so I have seen what it does. Absolutely devastating tragedy for our communities.

It has increased so much over the last years, and disproportionately affects certain communities, although really has spread across the entire spectrum of our Nation. I can commit to working with you and on continuing the great awareness that the NIDA has for understanding this issue deeply in ways that bring solutions to the people who need it.

Like many things, it has to do with not only medical care and understanding better treatment, it deeply has to do with getting that treatment to the people who need it.

Senator MURRAY. Thank you. Thank you very much, Mr. Chairman.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. I defer to Senator Tuberville.

Senator TUBERVILLE. Thank you, Senator. Doctor, thanks for being here. Congratulations on your nomination. Before I start, I would like to say something about your nomination. It is really nothing against you.

I would like to take the opportunity to draw a comparison between this nomination and other nominations pending in the Senate, ones that I am holding from passing by unanimous consent. Your predecessor, Dr. Collins, was approved by unanimous consent in 2009, only 4 weeks after being nominated.

The HELP Committee did not even hold a regular hearing like this. You have faced a much different confirmation process. Your nomination was held up by Chairman Sanders, which is his prerogative.

We have no—we have had no confirmed NIH Director for 21 months. Back in June, Chairman Sanders publicly vowed to oppose your nomination until he received the Administration's comprehensive plan on lowering drug prices, which we all know that is what he is about, and a lot of us are about.

As I recall, he promised to hold up not only your nomination, but all HELP related nominations going through the HELP Committee. As a Senator, he has a right to do that. He wanted a policy concession from the Biden administration, and apparently he got one. I

was one of the many who want us to have a confirmed NIH Director.

A lot of people have wanted us to have a confirmed Director. It is not unusual, but I don't remember any Democrats saying the sky was falling because we didn't have a confirmed NIH Director, because this is a very important position. I don't remember Democrats calling the Chairman names or even threatening him.

I don't remember anybody wanting to change the rules of the Senate because of it. I didn't really say a word about it. If it weren't for hypocrisy around this place, I don't think we could have anything to do. Chairman Sanders got what he wanted.

On September 8th, Chairman Sanders announced at the White House met his demands and he announced this hearing. Chairman Sanders used his prerogative as a Senator. I don't have all the details of the concessions the Biden administration made Chairman Sanders, but I respect his rights as a Senator. Frankly, I appreciate Chairman Sanders' defense of the Legislative Branch.

We ought to legislate around here. That is what we were sent here to do. We weren't elected to just outsource our jobs to Joe Biden or any other President. Mr. Chairman and I don't agree on everything, but at least he is standing up for what he believes in and the power of the Senate.

I will get off my horse now and ask you a question. This very,—being an educator, this really touches me here. The NIH funded a recent study about the psychosocial functioning in transgender youth after 2 years of hormones.

According to the letter NIH sent to Ranking Member Cassidy and me, the research seeks to understand the physical and psychosocial effects of medical intervention to evaluate the effectiveness of existing medical treatments already in use among transgender youth.

As you know, two young people committed suicide who were part of the study. That is obviously a tragedy. But what concerns me even more is the fact that the NIH was funding this research. And beyond that, I believe the NIH even called the study a success.

That is sick. It sounds to me like the NIH totally dropped the ball on quality control and oversight. So, if confirmed, how would you make sure nothing like that ever happens on your watch?

Dr. BERTAGNOLLI. First, Senator, I really thank you for your affirmation of the critical importance of NIH and what we are—and that we are here to serve the American people, and just how critical that is and how important this job is.

To that end, in response to your question, we have the greatest responsibility to ensure two things. First, that we serve all people, all people, all walks of life, and that we really are here to achieve the health of all.

But that No. 2, any research that we do that involves human beings, people, is conducted according to the highest ethical principles so that we make sure that the research is intending to do no harm, to achieve benefits, and is done in ways that have maximum respect for the dignity of people.

If confirmed as NIH Director, I will affirm to you that will be my mode of action and my highest priority for all human research.

Senator TUBERVILLE. Thank you. One more quick question, Chairman. The NIH used to be universally respected, nonpolitical organization before COVID, but that trust has been broken, especially in rural parts like my State of Alabama.

You are from a rural Wyoming, so you get the real perspective, and you understand just how much people in those parts of the country in particular have lost confidence in our public health institutions. They feel totally overlooked. What would you do as NIH Director to help gain back some of that respect in rural areas?

Dr. BERTAGNOLLI. Thank you so much for that question, and I will be very, very brief. Two things. No. 1, I believe deeply in the doctor, patient relationship. That is incredible value. That is trust.

A patient comes and puts their life in the hands—and their health in the hands of their doctors. And anything that we can do to strengthen the doctor, patient relationship is something that we should pursue to the fullest extent possible.

Then second, I believe in education at all levels, being very—and relating—our patients joining us in research to the fullest extent possible. Not science here and people here, but people joining us to do science. I think that also engenders great trust in the process if it is done in a respectful and appropriate way.

The CHAIR. Thank you.

Senator Kaine.

Senator KAINE. Thank you, Chair Sanders. And congratulations, Dr. Bertagnolli. I am happy to support your nomination. Every time a representative of the NIH comes before us, I asked for an update on the Recovery Initiative.

Congress provided NIH with $1.15 billion in funding to advance understanding, prevention, and treatment of the long term effects of COVID, including long COVID. And this is a topic very important to me because I live with a mild form of long COVID.

Because I have been public about that, I hear from people every day. In this body, I have colleagues, a former Senator or colleague, former colleague, Senator Inhofe, Senator Young have talked about long COVID experiences.

My wife went to a lawyer last week with a friend of ours to help her file for bankruptcy because her treatments for long COVID that knocked out her balance now leave her in a situation where if she doesn't file for bankruptcy, she could lose her home.

I was at an event Monday and a technology CEO came up and talked to me about his wife's experience with acceleration and deceleration of her heart rate, which is fairly common long COVID symptom.

About 5.3 percent of Americans now have long COVID, and of those—that group, 80 percent suggest that their long COVID significantly limits life activities. Americans depend on research coming out of NIH to help understand how to treat, cure, prevent symptoms that are often debilitating.

It frustrates and saddens me to hear how many long COVID folks who are dealing with it have both had a negative impact on their life, but often face skepticism and disbelief as they describe their symptoms to employers and others.

I am also frustrated when I hear long COVID sufferers indicate that NIH isn't doing enough on the issue and that their voices aren't being heard. Let me tell you what patient advocates tell me.

That NIH isn't considering the input of those living with long COVID in the design and enrollment of long COVID clinical trials. That NIH is not as responsive as it should be to advocate outreach. That with Recover being spread across multiple institutes, there is a lack of clear leadership, and the initiative lacks kind of a point person that is held responsible for decision-making.

There is a lack of transparency in the budget and future plans for the initiative. Dr. Bertagnolli, I know your work in the cancer institutes has not put you directly into this space, and so your knowledge of the inner workings of the Recovery Initiative are limited at this time.

But should you be confirmed as Director, I ask that you continue to work with me to address the concerns of those living with long COVID, including that you commit to meeting with patient advocates to discuss these issues.

Dr. BERTAGNOLLI. Senator Kaine, thank you very much for that question. And I can absolutely confirm that I will work with you on this issue. I think this is one of the greatest tragedies we have recently seen.

I will tell you one thing that is something I live by in my research, I love the expression, nothing about us without us. This comes from the people with lived experience community. We call them the patient advocates.

I love that expression because it really is the way we need to do our science. Not only are we then serving them because we are listening to them, but all the other issues of trust and accountability and respect for the people we serve happen when you do that. So you have hit something that goes to my core, and I would be delighted to work with you.

Senator KAINE. Thank you. Thank you very much. Next topic I want to ask you about is pediatric cancer research.

Along with Senator Moran and 13 other bipartisan Members of this body—of this Committee and the full body, we introduced a bill called the Gabriella Miller Kids First Research Act 2.0 to reauthorize a program that is aimed at combating childhood cancer.

The legislation is the result of continuing efforts by the Miller family to fight childhood cancer. And their revelation to me 10 years ago that of the NIH research budget, only a very, very tiny percent, less than 1 percent was devoted to pediatric research in the cancer space. I am pleased to say that the bill was voted out of Committee last month with a very strong bipartisan support.

I know you are familiar with the challenges in combating childhood cancer, in particular. As Congress looks to reauthorize the critical program, can you tell me how NIH will continue to expand

its efforts using data sharing to speed up research, for example, particularly for childhood diseases such as pediatric cancers?

Dr. BERTAGNOLLI. Yes, thank you. And this has been a major focus of my work since coming to NCI and would absolutely be carried over at NIH.

I just, since time is brief, the beautiful, beautiful Gabriella Miller, when she looked into that camera, I am sure you have seen it, looked into that camera, and I am paraphrasing, I don't remember exactly, but she looked in that camera and she says, quit talking, get working or something like that.

It just gets to your heart, and we take that very seriously and that is what inspires us to go forward.

Senator KAINE. Thank you very much. I yield back.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. I defer to Senator Marshall.

Senator MARSHALL. All right. Thank you, Senator Cassidy. Mr. Chairman, I want to submit for the record first an Op-Ed in The Washington Post, April 11th, 2002, by a Democrat Senator from the great State of Indiana, Senator Birch Bayh, and, of course, one of my boyhood heroes, the late great Senator Bob Dole from the State of Kansas. And it is an Op-Ed about the Bayh-Dole Act.

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

Senator MARSHALL. I am sure Dr. Bertagnolli you are familiar with this, that this encourages, entices the private practice to seek public, private research collaboration rather than poking on its own proprietary research. If confirmed, will you commit today to uphold the integrity and intent of Bayh-Dole?

Dr. BERTAGNOLLI. Thank you, Senator. And I, if confirmed, I will commit to uphold the integrity of the Bayh-Dole Act.

Senator MARSHALL. Thank you. Next, I want to talk about research. In 2022, nearly half of all NIH funding went to institutes in just five states, and they happened to all be on the coasts. I think that when we send all that research in one or two geographical locations, you have incest, you have a decreased randomness of thought, and it pickles things up.

The University of Kansas Cancer Center second to none NCI designated comprehensive cancer center since 2012. The Kansas State University received NIH funding in 2021 to support it becoming a national leader in emerging infections.

Children's Mercy Research Institute in Kansas City, advancing the genomic medicine, developmental behavioral health, and pediatric brain cancer research. Will you commit to actually correcting these issues so innovative research in the Midwest are equally prioritized?

Dr. BERTAGNOLLI. Thank you, Senator. And not only will I commit, I can give you an example of where my past work has really already tried to achieve this.

When I ran a cancer clinical trials group, one of my main goals was to make sure those trials reached as many communities as we

possibly could, and we partnered with a wonderful physician practice in Laredo, Texas, serving the border community, a wonderful physician who served the Oglala Sioux community at Pine Ridge Indian Reservation, and a wonderful oncologist in my own hometown of Rock Springs, Wyoming.

I agree with you completely, NIH research has to reach everywhere, and there are many, many centers of great excellence that we should have the ability to engage.

Senator MARSHALL. Okay. Well, my next question is a lot tougher one. And Dr. Bertagnolli, you and I both protect a very honored profession.

When I think about the horrors of medicine, the great horrors of medicine, the things we got wrong, think of bloodletting, I am afraid that 100 or 200 years from now, those same historians are going to go back and compare irreversible mutilation of adolescents for transgender surgery, irreversible, emphasizing, and giving them irreversible medication is going to be one of those two horrors that they are going to be talking about.

They are going to be talking about bloodletting and the horrification of disfiguring surgery for people that 80 percent of them just in a couple more years, once they have some hormones of their own, are going to say maybe that wasn't a good idea. And before you answer this question, I want you to think about the oath that you and I took. And it is way over quoted, but it is above all, do no harm.

Above all, do no harm. So here is my question, should taxpayers fund gender reassignment experiments or research that are purely cosmetic, where you destroy healthy tissue and organs, or when they use FDA approved products off label with significant negative, irreversible impacts?

Again, this off-label use isn't treating diseases or illnesses. Should taxpayer funds be used to do research or fund these irreversible, horrifying, irreversible procedures and the use of these hormones off-label?

Dr. BERTAGNOLLI. Senator, thank you very much, because it is very clear that you are—share my concern over the well-being of the LGBTQ community, especially young, vulnerable people. What I can tell you is that if confirmed, I will commit to leading NIH to conduct the research that will achieve the very best health for these vulnerable and special individuals.

Senator MARSHALL. I am sorry to cut you off, but right there, do you believe that it is Okay to fund this type of research where these irreversible procedures are being done? Do you think there is any experiment that you can think would justify irreversibly damaging these poor little boys and girls who are 14, 15 years old? Would you fund that type of research?

Dr. BERTAGNOLLI. Any research that we do, Senator, with regard to human subjects has to be done in a way that does no harm and produces the maximum benefit to the people that are participating in the research. And that will be the principle with which I approach any research, especially for this vulnerable population.

Senator MARSHALL. Thank you. I yield back.

The CHAIR. Senator Smith.

Senator SMITH. Thank you, Chair Sanders, and Ranking Member Cassidy. And thank you so much, Dr. Bertagnolli, for being here. It is wonderful to see you again, and I am just delighted to have the opportunity to support your nomination on this Committee and also as we move you forward to confirmation.

I would like to actually follow-up on something that Senator Barrasso started with and focused on, which is your personal experience in Wyoming, experience in rural America. I am not going to ask you about the ranch, although I would be tempted to. But I think it meshes with a very clear policy interest of mine, which is around our rural health and a focus on rural health.

We know that in health care settings across the country there is a real shortage of health care workers and that this effect is really felt particularly intensely in rural communities that are struggling to maintain hospitals and maintain access to care.

Now, we have had some important innovations over the last several years, I would point specifically to telehealth, as a way of delivering care, but could you please just talk with us a bit about, as you think about your own personal experience in rural communities, how can the NIH ensure access to the most advanced medical research and other treatments, regardless of and especially if you live in small towns and rural places in this country?

Dr. BERTAGNOLLI. Well, thank you so much for that question. Our job is not done if we just produce an effective treatment or an effective approach—the job is not nearly done.

Our job is only done when people are living long and healthy lives free—and so. That means that a critical area of NIH research needs to be health care delivery research. And I will just give you a quick personal note. Town where my parents lived in central Wyoming, no hospital within 100 miles.

Through city, through state, community, Federal, and tribal participation there is a new hospital being built there, and I am committed to seeing that new center in that new location be brought into the research enterprise so that we can understand how these kinds of Federal, state, tribal partner—community partnerships can be brought to bear to be able to deliver better care. Just one example.

Senator SMITH. Well, that is great, and you—I appreciate what you are highlighting, which is the importance of partnerships, but also the real importance of NIH attention to training and research opportunities in rural communities, because I think there is a lot of good data to show that if you are trained in a rural place, then you are much more likely to stay in that rural place.

There are good examples, good best practices for how to do that. And I have to say I share Chair Sanders's concerns about—our challenge is delivering care in this country. And so, I think there is lots for us to work on there.

Another area that I want to just touch on before I wrap up is the importance of focusing on research around mental health care. This is something that, again, is a very, very important issue to

me. Less than 5 percent of the NIH's health budget goes to the National Institute of Mental Health.

Less than 5 percent of the overall budget, while one in five or about 20 percent of Americans are going to experience some sort of mental health issue every year. So, we know that mental health and physically—physical health are not like two completely separate things. That is brain health and the rest of your body health.

Could you talk a bit about how you view the NIH's role in focusing on that connection between mental and physical health, brain health and the rest of your body health? And given this low percentage of funding, how can the NIH advance research on mental health?

Dr. BERTAGNOLLI. Oh, thank you. I think, first of all, mental health affects every single disease we treat.

Senator SMITH. Yes.

Dr. BERTAGNOLLI. It affects whether—how someone can manage their cancer journey. It affects how somebody can—who has got kidney failure is able to get the needed care. It affects every single thing we do.

One of the things that I am really excited about, if confirmed on taking on the role, is to really focus on all of these interactions between the various institutes where there are common themes that need to be addressed in—or even in order to treat these of individual diseases.

Mental health is overarching and really needs to get into every research institute. That is No. 1. And then No. 2, that will also help us best leverage the funding that goes into the Mental Health Institute, being able to pull on that for—through the resources throughout the entire NIH.

Thank you for your advocacy and raising this really important issue of raising awareness.

Senator SMITH. Thank you. Thank you very much, Mr. Chair.

The CHAIR. Thank you, Senator.

Senator Cassidy.

Senator CASSIDY. I defer to Senator Budd.

Senator BUDD. Thank you, Ranking Member, Mr. Chairman. Dr. Bertagnolli, thank you for being here. Congrats on your nomination. It is a great state you come from.

Research tells us that children in the womb respond to and that they can feel pain at 12 weeks, and fetal anesthesia is recommended for surgeries at 13 weeks.

Doctor, before obtaining consent for a fetal tissue donation, will you commit to requiring NIH contractors and grantees that they explicitly inform mothers that their child will feel pain during an abortion by 12 weeks of pregnancy?

Dr. BERTAGNOLLI. Thank you for raising this issue, Senator. I believe that it—the policies and procedures that govern any research with fetal tissues really prohibit any discussion whatsoever with the mother toward even the possible use of such tissue for research. So, it would not be acceptable for me to affirm this. That interaction is not allowed to take place.

Senator BUDD. Thank you. Chairman, I yield back.

The CHAIR. Senator Hassan.

Senator HASSAN. Thank you, Mr. Chairman. And thanks to you and Ranking Member Cassidy for this hearing. Dr. Bertagnolli, it is so good to see you and congratulations on your nomination.

Thank you for your willingness to serve. I want to follow-up on a line that you heard from Senator Murray and just now from Senator Smith. The National Institute on Drug Abuse at the NIH plays a vital role in responding to emerging trends in substance use and addiction.

This institute has contributed substantially to our understanding of medication assisted treatments for opioid use disorder and help validate the effectiveness and safety of evidence based medications to treat addiction, such as buprenorphine. As a result of NIH's leadership, buprenorphine is now widely accepted as a gold standard of care for individuals struggling with opioid use.

Last year, I worked with Senator Murkowski to pass into law the Mainstreaming Addiction Treatment Act, which eliminated an unnecessary hurdle for providers who are prescribing buprenorphine and further expanded access to this lifesaving treatment.

However, despite this push to increase access, research shows that high levels of stigma and lack of provider education still stand in the way of individuals receiving medication assisted treatment. Doctor, can you tell us how you will develop strategies to eliminate the stigma around medication assisted treatment?

Dr. BERTAGNOLLI. Oh, thank you for that question. And yes, I think that the overall issue of substance abuse is, first of all, it is a tragedy. And second of all, that tragedy is compounded when on top of it there is also stigma associated with the disease.

That stigma needs to be combated at every step. I always fall back to, what is the first and most important relationship? That is the treating physician and the patient together. I think trust between those two individuals is absolutely key trust and support.

But then I also think we can do more to raise community awareness in every regard. And this is yet another area of what is the best way, the most respectful way, the most appropriate way to garner community support for individuals battling substance abuse.

This is another really important area of research to make sure that we know how to do it respectfully and well.

Senator HASSAN. Well, thank you. Would you commit to continuing to grow the National Institute on Drug Abuse's work on treatment for substance use disorders?

Dr. BERTAGNOLLI. I will commit to working with you to fully pursue work at NIH to end the scourge of substance abuse.

Senator HASSAN. Thank you. I want to move to a different topic. Antibiotic resistance is a serious emerging threat to global public health. In July, you and I discussed the NIH's important role in antimicrobial resistance research and development.

We need to work together to encourage the development of new medications that are able to treat infections that are unresponsive

to current antibiotics. Doctor, how do you envision NIH's role in the public, private partnership to combat antimicrobial resistance?

Dr. BERTAGNOLLI. Certainly, this is a critical issue for drug development and has—which has been successful in a long time—to a certain degree in being able to head off the continual problem of antimicrobial resistance, and I fully support any research that can help us get to that aim for people.

I will also add that like virtually everything we do in medicine, there is also a social and an educational component to this, right. So, it is not just finding a new drug to beat the bug. It is making sure that prescribing practices for antibiotics or use in agriculture, all of these other efforts that really are—can be—can make the problem worse and perpetuate the problem also need to be an area of our research to be able to combat.

Senator HASSAN. Well, I thank you for that. Are there other new strategies that you could be looking at to improve clinical trials for new antimicrobial medications? Because I understand the last point you made, but I think we also need to make sure that we are continuing the research so that we have new classes of these medications.

Dr. BERTAGNOLLI. Yes, thank you. This is a very important issue for clinical trials. I will also just take it as a side to say we have so much work to do in the clinical trials arena.

One of the other commitments I want to make is for clinical trials, since it has been one of my core expertise, that are faster, more inclusive, more—and more responsive to the needs of people. It is one of the major initiatives that I would like to see happen at NIH.

Senator HASSAN. Well, I appreciate that. I just also want to look forward to working with you. I am interested in bipartisan approaches to support innovative microbial—antimicrobial research, including through leveraging the tax code, and I really look forward to working with you and the rest of the department to achieve this goal. Thank you, Mr. Chair.

[Technical problems.]

Senator CASSIDY. I defer to Senator Murkowski.

Senator MURKOWSKI. Thank you both to the Chairman and to the Ranking Member. Doctor, thank you for being here and taking our questions. I appreciate the response that you have just provided to Senator Hassan about clinical trials.

I am very invested in and very focused on what is happening within clinical trials for ALS. I have got a personal connection. I think so many of us do have a personal connection and we recognize just really the horrific progression of that.

I will submit to you a pretty specific question about how we can make ALS clinical trials more efficient, looking for perhaps alternative sources to better or more precisely measure ALS progression.

But it is what you have just said about leaning into this and placing a priority on it is something that I appreciate, and I look forward to further conversations with you on that. You have already responded to questions that I had.

Senator Smith asked about rural health. That is obviously something that coming from Alaska, we would certainly encourage greater research in rural areas that don't have care delivery sites.

One of the other issues that I wanted to bring up was what Senator Murray raised with menopause research. I was able to meet with some advocates just a few weeks ago. And, it is just shocking to me to know that one of the life stages in women, whether you like it or not, is menopause and how little we actually know about the impacts and many of the treatments for health—for adverse health conditions that are associated with menopause in particular. Let me ask my question about infectious diseases.

We, in Alaska, are plagued and have been for a long period of time, but it continues throughout our state. We see preventable chronic infectious diseases, particularly tuberculosis and hepatitis C.

As of 2021, Alaska had the highest incidence of TB in the country. Again, we have very rural areas. Hep-C, the rates there have been increasing statewide now for two decades despite the availability of the curative treatments. I have been in small rural airports and run into public health workers that are there just solely and specifically to monitor what we are seeing with hepatitis C.

I would ask how the NIH would approach coordinating with other Federal agencies, whether it is the state, the local, the tribal Governments to do more with eradicating these chronic infectious diseases, not only tuberculosis and hep-C, but the sexually transmitted infections as well.

Because again, this is an area where we see rates that are, in my view, beyond intolerable. So, whether there are possibilities for cheap point of care testing for STI. Talk to me a little bit about what progress we could make or what we could hope for.

Dr. BERTAGNOLLI. Oh yes, thank you, Senator. I am not an infectious disease specialist, and I was not previously aware of these unique features of the citizens of Alaska.

Senator MURKOWSKI. It is rough.

Dr. BERTAGNOLLI. Yes. I can comment briefly, though, and say that certainly for hepatitis C and tuberculosis, and perhaps even for sexually transmitted diseases, that the two keys to managing when it is prevalent within a population are diagnosis, detection. I mean, hepatitis C can be silent for decades and people don't realize they have it, so they don't get the proper treatment.

The same with tuberculosis. Many workplaces institute routine screening. Certainly, if you work in the hospital, you get screened every single year, and it is through that screening—and to identify individuals that need treatment, are a really important part of control. Instituting the best approaches for that.

Again, I have to defer to colleagues who are experts in infection control, but I would be very pleased, if confirmed, to work with you to address these specific issues for the people of Alaska.

Senator MURKOWSKI. Well, and we do have some great experts that are on the ground who are very familiar with this. But it is the coordination that I am hoping that we will be able to see be-

tween Federal, tribal, state, local. So, thank you very much. Thank you, Mr. Chairman.

The CHAIR. Thank you.

Senator Casey.

Senator CASEY. Mr. Chairman, thanks very much. Dr. Bertagnolli, thank you for putting yourself forward for this position, especially at this time with so many challenges that we face as a Nation. For more than a decade, I have led the annual bipartisan appropriations letter advocating for funding for the National Institutes of Health.

Most recently working with Senator Tillis on a letter that was joined, we were joined by 56 other United States Senators. And at the end of that letter this year, we say, and this is just quote in one part of the letter, "if we are to continue grappling with emerging threats, as well as improve the health of Americans and the quality of their lives, we must continue to invest in biomedical research that has a potential to save money, improve lives, and offer an economic return for our Nation."

We are proud to be able to do that and we will continue to advocate for robust funding for the National Institutes of Health. I don't have to remind anyone the reach and the scope of the National Institutes of Health.

They literally touch the lives of every American, and we are at a time where there is both enormous potential for advancements in health science, but also great, great challenges such as the risk of disinformation and the decreased trust in medical experts.

The National Institutes of Health in my home State of Pennsylvania provides tremendous value despite those challenges that I mentioned. Pennsylvania researchers successfully compete for thousands of grants each year, totaling over almost $2.5 billion.

The funding directly supports more than 28,900 jobs in Pennsylvania and also contributes to a thriving life sciences sector in the state. So, we have a lot at stake as a commonwealth, but also for our Country.

I want to commend the work that you have done at the National Cancer Institute related to pediatric cancers, diseases which were almost universally fatal decades ago, but which are now largely survivable thanks to investments in research.

If confirmed, how will you work to ensure that the NIH is continuing to invest in children's health and that children are being appropriately represented in clinical studies?

Dr. BERTAGNOLLI. Yes. Thank you very much for that question. There has long been, I think you—I can—you recognize that children have been definitely understudied and certainly the conditions that affect them have not been—not received as much attention from the pharmaceutical industry as some adult diseases.

What can we do at NIH? A couple of things. First of all, recognizing the importance of developing collaborative mechanisms that bring pediatric cases together for study and knowledge. Pediatric—many pediatric cancers are rare diseases, and one of the great successes that we have had at NCI has been to bring together a community of patients, researchers, and caregivers around bringing to-

gether data from those taking care of pediatric cancer cases across the nation.

But it doesn't obviously stop at NCI. Every single disease center needs to focus on the youngest Americans, making sure that we address their needs with clinical trials that are targeting the—targeting the diseases that they suffer from. Last thing I will say, prevention. Prevention is key.

All of us need to prevent. Prevention has to start when we are children, right. And so, not only targeting diseases that kids have, but targeting new strategies to make sure they get the preventive therapies that can last them a lifetime, I think are one of the strongest ways we can influence their health overall.

Senator CASEY. Thank you very much, doctor. I wanted to finally ask you about work that I have done with regard to rare disease patient groups over the years.

One challenge that has come up repeatedly is the difficulty in demonstrating that a potential therapy is effective due to poor natural histories of those—of these rare and ultra-rare diseases.

Can you talk about the role NIH can play when working with the FDA to support research into rare diseases that can help advance our understanding and support the development of safe, effective therapies?

Dr. BERTAGNOLLI. Yes. Thank you, Senator. I can give you a very specific example of this one. The NIH Clinical Center is an absolute treasure.

There is a program at the NIH Clinical Center today that I can speak to most easily because it has to do with pediatric cancers, that takes very rare pediatric—people with very rare pediatric tumors, assemble the team all the way from basic biology to clinical trials, importantly has—and partners, public, private partnerships and partners to bring together a community to be able to treat that disease.

Those individuals all come to the clinical center so that—throughout the nation. It is incredibly moving when you see people who have a rare disease or children with a rare disease, their families there, for the first time meeting another person who has that really rare disease, it is an incredibly moving experience, and that community built around that, centered around our clinical center is making tremendous progress one by one.

I would like to see that model scaled dramatically.

Senator CASEY. Thank you, doctor. Thank you, Mr. Chair.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Hey, Dr. Bertagnolli. I have got lots of questions, so if I interrupt you—please be tight with your answers, and if I interrupt you, I will apologize in advance.

You said during your staff interview you support the reasonable pricing clause included in the recent contract with BARDA, but you were not familiar with the NIH experience in the 90's. Clinton administration NIH Director Harold Varmus stated, when rescinding the policy, extensive review indicates that the pricing clause has driven industry away from potentially scientific—potentially bene-

ficial scientific collaborations, and eliminating the clause promotes research that enhances the health of the American people.

Research America, an alliance of hundreds of organizations advocating for biomedical research, expresses concerns about the policies that would "discourage the uptake of breakthrough—discourage the uptake of breakthrough discoveries by the private sector. This would be detrimental to patients." Would you apply reasonable pricing clauses to NIH contracts if confirmed?

Dr. BERTAGNOLLI. Ranking Member Cassidy, my absolute utmost priority would be securing effective treatments——

Senator CASSIDY. That is not my question. My question, would you apply reasonable contract pricing clauses to NIH contracts?

Dr. BERTAGNOLLI. I cannot commit to any specific action at this time.

Senator CASSIDY. I am asking you to commit to not an action.

Dr. BERTAGNOLLI. But I will work with you on this issue because I share your desire to make sure people have access to the treatments——

Senator CASSIDY. Of course, my concern is, based upon Dr. Varmus's experience, that if you do institute, you are going to stop the translation of basic research to taking care of patients.

This is not something that we need to kind of pussyfoot around. History tells us that if you do it, patients are damaged despite whatever rhetoric would be out there. So, I hope that you would be more forthright in your kind of embracing this issue. We have got scientific evidence.

My gosh, if we are doctors, we should actually look at the evidence, not listen to the rhetoric. I say that because I know that patients are going to be damaged by this and that should be our highest calling. I don't mean to rag, but I just get frustrated. Okay. Also, what about march-in rights?

You mentioned that you want to lower cost. People argue for march-in rights. Your predecessor, Francis Collins, consistently said during his tenure that the NIH does not have authority to use march-in rights to lower drug prices. It goes against congressional intent if you only use it to lower drug prices. Do you support using march-in rights to "lower drug prices"?

Dr. BERTAGNOLLI. Again, Ranking Member, I cannot commit to any particular policy right now. In my——

Senator CASSIDY. No, the law specifically gives you three ways to use it and one of them does not include lowering drug prices. I mean, we are just asking you, are you going to follow the law? That would be the action.

Dr. BERTAGNOLLI. I will follow all the laws of our land, certainly. And again, my goal will be to make sure that people get the treatments that they need.

Senator CASSIDY. Sounds good. Sounds like—with that answer, you are answering my previous question that you wouldn't do the other thing. Let me ask you about another issue.

Secretary Becerra chose not to continue an NIH ethics advisory board reviewing extramural fetal tissue research for appropriate-

ness during the previous Administration. Presumably a panel like this would help achieve what you tell me your preference is of ensuring fetal tissue is only used as a last resort.

I am told there were members of this board who supported fetal tissue research but still rejected some of the research projects put forward by NIH for the board's review because of a lack of informed consent.

Now, you stressed the importance of informed consent in an earlier answer. These pro-fetal tissue advocates rejected these proposals because of the lack of informed consent, but Secretary Becerra has discontinued this board, providing that safeguard. Do you agree with Secretary Becerra's decision to not continue this board?

Dr. BERTAGNOLLI. Senator, I do not have enough information about those specific actions to really comment on Secretary Becerra's decision. What I can affirm for you is that any research needs to be conducted according to the most stringent ethical principles——

Senator CASSIDY. I accept that, but this board was making sure that was the case and it rejected some of those. It was the mechanism by which you, what you were telling me was actually executed. The informed consent was not done. If we stipulate my, as a theoretical, that what I laid out, the facts are correct, would you support reinstituting the board?

Dr. BERTAGNOLLI. Again, I can't comment on the specifics of that activity. I can just say that if confirmed, I will uphold the principles of ethical human research.

Senator CASSIDY. It has been 4 years almost since the COVID–19 pandemic began. We still actually don't know where the virus originated. Many studies and reports have explored plausible alternatives.

Experts agree that further research is needed. Do you believe the Federal Government should do everything it can to determine the cause of COVID–19, including the possibility it emerged from a lab that was conducting gain of function research?

Dr. BERTAGNOLLI. Ranking Member Cassidy, I think no one wants to know what the true origin of the last COVID pandemic was more than the biomedical research community——

Senator CASSIDY. How will you accomplish that?

Dr. BERTAGNOLLI. To the fullest extent of our ability to gather the data, and have access to the data, and make a valid——

Senator CASSIDY. Making it public?

Dr. BERTAGNOLLI. Make data that we have available public and accountable to the American people, yes.

Senator CASSIDY. Okay. I yield.

The CHAIR. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chair. Dr. Bertagnolli, welcome to the HELP Committee, and congratulations on your nomination. A number of us on the HELP Committee are also on the Appropriations Committee and I want to address the budget for the Fiscal Year 2024.

Despite the challenges that we had faced in writing a Labor HHS appropriations bill because it included the availability of less funding overall than we had in Fiscal Year 2023, our bipartisan Fiscal Year 2024 bill builds on our long standing commitment to NIH and biomedical research in general.

We secured critical increases in our bill for some of the agency's most important programs, $100 million increase for mental health research, $100 million increase for Alzheimer's disease research, $60 million increase for cancer research, and $12 million for a new palliative care research program.

As a cancer researcher, I wonder if you can describe how the recent investments in NIH, and specifically in cancer research, have advanced care for patients and improved outcomes.

But I also want to have—challenge you to talk about the impact that the House passed—I am sorry, not the House passed, the House bill that is pending that has drastic cuts in biomedical research, how you would tackle that if that became law.

Dr. BERTAGNOLLI. Thank you, Senator. First, let me say that I speak for everyone at NIH to say that we are deeply grateful for what we receive from the Federal Government in order to conduct our research.

No. 2, let me speak as a physician to say that over my 30 plus years of being a physician, I have seen the tremendous advances that have been made as a result of NIH funding. I am not going to take down the clock in the many advances that have happened just in the last year. Just let me assure you that people are living better, longer as a result of NIH research.

I think that you are also asking to address how changes in funding will impact what we do. I will just say that every penny we get, we will use to the fullest extent possible to secure health for the American people.

We will focus on the issues that Congress brings to us as important, and I really embrace working with you on those key issues. And then finally, if our budget—there is a chance that our budget will force us to leave opportunities on the table, because the opportunities are enormous. And I will just leave it there.

Senator BALDWIN. Okay. There have been two biosafety incidents involving the H5N1 virus at the University of Wisconsin, Madison.

In both cases, there was a lack of guidance and oversight from NIH, which I find very, very concerning. As Chair of the Labor HHS Appropriations Subcommittee, I worked to secure language and funding focused on this issue in our bipartisan Fiscal Year 2024 bill.

In addition to directing NIH to articulate the roles and responsibilities of investigators and in institutions conducting this research, the Fiscal Year 2024 bill would establish for the first time an office at NIH to serve as a resource and to provide tools and guidance to the research community.

Dr. Bertagnolli, what steps would you take to enhance the oversight of NIH funding research involving potential pandemic pathogens?

Dr. BERTAGNOLLI. Thank you very much for your advocacy for this very, very important issue. Potential pandemic pathogen research stands to achieve great benefit for people by allowing us to respond immediately and save lives, but it also has risk.

I can commit to you, if confirmed as NIH Director, that I will fulfill the highest possible oversight for programs that engage in this kind of research—review and oversight to make sure that they are conducted safely and achieve the benefit we know, we can see for the American people.

Senator BALDWIN. Thank you, Mr. Chair.

The CHAIR. Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman, very much. Let me just begin by saying that LGBTQ people are living in a national state of emergency. More than one in two transgender and non-binary youth have seriously considered attempting suicide.

When elected officials use their bully pulpit to target gender affirming care or create barriers to evidence based lifesaving treatment and fuel the fire of the youth mental health crisis, this is a driving force in a nationwide campaign of discrimination, and it is unacceptable to LGBTQ youth, young people.

Let me just say this very clearly, trans rights are human rights, and I am never going to stop fighting for essential research and investments in the care which you need to make sure that everyone is free to exist as their authentic selves, and we won't rest until you are free to live openly, authentically, and safely.

Doctor, thank you for being here today. I have heard from many people in Massachusetts, including many oncologists, about your excellent work and your leadership, and it is clear that you have a commitment to public investment to drive research that will improve Americans' health, treat illness, and to cure disease.

Last year, Congress passed my bipartisan Children Media and Research Advancement Act requiring the National Institutes of Health to conduct research on technology and media's effects on infants, children, and adolescents, and provided the NIH with $15 million to launch this program.

We already know that big tech's exploitation of younger users is driving a mental health crisis, and this research will further document the serious harms caused by the online platforms' insatiable appetite for children and teens' personal Information.

Doctor, if confirmed, will you commit to prioritizing that research? We have an epidemic, a mental health epidemic amongst teens and adolescents in America.

Dr. BERTAGNOLLI. Thank you, Senator Markey. As the parent of very recently teenagers, I can certainly comment to a great concern about the amount of time spent in front of computers and the worry of a parent as to what that really is doing.

I can commit to you that this is a very important issue for NIH research, understanding what this new technology means for our young people, really everyone, but certainly more of a focus on the young.

I also know that this is an issue that is a great concern for our Surgeon General, and I also looking—look forward to working with others across HHS on this issue.

Senator MARKEY. Yes, the Surgeon General has identified the problem. Senator Cassidy and I already have, coming out of the Commerce Committee successfully, an upgrade of the protections for kids online up to age 17, and we are hoping to move that on the Senate floor.

But we also need the documentation from NIH as to the underlying pathology which is being created as we sit here right now. Since the passage of the National Alzheimer's Plan Act and Alzheimer's Accountability and Investment Act that Senator Collins and Senator Warren—Warner and I have worked on, NIH research has contributed to significant advancements to understand and treat Alzheimer's, yet we have a ways to go.

We are just beginning to understand the impact of air pollution and environmental justice on the brain. Black, brown, disabled, and rural Americans face discrimination and other barriers to access to treatment, including expensive treatments or long travel times to care.

Family caregivers still struggle every day with providing care to their loved ones with Alzheimer's. Doctor, can you just tell us how you view the NIH's role in continuing to lead Alzheimer's research in new directions, center equity, and access and support to family caregivers who are so often at the frontlines of providing care.

Dr. BERTAGNOLLI. Thank you so much, Senator, for that question. It raises many issues that I will just go back to maybe my core approach to things such as this.

First, understanding the biology of what has produced this condition. And that means going all the way back, maybe even into very early years of life, so that we can think about prevention rather than treatment. That is really critical and encompassing a very broad population of people to inform that.

Next, though, dealing with what we have today, people who are really suffering families for which this is a tremendous burden and having difficulties. Developing new treatments that can work now for people suffering from the disease.

As you have already said, it is part of NIH to think about care delivery, and that means delivering for the caregivers, taking care of the caregivers, because they are a really important part of what helps us achieve health.

Senator MARKEY. Thank you. And again, our goal is to continue to increase funding for NIH. Research is medicine's field of dreams from which we harvest the findings that will give hope to families, that we can find a cure for Alzheimer's. And NIH is really the National Institutes of Hope for all those Alzheimer's families. Thank you. Thank you, Mr. Chairman.

The CHAIR. Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. Last week, the House Oversight Committee subpoenaed Acting NIH Director Tabak for documents relating to the investigation of Dr. Moran.

Dr. Moran is a top adviser to Dr. Fauci who is accused of using a personal email to avoid public accountability, and according to him, delete anything he did not want to see in The New York Times regarding the origins of COVID.

The Subcommittee released emails allegedly from Moran's and requested information in June and again in September. If confirmed, will you comply with any subpoenas the House sends to you relating to the origins of COVID–19?

Dr. BERTAGNOLLI. Oh, thank you, Senator Braun. And I just can reassure you that I take Congress's responsibility for oversight for the NIH, and if confirmed, my responsibility as Director of the NIH to be compliant with policies regarding that oversight extremely seriously. I can confirm that if I assume the position, to be accountable and transparent, and to work with you to resolve these important issues.

Senator BRAUN. Have you ever spoken to Dr. Moran about the COVID–19 pandemic?

Dr. BERTAGNOLLI. No, Senator. I don't know Dr. Moran.

Senator BRAUN. Will you commit to not use a personal email for official NIH business, or to try to shield conversations from the American public?

Dr. BERTAGNOLLI. Yes, Senator. Absolutely.

Senator BRAUN. Also, I would like to comment before I got one more question for you. Senator Hawley and I actually passed legislation asking the White House to release all the material they hold in classification on the origins of COVID–19. There is a law out there, and they have not complied with that.

We are still trying to get them to comply with that law. And remember, you are working for that Administration. So, this one is a question in terms of any relationship you have got with big pharma.

I think you have received millions of dollars from big pharma to support your research, and you sat on the board of several companies receiving stock options and bonuses. Our Country relies on its public officials to have their best interests in mind when performing their duties as public servants.

How can the American people be sure that as NIH Director you would be focused on the job at hand rather than boosting the business of any past associates in the pharmaceutical industry?

Dr. BERTAGNOLLI. Thank you for that question. I just want to confirm for the record that the funding that I received from pharmaceutical companies was to conduct research. That none of that formed my own personal salary.

The only salary I received during that work was from Brigham and Women's Hospital, a salary set based on my academic rank. I have one instance of receiving a payment directly from a pharmaceutical company. It was for service on the board of directors of a single pharmaceutical company.

But finally, the more important question. I completely agree with the need to have one goal, one constituency that I am serving, and that is the health of the American people, and I will——

Senator BRAUN. Thank you for that. One quick final question here. I think you have signed an agreement with Senator Warren about what you might do after this post.

From the information I have got is that you won't seek employment or compensation from any pharmaceutical company. Is that correct? And does that mean then, if you do, you will turn down those offers?

Dr. BERTAGNOLLI. Well, the agreement with Senator Warren is designed to assure the American people and to Congress that I will act with the goal of the very best interests of the American people, if confirmed for this job.

I have agreed for a time of 4 years after stepping down in Government that I will not accept employment at a major pharmaceutical company.

Senator BRAUN. Thank you very much.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chair. And thank you, Ms. Bertagnolli. Appreciate your service and be willing to step in at this key time. Emerging Technologies, AI is top of mind. They are becoming ingrained into various parts of our lives. Health care is absolutely no exception.

AI is primed to assist with trial design, real time monitoring, predictive analysis, go down all the different aspects of clinical trials which are so expensive. I think we all have agreed, over a long period of time, that the cost is a barrier to progress.

Dr. Bertagnolli, do you think that the advent of AI will help create efficiencies in our clinical trial systems, and are there particular pitfalls we should be mindful of when considering technology in trials?

Dr. BERTAGNOLLI. Yes. Thank you very much for that question. Machine learning approaches, artificial intelligence are really wonderful new computational methods that we are all very, very excited about.

We have long had the scale of data that we just do not allow us to analyze it properly. However, the more we learn, the more we use these techniques, the more we realize that they have to be like any tool used in a very careful and responsible manner, particularly when it comes to human research.

The short answer is yes, absolutely. This is very exciting, but with a qualifier that the design, and conduct, and type of data used to train these models need to be very, very carefully considered to make sure we are getting the results that really matter and are meaningful for all people.

Senator HICKENLOOPER. Any specific pitfalls that you would want to put on the record?

Dr. BERTAGNOLLI. I think that, I guess the most serious one that we hear about a lot is an AI method that might be designed and trained on one particular ethnic group or one particular category of people who have perhaps more access to treatment than in other, and then it gets a result that continues to disadvantage others who need to be included in that kind of research.

I think that is one really serious one. But there are many. It is a computational method, after all, and it has to—it has to be doing what we want it to do.

Senator HICKENLOOPER. Right. And oftentimes the algorithms aren't as transparent as some of us might like it.

Dr. BERTAGNOLLI. Exactly. Exactly. Thank you.

Senator HICKENLOOPER. Harvard and Brigham and Women's Hospital created the Multi-Regional Clinical Trials Center. Obviously, you are very familiar with given your time at both institutions.

The Center's prime focus is improving the safety and efficacy of global clinical trials. They have trained representatives literally from dozens of countries, what is good clinical process and what is good clinical practice. This leadership, I think, is critically important and often underestimated the significance of it.

We live in an interconnected, wonderfully diverse world, but that interconnectedness and diversity does have its own challenges as well. And I think we should be making sure that we utilize all available data to inform our research decisions.

What more do you think that NIH could be doing to encourage the use of safe and rigorous global clinical trials?

Dr. BERTAGNOLLI. Thank you for that question. I actually have personally conducted global clinical trials in the area of cancer, and that was done through the use of very careful protocols that delivered data in very careful formats and that also monitored sites so that we knew exactly what care was being delivered as part of the trial that was testing a treatment.

Those, for things that really matter, that level of quality is very, very important. I will just add parenthetically, though, there are other things that we can do in public health globally that don't necessarily need to fit into that very tight model, so we should look at everything that we can to help inform our work.

Senator HICKENLOOPER. Could not have said that any better myself. And I think that Dr. Bertagnolli's eagerness and optimism is a reflection of her Western roots, which I have great appreciation for. I have other questions, but I will submit them on written record, and thank once again the witness for being here, for your commitment to public service, and turn back to the Chair.

The CHAIR. Thank you.

Senator Luján.

Senator LUJÁN. Thank you, Mr. Chairman, and to our Ranking Member for this important hearing and this conversation.

Dr. Bertagnolli, it is an honor to be with you today, and I want to begin by recognizing and thanking you for your help in providing archived data from the National Cancer Institute regarding radiation exposure from atmospheric nuclear testing in Western states, especially as we have an opportunity to provide more support for these families across the country.

I am very honored to have worked with Senators Hawley and Senator Crapo with the support of 61 of our colleagues for the inclusion of these provisions in the National Defense Authorization

Act. Thank you for that as well. Dr. Bertagnolli, the Institute Development Award, IDeA, with a small e, if you will.

The program plays a huge role in building capacity in biomedical research across the entire State of New Mexico. For example, the New Mexico networks of biomedical research, which are located on the New Mexico State University campus, provides a collaborative biomedical research environment for more than 10 other institutions across my state.

Despite the program targeting half of the country, IDeA's budget is around 0.9 percent of the overall NIH budget. If Congress were to provide additional funding specifically for IDeA, how would you, as NIH Director, expand the program?

Dr. BERTAGNOLLI. Well, first of all, thank you, Senator Luján. First of all, I would be delighted because as I think you have already heard in this hearing, I really want to see NIH research expand to encompass all of our Country, not just a few advantaged locations.

I would look forward to expanding that program, not only by partnering with the outstanding academic institutions within the IDeA states as they grow out their educational and research outreach programs, but also for programs that we have that are national infrastructure, such as the National Clinical Trials Network, and other infrastructure that literally goes down into individual communities.

It would be very welcome and quickly applied into action.

Senator LUJÁN. I appreciate that. And on the same note, do you support increasing IDeA program's state participation across other major research programs beyond the currently available mechanisms to programs such as those supporting biomedical research facilities, instrumentation, and training?

Dr. BERTAGNOLLI. Yes, Senator. I view this as one way we can engage more of the American people in the research that we conduct, and I think it would be very positive.

Senator LUJÁN. I appreciate that. You touched on this with your previous response around clinical trial diversity, and I appreciate your commitment to increasing clinical trial diversity participation.

An opportunity still exists to increase diversity among research staff that would have implications for diversity in research participants. A clinical research workforce that itself is diverse, is better able to prioritize, connect, care for, and successfully recruit a diverse participant population in research.

How will you ensure that NIH is granting funding to clinical trial research staff that reflect the people impacted by the study's conditions?

Dr. BERTAGNOLLI. Yes. Thank you. This is a priority. It is a priority. Why? Because we know that, as you have already alluded to, a diverse research staff, like a diverse care staff, brings excellence, really brings better outcomes for the people that we serve.

How are we doing this specifically? Targeting programs to identify very talented individuals who come from diverse backgrounds, giving them opportunities to participate, and then supporting them

through educational and other support programs to make sure that they succeed.

There are numerous efforts like this across all of NIH, and I would like to see this expanded even more.

Senator LUJÁN. I appreciate that. And, Mr. Chairman, I have some other questions I will submit into the record, and I yield back.

The CHAIR. Thank you very much.

Senator Cassidy, you wanted a second round?

Senator CASSIDY. Yes, please. Dr. Bertagnolli, you had said that you would maintain the Biden administration's policy for allowing fetal tissue research, but that it should only be used as a last resort. How could you ensure that fetal tissue is only used as a last resort?

Dr. BERTAGNOLLI. Thank you, Senator. Understanding the great sensitivity of many people and passionate feelings of many people on the issue of fetal tissue research, I would want to be very respectful of that.

Again, if confirmed as NIH Director, my job is to serve everyone, including the communities who care deeply about how that tissue are used.

Absolutely, I would follow the laws of the land in every aspect, and I would also follow within the laws of the land, the dictate is we are trying to achieve maximal good for people. We are trying to cure major diseases. That is our highest goal. But we need to do it with respect and obviously follow the law.

Senator CASSIDY. But let me ask, because that slippery slope, we are doing this for an end and therefore the means are justified. The specific question was, how would you ensure that fetal tissue is only used as a last resort?

Dr. BERTAGNOLLI. Thank you. I would follow our principles of review and oversight over the use of this tissue, which I understand is very stringent and asks that particular question as—by the review boards is one aspect of approving its use.

Senator CASSIDY. Okay. Now I am going to ask you some questions related to obesity. My state, unfortunately, is 50th or 49th in terms of obesity. So, I am told that the amount of funding directly for obesity—and by the way, we know this, but just for context, obesity is a major driver of health disparities, disproportionately affecting the poor, those of color, but also whites.

It is a major driver of morbidity from heart disease, from cancer, from COVID–19. We know that. I am told that the funding at NIH that is specific for obesity is only about $100 and roughly $1.2 billion a year, about 2.5 percent of the budget.

Again, but a major driver of health disparities, and of morbidity, and of all the things that you and I know of. So arguably, funding for obesity has lag—is lagging way behind funding for other conditions relative to its impact upon society.

How can we better address this issue? Would you commit to increasing funding for obesity? How do we better address the founda-

tion—foundational, translational, and implementation of research for obesity?

Dr. BERTAGNOLLI. Thank you, Senator. Thank you very much. I will say that from my current position as the Director of the National Cancer Institute, obesity and the rising obesity epidemic is one of the major causes of cancer in the United States.

We recognize this. And there has been a tremendous amount of work done by NCI to identify the ideology of this, how obesity drives cancer, and how that can be overcome. So, I can't speak to the way the funding has been distributed now, but I can assure you that this is yet another one of those topics that does not belong in a silo, for which we have got to work across all of the institutes that can have a piece of owning this problem.

Then the last thing I will say, again, stigma, making sure that people who suffer from this condition are respectfully included as being part of the solution to the problem.

Senator CASSIDY. I accept that. One suggestion, I am told that nutrition obesity research centers have kind of funding which is kind of stagnant. And just to increase that funding would be a place to start.

Again, if we are talking about something which is driving cancer, heart disease, hip replacement, you name it. I used to tell my medical students, obesity is here, and it has a hydra head. We seem like we just focus more on the manifestations than we do on the creature itself. If we address the creature itself, we address all these. That seems to have been lost. If you could address that, that would be great.

Dr. BERTAGNOLLI. If confirmed, I would be really delighted to work with you on this. I agree that this is a very serious health problem that takes a multifaceted approach, and I agree that is something that we need to work on and would love to work with you on.

Senator CASSIDY. Thank you. I yield.

The CHAIR. See, I knew, Senator Cassidy, that if we waited long enough, there would be an issue we would agree on, and obesity certainly is an epidemic. It is impacting diabetes and a host of other issues, and something this Committee must and will deal with on this. There is an issue that we didn't touch upon today.

I have raised my deep concerns that there are many millions of Americans who cannot afford the outrageous cost of prescription drugs in this country, and that is something that the NIH must deal with.

But there is another issue that we didn't talk about, and that is that we look at the global situation, we look at developing countries and millions of people throughout the world who are struggling to feed their families.

What we find is that many of the prescription drugs consumed are consumed in developed—in the developed world. The poor people around the world cannot afford the medicines they need. Medicines, by the way, which may cost a few cents to produce. And they don't get it, and they die, or they suffer.

The—sorry, all right. Okay. Thanks. Last May, President Biden announced that the U.S. Government would share some NIH funded COVID patents with the World Health Organization to expand access in low and middle income countries.

If confirmed, will you build on this commitment and make sure that medicines developed with NIH dollars are accessible and affordable in low and middle income countries? Will you ensure NIH funded technology is shared with manufacturers in developing countries so that they can produce the medicines that people need at a price they can afford?

Dr. BERTAGNOLLI. Senator, I will. I can confirm that I will. I share your concern. I share your passion for bringing life giving care to not just the United States, but the world. And I will work with you on this issue.

The CHAIR. All right. I would hope that you would appreciate that in some cases these drugs cost a few pennies to manufacture and yet they are not getting it to people for whom it might be life or death. That is something that you will pay attention to?

Dr. BERTAGNOLLI. I will—confirm that I will be very delighted to work with you on this issue. It is critically important.

The CHAIR. Okay. Well, thank you very much, Dr. Bertagnolli, for being with us today. That concludes our hearing. As a reminder, the Committee will have a markup next Wednesday, the 25th, on this nominee and a few others.

For any Senators who wish to ask additional questions, questions for the record will be due tomorrow, Thursday, the 19th at 5.00 p.m. The Committee stands adjourned.

ADDITIONAL MATERIAL

THE WASHINGTON POST

OUR LAW HELPS PATIENTS GET NEW DRUGS SOONER

BY: BIRCH BAYH AND BOB DOLE

April 11, 2002

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our Country relies on the private sector. The purpose of our Act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to 7 years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of

a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

The writers are, respectively, a former Democratic Senator from Indiana and a former Republican Senator from Kansas.

QUESTIONS FOR THE RECORD

RESPONSE BY MONICA BERTAGNOLLI TO QUESTIONS OF SENATOR SANDERS, SENATOR KAINE, SENATOR HICKENLOOPER, SENATOR MARKEY, SENATOR CASEY AND, SENATOR LUJÁN

SENATOR SANDERS

Question 1. In some cases, the National Institutes of Health (NIH) owns the underlying patents for key drugs, but then gives away exclusive control over the drug to pharmaceutical companies. For example, the National Cancer Institute (NCI) is on the verge of giving an exclusive license to a small biotech linked to a former NCI employee for a promising cancer treatment that may cost Medicare billions of dollars, even as NIH invented the treatment, currently manufactures the treatment, and runs clinical trials. One *report* called this exchange "The NIH's 'How to Become a Billionaire' Program."

> a. If confirmed, how would you ensure publicly owned inventions are not given away? Will you commit to only offer exclusive licenses when they are "reasonably necessary to provide the incentive for bringing the invention to practical application," as required under 35 U.S.C. § 209(a)(2)?

Answer 1. I commit to fully complying with all the laws that govern my role as the NIH Director including the requirements of Section 209 that you point out. I recognize the importance of making certain that the taxpayer sees a fair return on their investment in the science and innovation that NIH produces with taxpayer funding. To that end, I agree that the private sector must not realize unfair profits that are the result of publicly funded research. I commit to working with you and the HELP Committee in an effort to execute on these shared goals. I want to reiterate too that NIH's role isn't just to identify medical care innovation and understand the best treatment, but to ensure that we can deliver that care and treatment to all people who need it in a way that is affordable and accessible.

Question 2. In addition to march-in rights, the NIH has failed to use other tools that could make medicines affordable. Will you commit to using "royalty-free" rights to introduce additional low-cost producers, under 35 U.S.C. § 202(c)(4), for medicines developed with Federal funding?

Answer 2. If confirmed as NIH Director, I will use all the tools at my disposal to expand access to the treatments and technologies developed using NIH research to reach the patients that need them across the United States. To achieve this goal, I would consider the use of "royalty-free" rights as one mechanism to potentially help lower the cost of medicines.

Question 3. NIH currently does not disclose critical information the public needs to assess how much drugs cost to develop. Will you commit to publicly reporting the *full, disaggregated costs* of taxpayer-funded clinical trials?

Answer 3. I firmly recognize the importance of transparency, especially when it comes to taxpayer spending. If confirmed as NIH Director, I look forward to working with you and the HELP Committee to identify ways to further increase transparency around taxpayer-funded clinical trials.

Question 4. The "*Stevens Amendment*" requires recipients of taxpayer dollars to disclose how much of their own money they are putting into projects that receive Federal funding. Will you commit to following the law, so that the public is given timely and useful information about the respective contributions of the Federal Government, compared to private partners, for new treatments and cures?

Answer 4. I commit to fully following the law. If confirmed as NIH Director, I look forward to being a faithful steward of taxpayer dollars and ensuring that we do the most with every penny we are given. I firmly believe that transparency and accountability are paramount to restoring trust and faith in the agency.

Question 5. Over 4,000 clinical trials, including many that are funded by NIH, violate existing reporting requirements under Federal law. Will you commit to withholding grant money to responsible parties who fail to comply with *ClinicalTrials.gov* reporting requirements?

Answer 5. I commit to fully following the law. If confirmed as NIH Director, I will work with the NIH team to ensure that NIH takes appropriate action in situations where grant recipients have failed to meet reporting requirements.

Question 6. If confirmed, will you support routinely licensing technologies invented by government scientists and through taxpayer funds to health and humanitarian organizations like the Medicines Patent Pool in order to promote access to life-saving medicines in low-and middle-income countries?

Answer 6. If confirmed as NIH Director, I commit to using all the tools at my disposal to increase access to technologies and techniques developed through taxpayer investment to reach as many people in need as possible, in the United States and with our partners around the world.

Question 7. In addition to many topics, the National Institutes of Health (NIH) plays an important role in primary care research. Currently, the NIH spends approximately $108 million on primary care research, which accounts for less than 0.2 percent of NIH's overall funding. When comparing spending to delivery of care, the U.S. spends 5–7 percent on primary care while approximately 50 percent of doctors' visits are with primary care. This amounts to a disproportionately small investment in research compared to the amount of care delivered in the primary care setting.

a. Patient interaction with primary care equates to better quality and life and better health outcomes. However, without a single Federal entity charged with coordinating and advancing primary care research, primary care clinicians must rely on research from other health care settings, such hospitals, sub-specialty groups, or single disease states to inform their thinking around the delivery of care.

b. Dr. Bertagnolli—do you believe that there is a greater role for the NIH when it comes to coordinating and advancing primary care research? How as NIH director would you ensure that NIH can play a role in advancing primary care research?

Answer 7. I agree, primary care is critical to good overall health and if confirmed, I look forward to working with you on this.

SENATOR KAINE

Question 1. Despite progress in recent decades to reduce smoking rates, the public health impact of the mortality and morbidity associated with smoking remains staggering. In fact, according to a recent report from the *Centers for Disease Control and Prevention*, over 28 million U.S. adults currently smoke. Unfortunately, too many smokers seek to quit, but are unsuccessful in their quit attempts. Dr. Bertagnolli, efforts to address the smoking rate in the U.S. cuts across many Federal agencies. Where do you see NIH's role in reducing smoking rates?

Answer 1. NIH supports research on tobacco use prevention, including projects in regulatory science, addiction, tobacco control, health effects, cancer prevention, and behavioral studies. NIH-supported research shows that menthol in cigarettes makes it easier to start smoking by reducing the harshness of tobacco. To help inform the FDA's tobacco regulatory priorities, NIH and FDA have a unique interagency partnership called the *Tobacco Regulatory Science Program (TRSP)*, administered through the NIH Office of Disease Prevention. In April 2022, TRSP-sponsored research was cited in FDA-proposed rules to *prohibit menthol as a characterizing flavor in cigarettes and ban all characterizing flavors (other than tobacco) in cigars*.

SENATOR HICKENLOOPER

Question 1. The CDC has found that Black women are two to three times more likely to die from pregnancy-related complications than white women—with many of these deemed "preventable." The NIH has significantly prioritized maternal health research, across various Centers. Dr. Bertagnolli, if confirmed, how will you make sure that the results of this research are clearly disseminated to providers, educators, and most of all, patients?

Answer 1. This issue is a top priority for NIH, and would be one of my priorities if confirmed. NIH has a number of initiatives and activities dedicated to addressing maternal health. The Implementing a Maternal Health and Pregnancy Outcomes

Vision for Everyone (IMPROVE) Initiative supports research to reduce preventable causes of maternal deaths and improve health for women before, during, and after delivery with a special emphasis on health disparities and populations that are disproportionately affected, such as racial and ethnic minorities, very young women and women of advanced maternal age, and people with disabilities. I want to reiterate too that NIH's role isn't just to identify medical care innovation and understand the best treatment, but to contribute to efforts that ensure that we can deliver that care and treatment to all people who need it in a way that is affordable and accessible. This is critically important for maternal health care, especially in communities of color who have been impacted by the maternal health crisis.

Question 2. Dr. Bertagnolli, what is your philosophy toward entering into public-private partnerships and, if confirmed, what will your approach to these partnerships be?

Answer 2. The NIH funds primarily basic, translational, and early stage clinical research and relies on partnership with private sector to bring discoveries to market. Public-private partnerships can be an effective tool for ensuring that the research that NIH conducts is translated into techniques and treatments that improve the health outcomes for people across the United States. My experience as researcher and as Director at the NCI only underscores and validates this view for me. I look forward to working with you to ensure that public private partnerships at NIH reflect a balanced partnership between the private sector and the American people.

Question 3. Valley Fever is an infection caused by a fungus primarily found in the soil of the semi-arid desert regions of the southwestern United States, including Colorado. Thanks to climate change, Valley Fever has been diagnosed in every state. When the soil is disturbed, the fungus can become airborne and inhaled, ultimately causing infection.

a. Last year, the World Health Organization released a troubling *report* identifying the top fungal priority pathogens to serve as a guide to research, development, and public health. Listed among those priority pathogens, were coccidioides (Valley Fever). Studies have used climate projections to model Valley Fever's expanding geographical range. It found that by 2100, the affected areas will more than double, and the number of people who will become sick will increase by 50 percent.

b. Given these alarming projections, do you agree that Valley Fever poses a real threat to human and animal health?

Answer 3. The National Institute of Allergy and Infectious Diseases (NIAID) is committed to advancing research on Valley fever, including the development of a safe and effective Valley fever vaccine. The increasing threat that Valley fever poses to public health underscores the urgent need for the development of safe and effective medical countermeasures. If confirmed, I look forward to working with you to advance this research.

SENATOR MARKEY

Question 1. It is estimated that in 2021 around *2.5 million adults* in the U.S. had an opioid used disorder. Medication-assisted treatment (MAT) has been proven to be safe and effective in treating opioid use disorders (OUDs), yet research published in August 2023 in the Journal of the American Medical Association found that only *1 in 5 adults* received MAT to threat their OUD. Last year, Dr. Nora Volkow, Director of the National Institute on Drug Abuse, *affirmed* that American doctors should "absolutely" be allowed to prescribe methadone directly to patients. Allowing physicians who are board certified in addiction medicine and addiction psychiatry to prescribe methadone is consistent with the bipartisan *Modernizing Opioid Treatment Access Act*.

a. How will you commit to working across agencies to implement research findings at NIH to improve access to OUD medications like methadone?

Answer 1. The opioid crisis has been devastating for so many communities and if confirmed, I look forward to working with you and my colleagues across the Administration to combat this crisis. I agree, there is a need to continue to expand access to evidence-based treatments for opioid use disorder (OUD), and increase access to naloxone for overdose reversal. With funding from the *NIH HEAL Initiative*, NIDA has significantly expanded its support of rapid, multi-site clinical trials; medication development; implementation science; and additional priority areas to address the overdose crisis.

Question 2. This summer was the hottest ever recorded; *21 of the 30* hottest days ever recorded occurred in July of this year alone. Climate change not only wreaks havoc on our physical environment, but on our individual health and our health systems. Extreme heat is *responsible* for almost 235,000 emergency department visits and over 56,000 hospital admissions, resulting in almost $1 billion in associated health care costs. How would you lead the NIH in approaching climate change from a public health perspective from a strategic and funding perspective?

Answer 2. Everyone is affected by the changes we are seeing in the climate. Climate change is creating new risks to human health, safety, quality of life, and economic growth. NIH launched the Climate Change and Health Initiative (CCHI) in December 2021 and expanded the research portfolio with fiscal year 2023 funds to understand health impacts, inform intervention science, and ensure health equity to develop the knowledge communities need to adapt and prevent further health impacts from climate disasters. The Initiative is funding transdisciplinary biomedical research and training to build a diverse workforce that can identify risks, optimize mitigation health benefits, and develop interventions to reduce or prevent impacts from climate change. This NIH-wide initiative on Climate and Health is just one way the NIH is moving toward integrating data on environmental factors more completely into our studies of many diseases. If confirmed, I look forward to working with you to address the public health aspects of climate change.

Question 3. Massachusetts was *recently selected* to be one of ARPA-H's two satellite hubs. The Investor Catalyst Hub will allow for collaboration among researchers, entrepreneurs, and investors to facilitate innovative health research and expedite breakthroughs in medical research. How do you plan to leverage NIH's new agency, ARPA-H, and the innovation hubs to facilitate research into emerging technologies, including artificial intelligence and machine learning?

Answer 3. ARPA-H was proposed as a new entity in the fiscal year 2022 President's Budget Request and was established in the Consolidated Appropriations Act, 2022. ARPA-H has a distinct, but complementary mission to NIH. If confirmed, I look forward to continuing to work closely with ARPA-H to ensure there is effective coordination on research as well as leveraging expertise of both organizations.

SENATOR CASEY

Question 1. The National Institute of Minority Health and Health Disparities recently designated people with disabilities as a "health disparities population." This was a highly sought after designation by the diverse disability communities across the country. The designation has the potential to address a decades-long wrong of excluding people with disabilities as a population to be included in health research. What steps will you take to implement the designation and to ensure people with disabilities in the research conducted across all NIH institutes and their activities?

Answer 1. This designation recognizes the importance and need for research advances to improve our understanding of the complexities leading to disparate health outcomes and multilevel interventions and is one of several steps NIH is taking to address health disparities faced by people with disabilities and ensure their representation in NIH research. I also want to stress that as a mother of a son with disabilities, this is an important issue to me on a personal and professional level and if confirmed, I look forward to working with you to ensure people with disabilities are included in research conducted across NIH.

Question 2. I have heard from many patients and families about the terrible burden of sepsis—children who have died, adults who have lost limbs, and other serious outcomes. There are common themes to their stories: misdiagnosis, delayed diagnosis, and racial and age disparities in outcomes for sepsis patients. How can the NIH contribute to a better understanding of the causes of sepsis, and further the timely identification and treatment of sepsis for all sepsis patients?

Answer 3. NIH supports many studies focused on sepsis, some of which are *clinical trials* that will evaluate the effectiveness of potential treatments. Other scientists seek *molecular* clues in patients' blood that could diagnose sepsis early or predict who might be more prone to the condition, allowing doctors to prevent it. Some try to find ways to estimate when and how a sepsis patient's condition will decline, or if a certain therapy is appropriate for particular patients. Still others examine sepsis in specific populations, such as premature babies; people with known risk factors, such as diabetes, cancer, or kidney or liver disease; or long-term sepsis survivors. If confirmed, I look forward to continuing to working with you on this issue.

Question 3. We know that early screening and detection of cancer is critical to ensure timely treatment, but many people either aren't receiving recommended screenings on time, or experience delays between screening and diagnosis. If you are confirmed, what further actions do you believe NIH can take to advance our research and practice of early screening for different types of cancer, and where do you see the greatest potential for improvement?

Answer 3. This is a critically important issue. As a breast cancer patient myself, I know that my own hopeful prognosis is directly linked to the fact that I caught this disease in its early stages. Increasing uptake of cancer screening is an important priority across the National Cancer Institute (NCI). NCI supports several key programs, partnerships, and individual research grants that aim to increase screening access and uptake. To give one example of many, the "Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS)" Program is a Cancer Moonshot Initiative that supports research to improve colorectal cancer screening, follow-up, and referral for care among populations that have low colorectal cancer screening rates. NCI is also supporting several research efforts to reduce barriers and increase uptake of cervical cancer screening, including in rural areas. Activities to increase cancer screening in rural regions are also part of NCI-Designated Cancer Centers' Community Outreach and Engagement efforts. There continues to be critical work in this field that NIH is well equipped to lead.

SENATOR LUJÁN

Question 1. Minority-Serving Institutes (MSIs) are institutions of higher education that serve significant percentages of students from historically underrepresented communities. MSIs are unique in that they all support the common mission of meeting the needs of the communities they serve to ensure access and retention among institutions of higher education.

a. How can the NIH support and leverage MSI strengths and capabilities to ensure they are able to keep up with other large research institutions and contribute to the larger biomedical research enterprise? What would you do as NIH Director to better support MSIs?

Answer 1. Increasing diversity both in the communities that NIH serves and in researchers and scientists who make up NIH is a top priority for me. Throughout my career I have worked with diverse communities and different types of providers. We know that a diverse research staff like a diverse care staff brings scientific excellence and brings better outcomes for the people that we serve.

The Research Centers in Minority Institutions (RCMI) program develops and strengthens the research infrastructure necessary to conduct state-of-the-art biomedical research and foster the next generation of researchers from underrepresented populations. It provides grants to institutions that award doctoral degrees in the health professions or health-related sciences and have a historical and current commitment to serving students from underrepresented populations. If confirmed, I look forward to working with you to better support MSIs and other efforts to support underserved communities.

Question 2. Valley Fever is an infection caused by a fungus primarily found in the soil of the semi-arid desert regions of the southwestern United States, is endemic in New Mexico, and has been diagnosed in every state. When the soil is disturbed, the fungus can become airborne and inhaled, ultimately causing infection.

a. Last year, the World Health Organization released a report identifying the top fungal priority pathogens to serve as a guide to research, development, and public health. Listed among those priority pathogens, were coccidioides (Valley Fever).

b. Given these reports, do you agree that Valley Fever poses a real threat to human and animal health? Do you commit to prioritizing research to prevent and treat Valley Fever and other fungal infections?

Answer 2. The National Institute of Allergy and Infectious Diseases (NIAID) is committed to advancing research on Valley fever, including the development of a safe and effective Valley fever vaccine. The increasing threat that Valley fever poses to public health underscores the urgent need for the development of safe and effective medical countermeasures. If confirmed, I look forward to working with you to advance this research.

Question 3. In the past decade, we have seen a growing body of research pointing to promising implications for the use of psilocybin-assisted therapy in the treatment

of mental health. When it comes to improving and expanding access to mental health treatment, I am in favor of thinking creatively.

a. How can NIH expand the resources available for research focusing on psilocybin-assisted therapy, and would you be supportive of such measures as director?

Answer 3. I enjoyed the opportunity to talk with you about this issue during our meeting this summer. Natural therapies such as psilocybin offer a new and interesting avenue for research. We can and we must do more to address mental health issues and trauma in Americans, and that includes research into new treatments.

Some types of psychedelic drugs, such as psilocybin, have shown promise as therapies for treatment-resistant depression and post-traumatic stress disorder. Important research questions remain, and the NOH funds more than 70 currently active projects on the therapeutic use of psychedelics. If confirmed, I look forward to working with you on this issue.

Question 4. Diet-related diseases including obesity, diabetes, high blood pressure, heart disease, and stroke disproportionately impact our Native communities.

a. As Director, how will you advance NIH's research investments in nutrition security, diet-related diseases, and diet-related health disparities in the U.S.?

Answer 4. This is a critical issue and if confirmed, I look forward to working with you to address diet-related diseases, as well as other areas where Native communities are facing disparate impacts. Health conditions linked to poor diet constitute the most frequent and preventable causes of death in the U.S. and are major drivers of health care costs. The Office of Nutrition Research (ONR) lead NIH-wide coordination and development of new collaborations focused on nutrition research within and outside NIH. ONR's Food Is Medicine Initiative includes support for nutrition science research addressing medically tailored meals and groceries, produce prescriptions, nutritious food referrals, culinary medicine programs, and teaching kitchens.

I will also add that from my current position as the director of the National Cancer Institute, the rising obesity epidemic is one of the major causes of cancer in the United States. We recognize this, and there's been a tremendous amount of work done by NCI to identify the ideology of this—how obesity drives cancer and how that can be overcome.

Question 5. The topic of diet and its impact on our health does not belong in a silo and is one in which we must work across all of the institutes.

a. In 2015, the NIH announced plans to end chimpanzee research and retire all government-owned chimpanzees in laboratories to sanctuary following an Institute of Medicine report that determined that chimpanzees are unnecessary for most biomedical and behavioral research. As you may know, there are still 28 chimpanzees stuck at the Alamogordo Research Facility in New Mexico after the NIH reversed its decision and announced in 2019 that it will not be retiring government-owned chimpanzees to sanctuary.

b. What is your plan as Director to carry out the promise made by the NIH to retire all chimpanzees to sanctuary as the CHIMP Act (passed by Congress in 2000 and reauthorized in 2013) requires by law?

Answer 5. I appreciated the chance to learn about this issue during our conversation this summer and I am committed to carrying out the goals of the CHIMP Act to ensure that these chimpanzees get the sanctuary and care they deserve.

RESPONSE BY MONICA BERTAGNOLLI TO QUESTIONS OF SENATOR CASSIDY, SENATOR PAUL, SENATOR COLLINS, SENATOR MURKOWSKI, SENATOR BRAUN, SENATOR MARSHALL, SENATOR TUBERVILLE, MULLIN AND, SENATOR BUDD

SENATOR CASSIDY

Leadership and Vision

Question 1. During your nomination hearing, I asked you about your ability to lead NIH through its next phase. This will require effective leadership that can make policy decisions and stand up for the best interests of the agency and the patients NIH research serves.

a. What role does the NIH Director have in making policy decisions for the agency?

b. If confirmed, how will you make policy decisions for the agency?

c. Will you defer to the White House and other political appointees at the Department of Health and Human Services?

Answer 1. The NIH Director is responsible for ensuring that the overall NIH community never loses sight of the core principles that guide the NIH's mission: to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness of people across the United States. If confirmed as NIH Director, I will always make decisions, with full fidelity to the laws passed by Congress and signed by the President, that serve to further this mission.

Question 2. If confirmed, what will your top priorities be as NIH director?

Answer 2. If confirmed to serve as NIH director, my top priorities include:

- Ensuring that NIH supports research that is equitable and accessible to all populations—that includes dramatically increasing clinical trials that reflect the diversity of Americans because we know that's what yields the best scientific results. This is critical to capitalizing on new innovations in uncovering fundamental biology, in health information technology, and in exciting new data analytics. And we must interrogate the broad range of behavioral and social science challenges we face today while laying the foundation to study and address new issues that will arise in the future.
- Embracing and increasing access to innovation. As a physician-researcher for more than 30 years, I have seen the transformative power of NIH research to produce results that save lives, but I've also seen the patients whose prospects were compromised by preventable factors. We should be able to guarantee that the American people are getting a return on their investment by ensuring that healthcare innovations are available and affordable for everyone.
- Restoring faith and trust in our Nation's top scientists and scientific integrity. I am committed to ensuring that NIH continue to be the stewards of our Nation's medical research and a force of innovation and discovery. We must also continue to support education in all fields of biomedical research and to inspire young people to become doctors and scientists, so that our critically important work will continue for generations.

Question 3. What specific actions will you take in your first few months as director to achieve each of these priorities?

Response: If confirmed as NIH Director, I would take the following actions to address each priority:

- ***Ensuring that NIH-supported research is equitable and accessible to all populations***: This goal must be embraced across all NIH programs. To ensure this, I will first work with the Director of NIH's National Institute on Minority Health and Health Disparities to develop and disseminate a set of guiding principles that all NIH program leaders can adopt to achieve this goal. This goal and principles for execution will be addressed in all of my initial planning meetings with NIH Institute and Center Directors, and I will require each to provide a plan for how their Institute or Center will make significant progress to eliminate health inequities. Finally, if confirmed as NIH Director, I will monitor progress toward this critical goal throughout my entire tenure and hold all leaders accountable for progress.
- ***Embracing and increasing access to innovation***: If confirmed, I will lead with the mandate that every effort undertaken by NIH must be viewed through the lens of "how does this directly and significantly improve the health of our Nation?". This means that, beginning with the initial planning phases, I will require that every major project consider and account for how, if successful, its products and services will be effectively adopted by the Nation's biomedical research and health care delivery communities to serve all who can benefit.
- ***Restoring faith and trust in our Nation's top scientists***: The NIH Director has a powerful position as the leader of the world's largest biomedical research institute. It is critical that the Director use this position to engender trust by ensuring that all funds received from the American people are responsibly managed to provide clear and tangible benefits to

our citizens, that all NIH activities are conducted according to the highest possible ethical standards, and that NIH work is executed in a transparent and accountable manner. If confirmed, one of my first actions will be to broadly communicate NIH's commitment and my personal commitment to these principles. In addition, I consider our front-line health care providers and educators to be key partners in restoring people's trust in science. If confirmed, I will develop a program to engage and support these partners so that they are able to communicate the value of biomedical research widely and effectively.

Question 4. Based on your time at NCI and your career as an investigator, do you see any specific opportunities for improvement within NIH or areas in need of reform? If so, please explain in detail.

Answer 4. There are always opportunities for reform and improvement and, if confirmed as NIH Director, I look forward to helping lead NIH during this next phase. I believe we need a major focus on our clinical trial operations so that clinical trials can be better, faster, and more inclusive of the population which we serve.

We also need to pay attention to our data collection and use throughout all of NIH and do an assessment of who we are reaching to understand how we can continually track and monitor progress to address disparities.

In addition, I want to carefully revisit the distribution of funding to institutions and individuals across the U.S. with a focus on making sure we buildup outreach to Institutional Development Award (IDeA) states and other research teams that have been historically under supported by NIH. NIH research has to reach everywhere; and there are many, many centers of great excellence across the country that we should engage in order to most effectively advance science.

Question 5. As you know, NIH has a decentralized structure in which individual institute and center directors retain substantial power.

a. How do you intend to navigate this dynamic as NIH director and lead the agency as a whole?

Answer 5. I firmly believe collaboration with and between the individual institutes and centers will be critical. As NIH Director, I intend to put forward a new initiative on data sharing which will establish the policies and infrastructures as well as the central support system to allow institutes and centers to better coordinate and share data from the broad research community.

I also believe there is an opportunity to reimagine the National Library of Medicine as a knowledge center for the world. Finally, there is an opportunity for NIH to lead in developing best practices on how to leverage artificial intelligence and machine learning. These activities, alongside many others, will help eliminate silos and ensure that we are maximizing NIH to its fullest potential.

Question 6. Under current law, NIH is required to maintain a Scientific Management Review Board (SMRB) to advise on NIH's structure and operations. However, the SMRB was last chartered in 2011 and has not been effectively leveraged.

a. Will you commit to reestablishing and fully utilizing the SMRB?

b. If so, what specific areas related to NIH's structure and operations would you charge the SMRB with reviewing?

Answer 6. If confirmed, I commit to review the groups that advise the NIH Director to ensure that we can ensure that NIH's operation and structure is run effectively with the maximum benefit to the American people.

Question 7. One of the statutory functions of the NIH director is to conduct priority-setting reviews and provide direction on institute and center operations.

a. What steps will you take to carry out these responsibilities, if confirmed?

b. What criteria will you apply to prioritize institutes and centers for review?

Answer 7. If confirmed, I commit to ensuring proper stewardship of taxpayer funds. NIH priority setting principles include funding meritorious science, portfolio balance, and balancing public health needs with scientific opportunities. Scientific priority setting at NIH encourages input from a range of sources, including the research community; public forums; the Advisory Committee to the NIH Director; U.S. Congress; Administration objectives; and consultation with advocacy groups, professional societies, and research participants. The NIH Director provides overall leadership to the Institutes and Centers (ICs) and the Office of the Director (OD) offices, especially on efforts involving several components of the agency. Strategic plans de-

veloped by individual ICs and OD offices, committees composed of representatives from multiple ICs, and interagency working groups describe a multitude of scientific priorities and themes of interest to the agency. If confirmed, my guiding principle will be to conduct all of these activities in a manner that achieves maximal health benefits to the American people and the world.

Question 8. You've spoken about your interest in establishing agency-wide systems to leverage data analytics, artificial intelligence, and machine learning.

a. How will you balance these goals with protecting the privacy and security of human subject data and ensuring appropriate informed consent?

Answer 8. Data science is foundational to NIH's acceleration of biomedical research. NIH supports innovative technologies and promotes best practices in data science to streamline data access, facilitate data management, and enhance data interoperability through the adoption of data standards, the use of unique persistent identifiers, and common data elements. NIH supports capabilities to broaden the use of clinical and healthcare data while preserving participants' anonymity and enhancing informed consent. New technologies capture and analyze the rich and abundant data from wearable monitors as an integral component of telehealth and are collected in the *All of Us* program and others.

I also want to emphasize the importance of informed consent and individual participation in the research process as fundamental to our strategy. In addition, data safety and security of data are critical, and we must take all required measures to assure this. If confirmed, I look forward to working with you to ensure that while we enhance our data science capabilities, that we also protect the privacy and security of individuals while continuing to collaborate and data-share to further break down silos at NIH.

Bioethics Issues

Question 9. Do you believe that Congress, or NIH and the scientific community, should set the policy for whether embryonic stem cells or fetal tissue are acceptable to use in research?

Answer 9. As NIH Director, I will follow the laws, including with respect to this type of research.

Question 10. What safeguards would you use to ensure that human fetal tissue is used as a last resort?

Answer 10. If confirmed, I commit to fully upholding the principles and established standards of ethical human research. I recognize and appreciate the great sensitivity and passionate feelings of many people on the issue of fetal tissue research, and I want to be respectful of that. As I shared before the Committee, it is my belief that my job is to serve everyone, including the communities who care deeply about how fetal tissue is used. As NIH Director, it is my responsibility to follow the laws of the land in every aspect and ensure that while we work to achieve the maximal good for people, we do so in a way that follows our principles of review and oversight of fetal tissue.

Question 11. During your nomination hearing, you said you would lean upon the principles of ethical human subjects research and institutional review boards (IRB) to ensure that fetal tissue research is conducted appropriately. However, as is clear in the findings of NIH's Human Fetal Tissue Research Ethics Advisory Board in Fiscal Year 2020, even proposals that successfully pass IRB and peer review can lack sufficient ethical protections, particularly around informed consent.

a. If you continue to permit the use of fetal tissue in research, how specifically would you ensure NIH-funded researchers are doing so in a responsible and consistent manner?

Answer 11. If confirmed, I commit to prioritizing this issue and as a first step, reviewing the findings of the NIH's Human Fetal Tissue Research Ethics Advisory Board in Fiscal Year 2020 as well as providing review when future fetal tissue research comes before the NIH for review to assure fidelity to the highest ethical standards.

Question 12. In your role at NCI, is there currently or has there been past work done with embryonic stem cells?

Answer 12. The NIH Research Online Reporting Tools (RePORT) includes reporting on NIH-supported research projects by various research topics and categories. This includes reporting on projects studying human embryonic stem cells and non-human embryonic stem cells to advance biomedical research across diseases and conditions, including cancer. This response addresses NCI-supported research

projects utilizing human embryonic stem cells. In fiscal year 2022, the last year for which NIH has final data, the Institute supported twenty-four projects involving human embryonic stem cell research. Projects were supported based on scientific merit and in accordance with NIH policies.

Question 13. In your role at NCI, is there currently or has there been past work done with fetal tissue?

Answer 13. In fiscal year 2022, the institute supported five projects studying human fetal tissue to advance cancer research. Projects were supported based on scientific merit and in accordance with NIH policies.

Question 14. Have you conducted research in your personal capacity using fetal tissue or embryonic stem cells?

a. If so, please provide the dates such research was conducted and the outcome of this research.

Answer 14. I have never used embryonic stem cells. I used fetal tissue once in approximately 1988 under the direction of a senior scientist when I was a trainee in a research lab in the Department of Tumor Immunology at the Dana Farber Institute. The research studied how T cells could be programmed to eliminate tumors. As a first step, we needed to understand how T cells could be programmed to eliminate abnormal cells and the only way to do that was to look at T cells of fetal tissue because these had not yet encountered any type of abnormal or "foreign" cell. The result was that we found no difference in the way fetal T cells responded to our approaches to eliminate tumors than in regular adult T cells and, as a result, we did not do any further research using fetal tissue.

Question 15. If confirmed, will you continue to allow NIH-funded research to use NIH-approved embryonic stem cell lines? If so, why?

Answer 15. If confirmed as NIH Director, it is my responsibility to follow the laws and ensure that, as we work to achieve the maximal good for people, we do so in a way that follows our principles.

Question 16. On August 31, a new stem cell line was submitted for NIH review. There are already 502 NIH-approved stem cell lines.

a. What is the scientific value of continuing to approve new lines?

b. At what point do you believe there will be enough stem cell lines?

c. What steps can NIH take to advance the transition away from using embryonic stem cells and fetal tissue in biomedical research?

Answer 16. Newer human embryonic stem cell lines are being derived under conditions that are better for clinical use, such as reduced exposure to animal products. Future embryonic stem cell lines may also have mutations associated with particular diseases and enable research on those disease mechanisms.

We do not know where the next cure or treatment will come from, and maximizing access to diverse tools, methods, and experimental systems is critical for enhancing the likelihood of success in advancing the NIH mission. I am committed to upholding the highest standards in research as a responsible steward of public funds.

Question 17. This March, you retweeted a tweet from the official HHS Twitter account stating that "transgender health care is health care. PERIOD."

a. Do you stand by this tweet?

Answer 17. As shared in my opening statement, I believe we must provide care for all people, including trans individuals, to ensure that they can live healthy and productive lives. How to best achieve these outcomes is a private decision between a doctor and their patient.

Question 18. If so, please explain. You have suggested that you would permit NIH to proceed with research on transgender youth, citing a lack of available science. As you know, I have expressed serious concerns about an NIH-funded observational study on transgender youth where two participants died by suicide.

a. How would you ensure that future studies on this issue, especially involving children, would be safe and live up to ethical scrutiny?

Answer 18. Like you, I share deep concern over the mental health of young people, particularly those in the LGBTQ+ community who face unique challenges. If confirmed, I will ensure that NIH takes seriously the protection of participants in NIH-funded clinical research while also better understanding the impact of medical treatment in transgender youth.

Question 19. While I appreciate that NIH has to date only funded observational studies related to transgender youth, NIH is responsible for the health and well-being of all participants in NIH-funded research. The use of observational studies rather than interventional studies does not absolve NIH and its investigators of this responsibility.

a. What specific steps will you take as director to ensure that participants in taxpayer funded NIH studies, including observational research, are fully protected in keeping with the spirit of the Common Rule, not just complying with the letter of the law?

Answer 19. If confirmed, I will ensure that NIH takes seriously the protection of participants in NIH-funded clinical research while also better understanding the impact of medical treatment in transgender youth. To underscore this, I firmly believe any research that we do with regard to human subjects has to be done in a way that does no harm and produces the maximum benefit to the people that are participating in the research. And that will be the principle with which I approach any research, especially for this vulnerable population.

Question 20. As a researcher, do you believe that biological sex is a relevant variable that must be considered in biomedical research?

Answer 20. Consideration of biological sex may be critical to the interpretation, validation, and generalizability of research findings. Adequate consideration of all sexes in experiments and disaggregation of data by sex allows for sex-based comparisons and may inform clinical interventions. Appropriate analysis and transparent reporting of data by sex may therefore enhance the rigor and applicability of preclinical biomedical research. NIH expects that *sex as a biological variable* will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

Question 21. As the head of NIH, would you maintain the current policy that requires biological sex be factored into research design, analysis, and reporting?

Answer 21. Consideration of sex may be critical to the interpretation, validation, and generalizability of research findings. Adequate consideration of both sexes in experiments and disaggregation of data by sex allows for sex-based comparisons and may inform clinical interventions. Appropriate analysis and transparent reporting of data by sex may therefore enhance the rigor and applicability of preclinical biomedical research. NIH expects that *sex as a biological variable* will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

Question 22. How will you ensure that research is not compromised as a result of external pressures to regard sex as a social construct versus a biological variable?

Answer 22. As listed on *nih.gov*, sex is a biological category based on reproductive, anatomical, and genetic characteristics, generally defined as male, female, and intersex. Meanwhile, gender is a social construct that varies from society to society and can change over time. As NIH director, I look forward to prioritizing the importance of studying LGBTQ+ communities, a population that has been historically understudied.

Other Policy Issues

Question 23. NIH funding for obesity and related research is significantly low relative to the burden of disease in the United States. This is particularly concerning, given that obesity strongly correlates with other diseases and conditions in which NIH invests billions each year.

a. If confirmed, how will you prioritize obesity, from basic science to clinical research, across NIH and improve the output of existing NIH funding for this work?

Answer 23. From my current position as the Director of the National Cancer Institute (NCI), I recognize that obesity and the rising obesity epidemic is one of the major causes of cancer in the United States. There has already been significant work done by NCI to identify the etiology of this—how obesity drives cancer and how that can be overcome. Much more needs to be done, however, for cancer as well as for many other disease states associated with obesity and metabolic syndrome. If confirmed, I can assure you that this is an area where we will work across all of the Institutes to address this problem.

Question 24. Your predecessor made a commitment to retire all NIH-owned and—supported chimpanzees to the Federal sanctuary at Chimp Haven in Louisiana, as mandated by the CHIMP Act.

a. How do you plan to prioritize the transfer of the remaining chimps at Alamogordo Primate Facility, as well as other facilities that still possess NIH-owned or NIH-supported chimpanzees, to their long overdue retirement at Chimp Haven?

Answer 24. I remain committed to carrying out the goals of the CHIMP Act to ensure that these chimpanzees get the sanctuary and care they deserve.

Question 25. How can we support the recruitment and retention of young investigators?

a. What specific strategies would you consider implementing to accomplish this goal?

Answer 25. My greatest accomplishment to date has been helping train the next generation of scientists. These are the physicians, surgeons, and scientists who are tackling the most ambitious and complex issues in medicine today. As a clinical researcher, I know what it takes day-to-day to run laboratories on the cutting edge of science and as a leader, I've been proud to help harness structural changes at hospitals and institutions to make sure that we are bringing these treatments to Americans as effectively and efficiently as possible.

NIH has various programs to enhance support of early career and postdoctoral researchers. This is a top priority for me, and I look forward to working with you to further cultivate and support talent entering the biomedical and behavioral research workforce.

Question 26. How can NIH be more supportive of researchers from outside the traditional NIH grantee community who want to contribute to cross-cutting biomedical research?

Answer 26. NIH is committed to funding meritorious research, regardless of the source of the proposal. If confirmed, I will remain committed to increasing equity of the research we fund. Notably, NIH just announced *simplified peer review criteria* which has the goal of, among other things, minimizing the effect of reputational bias and ensuring the best proposals from a scientific perspective rise to the top.

Question 27. How will you bolster cybersecurity protections across the agency, particularly related to research participant data?

Answer 27. Data science is foundational to NIH's acceleration of biomedical research. NIH supports innovative technologies and promotes best practices in data science to streamline data access, facilitate data management, and enhance data interoperability through the adoption of data standards, the use of unique persistent identifiers, and common data elements. NIH supports capabilities to broaden the use of clinical and healthcare data while preserving participants' anonymity and enhancing informed consent. New technologies capture and analyze the rich and abundant data from wearable monitors as an integral component of telehealth and are collected in the *All of Us* program and others. If confirmed, I will require optimal safety and security procedures for all sensitive data, and, as this landscape is constantly shifting, I look forward to working with you to ensure we have the right balance of data and security.

Question 28. What opportunities do you see to improve NIH's relationships and collaborations with other agencies?

Answer 28. NIH's collaborative efforts with other HHS agencies as well as across government are vital to transforming fundamental scientific and technical information into effective, knowledge-based approaches that advance the health and safety of the public, such as disease treatments, preventive interventions, protective health policies and regulations, and public health campaigns. In turn, the information provided by other HHS agencies on public health needs informs the policies and priorities of NIH-funded research. If confirmed, I look forward to working with my colleagues across HHS and the U.S. Government to improve the health of the American people.

Question 29. How can NIH help better position the U.S. internationally, particularly in the context of China and other countries' biotech ambitions?

Answer 29. As the world grows increasingly connected, NIH remains committed to developing and sustaining relationships with partners around the globe. Recent events, including the COVID–19 pandemic, have illuminated the importance of a coordinated approach to global health aligned with humanitarian and scientific values. Geographic boundaries do not prevent infectious disease spread, nor should they prevent the advancement of research on such diseases. For this reason, NIH collaborates internationally with foreign governments and organizations.

The safety, security and health of our people are our highest concern, and as we work across borders, it is imperative that NIH uphold the highest standards of oversight and accountability while continuing to further NIH's leadership as the world's premier medical research institute.

Question 30. As you likely know, Louisiana is an Institutional Development (IDeA) Program state, as are many states represented on HELP. Despite these investments in research capacity building, no Louisiana institutions rank in the top 50 NIH funding recipients, and relatively few institutions in the top 50 represent rural or underserved patients. While you've spoken generally about your commitment to making sure NIH research reaches more Americans, I would like more specifics.

a. How specifically will you work to more evenly distribute NIH extramural research funding across the country?

Answer 30. Growing up on a ranch in Wyoming, I have seen firsthand what it means to deliver care to those living in rural communities. NIH can and must support research that is equitable and accessible to all populations, and this will be a top priority of mine. The Institutional Development Award (IDeA) has been critical to building research capacity, supporting competitive basic, clinical, and translational research, faculty development, and infrastructure improvement, in states that historically have had low levels of NIH funding. If confirmed, I look forward to working with you to continue to make sure all states and communities are participating in the research enterprise.

Question 31. You've spoken before about your experience growing up in a rural area.

a. What ideas do you have to improve rural access to clinical trials?

b. How do you plan to implement these ideas at NIH?

c. What other opportunities do you see to modernize clinical trials, and how can NIH better coordinate with FDA?

Answer 31. Growing up on a ranch in Wyoming, I've seen how rural communities and underrepresented groups have too often lacked access to quality care. When my father had cancer, there was no one within 200 miles who could get him the care he needed. His story is all too familiar and is the story of millions of Americans who can't access or afford health care. I've spent my career searching for and implementing ways to take our discoveries and turn them into better health for people everywhere. As the leader of a large national clinical trial collaborative, I have seen firsthand how working with local providers, including tribal providers, expands access to patients in rural areas. NIH can and must truly support research at the community level, research that is inclusive and accessible to all populations regardless of county or zip code.

Question 32. What steps will you take to improve the rigor and reproducibility of NIH-funded research?

Answer 32. Two of the cornerstones of science advancement are rigor in designing and performing scientific research and the ability to reproduce biomedical research findings. This is a top priority for me and if confirmed, I look forward to working with you.

Question 33. How can NIH research become more outcomes-driven, particularly in terms of improving the utility and success of its clinical research (e.g. having more NIH-funded trials producing well-powered results)?

Answer 33. NIH is committed to supporting clinical research studies that are more transparent, efficient, faster, more inclusive, and more responsive to the needs of people and build trust. At the heart of every clinical study are the study participants who contribute their time and energy to help make it a success.

NIH has long recognized that the public is an equal partner in the research it supports, and it is critical to have meaningfully public engagement them in the planning, implementation, and dissemination of research. In addition, NIH is employing new methodologies and study designs to ensure that clinical trials are well-powered and produce meaningful results. NIH is committed to enhancing our scientific research review process to ensure that the highest quality clinical research is funded. If confirmed as NIH Director, I look forward to working with the NIH community to uphold these objectives.

Question 34. What role, if any, do you believe NIH has to play in the drug pricing debate?

Answer 34. The NIH funds primarily basic, translational, and early stage clinical research and relies on partnership with private sector to bring discoveries to market. I share concerns about high drug prices and the burden they place on patients and families, particularly the uninsured and the underinsured. Patient access to new therapies is something that NIH should be thinking through, including ways to engage the community, address broader concerns about price, and ensure good stewardship of taxpayer dollars. I look forward to working with you to address this issue if confirmed as the NIH Director.

Question 35. During the hearing you noted that if confirmed as NIH director you would work to ensure that the "benefits of our [NIH] research are affordable and available" to the American people. Given that NIH does not have a role in determining access or prices for agency-funded products, what actions were you referring to by this comment?

Answer 35. If confirmed, one of my top priorities will be increasing access to innovation. As a clinician-researcher for more than 30 years, I have seen the transformative power of experimental therapy in saving lives, but I've also seen the patients whose cancer could have been successfully treated but was compromised by preventable factors—including late diagnosis or inability to access or afford health care. As we work to bring innovation to patients, we must ensure transparency and accountability for taxpayer-funded research, guaranteeing that the American people are getting a return on their investment with health care innovation that is both accessible and affordable.

Question 36. Several Members of our conference have expressed frustration over a lack of transparency from NIH on document request and other inquiries related to gain-of-function research.

a. What steps do you plan to take to improve the responsiveness and transparency of NIH to Congress?

Answer 36. I deeply respect the oversight functions of Congress and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with the constitutionally mandated accommodation process.

Question 37. What opportunities do you see for more targeted research on rare and orphan diseases?

Answer 37. While individual rare diseases are uncommon, they collectively affect 25–30 million Americans. NIH has several programs that support rare disease research. The National Center for Advancing Translational Sciences (NCATS) established the Division of Rare Disease Research Innovation, which facilitates and coordinates NIH-wide activities involving research for a broad array of rare diseases. This division develops and maintains a centralized data base on rare diseases, coordinates and liaises with organizations worldwide concerned with rare diseases research and orphan products development, and advises the Office of the Director on matters related to NIH-sponsored research involving rare diseases. One example of this research is Rare Disease Clinical Research Network, which is funded by NCATS and 9 other Institutes and Centers (ICs). If confirmed as NIH Director, I intend to continue the important work the agency is doing to address rare diseases.

Question 38. Several years ago, the NIH launched the NIH Pediatric Research Consortium to better coordinate pediatric research activities across multiple Institutes and Centers.

a. If confirmed, will you commit to review the activities of the consortium and publicly report on its outcomes, as well as potential process improvements to ensure it is achieving its stated aims and objectives?

Answer 38. NIH support for pediatric research currently totals more than $4 billion. The NIH Pediatric Research Consortium (N-PeRC) aims to harmonize these activities across institutes, explore gaps in the overall pediatric research portfolio, and share best practices to advance science. The consortium meets several times a year to discuss scientific opportunities and potential new areas of collaboration, including efforts to enhance research training for the next generation of pediatricians. If confirmed, I would be pleased to work with you to advance pediatric research at NIH.

Question 39. Currently, policies such as paylines, success rates, and impact scores used in the review process vary widely across NIH.

a. Should NIH take a more unified approach to funding policies across its institutes and centers?

b. What steps would you take to make NIH's funding strategy more transparent for applicants?

Answer 39. Following NIH's rigorous two-stage peer review process, IC Directors make final funding decisions taking into consideration the research program priorities of their ICs in the context of the existing funding portfolio. A one-size-fits-all approach may not be successful in achieving the goals of each IC. If confirmed, I am committed to identifying potential areas in which NIH can be more transparent about its funding process and strategy, while following all applicable laws and regulations.

Question 40. Do you anticipate that NIH will change any of its operations or focus areas in response to the creation of ARPA-H?

Answer 40. ARPA-H was proposed as a new entity in the fiscal year 2022 President's Budget Request and was established in the Consolidated Appropriations Act, 2022. ARPA-H has a distinct, but complementary mission to NIH. If confirmed, I look forward to continuing to work closely with ARPA-H to ensure there is effective coordination on research as well as leveraging expertise of both organizations.

Question 41. How will components of NIH, such as the National Center for Advancing Translational Sciences and the Common Fund, that also support high-risk high-reward research, differentiate themselves from ARPA-H?

Answer 41. ARPA-H has a distinct, but complementary mission to NIH, including the work of the National Center for Advancing Translations Sciences and the Common Fund. If confirmed, I look forward to continuing to work closely with ARPA-H to ensure there is effective coordination on research as well as leveraging expertise of both organizations.

Ethics

Question 42. If confirmed, do you commit to providing the Committee, including minority Members, with information and/or documents in the requested timeframe?

Answer 42. I deeply respect the oversight function of Congress, including this Committee, and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with the law and the Constitution.

Question 43. If confirmed, do you commit to providing the Committee, including minority Members, with briefing requests from you and/or your staff, within the requested timeframe?

Answer 43. I deeply respect the oversight function of Congress, including this Committee, and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with the law and the Constitution.

Question 44. Do you commit to providing the Inspector General and the Government Accountability Office with any information, briefings, and documents they may request?

Answer 44. If confirmed as NIH Director, I am committed to working in good faith with all entities that are responsible for conducting oversight of NIH, including Congress, the Office of the Inspector General, and the Government Accountability Office.

Question 45. Do you commit to not seeking a waiver from your ethics pledge?

Answer 45. As part of the Biden-Harris administration ethics pledge, I have committed to recusing myself for 2 years from all particular matters involving specific parties involving my former employer or former clients. As I do in my current position as NCI Director, I will also continue to work with the agency's ethics officials—if confirmed—to identify and resolve any potential conflicts of interest. Any matters involving specific parties involving my former employer or former clients will be handled by the appropriate entities at NIH without my participation. If confirmed, I am committed to bolstering public trust in government and rendering decisions based on the best available data and science.

SENATOR PAUL

Question 1. Congress is running a $1.7 trillion deficit. The Federal debt is about 100 percent of GDP. To address our fiscal crisis, I have proposed legislation, the "five penny plan," to apply modest 5 percent spending reductions across the Federal Government. The NIH has a budget of $44 billion, and this year it received a budget increase of 9 percent. Over its lifetime, the NIH has received average annual budget increases of 11 percent. The economy is not growing that fast. Taxpayers' incomes

are not growing that fast. Can you commit to recommending options for reducing NIH spending so that the NIH can do its part to eliminate the Federal deficit?

Answer 1. NIH investment drives growth of the whole biomedical research enterprise. Discoveries arising from NIH-funded research provide a foundation for the U.S. biomedical industry, which contributes over $69 billion to the U.S. GDP each year and supports over 7 million jobs. As NIH Director, I commit to always being a faithful steward of taxpayer dollars, to ensure we use every penny to its fullest extent, and root out waste, fraud, and abuse to ensure fidelity to that mission.

Question 2. How will you address redundancies in research topics across the institutes and centers within the NIH to ensure that taxpayers receive the maximum benefit for their money?

Answer 2. I take seriously the stewardship of taxpayer dollars, including minimizing redundancy of research. If confirmed, I will work with Institute, Center, and Office Directors to consider strategies for research prioritization and reducing redundancy, potentially through leveraging novel technology.

Question 3. To compete scientifically with other advanced nations, we must not allow science to become politicized or dictated by ideology. We advance scientific knowledge by challenging prevailing assumptions, yet today it is more difficult to get an NIH grant that challenges prevailing (and politically correct) assumptions on a range of issues, including (1) the long-term health effects of puberty blockers on minors; (2) quality research on whether gender transition surgery is beneficial or harmful; (3) randomized controlled studies on the efficacy of face masks to prevent the spread of upper respiratory viral illnesses such as COVID–19; and (4) randomized controlled trials to investigate whether repeatedly getting booster vaccinations against upper respiratory viruses such as COVID–19 are effective or whether they yield diminishing returns because of immune imprinting and immune exhaustion. If confirmed, what policies will you put in place at the NIH to prevent or reduce confirmation bias in decisions about issuing research grants?

Answer 3. As scientists, eliminating confirmation bias is one of the most important things we can and must do in our line of work. Without challenging our preconceived notions, we risk our ability to innovate and deliver for the American people. If confirmed as NIH Director, I believe it is imperative that I model a transparent research atmosphere where colleagues feel comfortable challenging the status quo and disagreeing with one another. We must not be afraid of hard conversations. If confirmed, I look forward to working with you to determine the best policies and practices to deliver on that mission.

Question 4. As a director of a research funding organization, is it appropriate for the NIH Director or any institute director within the NIH to advocate for specific public health policies or policies that may discourage open scientific debate, as scientists are afraid to contradict those that control their research funding?

Answer 4. This question is paramount to what it means to be a leader, both at NIH and beyond. It is the responsibility of NIH leadership across the institutes to help inform and shape the issues facing Americans health and well-being, while continuing to ensure that they foster an environment that allows for disagreement and candid discussion.

Scientists must always encourage open scientific debate and have the courage to challenge the status quo. As history has taught us, science is always changing, and we must be ready to reevaluate the conclusions that came before in light of new evidence. The most dangerous attitude in science is one that stifles our ability to question. It is my goal to be a role model in this space.

Question 5. A 2022 Swedish study reviewed "published data on bone development in transgender adolescents, focusing in particular on differences in age and pubertal stage at the start of puberty suppression, chosen strategy to block puberty progression, duration of puberty suppression, and the timing of re-evaluation after estradiol or testosterone administration. Results consistently indicate a negative impact of long-term puberty suppression on bone mineral density, especially at the lumbar spine, which is only partially restored after sex steroid administration. Trans girls are more vulnerable than trans boys for compromised bone health." [1] Do you believe the long-term safety of gender affirming therapy in minors, including pharmaceutical administration, has been established by the FDA?

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[1] Ciancia S, Dubois V, Cools M. Impact of gender-affirming treatment on bone health in transgender and gender diverse youth. Endocr Connect. 2022 Sep 28;11(11):e220280. doi: 10.1530/EC–22–0280. PMID: 36048500; PMCID: PMC9578106.

a. If not, should gender affirming therapy in minors be considered experimental and subject to FDA oversight?

b. Do you believe gender affirming therapy should require the consent of a parent or legal guardian?

Answer 5. As current NCI Director and NIH Director nominee, I can't speak to FDA's role on this issue. If confirmed as NIH Director, my role may include providing data on gender affirming therapy and its impact, but it would not extend to the parental/guardian consent structure of personal medical decision that exist outside of NIH.

Question 6. Does the NIH fund, request, direct, and/or otherwise facilitate classified life sciences research?

Answer 6. To my knowledge as NCI Director, NIH does not fund, request, direct, or otherwise facilitate classified life sciences research.

Question 7. It is widely accepted that pandemics can come from nature, from laboratory accidents, or from deliberate releases by humans. Are you aware of the NIH or any other agency performing a formal cost-benefit analysis to inform decisions on whether to create or publicly identify a new potential pandemic pathogen?

Answer 7. As NCI Director, I am not aware of the NIH or any other agency performing such an analysis.

Question 8. In the past, the NIH has failed to fully comply with its requirements for oversight of enhanced potential pandemic pathogens research mandated by the HHS P3CO Framework. If confirmed, how will you ensure that enhanced potential pandemic pathogens research proposals are forwarded to HHS for the risk-benefit and risk-mitigation review mandated by the HHS P3CO Framework, and how will you ensure that officials who failed to do so under your predecessors are held accountable?

Answer 8. Potential pandemic pathogen research stands to achieve great benefit for people by allowing us to respond immediately and save lives, but it also has risk. If confirmed as NIH Director, I am committed to adhering to all relevant oversight policies and protocols for programs that engage in this kind of research, to make sure that they are conducted safely and achieve the benefit we know we can see for the American people.

Question 9. Do you believe Federal oversight of synthetic bioengineering gain-of-function research is adequate? If not, what reforms would you like to see?

Answer 9. I believe we can and must continually revisit and review our policies as science advances to ensure that we are identifying areas for improvement. If confirmed as NIH Director, I look forward to reviewing our polices and identifying any areas for reform.

Question 10. If Congress finds that the COVID–19 pandemic originated from a laboratory-acquired infection of a virus that had been part of gain-of-function experiments, would you support a ban on viral gain-of-function research funding by the NIH? If not, why not?

Answer 10. I am committed to working with Congress on all efforts to improve biosecurity policies and to enhance our pandemic preparedness.

Question 11. HHS initiated debarment of the Wuhan Institute of Virology from receiving Federal funding for the next 10 years. However, according to the NIH website, over two dozen other animal labs in China, including many with ties to the Chinese Communist Party (CCP), are currently eligible for more taxpayer funding. Additionally, Government Accountability Office (GAO) audits in March and June 2023 detailed problematic NIH loopholes that exempt labs in China and other foreign countries from oversight and transparency required of U.S. labs that receive taxpayer dollars. A recent review of Federal spending identified millions of U.S. tax dollars still being sent to Chinese animal labs for virus experiments, including at several labs run by or tied to the CCP. Do you think the NIH should be sending tax dollars to labs in China?

a. Do you think it makes sense for the NIH to exempt labs in China, Russia, and other foreign countries receiving taxpayer dollars from adhering to the same reporting, oversight and biosafety rules that govern domestic labs, especially ones handling dangerous pathogens?

Answer 11. NIH supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease. We must collaborate with researchers in other countries where these sorts of viruses are prevalent because once a virus spreads to humans, it is not contained

by geographical boundaries. The body of research on pathogens and infectious diseases is what has made it possible for the U.S. Government to move so quickly to get a COVID–19 vaccine in an unprecedented timeframe. Countless lives have been saved as a result.

In addition, if confirmed as NIH Director, I will be committed to upholding all critical policies related to scientific review, monitoring and accountability, no matter the location of the research.

Question 12. Some of the boards overseeing NIH-funded clinical trials continue to mandate COVID–19 vaccination even though vaccination status is not germane to the research being conducted or the data being analyzed. Do you think it is ethically problematic for boards that are entrusted with overseeing clinical trials to mandate COVID–19 vaccination during study enrollment even when vaccination status is not relevant to the integrity of the data?

a. Will you commit to ensuring that NIH funding recipients do not discriminate against unvaccinated candidates for participation in clinical trials?

Answer 12. NIH does not have a blanket policy requiring COVID vaccination for participation in clinical trials, but specific trials may have additional requirements that are set by the clinical trial sponsor based on the information that is being gathered for that particular trial.

Question 13. If confirmed, how will you ensure that congressional requests for information are answered promptly and in full, and how will you ensure that officials who failed to do so under your predecessors are held accountable?

Answer 13. I deeply respect the oversight function of Congress and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with constitutionally mandated accommodation process.

Question 14. Will you publicly commit to releasing all records requested by Members of Congress?

Answer 14. I deeply respect the oversight function of Congress and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with the constitutionally mandated accommodation process.

Question 15. The next NIH Director will be tasked with leading the development of the agency-wide strategic plan for fiscal years 2026–2030. As you know, this is an important responsibility that sets out agency priorities for the next 5 years. During the previous strategic planning process, the NIH only gathered stakeholder input on a short, rough framework of the proposed strategic plan, preventing the public from providing feedback about specific language or programmatic details. In addition, it is unclear how that input was considered as the agency developed its final strategic plan. Given the tremendous amount of taxpayer money spent to fund the agency's work, the public is due the opportunity to comment on a full draft plan and transparency on how that feedback is incorporated into the final strategic plan. To ensure public accountability, how will you enhance transparency and opportunities for stakeholder input during the development of the upcoming NIH Strategic Plan?

Answer 15. NIH is the steward of our Nation's medical and behavioral research, and I am committed to ensuring that NIH continues to be a force of innovation and discovery. To do that, we need to rebuild trust in science and engage with the American people transparently and consistently in our efforts. I look forward to engaging with the broadest possible group to bring health solutions to the American people.

Question 16. Is it reasonable for intramural NIH scientists to receive patent royalty payments for their taxpayer-funded research discoveries?

a. If you believe royalties are appropriate to attract top scientists to the NIH, can you explain how it helps science in this country if the NIH recruits the top scientists away from universities and other research institutions around the country?

Answer 16. The Federal Technology Act of 1986 authorizes government agencies to license their inventions in exchange for royalties that the agency can use to fund further research. NIH typically receives annual minimum royalty payments and a percentage of the sales of the end-product. The law requires that NIH pay a portion of the royalties it receives to the inventors according to a statutory formula (15 U.S.C. 3710c) and the remainder to the NIH Institutes where the inventions were made. NIH-funded universities and research hospitals have similar programs governed by the Bayh-Dole Act of 1980 (35 U.S.C. 202(c)(7). Royalties to NIH also pay

for the cost of obtaining patents. If confirmed as NIH director, I would ensure that all NIH policies are consistent with the law.

Question 17. Many academic scientists receive funding from both the government and the pharmaceutical industry. Does this funding mechanism create a potential conflict of interest?

a. Should the NIH try to ensure that there are academic scientists who are independent of the pharmaceutical industry?

b. How can such scientific independence be accomplished?

Answer 17. NIH requires the disclosure of all sources of research support, foreign components, and financial conflicts of interest for senior/key personnel on research applications and awards. NIH uses this information when making its funding decisions to determine if the research being proposed is receiving other sources of funding that could be duplicative, has the necessary time allocation, or if financial interests may affect objectivity in the conduct of the research. I am committed to ensuring proper stewardship of taxpayer dollars.

Question 18. Should the NIH coordinate its research activities with pharmaceutical companies?

Answer 18. The NIH funds primarily basic, translational, and early stage clinical research and relies on partnerships with the private sector to bring discoveries to market. Coordination with private companies, like those in the pharmaceutical industry, can lead to accelerated innovation toward techniques and treatments that improve the health outcomes for people across the United States. I believe, however, that NIH must always ensure that companies do not unfairly profit from the investment that taxpayers have made into NIH for the public good, and that public investment yields public benefits. I look forward to working with you to ensure that NIH coordination with private industry remains a balanced partnership between the private sector and the American people.

Question 19. Documents obtained by the independent watchdog group OpenTheBooks revealed that between 2009 and 2021, approximately 54,000 royalty payments totaling $325.8 million were paid by third party entities to NIH researchers credited as co-inventors. However, important information including the sources of the payments was redacted by the NIH. To avoid the appearance of conflicts of interest, will you commit to disclose publicly any royalty payments to NIH researchers by third parties, including the sources of those payments?

Answer 19. If confirmed, I am committed to transparency, and ensuring that the NIH provides information to the public consistent with applicable law.

Question 20. A bill I introduced, the FDA Modernization Act 2.0, which became law on December 29, 2022, amended the Federal Food, Drug, and Cosmetic Act to remove an outdated animal testing mandate and give drug sponsors the freedom to use modern alternatives to animal testing to assess the safety and effectiveness of new drugs. Unfortunately, despite the change in law, there have been several recent examples of expensive testing on dogs and other animals that were commissioned by the NIH and only canceled and determined to be unnecessary after criticism from Congress and independent watchdog groups. How would you improve the current review system to ensure the NIH does not spend taxpayer dollars wastefully on drug tests on animals that are no longer required by law?

Answer 20. All animals used in NIH-funded research are protected by laws, regulations, and policies to ensure the smallest possible number of subjects and the greatest commitment to their welfare. This includes ensuring that harm and distress is minimized as much as possible. Domestic institutions receiving funds from the Public Health Service (PHS) must conduct research involving live vertebrate animals in accordance with the PHS Policy on the Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy requires all institutions to comply, as applicable, with the Animal Welfare Act and other Federal statutes and regulations relating to animals. Compliance with this Policy is a collaborative effort between the NIH, scientific investigators, and research institutions.

The NIH Office of Laboratory Animal Welfare (OLAW) provides oversight of compliance with the PHS Policy in all NIH-supported research that involves vertebrate animals. All institutions that conduct PHS funded research, testing, or training are responsible for ensuring animal welfare and are obligated to protect the Federal investment in these activities. OLAW investigates allegations concerning animal welfare and appropriate animal care in NIH-funded studies. NIH-funded institutions must report promptly to OLAW any violation of the PHS Policy. OLAW considers these reports and requires the institution to make appropriate corrections and to prevent further violations.

If confirmed as NIH Director, I will work to ensure NIH continues to comply with all applicable laws and policies and continues to support the use of alternatives to animal testing, when appropriate.

SENATOR COLLINS

Question 1. The next generation of biomedical scientists are key to helping us unlock cures for diseases such as Alzheimer's, diabetes, and cancer. A robust research ecosystem that supports the post-doctoral and early career workforce is critical and ensures that the NIH retains its place as the world's leading biomedical research agency. For example, post-doctoral researchers at MDI Biological Laboratory in Bar Harbor are studying how diet and nutrition can increase lifespan and protect against age-related diseases. What are your plans to support post-doctoral training initiatives across NIH?

Answer 1. My greatest accomplishment to date has been helping train the next generation of scientists. These are the physicians, surgeons, and scientists who are tackling the most ambitious and complex issues in medicine today. As a clinical researcher, I know what it takes day-to-day to run laboratories on the cutting edge of science and as a leader, I've been proud to help harness structural changes at hospitals and institutions to make sure that we are bringing these treatments to Americans as effectively and efficiently as possible.

NIH has various programs to enhance support of early career and postdoctoral researchers. This is a top priority for me, and I look forward to working with you to further cultivate and support talent entering the biomedical and behavioral research workforce.

Question 2. NIH has a long and venerable history of Institutional research. What is your vision for the evolving role of intramural research programs, and what changes in emphasis or operation do you plan?

Answer 2. NIH's Intramural Research Program conducts distinctive, high-impact laboratory, clinical, and population-based research, facilitates new approaches to improve the health though prevention, diagnosis and treatment, responds to public health emergencies, and trains the next generation of biomedical researchers. If confirmed, I look forward to continuing this important work.

Question 3. There is considerable concern about the ever-increasing cost of biomedical research. Yet the NIH has not followed with an associated increase in individual extramural research support, specifically for R01 grants, the staple support for individual academic research programs. How will you meet this challenge?

Answer 3. NIH understands and is aware of the increasing fiscal pressures that institutions and scientists face when conducting biomedical research, including the effects of inflation on the costs to do research (see for example *this recent publication*). If confirmed as NIH Director, I will work closely with you and with IC Directors to implement approaches that enable us to fund as many scientists as we can, while also assuring that those scientists who are funded have enough support to be successful.

SENATOR MURKOWSKI

Question 1. One of my priorities in the Senate is trying to find ways to help end ALS. I have a personal connection to the disease. One of the problems with clinical trials and ALS is the endpoint, the ALS FRS score. It is currently the only accepted endpoint in ALS clinical trials because until now, there really hasn't been any better way developed to measure progression. However, technology has progressed and ALS clinical trials are starting to bring promise. I would appreciate a commitment to working with NINDS to develop and sponsor programs to measure ALS progression using alternative methods of ALS progression, to determine if they would provide a better measure of ALS progression and clinical endpoints. Alternatives could include progression of movement with muscle accelerometers, progression of speech with voice recordings, which have been used in several ongoing natural history studies in the ALS community.

> a. If there were more precise measures of ALS progression within ALS clinical trials, it could bring us closer to finding a treatment for ALS. The subjective ALS FRS score alone will not lead us to clinical trial success. Newer technologies will bring us closer much faster. Can I get your commitment to working on this issue, and to make ALS clinical trials more efficient?

Answer 1. ALS is a devastating fatal disease, and it is so important to be able to accurately track its effects in individual people, as a critical step in research to

combat this disease. We are seeing some exciting new technology that can help, and I would be honored to work with you to advance these important clinical trials.

Question 2. Dr. Bertagnolli, having grown up in rural Wyoming, you have written extensively about disparities in access to clinical trials for rural populations and have suggested several opportunities for improvement including by use of tech platforms, information sharing among academic networks, improved Electronic Health Record interoperability, and aligning with the close-knit cultural bond of rural communities.

a. Given your personal experience working with rural populations, how do you plan to close the gap in research conducted far from major population centers, especially among rural AI/N populations? How do you propose to perform research in rural areas without care delivery sites?

Answer 2. I have seen firsthand what it means to deliver care to those living in rural communities. NIH strives to make clinical trials as accessible as possible and has established programs to increase participation among rural communities. Several NIH programs are seeking to expand the footprint of clinical trials to more patients including rural populations through decentralized trial design and remote monitoring.

To give you a concrete example of my own work, when I ran a cancer clinical trials group, one of my main goals was to make sure those trials reached as many communities as we possibly could. And we partnered with a wonderful physician practice in Laredo, Texas, serving the border community; a dedicated physician who served the Oglala Sioux community at Pine Ridge Indian Reservation; and a wonderful oncologist in my own hometown of Rock Springs, Wyoming. I understand firsthand that the challenge of bringing both care and research to all communities is considerable, but it is one that we must overcome.

NIH research must reach everywhere; and there are many, many centers of great excellence that we should have the ability to engage.

Question 3. The estimated yearly impact of menopause symptoms on the economy annually is $1.8 billion due to missed workdays, but there have been few advancements in treatment in the last few decades. Research in this subject area has been deprioritized since the early 2000's.

a. As NIH Director, would you commit to prioritizing research on women's health in general, and identifying improved treatments for the adverse health conditions associated with menopause in particular?

Answer 3. Multiple NIH Institutes are funding research to advance the understanding and impact of changes experienced by women during menopause, providing effective alternatives for the relief of menopausal symptoms, and examining the ways menopause affects women's overall health and well-being. If confirmed, I commit to continuing to this important research.

Question 4. Alaska continues to be plagued by preventable chronic infectious diseases such as tuberculosis and hepatitis C. As of 2021, Alaska had the highest incidence of tuberculosis in the country due to very high rates in rural areas, especially in our Southwest region. Rates of hepatitis C have been noted to be increasing statewide for two decades despite the availability of curative treatments. The NIH has also recently reported promising research around temperature-stable vaccines for TB.

a. How would the NIH approach coordinating with other Federal agencies, state, local, and Tribal governments toward the goal of eradicating chronic infectious diseases such as tuberculosis and hepatitis C?

b. Under your leadership, would you commit to funding research for technologies such as temperature stable vaccines for tuberculosis which could help to address disparities in infectious disease treatment and prevention for rural populations?

Answer 4. I would be very pleased, if confirmed, to work with you to address these specific issues for the people of Alaska. As you mentioned, an experimental tuberculosis vaccine that can be stored at room temperature was safe and provoked an immune response in a phase 1 clinical trial. If proven effective in larger trials, the vaccine could make tuberculosis prevention more accessible to those most at risk. This is just one example of more approaches to combating infectious disease in diverse communities. NIH is eager to work with state, local, and tribal governments to advance this research.

SENATOR MIKE BRAUN

Question 1. Recently, leaked documents indicated that HHS has implemented a new mandate requiring all its employees to use a person's preferred pronouns, even if those pronouns do not align with the person's biological sex. Alarmingly, the policy does not mention any first amendment rights against compelled speech or the free exercise of religion, the Religious Freedom Restoration Act, or any religious accommodations.

a. Do you support this policy?

Answer 1. I firmly support employee rights and protections related to gender identity.

Question 2. Will you commit to ensuring that all at NIH are granted their full first amendment rights by protecting religious accommodations and free speech?

Answer 2. If confirmed as NIH Director, I am committed to ensuring that all Constitutional rights, including first amendment rights, are protected for all NIH employees.

SENATOR MARSHALL

Question 1. We appreciate your statement that you would preserve the integrity of the Bayh-Dole Act. However, we would like you to clarify what you mean on preserving the integrity of the Bayh-Dole Act. Earlier this year, the U.S. Department of Health and Human Services announced a working group to review its march-in authority, and it remains unclear the agreement reached by the Biden administration and HELP Committee Majority in moving this nomination forward. One needs to look no further to confirm the intent of the Bayh-Dole Act than the letter of the law and the U.S. Senators that wrote it. In a 2002, former Senators Birch Bayh and Bob Dole *penned an op-ed* in response to misinformation on march-in rights authority and the intent of the Bayh-Dole Act.

a. If confirmed, will you follow the letter of the law and precedent set by the Obama, Trump, and Biden administrations, along with your predecessor Francis Collins, that you do not have the authority to weaken IP protections by marching-in on a drug because of its price?

b. Do you acknowledge that the Administration does not have the legal authority to use march-in rights to lower drug prices?

Answer 1. March-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably available to the public. It is my understanding that there is a whole-of-government effort to develop a march-in implementation framework that will consider how different factors, including price, impact these decisions. I look forward to seeing this framework, and if confirmed, I will follow both the letter and the spirit of the law.

Question 2. To build capacity in biomedical research across the entire United States, NIH uses the Institutional Development Award (IDeA) program, which is vital to Kansas and institutions like the University of Kansas and its medical center, as well as specific initiatives like the Centers of Biomedical Research Excellence (COBRE) and IDeA Networks of Biomedical Research Excellence (INBRE). What do you see as the most important benefits and successes of the IDeA program thus far?

a. Despite the program targeting half of the country, IDeA's budget is only around 0.9 percent of the overall NIH budget. If Congress were to prioritize more funding specifically for IDeA, how would you, as NIH Director, look to expand the program?

b. Do you support increasing the IDeA program's participation beyond the currently available mechanisms, to programs such as those supporting biomedical research facilities, instrumentation, and training?

Answer 2. If confirmed as NIH Director, I look forward to expanding that program not only by partnering with the outstanding academic institutions within the IDeA states as they grow out their educational and research outreach programs, but also for programs that we have that are national infrastructure, such as the National Clinical Trials Network and other infrastructure that literally goes down into individual communities. I view increasing the IDeA program's participation as one way we can engage more of the American people in the research that we conduct, and I think it would be very positive.

Question 3. First launched in 2015, the All of Us Precision Medicine Initiative has the potential to transform medicine and health care by providing an in-depth look at how genes, lifestyles, and environments impact human health. How will NIH continue to prioritize precision medicine and engagement with all communities—from urban centers to rural areas across the country—to advance precision medicine to enhance patient care among different patient populations?

Answer 3. The All of Us Research Program is an ambitious effort to gather data over time from 1 million or more people living in the United States, with the ultimate goal of accelerating research and improving health. Unlike research studies that are focused on a specific disease or population, All of Us will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions. Researchers will use data from the program to learn more about how individual differences in lifestyle, environment, and biological makeup can influence health and disease. I fully support this program, and affirm its commitment to delivering results that benefit all people, in all communities.

SENATOR TUBERVILLE

Question 1. The NIH funded a study recently about the "Psycho-social Functioning in Transgender Youth After 2 Years of Hormones." According to the letter NIH sent to Ranking Member Cassidy and me, the "research seeks to understand physical and psycho-social effects of medical intervention to evaluate the effectiveness of existing medical treatments already in use among transgender youth." Two young people committed suicide who were part of this study.

a. If you are confirmed, how will you make sure nothing like that happens again on your watch?

b. Has the NIH funded research—through this study, or others—that might tell us the long-term impacts of puberty blockers, hormone therapies, surgeries, or other alterations on an individual's bones or muscles?

c. Specifically, how those interventions might alter an individual's bones or muscles to make them stronger or weaker?

d. Given the interest in society today around this issue, do you think that's something the NIH should consider in a future study—safely, of course?

e. How will you undertake future studies?

Answer 1. Like you, I share deep concern over the mental health of young people, particularly those in the LGBTQ+ community who face unique challenges. The study you reference was not funded by NCI. If confirmed, I will ensure that NIH takes seriously the protection of participants in NIH-funded clinical research while also better understanding the impact of medical treatment in transgender youth.

Question 2. The NIH used to be a universally respected non-political organization before COVID. But that trust has been broken, especially in rural parts of the country like Alabama. People in these parts of the country in particular have lost confidence in our public health institutions. They feel totally overlooked.

a. What would you do as NIH Director to help gain back some of that trust, especially among rural populations?

Answer 2. NIH is the steward of our Nation's medical and behavioral research, and I am committed to ensuring that NIH continues to be a force of innovation and discovery. To do that, we need to rebuild trust in science and engage with the American people transparently and consistently in our efforts. No. 1, I believe deeply in the doctor-patient relationship. A patient comes and puts their life and their health in the hands of their doctors. Anything that we can do to strengthen the doctor-patient relationship is something that we should fully pursue where possible. Second, I believe that patients are valued and full participants in the research and science. A strong researcher-patient relationship engenders great trust in the process if it's done in a respectful and appropriate way.

Question 3. In your past job as a cancer researcher and in your current job as the head of the National Cancer Institute, you've had hands-on experience with the kind of groundbreaking drugs and therapies that have changed the outcomes for so many patients and families. This Administration has made curing cancer a huge priority, which I support. They—and our Chairman—also talk a lot about lowering drug prices.

a. In your experience, would these breakthrough therapies and drugs have ever been possible without substantial research and investment from pharmaceutical companies?

Answer 3. Industry can play a critical role in helping develop drugs and their partnership can be paramount in helping drive innovation. But I believe it is also imperative that NIH-funded research must be conducted in a manner that ensures a fair return on the taxpayer investments.

Question 4. Setting aside any speculation about suspected origins of the COVID virus, I think we can all agree that the NIH has a lot to do to regain the trust of the public—both in the U.S. and internationally.

a. As head of the NIH, how would you ensure that taxpayer dollars don't go toward funding dangerous research—like gain of function—in countries of concern?

Answer 4. If confirmed as NIH Director, I am committed to adhering to all relevant oversight policies and protocols for programs that engage in enhanced potential pandemic pathogen research, to make sure that they are conducted safely.

Question 5. Do you regret signing a letter in May 2020 urging governments to implement mask mandates "in all public places" and "public buildings"?

Answer 5. If confirmed as NIH Director, my responsibility would be to bring forth the data for public health officials and policymakers to make informed decisions about public health. Having reviewed the data myself, I appreciate the benefits of masking and slowing the spread of COVID–19, especially in the early days of the pandemic.

Question 6. The aforementioned May 2020 letter that you signed states that "laws appear to be highly effective at increasing compliance and slowing or stopping the spread of COVID–19." Given this statement, do you support the following mandates imposed by the Biden administration:

a. The vaccine mandate imposed through the Occupational Safety and Health Administration, which was blocked by the Supreme Court in January 2022?

b. The vaccine mandate imposed by the Department of Defense issued in August 2021, which Congress voted to rescind in the fiscal year 2023 NDAA?

c. The vaccine mandate imposed by the Center for Medicare and Medicaid Services issued in November 2021 requirement?

Answer 6. While NIH helps to support research on vaccines, therapeutics, and diagnostics regarding COVID–19 and other threats, we do not make the decision on whether to recommend or mandate use of any vaccine.

Question 7. Please describe your role as Chair of the National Cancer Institute's Equity Council.

Answer 7. The council is comprised of a diverse group of leaders from across NCI with a passion and commitment to: ensuring that NCI has a robust research portfolio to effectively address cancer disparities; nurturing a workforce at all career levels that is representative of all the people we serve; and cultivating and ensuring that a community at NCI that is diverse in thought and representation, including at leadership levels across the institute. As chair, I am responsible for helping guide the agenda of the council to best achieve our mission.

Question 8. Please describe any materials that the council has endorsed related to diversity, equity, and inclusion.

Answer 8. NCI makes information about equity, diversity, and inclusion available on its website. This includes publicly available content such as blogs focused on health disparities research, and presentations focused on equity, inclusion, and diversity from NCI leadership and program staff, as well as NCI-supported researchers.

Question 9. The NIH has funded a number of troubling projects in the recent past. Please comment if you think that it is appropriate to continue to fund this research and if not, how you would ensure it does not continue:

a. According to media reports, the NIH spent more than $8 million on a research study that pays gay and transgender boys as young as 13 hundreds of dollars to report their sexual behavior on a mobile app, all without parental permission. NIH-funded researchers at Columbia University *offer* up to $275 to gay and transgender boys, between the ages of 13 and 18,

to document their sexual activity on MyPEEPS Mobile, including whether they have "condomless anal sex."[2]

b. According to media reports, between 2016 and 2020, NIH awarded approximately $1.5 million to Pitt for a project related to the GenitoUrinary Developmental Molecular Anatomy Project (GUDMAP) program to provide the scientific and medical community tools to study "congenital diseases of the genitourinary tract (kidneys, bladder, ureter, uretha)" by obtaining such organs from aborted babies for research. [3]

- FOIA documents from NIH indicate that University of Pittsburg may have been altering abortion procedures solely to obtain fetal tissue, which is illegal under 42 USC 289g–1.
- The reports show that university researchers may have caused the death of the children by harvesting organs from babies who were old enough to live outside the womb.

Answer 9. As the current NCI Director, I am not familiar with the projects that you listed and cannot speak to their appropriateness.

Question 10. Previously, you sat on the board of Natera, which has drawn attention from the New York Times for promoting prenatal tests for various diseases, which apparently have a False Positive Rate of 85 percent or higher. Tragically, these false positives prompt many parents to abort their unborn child.

a. Were you ever aware of the high false positive rate for neonatal tests?

b. If so, when were you made aware?

c. Did you ever exercise oversight of the prenatal tests?

Answer 10. The article that I believe you are referring to had this incorrect test accuracy claim removed. The Natera test is accurate in >99 percent of cases.

SENATOR MULLIN

Question 1. If confirmed, would you maintain the current policy of the NIH that allows taxpayer dollars to fund research on the effects of gender transition procedures on youth? If so, would you allow NIH to fund studies on procedures such as sterilizing surgeries, cross-sex hormones, or puberty blockers in minors?

Answer 1. Transgender children and adolescents are a distinctly understudied population in the United States. If confirmed, I will ensure that NIH takes seriously the protection of participants in NIH-funded clinical research while also better understanding the impact of medical treatment in transgender youth.

Question 2. The NIH gave almost half a million dollars to fund a study published in 2023 called "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones." The study evaluated the impact of gender transition procedures on youth, and two of the study participants tragically committed suicide. Do you think it was ethical for the NIH to fund a study evaluating gender transition procedures that led to these outcomes?

Answer 2. Transgender children and adolescents are a distinctly understudied population in the United States. If confirmed, I will ensure that NIH takes seriously the protection of participants in NIH-funded clinical research while also better understanding the impact of medical treatment in transgender youth.

Question 3. If confirmed, would you maintain the Biden administration's current policy that permits NIH research using fetal tissues that are derived from abortions?

Answer 3. Fetal tissue research is critical to our understanding of a variety of diseases. I recognize and appreciate the great sensitivity and passionate feelings of many people on the issue of fetal tissue research, and I want to be respectful of that. As I shared before the Committee, it is my belief that my job is to serve everyone, including the communities who care deeply about how fetal tissue is used. As NIH Director, it is my responsibility to follow the laws of the land in every aspect and ensure that while we work to achieve the maximal good for people, we do so in a way that follows our principles of review and oversight of fetal tissue. As NIH Director, I would ensure full compliance and inclusion of the review boards when considering the use of fetal tissue.

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[2] *https://freebeacon.com/latest-news/taxpayer-funded-study-pays-gay-minors-to-report-sexual-activity-without-parental-permission/*.

[3] *https://www.foxnews.com/politics/congress-letter-biden-admin-pittsburgh-fetal-tissue-research*.

Question 4. In 42 U.S. Code § 289g–2(a), the law prohibits a person from knowingly acquiring, receiving, or transferring any human fetal tissue "for valuable consideration if the transfer affects interstate commerce." Would you say that it is a violation of the law for abortion and tissue procurement entities to profit off of the remains of aborted children?

Answer 4. If confirmed NIH Director, I am committed to following all applicable laws related to human fetal tissue.

Question 5. Should the NIH be conducting research using the fetal tissue remains of unborn children who were aborted at 24 weeks gestation or later?

Answer 5. Fetal tissue research is critical to our understanding of a variety of diseases. If confirmed, I will ensure we are continuing to follow existing policies and statutory requirements on fetal tissue research.

Question 6. What guidelines are in place to ensure that the fetal tissue from unborn children used in NIH funded research is not coming from illegal abortions that could occur in pro-life states like Oklahoma?

Answer 6. Fetal tissue research is critical to our understanding of a variety of diseases. If confirmed, I will ensure we are continuing to follow existing policies and statutory requirements on fetal tissue research.

Question 7. According to the Office of Director congressional Justification Fiscal Year (FY) 2024, "NIH has long prioritized supporting a safe and respectful workplace, free from harassment and discrimination, wherever NIH-funded research is conducted." Over the past several years, however, there have been concerns raised over NIH's handling of sexual harassment complaints involving scientists funded through NIH. In one particularly troubling case involving an NIH-funded scientist at San Diego Biomedical Research Institute, it appears that NIH failed to stop "pass the harasser." If confirmed, will you commit to answer all congressional requests concerning the NIH's handling of sexual harassment complaints and will you commit to working with lawmakers to address these concerns?

Answer 7. Over the past several years, NIH has taken many substantive actions within the scope of NIH's grant authorities to address harassment and discrimination in NIH extramural biomedical science, including the development and implementation of policies and processes. I appreciate Congress' continued interest and support as the agency works toward ensuring safe and respectful workplaces, free from harassment and discrimination, wherever NIH-funded research is conducted. I commit to working with you on this important issue.

SENATOR BUDD

Question 1. As an oncologist, what opportunities do you see for more targeted research on rare and orphan diseases including non-cancer genetic disorders and prion-based illnesses?

Answer 1. At NCI, the Center for Cancer Research (CCR) has a mandate to confront the special challenges presented by rare cancers and diseases as well cancers that may be predominant in medically underserved populations. In many cases, the knowledge CCR's investigators gain from studying and treating rare cancers and related diseases provides them with insights into the mechanisms that underlie other more common malignancies. CCR, working with the NIH Clinical Center, brings together patients from around the world who share rare disease diagnoses. If confirmed, I look forward to working with you to expand this work.

Question 2. How can we best leverage interagency cooperative efforts, similar to those used in the fight against cancer, against other rare diseases? Is NIH appropriately structured or are there institutional hurdles that currently prevent us from maximizing the return on moneys spent on biomedical research in the United States? And if so and confirmed, how would work to address these hurdles?

Answer 2. NIH's collaborative efforts with other HHS agencies are vital to transforming fundamental scientific and technical information into effective, knowledge-based approaches that advance the health and safety of the public, such as disease treatments, preventive interventions, protective health policies and regulations, and public health campaigns. In turn, the information provided by other HHS agencies on public health needs informs the policies and priorities of NIH-funded research. Recent cooperative efforts include ending the pandemic, tackling health disparities, and strengthening behavioral health. If confirmed, I look forward to working with my colleagues across HHS and the U.S. Government to do even more to improve the health of the American people.

Question 3. If confirmed to serve as the next NIH Director, what specific actions will you take to continue advancing the science behind prion-based illnesses such

as Creutzfeldt-Jacob Disease (CJD), and ensure that NIH does not miss opportunities to advance our understanding of rare diseases that share biochemical pathways with other diseases? How will you ensure that the patient voice is equally leveraged across NIH, including with respect to intra and extramural biomedical, clinical, and translational research for rare diseases? How do you plan on collaborating with your colleagues across HHS, including those at FDA, so that the learnings from this NIH work might also be applied in their endeavors on behalf of patients?

Answer 3. NIH supports dozens of studies on Creutzfeldt-Jakob disease (CJD) and other prion diseases such as transmissible spongiform encephalopathy. NIH's collaborative efforts with other HHS agencies as well as across government are vital to transforming fundamental scientific and technical information into effective, knowledge-based approaches that advance the health including rare disease treatments. If confirmed, I look forward to working with patients and their families as well my colleagues across HHS and the U.S. Government to advance scientific understanding to improve the health of the American people.

[Whereupon, at 12:30 p.m., the hearing was adjourned.]