# FIELD HEARING ON ACCESS TO HEALTH CARE IN AMERICA: UNLEASHING MEDICAL INNOVATION AND ECONOMIC PROSPERITY

## HEARING

BEFORE THE

## COMMITTEE ON WAYS AND MEANS
## HOUSE OF REPRESENTATIVES

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United States House Committee on
# Ways & Means
CHAIRMAN JASON SMITH

FOR IMMEDIATE RELEASE
July 5, 2024
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CONTACT: 202-225-3625

## Chairman Smith Announces Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity

House Committee on Ways and Means Chairman Jason Smith (MO-08) announced today that the Committee will hold a field hearing on the power of advancing and supporting health care innovation in the Mountain West. The hearing will take place at **10:00 AM (Mountain Time) on Friday, July 12, 2024, at ARUP** in Salt Lake City, Utah.

In view of the limited time available to hear the witnesses, oral testimony at this hearing will be from the invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

**DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:**

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record can do so here: WMSubmission@mail.house.gov.

Please ATTACH your submission as a Microsoft Word document in compliance with the formatting requirements listed below, **by the close of business on Friday, July 26, 2024**. For questions, or if you encounter technical problems, please call (202) 225-3625.

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The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission but reserves the right to format it according to guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with

these guidelines will not be printed but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Please indicate the title of the hearing as the subject line in your submission. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

**ACCOMMODATIONS:**

The Committee seeks to make its facilities accessible to persons with disabilities. If you require accommodations, please call 202-225-3625 or request via email to WMSubmission@mail.house.gov in advance of the event (four business days' notice is requested). Questions regarding accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

**Note**: All Committee advisories and news releases are available on the Committee website at http://www.waysandmeans.house.gov/.

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# ACCESS TO HEALTH CARE IN AMERICA: UNLEASHING MEDICAL INNOVATION AND ECONOMIC PROSPERITY

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**FRIDAY, JULY 12, 2024**

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
*Washington, DC.*

The committee met, pursuant to call, at 10:02 a.m. Mountain, ARUP Laboratories, 540 S. Chipeta Way, Salt Lake City, Utah, Hon. Jason Smith [chairman of the committee] presiding.

Chairman SMITH. The committee will come to order.

Without objection, the gentleman from Mr. Utah, Mr. Owens, and the gentlewoman from Utah, Ms. Maloy, are authorized to participate in the hearing of the best committee in Congress and ask questions.

Good morning. I want to thank everyone for joining us, and especially thank our host, ARUP Labs, for welcoming us to your impressive facility. It is incredible to be able to watch the future of medicine happening right before us during this hearing.

I also want to thank Congressman Moore for hosting us here today. We had a great tour this morning of a private charity that helps meet basic needs and uses the power of meaningful work to help lift families out of poverty. And I am looking forward to another great event here.

Everyone here should know that back in D.C., Blake is not shy about sharing how Utah could be a model for the rest of America at everything. So he is your advocate and he never stops. And we are proud that he is one of our shining members of the Ways and Means Committee.

The Ways and Means Committee is in Salt Lake City to listen and learn directly from Americans making the next generation of medicines and the patients who are benefiting from those breakthroughs to see what Congress can do to encourage medical innovation in America.

American innovators are the world's best. Our researchers, scientists, and doctors discover and develop new tests, treatments, and technologies that have improved the lives of millions. Today, new treatments are providing levels of quality care and transforming lives in ways that once seemed unthinkable.

Today, tens of millions of Americans can consult with their doctor, have their vital signs monitored, receive drug infusions or even dialysis all from the comfort of their home. Patients have more con-

trol over their care and, most importantly, these breakthroughs are improving their health.

Thanks to the work of this committee, seniors are one step closer to having access to more cutting-edge treatments. Just recently, the committee voted, with support of both Republicans and Democrats, to allow Medicare to cover anti-obesity medication, multi-cancer early detection screenings, and breakthrough medical devices. When these bills become law, seniors will have access to some of the most advanced treatments available. Importantly, the legislation is an investment to help America tackle the explosive growth of healthcare spending in the coming decades. With 95 percent of adults 60 and older having at least one chronic disease, innovation and access is a must for the long-term health of our country.

America has the infrastructure, the people, and know-how to stay the world's leader in medical innovation, but the next groundbreaking cure or treatment will only be found because of strong support for research and development. Policies coming out of Washington must encourage more R&D to happen here in America. We must act to ensure Americans stay at the forefront of developing the best, most effective medical treatments.

One of the first steps to growing R&D is cutting the red tape keeping new breakthroughs, like revolutionary Alzheimer's medication, out of the hands of patients. Legislation also approved by this committee this year would provide better access to these innovative therapies.

The next step is looking at the Tax Code to foster an economy where innovators want to take risks and invest in more R&D. The 2017 Trump tax cuts encouraged American companies to hire new workers, create new products, and invest in America. More than $2 trillion was invested in new facilities and R&D activities, but it also succeeded in another key way: jobs. The R&D deduction supports 2 million jobs directly and 21 million more indirectly. These pro-growth policies under President Trump led to bigger paychecks for workers, low unemployment, and a booming economy.

The House of Representatives took action earlier this year to keep our R&D incentives strong, but a massive tax hike awaits American families, farmers, innovators, and job creators. Republicans on this committee have formed tax teams to find ways to protect Americans from these tax hikes and also find new ways the Tax Code can be utilized to better incentivize research and development here in the U.S. and to outcompete our competitors like China.

Members are fanning out across the country to listen to Americans directly affected by these issues and turn their ideas into policies that help workers, that help families, farmers, and small businesses thrive. Part of that effort includes this hearing today and listening directly to our witnesses here today about their stories and ideas for keeping medical innovation alive and well in America.

We also want to hear from everyone that is in the audience. There will be clipboards, as you see before you, passed out, and we ask that you take time to fill them out and let us hear from you. It will be entered into the official hearing record, and we will take

those back to Washington as we consider how to unleash medical breakthroughs across the country.

I am now pleased to introduce the host of this committee, Mr. Congressman Moore.

Mr. MOORE of Utah. Thank you, Chairman.

And before we hear from our witnesses—that will be next, correct?—I just wanted to echo that welcome to everyone.

To my colleagues that are not on this committee, Mr. Owens and Ms. Maloy, thank you for also being here.

A sincere thank you to all the committee staff—we know where this really all gets done—to be able to organize and make all this happen. So thank you all for being here.

And to our witnesses, I look forward to hearing you in just a moment.

But you sensed some levity when Chairman Smith joked that I am not bashful, and I am probably a little outspoken on the best practices that we see out of Utah. I am passionate about it. I mean it.

And I want our federal government to operate a lot more like some of the things that I have grown up with and some of the things that I have seen work time and time again, from this morning, where we go out of our way to help those in need, to creating innovation that is not going to stymie our ability to not only lower costs but provide care for those that need it.

So, again, thank you, Chairman, and thank you all for being here.

I yield back.

Chairman SMITH. Thank you. Thank you, Blake.

I am pleased to recognize the gentleman from Utah, Mr. Owens.

Mr. OWENS. Thank you. Are we ready to do the questions right now or just——

Chairman SMITH. No.

Mr. OWENS. Okay.

Well, first of all, just know, back in D.C., Blake, Celeste, and John, we are continually talking about this remarkable state we live in. I have been blessed the last 10 years to be a Utahan, and I cannot say enough. Matter of fact, I warn my colleagues whenever they come to visit—and they will all tell you this—the warning is, if you come out to Utah too often and stay too long, you become a Utahan.

So let's keep that up. Let's keep up with innovation. Let's keep our service, our collaboration, which you do so well with.

And I am just very, very excited to be a part of this panel. Thank you so much for the opportunity, and I look forward to the things that will come out of this for sure.

Chairman SMITH. Thank you, sir.

I am pleased to recognize the gentlewoman from Utah, Ms. Maloy.

Ms. MALOY. Thank you, Mr. Chairman. Thank you for being in Utah. This is really important.

I have been in Congress for a short time, and some of the best news and some of the worst news I have heard from constituents comes out of the healthcare industry. Some of the worst news is we have got constituents who struggle to afford medications, rural pa-

tients who don't have access, independent pharmacies that are going under, which harms patients. It also harms Main Street economies, especially in our small towns, and we have got families choosing between medical bills and mortgages.

The best news is we have more telehealth access, more remote patient monitoring, more home dialysis, and Utah companies that are doing really innovative research that will make people's lives better.

And so I am excited to be here supporting your committee and talking to people in Utah about the need to unleash American innovation both in technology, which we are sitting right here looking at—they are working while we are talking—and in policy, which this committee is doing.

So thank you for allowing me to be a part of it.

Chairman SMITH. Thank you.

I will now introduce our witnesses. We have, first, Kasey DeLynn Shakespear, who is a parent of a rare disease patient and a rural health champion. We have Ms. Heloisa Soares, who is an associate professor and medical director of Clinical Trials Office for the Huntsman Cancer Center at the University of Utah. We have Frank Watanabe, who is president and CEO of Arcutis Biotherapeutics. And we have Kelvyn Cullimore, who is the CEO of BioUtah.

Thank you all for joining us today. Your written statements will be made part of the hearing record, and you each have 5 minutes to deliver remarks.

Mr. Shakespear, you may begin when you are ready.

**STATEMENT OF KASEY DELYNN SHAKESPEAR, PARENT OF A RARE DISEASE PATIENT, RURAL HEALTH CHAMPION**

Mr. SHAKESPEAR. My name is Kasey Shakespear, and I am here today to discuss with you my family's medical journey with innovation and the limitations of living in a rural community.

Chairman SMITH. Could you pull your mic a little bit closer?

Mr. SHAKESPEAR. Sure.

In 2021, my wife and I were expecting our third child. We found ourselves facing the unthinkable during an OB appointment at 19 weeks gestation. Our unborn son was diagnosed with bilateral renal agenesis, formally known as Potter Syndrome.

BRA is a congenital condition in which the fetus does not develop kidneys. BRA is considered by medical text as a universally fatal condition with no treatment options. One in three BRA babies die before birth—thank you. One in three BRA babies die before birth with the others dying shortly after due to underdeveloped lungs.

When we received the news, my mind immediately went to which cemetery will we bury my son in, and how will we explain to our other children why their brother isn't coming home?

Unlike me, my wife did not accept defeat. She researched and discovered an innovative clinical trial happening at a handful of centers around the country called the Renal Anhydramnios Fetal Therapy Trial, or RAFT.

RAFT is an innovative treatment program that involves serial amnioinfusions of fluid into the womb with an ultrasound-guided needle. The closest centers to us that offered RAFT were in Denver,

Colorado, 630 miles away, and Pasadena, California, 380 miles away.

We chose to go to Pasadena and met with Dr. Ramen Chmait and Dr. Martha Monson at L.A. Fetal Surgery. My wife and unborn son were screened and deemed eligible to be entered into the trial as a fetal-maternal pair. However, Dr. Chmait counseled us that pursuing treatment would be a long road. If we proceeded, it could threaten our marriage, my career, our financial stability, our home, and the well-being of our other children. And treatment was still a Hail Mary with a small chance of success.

We considered the factors and decided to pursue treatment. Doing so required us to temporarily relocate from rural Utah to Pasadena, California.

Over the next 11 weeks, my wife received 11 serial amnioinfusions. At 31 weeks gestation, my wife's sac began to leak, and we had to halt treatment. The original medical plan was for my son to be cared for at Children's Hospital Los Angeles, but he was measuring too small to receive a peritoneal catheter for PD dialysis. We found ourselves suddenly forced 360 miles north to Palo Alto, California, just 1 week before my son's birth, at Lucile Packard Children's Hospital at Stanford.

In late 2021, my son was born with Apgar scores of 8 and 9. The amnioinfusions had been successful, but over the next 5 and a half months, he would battle for his life daily in the NICU. He was placed on dialysis 2 days after birth with an Aquadex machine, which was developed for adults with congestive heart failure but adapted for neonates to receive dialysis.

He went through blood pressure issues that were ultimately resolved with angiotensin II, becoming the first neonate kidney patient at Stanford to ever be treated with this innovative medication. During his NICU stay, he contracted a serious infection, underwent multiple high-risk surgeries, experienced seizures, and overcame it all.

At 6 months old, my son was transported via air ambulance to Salt Lake City, Utah, where he was admitted for 2 weeks at Intermountain Health Primary Children's Hospital. During that time, my wife and I were trained on how to perform all the necessary functions to care for our son and administer dialysis on a nightly basis at home. He was discharged from the hospital for the first time at 6 and a half months old.

It has been just over 2 years since my son was discharged, and over that time, he has been readmitted five times for stays varying from 3 days to a little over 3 weeks, each stay requiring a life flight from St. George due to the complexity of his condition.

Although telehealth has helped us connect with some specialists, we have had to travel 9 hours round trip from St. George to Salt Lake City every single month to attend mandatory in-person dialysis appointments.

Our little Isaac is now nearly 3 years old and active on kidney recipient lists in multiple regions. We hope to receive a call any moment to bring him in to receive his kidney.

My wife and I have walked through hell to save our son, but we were only able to do so because the stars aligned for us. We re-

ceived tremendous support from family, friends, neighbors, members of our religious congregation, and complete strangers.

We found RAFT and were able to navigate the American healthcare system because of our education. We were able to overcome the cost of treatment because of insurance, and the ability to continue working remotely, as well as the generosity of so many people. And we continue to receive adequate care thanks to programs such as Utah Medicaid's Medically Complex Children's Waiver program.

Our story stands as a testament to the innovations and technology that our healthcare system has to offer, but according to HRSA, a little over 25 million rural Americans live in health profession shortage areas. Innovations in healthcare brought about lifesaving procedures for my son, but our opportunity is not representative of so many others. My wife receives messages on social media from frantic parents trying to find treatment options for BRA and other similar conditions almost on a weekly basis. Many rural Americans simply cannot make it work to pursue care.

There are so many details and barriers about the challenges that my family has faced that I wish I could share, but I can testify that the cost of accessing these innovative treatments coming from rural America is extremely high.

I applaud this committee for your efforts to improve care, especially in rural communities, and I want you to know that what you are doing makes a difference to families like mine. But I implore you to keep working to ensure that every American has an equitable opportunity to receive this type of innovative care in their most dire moments.

Thank you.

[The statement of Mr. Shakespear follows:]

Kasey Shakespear
Ways and Means Committee Hearing
July 12, 2024

My name is Kasey Shakespear, I am an Assistant Director for the Utah Center for Rural Health at Southern Utah University. I am here today to discuss my family's journey with medical innovation and the limitations of living in a rural community. The views that I will share are personal and not representative of SUU.

In July 2021, my wife and I were expecting our 3rd child. We found ourselves facing the unthinkable during an OB appointment at 19 weeks gestation. Our unborn son was diagnosed with Bilateral Renal Agenesis formerly known as Potters Syndrome. BRA is a congenital condition in which the fetus does not develop kidneys. BRA occurs in approximately 1 in every 4,500 live births. At the beginning of the second trimester of pregnancy, the fetus' renal system becomes active and takes over the production of amniotic fluid. In the absence of kidneys to generate amniotic fluid, anhydramnios occurs. This is a complete lack of fluid in the womb.

BRA is considered by medical text as a universally fatal condition with no treatment options. 1 in 3 BRA babies die before birth usually due to pinching off the umbilical and blood supply from the mother. The rest will suffocate and die in the minutes and hours after birth due to critically underdeveloped lungs. When we received the news, my mind immediately went to what cemetery we would bury him in, and how we would explain the situation to our two older children. My wife on the other hand had already begun researching the condition before the visit.

She had discovered an innovative clinical trial happening at a handful of centers around the country called the Renal Anhydramnios Fetal Therapy (RAFT). Originating from Johns Hopkins, the RAFT Trial was an innovative treatment program involving serial amnioinfusion of fluid consisting of saline and antibiotics into the womb done with ultrasound-guided needles. The closest centers to us that offered RAFT were in Denver, Colorado 630 miles away, and Pasadena California 380 miles away. We chose to go to Pasadena and meet with Dr. Ramen Schmidt and Dr. Martha Monson at LA Fetal Surgery.

My wife and unborn son were screened and deemed to be eligible to be enrolled as a fetal-maternal pair for the trial. We didn't know it at the time, but they were 1 of 20 fetal maternal pairs selected, out of over 600 BRA cases screened. However, Dr. Schmidt warned us that pursuing this treatment would be a very long road. If we proceeded, he warned it could threaten our marriage, my career, our financial stability, our home, and the wellbeing of our other children. And that the treatment was still a Hail Mary with a small chance of success. We considered those factors and decided to pursue treatment.

Doing so required us to temporarily relocate from rural Utah to Pasadena, California. Over the next 11 weeks, my wife received 11 serial amnioinfusions. At 31 weeks gestation, my wife's sac began to leak, and we had to halt treatment. The original medical plan was for my son to be

cared for at Children's Hospital Los Angeles, but he was measuring too small to have a peritoneal catheter placed for PD dialysis. We found ourselves suddenly forced 360 miles north to Palo Alto California, just one week before my son's birth at Lucile Packard Children's Hospital at Stanford.

In late 2021, my son was born with Apgar scores of 9 and 8. The amnioinfusions had been successful, but over the next five and a half months, my son battled for his life daily in the NICU. He was placed on hemodialysis two days after birth with an Aquadex machine developed for adults with congestive heart failure and adapted for dialysis on neonates. This innovation allows babies that are too small for PD catheters to instead have a smaller tunneled central line placed, which cycles the blood directly from the bloodstream, into the machine to be cleaned, and then returned to circulation. Our son remained on Hemodialysis daily until he was three months old, at which point, a PD catheter was placed, and he eventually transitioned to Peritoneal Dialysis at 4 and a half months old. The significance of this transition is that PD dialysis can be performed at home, whereas Hemodialysis cannot.

Our son went through blood pressure regulation issues stemming from the absence of kidneys. These issues might have required constant use of multiple daily medications to maintain appropriate blood pressure. However, our son was treated with Angiotensin-II at four months old, becoming the first neonatal kidney patient at Stanford ever to be treated with this innovative medication. Within 10 days, his blood pressure stabilized, and he was able to be removed from the medication altogether and has maintained healthy blood pressure without medications ever since. Through his stay in the NICU, he contracted a serious infection, underwent multiple high-risk surgeries, experienced seizures, and overcame it all.

At 6 months old, my son was transported via air ambulance to Salt Lake City, where he was admitted for two weeks at Intermountain Health's Primary Children's Hospital. During that time, my wife and I were trained in how to perform all necessary functions to care for our son and administer dialysis on a nightly basis at home. Settings for his PD dialysis machine are transmitted electronically directly from the provider, and the data from each round of dialysis can be transmitted back, allowing us to work in tandem with our dialysis team located 310 miles away to constantly monitor and adjust the dialysis as needed. He was discharged from the hospital for the first time at six and a half months old. He is one of approximately 20 children who have survived BRA and made it home.

It has been just over two years since our son was discharged and over that time, he has been readmitted five times, for stays varying from 3 days to a little over 3 weeks. Each stay required a life flight from St. George due to the complexity of his condition. Our local hospital cannot perform his dialysis care, which means he cannot be admitted here for any reason. In all, our son has faced certain death on five occasions, including most recently in April 2023. He was admitted and transported to Salt Lake City with an unknown virus causing respiratory distress. The illness appeared minor, and precautions were taken to keep him stable. I remained in St. George the morning he was life-flighted, preparing to travel up the following day with my older children. My wife called me that afternoon in tears telling me that I had to come now, that our

son was not going to make it. I drove the 4 and a half hours to Salt Lake City, my wife on the phone, racing to be by my son's side to say goodbye. I don't know how, but I made it to the hospital safely, and my son pulled through despite going into cardiac arrest the following morning, and weeks of intensive care. These types of frantic trips to the hospital are not something most urban counterparts will ever experience.

Our son now has numerous specialty providers including nephrologists, urologists, cardiologists, pulmonologists, neurologists, gastroenterologists, immunologists, and transplant surgeons, all of whom are in Salt Lake City. The only provider he can see locally is his primary care provider and his neurologist who travels down to see patients once a quarter. Although telehealth has helped connect with some specialists, we have also traveled 9 hours round trip from St. George to Salt Lake City every month to attend mandatory in-person dialysis appointments and other specialty visits. We make these trips, rain, shine, or in traffic. We even traveled home during a blizzard that created white-out conditions making it nearly impossible to see and drive. Our little Isaac is now nearly 3 years old and active on the kidney recipient lists in multiple regions. We hope to receive a call any moment to bring him in to receive his kidney. He will become just the second male BRA survivor to receive a kidney transplant With so few who have gone before him, it's impossible to understand the long-term ramifications of our son's condition, but we know for certain that he will continue to rely on innovations in treatment throughout his life.

My wife and I have walked through hell to save our son, and we were only able to do so because the stars aligned for us. We received tremendous support from family, friends, members of our religious congregation, and strangers. We found RAFT and were able to navigate the American healthcare system because of our education, we were able to overcome the costs of treatment thanks to insurance, the ability to continue working remotely, and the generosity of so many. And we continue to receive adequate care thanks to programs such as Utah Medicaid's Medically Complex Children's Waiver Program. We didn't have farm animals, pets, crops, or other responsibilities that prevented us from being absent for long periods.

Our story stands as a testament to the innovations and technology that our healthcare system has to offer. According to the HRSA, a little over 25 million rural Americans live in Health Professional Shortage Areas. These individuals struggle to access basic care, let alone specialty care or the type of treatment BRA and other rare conditions require. Innovations in healthcare brought about lifesaving procedures for my son, but my family's opportunity is not representative of so many others. My wife receives messages on social media from frantic parents trying to find options for treatment for BRA and other similar conditions on almost a weekly basis. Many simply cannot make it work to pursue care, usually because of the logistical challenges and economic burden incurred to pursue treatment.

Put yourself in their shoes. The economy of rural America is typically labor-intensive jobs, which cannot be carried out remotely. Typically, these are hourly jobs, with no paid time off. Rural folks often have livestock and pets, even if it is not their primary occupation. They grow gardens to supplement their food supply and do whatever it takes to get by. For those lucky enough to own homes, many would not be able to purchase their own homes at today's market value. When

these individuals face serious illness, they often must travel several hours, if not more, to find care. For the rarest conditions, they may have to traverse multiple states. Bear in mind, that not all urban cities are created equal, the care we needed for Isaac wasn't available anywhere in Utah. To pursue care in these circumstances, when the outlook for recovery is bleak even with treatment, simply cannot be done.

I applaud this committee for your efforts to improve care, especially in rural communities. I want you to know that they make a difference for families like mine. But I implore you to keep working to ensure that every American has an equitable opportunity to receive the innovative care they need in their most dire circumstances. Thank you.

Chairman SMITH. Thank you, Mr. Shakespear. Powerful testimony.

Dr. Soares, you are now recognized.

**STATEMENT OF DR. HELOISA P. SOARES, ASSOCIATE PROFESSOR AND MEDICAL DIRECTOR OF CLINICAL TRIALS OFFICE, HUNTSMAN CANCER INSTITUTE AT THE UNIVERSITY OF UTAH**

Dr. SOARES. Thank you so much for the opportunity of being here. Thank you.

I am Dr. Heloisa Soares. I am a medical oncologist at the Huntsman Cancer Institute at the University of Utah, and I care for patients with neuroendocrine cancers, a cancer that is very rare and poorly understood.

Improving cancer care is particularly personal to me. My father lives with a rare cancer for which there has not been a lot of medical innovation in the last several years, and he doesn't have any treatment options. In a twist of faith, my own 35-year-old brother was diagnosed with neuroendocrine cancer, the cancer that I specialize at. It was devastating to me initially, but he underwent his complex surgery and is now on a clinical study.

He asked me last year if he should put his affairs in order because of his cancer, and I look him in the eyes with confidence and I told him, yes, but not because of the fact that you have this cancer. You should always do that because that is what responsible people do. Live your life, enjoy life, and if you want to expand your family, do so. Live your dreams. And I can say that with confidence because of the medical innovations that we have been able to provide to our patients.

And I am not saying this out of nothing. I have here behind me Charlene Edwards, who is a patient of mine, who has been living with neuroendocrine cancer for the last 18 years. When Charlene was diagnosed, the doctors gave her very little hope and told her that there was only one treatment that was available. At the time, she felt that she was without really any hope. However, there are several new treatments that have been developed to treat her cancer, and now I can think about at least five other medical treatments that we can use for this disease. In fact, Charlene has benefited from some of these treatments in clinical trials and as a standard of care.

Which brings me to the fact that I am the medical director for the Huntsman Cancer Institute Clinical Trials Office. I oversee more than 250 active clinical trial treatments at a given time. I can do that because the Huntsman Cancer Institute and the National Cancer Institute-Designated Comprehensive Cancer Center serves the entire Mountain West, including Utah, Idaho, Montana, Wyoming, and Nevada.

Thirty percent of our patients that are in clinical trials come from far away, from rural and frontier regions, more than 150 miles away from me. These trials represent lifelines for these patients, offering novel treatments when there is little hope with conventional treatments. We are constantly developing new treatment strategies to care for our patients in the frontier and rural popu-

lation. One example is the development of clinical trials using short course radiation for patients.

I had patients that had declined radiation treatment for their cancers, because traditionally these treatments have to be delivered within a span of 5 to 6 weeks. However, our tireless radiation oncology teams and researchers have developed the strategies to deliver these radiation treatments effectively and safely in a much shorter span of time. So now patients can receive the care that they need and continue to live their lives and not have to go away from family for so long, which can be a barrier because of financial issues, or even because they have to care for their children or elderly patients or spouses that are also sick.

To address distance as a disparity for our rural and frontier populations, we have developed additional several strategies. We collaborate very closely with different centers, including Sweetwater Regional Cancer Center in rural Wyoming, to enhance accessibility for patients to care and clinical trials.

We also, an example that I am proud to say, we have our neuroendocrine cancer designation care program providing specialized care for patients who travel from far away, and they can have access to our experts and the standard of our treatments.

But to do all this, we need help. Federal support is crucial to sustain these efforts. Innovative programs need to be supported and recognized. Our nationally appraised Huntsman at Home program delivers specialized care to patients at their home, but programs like that need a sustainable funding pathway, as they not fit the traditional reimbursement model for inpatient or outpatient care.

So I am here in front of you to advocate for a few things. Development of innovative payment models to support these new care modalities, extending healthcare—telehealth services and refining care models so I can care for the patients receiving advanced therapies, such as cell therapy or theranostics, which is the use of radioligand therapies in these patients, and I can monitor them from a distance, leveraging technology and novel strategies. And also, asking to leveraging AI and data science to advance cancer care. There is a need for federal support to enhance the infrastructure of data management and sharing across healthcare systems.

Medical innovation is the cornerstone of our progress for cancer care. Innovations had allowed me to conduct telehealth visits, coordinate local care with patients at home, administering treatments remotely, and significantly enhance symptom management and the quality of life of our patients in our community.

Another day Charlene, reminded me that Huntsman Cancer Institute is located at Circle of Hope Drive. Thanks to medical innovation that we have, I can share hope to my patients and to my brother.

It takes a village to take care of our patients, and I ask for federal support to continue doing so and continuing doing our job. I am honored to be here in front of you, and I am grateful for Congress' role in advancing innovations, and I hope to receive the support that I can continue to care for my community.

Thank you very much.

[The statement of Dr. Soares follows:]

UNIVERSITY OF UTAH
HUNTSMAN
CANCER INSTITUTE

Testimony of Heloisa Soares, MD, PhD
Before the U.S. House of Representatives Ways and Means Committee
*Field Hearing on Access to Health Care in America:*
*Unleashing Medical Innovation and Economic Prosperity*
July 12, 2024
Salt Lake City, Utah

I am Dr. Heloisa Soares, a medical oncologist specializing in gastrointestinal and neuroendocrine cancers at Huntsman Cancer Institute, University of Utah. Neuroendocrine cancer is a rare cancer that can affect any part of the body, but mostly presents in the gastrointestinal tract and lungs. I take pride in our institution's Neuroendocrine Cancer Destination Care Program, designed to provide specialized care for patients who travel from afar. Our program is supported by a dedicated team of experts and offers state-of-the-art treatments that draw patients seeking advanced care.

For me, the journey into medical innovation is deeply personal. My father has courageously battled a rare, slow-growing cancer for the past 20 years. Regrettably, effective treatments for his type of cancer remain limited, leaving us uncertain about how much longer we will have him with us. In a twist of fate, my 35-year-old brother was diagnosed with neuroendocrine cancer, the very disease in which I specialize. He underwent a complex surgery to remove his tumors and is now enrolled in a research study. Witnessing his journey firsthand and the advancements made in the field, when he asked me about putting his affairs in order, I reassured him with heartfelt conviction: "*Always plan ahead, but not because of cancer. Live your life to the fullest, pursue your dreams, and if you desire, expand your family*." The remarkable progress and innovations in treating his type of cancer have given us hope and underscored the transformative impact of medical research and innovation.

However, I am not here to delve into my family history; rather, I wish to highlight the journey of patients like Charlene Edwards, who joins us today with her husband, Rick, from Lindon, Utah. Charlene was diagnosed with neuroendocrine cancer over 18 years ago, a time when her youngest child had not yet entered high school. Upon diagnosis, most of her physicians had never heard of the disease. She was given little hope as, at the time of her diagnosis, there was only **one medical treatment available** to care for her disease. Now, at least another 5 treatments can be offered to patients with her disease, and many more are expected given the progress made thanks to investments and innovations in the field. Charlene's story is a testament to the rapid advancements in medical innovation. Much of this progress is made possible by the robust infrastructure supporting cancer research in the U.S., including the vital contributions of the National Institutes of Health and other federal institutions supporting innovative research and clinical trials.

As the Medical Director of the Clinical Trials Office at Huntsman Cancer Institute, I have the privilege of overseeing over 250 active treatment intervention clinical trials at any given time. These trials are not merely “experiments”; they represent lifelines for patients, offering novel treatments and avenues for hope where conventional therapies have fallen short. One of the

important reasons we can offer these trials in Utah is because the Huntsman Cancer Institute is a National Cancer Institute (NCI) Designated Comprehensive Cancer that serves the entire Mountain West – an area that comprises 17% of the landmass of the continental U.S. We are the **only federally designated cancer center in our region**, **serving Utah, Idaho, Montana, Wyoming, and Nevada**. We work across state lines to serve patient needs in all domains of cancer – these include community partnerships, six affiliate hospitals in neighboring states, collaborative research grants, working with federally qualified health centers, working together to organize state cancer plans, and so much more.

A primary focus of our work at Huntsman Cancer Institute is elevating the standard of cancer care in local communities. Conducting clinical trials is resource-intensive, involving specialized teams and often requiring patients to travel long distances; approximately 30% of our trial participants travel over 150 miles each way. Despite these challenges, we continuously strive to extend research innovations closer to patients' homes, fostering stronger connections to family and community.

Because our mission includes serving rural and frontier communities, where access to specialized care poses significant challenges, we use innovation to improve the care of our patients. Through initiatives like our "short course" radiation therapy clinical trials, we are working to reduce the burden on patients who must travel long distances for treatment by developing effective radiation treatments given in a shorter period of time compared with the traditional 6 weeks of treatment. These trials not only aim to improve accessibility and compliance but also strive to enhance treatment outcomes and quality of life for our patients.

Our researchers have shown that rural residents face higher mortality rates and later-stage diagnoses than their urban counterparts (Cancer Med. 2018, PMID: 29533005). To address distance as a disparity, Huntsman Cancer Institute, for example, collaborates closely with Sweetwater Regional Cancer Center in Wyoming, advising and facilitating trials to enhance accessibility for patients in rural areas. This initiative addresses the unique disparities faced by patients living far from major medical centers.

Federal support is crucial to support these efforts. The federal government in the U.S. has been a major catalyst of medical innovation. There are many ways this can continue. Initiatives like our nationally praised *Huntsman at Home program*, delivering specialized cancer care directly to patients at their homes, exemplify innovative care models that require sustainable funding pathways. So, I advocate for the **Development of Innovative Payment Models** (models outside of traditional "inpatient" or "outpatient" modes of care). Additionally, **coordinating care across state lines** remains challenging, particularly for patients receiving advanced and complex emerging therapies like cellular therapy or radioligand therapies, also known as Theranostics. **Extending telehealth services** and **refining care models for established patients** are critical steps to improve access and support innovation**. Implementation science** is essential for translating cutting-edge therapies and AI into sustainable clinical practice and addressing regulatory and payment challenges. In fact, Huntsman Cancer Institute researchers are leveraging AI and data science to advance cancer research, highlighting the need for federal support to enhance infrastructure for data management and sharing across healthcare systems.

In conclusion, medical innovation is the cornerstone of our progress in cancer care, bridging gaps and enhancing outcomes for individuals and families in our community affected by this disease. Through these innovations, I've been able to conduct telehealth visits with patients who reside

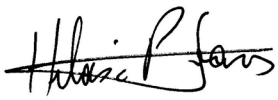
hundreds of miles away, facilitating local coordination of care and administering anti-cancer treatments remotely. This approach has improved treatment adherence and broadened access to virtual care, significantly enhancing symptom management and overall quality of life for cancer patients. Furthermore, I've had the privilege of offering cutting-edge treatments available only at a few select centers nationwide, witnessing firsthand their immediate impact in relieving pain and shrinking tumors….Charlene has received some of these treatments. Providing such new avenues of treatment instills hope where previously there was little, a deeply gratifying aspect of my work. As a poignant reminder, Charlene often reminds me that Huntsman Cancer Institute is located on Circle of Hope Drive, a testament to our commitment to advancing cancer care and inspiring optimism.

I am honored to be with you today and grateful for Congress' role in advancing innovations through federal programs, notably the National Institutes of Health and the National Cancer Institute Cancer Centers Program. This has fostered an outstanding infrastructure that translates research highlights into medical innovations daily through community collaborations, clinical trials, transformation of healthcare delivery, and so much more.

And, I am incredibly grateful to my patients, like Charlene, and their families. Patients are our critical partners in advancing innovation.

I'd be happy to answer any questions you may have.

Sincerely



Heloisa Soares

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Chairman SMITH. Thank you.

I now recognize Mr. Watanabe. You are now recognized.

**STATEMENT OF FRANK WATANABE, PRESIDENT AND CEO, ARCUTIS BIOTHERAPEUTICS**

Mr. WATANABE. Thank you.

Chairman Smith, Congressman Moore, members of the committee, I am honored to share my perspectives as president and CEO of Arcutis Biotherapeutics. In addition, I am also on the board of directors of Bio.

Arcutis was founded in 2016 to develop novel treatments for dermatologic diseases. The FDA approved our first product in July of 2022, and has granted us two additional approvals since; in fact, the third one this week.

We have grown from three employees in 2016 to nearly 350 today, with operations in all 50 states and employees in 39 states, including an office near here in Park City, Utah.

Turning to the broader U.S. biopharmaceutical sector, our industry plays a vital role in improving public health in the U.S. and around the world. Our innovations transform patient care, improve outcomes, and give hope. Roughly a third of the increase in Americans' life expectancy over the last quarter-century can be directly attributed to biopharmaceutical innovations.

For example, the American Cancer Society estimates that cancer death rates in the United States have declined by one-third since 1991, preventing 3.8 million deaths, and much of that is due to better cancer treatments.

Biopharm also contributes to our economy, employing more than 2 million people in more than 127,000 firms across the country, and we constitute somewhere between 5 and 7 percent of U.S. GDP. We also contribute directly and indirectly to U.S. national security. It is my fervent belief that promoting our sector should be a cornerstone of our government's policy agenda.

Although we are the undisputed global leader in biopharm, that leadership cannot be taken for granted. Today, we face threats from both overt policy choices and long-term neglect. We have seen what can happen in other critical industries like semiconductors when neglect or misguided policies cause the U.S. to lose our leadership position.

Biotech companies are committed to championing broad access to transformative therapies. Policies that focus all of the scrutiny on biopharmaceutical innovators ignore the real barriers that affect American's access to innovative treatments.

A significant factor in the high and ever-increasing cost of innovative therapies in the United States is the growing power of middlemen who, in most cases, pocket more than half of what is paid for treatments. For example, my company only realizes about 40 cents every dollar that is paid for our treatment with the remainder going to intermediaries.

In particular, concentration in the PBM sector gives these firms immense power to influence prices, control access to treatment, and deny coverage. And the growing trend of PBMs merging with other intermediaries only increases their power.

This vertical integration also gives intermediaries significant power over physicians' ability to select treatments for their patients with utilization management criteria like prior authorizations and step edits substantially restricting doctors' ability to tailor treatments for their patients.

Congress should urgently move forward with PBM reforms, and the Lower Costs, More Transparency Act is an important step forward.

Another major barrier to American's access to innovative therapies is patient out-of-pocket costs, which insurers and PBMs continue to increase through higher patient copays, expanded high deductible plans, and increased use of patient co-insurance. Congress should pass the bipartisan Help Ensure Lower Patient Copays Act to reduce patient out-of-pocket burdens.

The IRA is already negatively impacting drug development. Fortunately, there are two bipartisan bills that could help. First, the ORPHAN Cures Act would fix the IRA's disincentive around rare disease drug development. And second, the EPIC Act would fix the so-called pill penalty that favors biologics. Both biologics and small molecules are critical to treating patients.

Our R&D investment should flow to the best science that can have the greatest impact, and these two bipartisan bills would help make that possible.

Intellectual property protections are the foundation of our industry but currently are under threat both at home and abroad. I implore Congress and this committee to fervently defend IP rights against those threats.

U.S. small and mid-sized biotech companies, or SMEs for short, account for three-fourths of the global drug pipeline, and roughly a third of all new drugs approved by the FDA since 2009 were developed by smaller biotechs. Congress should prioritize fostering investments in SME biotechs.

My written comments contain details on specific policies, and I would be happy to answer more questions on specific ideas if you would like later.

Investing in domestic biomanufacturing, strengthening our local workforce, and ensuring critical cutting-edge clinical studies are conducted in the United States should be a core tenet of our government's agenda.

Finally, the interconnected bioscience ecosystem is not confined just to biopharmaceuticals. Promoting biopharmaceutical innovation can also strengthen the broader U.S. biotechnology ecosystem where innovators are applying biotechnology to food security, sustainability, and climate change.

Thank you for your time.

[The statement of Mr. Watanabe follows:]

# Testimony of Frank Watanabe
# President and CEO, Arcutis Biotherapeutics
# Committee on Ways and Means
# Full Committee Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity
# Salt Lake City, Utah
# July 12, 2024

Chairman Smith, Ranking Member Neal, Congressman Moore, and Members of the Committee, thank you for the opportunity to testify today. I am honored to share my perspectives as President and CEO of Arcutis Biotherapeutics, a biopharmaceutical company based in California.

**About Arcutis Biotherapeutics, Inc.**

Arcutis Biotherapeutics, Inc. is a young medical dermatology company dedicated to developing meaningful innovations to solve the most persistent challenges facing patients with immune-mediated dermatological diseases. Our unique dermatology expertise and our dermatology development platform drive our innovation, with a focus on unmet needs in the treatment of immune-mediated skin diseases such as plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. In addition to my capacity as CEO of Arcutis Biotherapeutics, I also serve on the Board of Directors of the Biotechnology Innovation Organization (BIO). My comments below are not unique to Arcutis and broadly reflect the views of hundreds of innovative U.S. biopharmaceutical companies.

Arcutis was founded in 2016, and we raised three rounds of private financing prior to going public in January 2020 on the NASDAQ exchange (ARQT). Arcutis was created out of a recognition that innovation in the medical dermatology space had atrophied, forcing many patients to rely on outdated and suboptimal treatments. We have focused our efforts on developing novel treatments for immune-mediated dermatological diseases and conditions, including plaque psoriasis, atopic dermatitis, seborrheic dermatitis, and scalp psoriasis. We received our first FDA approval in July 2022, and have received FDA approval for two additional treatments since (the third earlier this week), in addition to continuing to invest in an innovative portfolio of drug candidates.

Our three FDA-approved products are all different versions of topical medications for the treatment of plaque psoriasis, seborrheic dermatitis, and atopic dermatitis. All contain an ingredient called "roflumilast" that inhibits a key enzyme inside of cells in the body, and the inhibition of that enzyme reduces the inflammation and itching associated with all three of those conditions. Our products differ from preexisting topical anti-inflammatory drugs in their unique combination of high efficacy, low side effects, and the ability to be used anywhere on the body for any duration. This profile means that clinicians and patients do not have to make trade-offs between efficacy and safety, as is often the case with older therapies. We have also formulated our products to be cosmetically pleasing to patients, which aids in compliance to treatment. Our products are covered by most commercial insurance plans in the US and by Medicaid in several states, and we are currently negotiating Medicaid coverage in the remaining states along with Medicare Part D coverage.

Since our founding, we have grown from 3 employees to nearly 350 staff today, with operations in all 50 states and employees in 39 states. Our team has deep medical dermatology expertise, and our executive team includes leaders who have worked on more than 50 FDA-approved products, and we are proud to have 3 dermatologists and 8 dermatology clinicians on staff. Our headquarters are in Westlake Village, California, we manufacture our products in San Antonio, Texas, and we have a small office near here in Park City, Utah.

**Innovation in The U.S. Biopharmaceutical Sector**

The U.S.-based biopharmaceutical sector plays a vital role in improving public health in the United States and around the world. We develop breakthrough products and treatments that give individuals suffering from medical conditions the ability to live fuller, healthier lives and give hope to those still waiting for a cure. The biotech industry contributes to the strength of the U.S. economy and is a key element of our national security. From research to manufacturing to commercialization, we generate high-paying jobs in a wide variety of fields.

Biotech innovation, however, is a highly risky and costly endeavor. It relies on a delicate ecosystem that has delivered revolutionary medical breakthroughs over the past half century. Disruptions to this ecosystem have the potential to significantly reduce investment flows into the biopharmaceutical sector, resulting in fewer innovations for patients and a diminished economic footprint in the United States.

We all agree that a strong biotech industry is critical for U.S. economic growth and national security, and it is an imperative that the U.S. maintains our role as the undisputed world leader in this field. But our current leadership in biotech can't be taken for granted. While today the US is the source of two-thirds of innovative drugs worldwide, as recently as the late 1970s, Europe developed twice as many innovative drugs as America, until ruinous government policies across the Atlantic destroyed a once vibrant European industry. Foreign adversaries recognize the value of robust life sciences within their borders and are committed to establishing their own global leadership. They look at U.S. policies that impact the sector closely. If we do not maintain the appropriate balance of incentives, we risk weakening our influence on the future of healthcare, biopharmaceutical innovation, and biopharmaceutical manufacturing throughout the world.

I appreciate the opportunity to share how the biotech industry will continue to excel if we have clear regulatory frameworks, robust legal protections, creative tax incentives, and a motivated workforce. Patients in America and around the world depend on us.

**Biopharmaceutical Innovation: Transforming Lives, Giving Hope, and Driving Economic Prosperity in America**

*Transforming Lives and Giving Hope*

Biopharmaceutical innovations transform the way we treat patients, improve health outcomes, and give hope to individuals who suffer from medical conditions. When we gain deeper understandings of disease pathways, we can develop increasingly targeted treatments with improved efficacy and safety. When we transform the pipeline of new therapies, we can profoundly improve quality of life

around the world. We can revolutionize medicine by delivering cures for once incurable diseases. In the last quarter century, American life expectancy has continued its steady increase upwards, with roughly one-third of that improvement directly attributable to biopharmaceutical innovations.[1] For example, the American Cancer Society estimates that cancer death rates in the United States declined by one-third since 1991, saving 3.8 million Americans from death, and much of that improvement is due to better cancer treatments.[2] Biopharmaceutical innovation also gives hope to the over 90 percent of rare disease patients who are still waiting for treatments tailored to address their medical condition.

*Driving Economic Prosperity and Biotech's Relationship to National Security*

Biopharmaceutical companies not only make incredible contributions to humankind through their scientific research efforts but also contribute to economic growth in the United States. One of the hallmarks of the American biotech sector is its embodiment of the quintessentially American entrepreneurial spirit. U.S.-based SME biotech firms are a critical innovation force in the biomedical industry. These life sciences start-ups and emerging biotech companies create inclusive and high-paying jobs for American workers and are responsible for over 73% of the global pipeline of new drugs in development and 85% of all orphan-designated products in development.[3]

Collectively, the innovative U.S. biotech sector includes early-stage startup biotech firms, pre-commercial SMEs, emerging commercial-stage firms like my own, and larger multinational biotechnology companies that directly employ 2.14 million people across more than 127,000 U.S. business establishments. The industry has grown its employment base by 11% since 2018, while the overall economy shed 1.5% of its jobs base due to steep job losses experienced during the initial pandemic wave and economic shutdowns of 2020.[4] Average wages have also been growing and the sector stands out as a major job generator among knowledge- and technology-driven sectors for the U.S. economy. Our sector's economic impact on the U.S. economy totaled $2.9 trillion dollars in 2021, as measured by overall output.[5]

In 2020, the U.S. also had over 1,500 facilities across the country manufacturing FDA-approved human-use products under Good Manufacturing Practice (GMP) regulations, a gold-standard level of manufacturing not required in most other countries.[6] These biopharmaceutical manufacturing operations span across 47 States, the District of Columbia, and Puerto Rico.[7] There are currently 40 States that have five or more manufacturing facilities producing FDA-approved medicines; New Jersey, California, and Pennsylvania have 180, 174, and 104 registered manufacturing facilities, respectively.[8]

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[1] *Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015,* Jason D Buxbaum et al, Health Aff, 2020 Sep;39(9):1546-1556; doi: 10.1377/hlthaff.2020.00284

[2] *Cancer Statistics 2023,* Rebecca Siegal et al, CA, https://doi.org/10.3322/caac.21763

[3] *2019 Emerging Therapeutic Company Trend Report*, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

[4] *The Bioscience Economy: Propelling Life Saving Treatments, Supporting State and Local Communities 2020*, TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

[5] *Id*

[6] The Economic Impact of the U.S. Biopharmaceutical Industry:. (2022). TEConomy, PhRMA. https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf

[7] *Id*

[8] *Id*

The U.S. biopharmaceutical industry generated more than $131 billion in employee income in 2020, averaging more than $145,000 in annual compensation per worker, which is directly invested back into the U.S. economy.[9] The U.S. biopharmaceutical manufacturing industry has a significantly higher-than-average productivity measure, exceeding $380,000 in value added per worker per year (compared to a $163,000 for other non-pharmaceutical U.S. manufacturing jobs).[10] For every one biopharmaceutical job, the industry supports an additional 3.92 jobs in the U.S. economy.[11] In total, the biopharmaceutical industry provided $359 billion in wages and benefits to Americans in 2020.[12] It is also important to note that many of these manufacturing jobs do not require a college degree.

There have been years in which the biotechnology industry has contributed more than $400 billion into the domestic economy, equal to over two percent of the U.S. gross domestic product (GDP).[13] There have been other studies which estimate the biotechnology industry contributes between 5-7% of the U.S. GDP.[14] In terms of scale, the size of the U.S. biotechnology industry is approximately equal to the worldwide semiconductor industry.[15]

*Biopharmaceuticals and U.S. National Security*

The strength of the U.S. biopharmaceutical industry contributes both directly and indirectly to U.S. national security. It contributes to the economic prosperity that is the foundation of our national power. The vibrancy and productivity of the biopharmaceutical sector is a testament to our market-based economic model, and stands in stark contrast to the command economies of our adversaries. Our contributions to improving health worldwide enhances our "soft" diplomatic power globally. Biopharmaceutical innovation also plays a key role in ensuring the health of US servicemen and women. For instance, consider the implications, if the US military were forced to rely on foreign-developed vaccines or treatments in some future pandemic. And it is vital that the U.S. remain at the cutting edge of emerging technologies like synthetic biology and gene editing, to ensure that we have the ability to defend against the malign use of such technologies by our adversaries.

Promoting the strength and resiliency of the U.S. biopharmaceutical sector and harnessing the innovative potential of the American private sector should be a cornerstone of our government's public health, economic and national security policy.

*Maintaining U.S. Leadership in the Life Sciences*

Maintaining U.S. leadership in biopharmaceutical innovation depends on a carefully balanced legal, regulatory and economic ecosystem that preserves strong incentives to innovate and to drive science forward despite the risks for failure. A domestic policy environment that does not robustly support the U.S. biopharmaceutical sector would consequently impact the health and resilience of the U.S. economy and U.S. national security.

Without proper attention to the domestic environment for biotech innovation, we will lose ground to other countries, and most troublingly, to our economic adversaries. A strong domestic biotech

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[9] *Id*
[10] *Id*
[11] *Id*
[12] *Id*
[13] Carlson, R., Sbragia C., & Sixt, K (2021). Beyond Biological Defense: Maintaining The U.S. Biotechnology Advantage. https://warontherocks.com/2021/09/beyond-biological-defense-maintaining-the-u-s-biotechnology-advantage/
[14] *Id*
[15] *Id*

industry is essential for our national security, but the robust biotech ecosystem in the United States is at risk both from recent overt policy choices and through long term neglect of the critical elements necessary for the domestic industry to grow and thrive. We have seen what can happen in other critical industries like semiconductors, when neglect or misguided policies causes the U.S. to lose our leadership position, which necessitated a substantial investment via the CHIPs and Science Act to help restore the atrophied U.S. semiconductor industry. It is my hope that we learn from this experience and continue to create the right domestic environment to foster innovation and maintain U.S. leadership in the biotech industry, thereby avoiding a future need to rebuild what we have lost.

To ensure this, we need a predictable regulatory process to bring cures to patients safely and quickly. Patients also need efficient markets without unnecessary barriers to access once new drugs are approved. The industry needs supportive legal regimes that protect our intellectual property and allow productive merger activity so that promising products do not wither on the vine. We also need to invest in robust domestic biomanufacturing capabilities and a skilled workforce across the country to make the next generation of life-saving and life-improving treatments here at home. Finally, biotech entrepreneurs need sufficient access to capital to see treatments through the lengthy, expensive, and risky journey through the development process. All too often, promising technology fails to move forward simply due to a lack of funding.

Ultimately, the unchecked deterioration of the ecosystem that supports biopharmaceutical innovation has significant short-, medium-, and long-term implications for the broader U.S. private sector and, consequently, for our nation's economic interests and leadership in the life sciences.

**Preserving Incentives to Innovation and Ensuring Access to Biomedical Breakthroughs**

*Ensuring Access to Biomedical Breakthroughs*

Biotech companies ultimately exist to help people living with disease, and as such we are committed to championing broad access to transformative and disruptive therapies so that all patients can benefit from the achievements of modern biotechnology. Policies that myopically focus all of the scrutiny on the biopharmaceutical innovators are doing a disservice to addressing the genuine barriers that affect Americans' access to cutting-edge biotechnology innovations.

A significant factor in the high and ever increasing cost of innovative therapies in the United States is the proliferation and growing power of "middle men" who extract substantial economic value from the biopharmaceutical sector. These middle men … including insurers, pharmacy benefits managers (PBMs) and their group purchasing organizations, as well as distributors and others in the supply chain … are in most cases pocketing more than half of what is paid for treatments. For example, my company currently only realizes about 40 cents of every dollar paid for our treatments, with the remainder going to intermediaries between us and the patients we serve.

The market structure for PBM services has evolved haphazardly, without adequate consideration of the full consequences of its framework and marketplace consolidation. The three largest PBMs currently control 80% of the PBM market, and when combined with the three next largest, that figure raises to almost 96%. This gives them immense power to set prices, control access to treatment, deny coverage and generate corporate profits. Drug manufacturers must negotiate with PBMs for formulary status so that patients prescribed their medication will be able to access them.

The rising concentration of pricing power by PBMs is a fundamental factor in the increasing cost sharing paid by patients. The fixation on discounts in the form of rebates paid to PBM or insurer has also led to practices that may hamper competition in certain therapeutic categories by preferring products that generate the highest rebate for payors, not necessarily those products that are more clinically appropriate or less expensive for the patient.

As the PBM industry becomes more concentrated, they are also merging with insurers. This trend bears the close attention of consumers, law makers and regulators. When a health insurer merges with a PBM, the overall incentives of the merged organization may change. As the PBM operations and strategy hold sway in the new entity, insurers direct patients toward biopharmaceutical treatments that generate the highest profit margins and the largest rebates. Patients then pay more for drugs and health insurance premiums and receive less efficacious medical treatments. A PBMs' pursuit of rebates could also spill over into other areas of care, including specialty pharmaceutical products and cancer therapies. Consequently, these powerful conglomerates effectively control pharmaceutical innovation and direct patients toward treatments that offer higher PBM/insurer profit margins rather than higher value care.

Insurers' and PBM's control over which drugs are reimbursed, and under what conditions, has also allowed them to exert significant power over physicians' ability to choose the right treatment for their patients. The proliferation of so-called "utilization management" criteria like prior authorizations and step edits has substantially restricted doctors' freedom to tailor individual treatment plans for their patients. In many cases, these UM criteria require physicians to use older and often less effective or less safe medications, sometimes even for uses that are not FDA approved, or steer physicians to use costlier medications that are more financially advantageous for the insurer or PBM. Recent efforts in Congress such as the Lower Costs, More Transparency Act (HR5378) and similar legislation in the Senate are important positive steps in the right direction of reforming our dysfunctional drug reimbursement system.

Another major barrier to Americans' access to innovative therapies is patient out-of-pocket costs. While the IRA included a new $2,000 out-of-pocket cap in Medicare, this does nothing to help the hundreds of millions of Americans covered by commercial insurance. Insurers and PBMs continue to increase patient out-of-pocket costs through higher patient copays for prescriptions, the expansion of high deductible plans, and increased use of patient "co-insurance", where patients are required to pay a percentage of a prescription's costs instead of a flat copay. As a result, patients may struggle to afford and adhere to their medications as insurers and PBMs seek to shift more cost-sharing responsibility to patients.

A recent investigation – which included interviews with more than 300 current and former PBM employees as well patients, physicians and pharmacists, found "…the largest P.B.M.s often act in their own financial interests, at the expense of their clients and patients."[16] Congress should move forward with PBM reforms that rein in these shadowy tactics that fly in the face of physician expertise, hurt patient access to needed therapies, and drive up overall health care system costs. To that end, Congress should pass the bipartisan Help Ensure Lower Patient (HELP) Copays Act that, among other things, would require copay assistance to count toward a plan's cost sharing requirements.

[16] https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html

One special area that warrants urgent action is the need to protect patient access to orphan drugs that treat rare diseases. While the IRA exempts some orphan drugs from Medicare price negotiations, this exemption only applies to drugs approved to treat a single rare disease. This policy fails to recognize how orphan drug development occurs today. Orphan drugs initially developed and approved for one condition often prove effective against other rare diseases following additional clinical testing. But the IRA disincentivizes researchers and investors from pursuing such costly follow-on research to find new orphan designations and approvals because, if their efforts prove successful, the drug would no longer be exempt from government price controls. Incentives for orphan drug development should be structured to maximize the potential clinical benefit of each new medication, ensuring that patients with rare diseases have the broadest possible access to effective treatments. The bipartisan, bicameral Optimizing Research Progress Hope and New Cures (ORPHAN Cures) Act would fix this harmful flaw in the IRA and help clear the way for ongoing research and investment into finding new treatments for patients who suffer from rare diseases.

*Preserving Incentives to Innovate*

Developing drugs is extraordinarily risky. Approximately 9 out of 10 new drugs that enter clinical trials ultimately fail.[17] This high failure rate contributes to the high costs of the small percentage of new medicines that successfully complete development. Still, our current system has been remarkably effective at producing life-saving medicines and the price of medications comes down over time as drugs go off-patent and generics enter the market. This carefully balanced system has led to dramatic improvements in health and life expectancy, and has made the United States the world leader in drug development.

Unfortunately, policymakers continue to pursue policies that will curtail incentives for drug development across all disease areas. The Inflation Reduction Act (IRA) gave Washington bureaucrats the power to "negotiate" prices for drugs covered by Medicare. But these will be negotiations in name only. Drugmakers who don't comply with this price setting process face crippling penalties. By imposing arbitrary price caps, the government will prevent firms from investing in future innovation. A 2021 study found that price controls would lead to 135 fewer drugs being developed through 2039.[18]

Lawmakers provided newly approved medications a period of exemption from the IRA's price controls. In doing so, they divided drugs into two categories: "biologics" and "small molecules". Biologics received 13 years of exemption following FDA approval while "small-molecule" drugs receive nine years. What the authors of these provisions failed to understand is that half of the cumulative sales of a new medication following FDA approval accrue in years 10 through 13. The implication for investors today is clear: direct your funding to biologics, where the potential revenue is significantly higher. This discrepancy fails to capture that small-molecule drug development is similarly risky, just as costly, and is clinically valuable and critical to patients. And for many diseases, for instance mental illnesses, small molecules are the preferred treatment modality. This is why we need Congress to urgently pass the bipartisan Ensuring Pathways to Innovative Cures (EPIC) Act, which would fix this so-called "pill penalty" by bringing the small-molecule exemption to 13 years

[17] *Innovation in the Pharmaceutical Industry*, Di Masi et al, J Healht Econ, 2016; 47:20-33

[18] https://ecchc.economics.uchicago.edu/2021/11/30/issue-brief-the-impact-of-hr-5376-on-biopharmaceutical-innovation-and-patient-health/

and ensuring that private investment continues to flow to both promising biologics and small molecule drugs.

Exacerbating this policy scenario brought on by the IRA, U.S. biopharmaceutical companies are also contending with an array of challenges to the domestic and international legal ecosystems that protect intellectual property (IP) rights. IP rights are the currency used by innovative biotech companies to encourage investment in new and emerging technologies with significant promise and allow companies to safely collaborate on new treatments.

Developing a new drug has a greater than 90 percent failure rate, often takes decades, and can cost more than a billion dollars. We cannot expect rational investors to fund this work if we cannot demonstrate that we have secure and enforceable rights to our technology that allows investors to eventually recoup their investment. Investors scrutinize our patent portfolio as part of any due diligence. It can make or break a company long before we have our first approved product. The uncertainty around the ability to control and enforce our IP rights discourages investment in this space, especially into pre-revenue early-stage biopharmaceutical companies whose most important assets are their IP. The threat to the delicate balance of investment risk cannot be understated in an already highly competitive environment.

The strength of the domestic and global IP system is critical to realize and deliver promising biotechnology solutions to humanity by providing a framework to unite and empower biotech innovators to improve lives. Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed. Without strong and predictable patent protection, investors will shy away from investing in biotech innovation and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society. I encourage Congress and this Committee to fervently defend American IP, both against domestic and international threats.

**Unique Considerations of U.S.-based Small and Medium-Sized Biotech Firms in the broader Biopharmaceutical Ecosystem**

SME biotech firms account for over 73% of the global clinical pipeline and 85% of all orphan-designated products in development.[19] And approximately one-third of all new drugs approved by the FDA since 2009 were developed by biotech companies with annual revenues of less than $100 million.[20] Accordingly, policies that disrupt market dynamics for the overall biopharmaceutical sector have a particularly acute impact on SME biotech firms, which are the lifeblood of the innovative U.S.-based biotech ecosystem. Policies which promote the biotech ecosystem in the U.S. and invigorate the American entrepreneurial spirit, which is the hallmark of the biotech sector, should therefore be a cornerstone of our economic and national security agenda.

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[19] *2019 Emerging Therapeutic Company Trend Report*, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

[20] *Research and Development in the Pharmaceutical Industry*. Congressional Budget Office, April 2021. https://www.cbo.gov/publication/57126#:~:text=The%20expected%20cost%20to%20develop,to%20more%20than%20%242%20billion.

Bringing a drug to market is a lengthy, expensive, and risky endeavor, costing on average upwards of $2 billion and taking over 10 years to get through the approval process. At Arcutis, we feel quite fortunate that it only took six years and nearly $1 billion from our founding to our first FDA approval. With an industry average 10 % success rate, attracting investors is a never-ending challenge in an already very competitive marketplace. Congress has many tools to help encourage investment in small biotechs, however. Below are some policy recommendations that can create an improved environment that facilitates access to essential capital.

*Use the Tax Code to Unlock Innovation*

Even pre-revenue biotechs benefit from changes to the tax code. For example, restoring full deductibility for R&D expenses will help save many small and medium-sized biotechs from substantial new tax liabilities caused by the switch to five-year amortization. Many small biotechs have been hit hard by this change even though they have no product on the market and thus no sales revenue. It is preposterous for small firms to pay tax bills when they have no revenues and no profits due to a quirk in the tax code. Funding should be spent on research, not tax consultants. The "Tax Relief for American Families and Workers Act" (H.R. 7024) passed by the House of Representatives earlier this year would restore the R&D deduction.

Another way to help small and mid-sized biotechs is to unlock their Net Operating Losses (NOLs). Due to the high costs of drug development, small biotechs generate substantial NOLs over the course of bringing a product to market. Allowing smaller biotechs to receive the value of a portion of these NOLs immediately could provide much-needed funding at a time when capital is both essential and scarce. In addition, reforming Section 382 so small biotechs' NOLs are not limited if they accept new investment would preserve these valuable tax assets without violating Section 382.

High-paying biotech jobs make substantial contributions to the economy both directly and indirectly but are one of the primary drivers of the high cost of drug development. For instance, roughly half of my firm's expenses are labor and benefits for our staff. Tax benefits like the payroll R&D credit help offset these high costs and should be expanded and improved. Other tax incentives for training and maintaining a highly skilled workforce can be critical to help a small biotech attract or develop top talent.

Finally, creating and expanding incentives like the capital gains exemption under Section 1202 for Qualified Small Business Stock for investment in exceedingly risky areas like biotech will make investments more attractive to cautious investors and help encourage greater private investment in nascent biopharmaceutical companies.

*Reauthorize and Expand the SBIR/STTR Grant Programs*

The Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) grants are critical for early-stage companies. Both programs need to be expanded to provide improved access to this critical funding.

*Reduce Burdensome SEC Reporting Requirements*

Small public companies must spend millions to comply with onerous SEC requirements to report information that is of low or no value to investors. Exempting small companies from these

requirements would allow these smaller companies like mine to reinvest that money in their life-saving mission.

**Biotech, Big Pharma, and Beyond - An Interconnected Bioscience Ecosystem Contributing to Economic Prosperity**

The innovative U.S. biotech sector, spanning early-stage startup biotech firms, pre-commercial SMEs, emerging commercial-stage firms, and larger multinational biotechnology companies contribute tremendously to global public health and to the U.S. economy. Multi-way collaboration between private sector members of the life sciences community with governments, universities, foundations, and non-profit entities is a hallmark of the biotech sector. Innovation is increasingly driven by horizontal collaborations with partners, leveraging expertise residing across a range of organizations and disciplines. Policies, therefore, that impact the broader ecosystem will have an impact on the ability to cultivate long-lasting scientific collaborations and, as a result, impact the degree and speed to which innovative treatments are ultimately developed and delivered to patients in need.

As firms of all sizes face increased pressure on margins across the health care system, there are strong incentives to reduce costs. Biotech firms may out-license early-stage drug development and transfer technology to partners, either domestic or foreign-domiciled companies, at an earlier stage, and potentially at a lower valuation, than had been anticipated. Companies may also be forced to explore the need to offshore certain research and development efforts, including conducting cutting-edge clinical studies. Companies may also be compelled to explore alternative or supplementary manufacturing arrangements in foreign countries for approved drug products. Investing in biomanufacturing, strengthening local workforce, and ensuring cutting-edge clinical studies are conducted in the U.S. so that patients here are the first to benefit from biotech innovations should be a core tenet of our public health, economic, and national security agenda in the life sciences.

Finally, the interconnected bioscience ecosystem – and U.S. leadership in the life sciences – is not necessarily confined to the biopharmaceutical space. Policies that promote biopharmaceutical innovation have the potential to also strengthen the broader U.S. biotechnology ecosystem where innovators are applying biotechnology solutions to address food security, sustainability, and climate concerns. A robust policy and investment ecosystem in the biopharmaceutical space not only promotes U.S. leadership in the biopharmaceutical sector but also contributes to infrastructure and a skilled workforce development that is translatable across biotech sectors, bringing American scientific ingenuity and leadership to the world along with increased economic opportunity, jobs, and prosperity across diverse regions of the United States.

Chairman SMITH. Thank you.
Mr. Cullimore, you are now recognized.

**STATEMENT OF KELVYN CULLIMORE, CEO, BIOUTAH**

Mr. CULLIMORE. Thank you, Chairman Smith and distinguished members of the committee. Thank you for the opportunity to participate in today's hearing.

I am also grateful to Representative Blake Moore, our Utah member of the committee, as well as Representatives Celeste Maloy and Burgess Owens, members of the Utah delegation, for engaging in these important discussions.

My name is Kelvyn Cullimore. I am the president and CEO of BioUtah, the trade association for the state's life sciences industry. BioUtah is a common voice for the industry consisting of medical device development and manufacturing, diagnostics, biotechnology, and biopharmaceuticals.

In addition to my position at BioUtah, I have personal experience in the industry as a medical device entrepreneur. I co-founded Dynatronics, a Utah-based manufacturer of physical therapy products. I have also served for 13 years as the first mayor of Cottonwood Heights, a Salt Lake City suburb. So I am very sincere when I say thank you for your service.

We are immensely proud of what we are building here. We have organized an onsite innovation showcase with nearly 20 Utah life sciences companies exhibiting their contributions to healthcare innovation. We encourage you to pay them a visit if you haven't already.

Despite the 100-degree temperature today, you may know that Utah has the greatest snow on Earth, but you may not know that over the past decade, Utah has been the third fastest growing bioinnovation hub in the Nation.

One of the first COVID–19 tests to receive FDA emergency use authorization was developed here in Utah, as was the saliva-based test for COVID–19.

Utah companies are also creating lifesaving solutions for stroke, advances in genetic-based cancer diagnostics, drug discovery for MS, Alzheimer's, and other neurodegenerative diseases, treatment for Parkinson's disease, regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative diseases of the spine, improved heart valve replacements, cutting-edge diagnostics for chronic kidney disease, brain computer interface technology that would make Elon Musk jealous. And AI-enabled drug discovery and more are all part of Utah life sciences world.

I have seen firsthand the challenges faced by our industry and, more specifically, how government's laws and regulations can promote or impede innovation.

In Utah, we are very fortunate to have a state government that supports our industry. However, no matter how favorable a state's innovation landscape, misguided federal policies can erode any home team advantage.

To that end, we offer a number of policy considerations. First, we urge enactment of the Ensuring Patient Access to Critical Breakthrough Products of 2023 to provide provisional Medicare coverage

for FDA-authorized breakthrough medical technologies. Such a policy would accelerate patient access to innovative treatments.

PhotoPharmics, a Utah company working on phototherapy to treat Parkinson's disease, received that designation from the FDA, opening the door for early coverage under the prior Medicare Coverage for Innovation Technology, or MCIT, final rule. But when this policy was reversed by the current administration, the resulting uncertainty caused investors to pull back, delaying efforts to bring this product breakthrough technology to market and depriving Medicare patients of this important therapy.

We applaud the committee for marking up this legislation last week with strong bipartisan support. We also want to thank the committee for agreeing to fix the drafting error that inadvertently omitted diagnostics from the marked-up bill.

We thank our Representatives, Moore, Maloy, and Owens, for supporting the bill. We have great hope this legislation will better serve patients by breathing new life into this expedited coverage concept.

Secondly, robust R&D is essential to creating solutions to serious medical conditions. However, policies like the Inflation Reduction Act or changes to R&D expensing under the Tax Cuts and Jobs Act can put brakes on the R&D momentum.

We urge Congress to establish a pro-innovation tax structure, including full and immediate expensing of R&D costs, bonus depreciation for equipment, and other pro-innovation provisions as proposed in the Tax Relief for American Families and Workers Act of 2024.

BioUtah supports this House-passed bipartisan tax bill which favorably addresses these policies. Furthermore, tax policies related to capital gains and that operating losses should be carefully crafted to attract investment in the life sciences innovation.

Finally, the Federal Trade Commission and the Department of Justice have overreached in restricting merger and acquisition activity. This is particularly problematic for life sciences where M&A plays a critical role in bringing new therapies to market. That process is like a relay race where M&A allows companies to pass the baton and leverage complementary expertise which would otherwise be too costly or duplicative.

More details on these and other policy considerations can be found in my written testimony.

To sum up, Utah has a thriving patient-centered life science ecosystem fueled by entrepreneurship, a passion to innovate, and a unique culture of collaboration. Federal policies can either empower or undermine these strengths.

Creating a sound tax structure, ensuring timely Medicare coverage of breakthrough products, and taking a reasoned approach to M&A, Congress can help unleash the full potential of life sciences innovation in Utah and beyond and spark the next generation of technologies, treatments, and cures that will change patients' lives.

I thank the committee for taking the time to come to Utah, and I welcome any questions you may have.

[The statement of Mr. Cullimore follows:]


# WRITTEN STATEMENT

# of

# BioUtah

# to the

# Committee on Ways and Means
# U.S. House Of Representatives

## *Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity*

## Presented by Kelvyn Cullimore
## President and CEO of BioUtah

## July 12, 2024
## Salt Lake City, Utah

230 E. South Temple, Suite 100
Salt Lake City, 84111

WRITTEN STATEMENT

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*Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity*

Presented by Kelvyn Cullimore
President and CEO of BioUtah

July 12, 2024
Salt Lake City, Utah

BioUtah appreciates the opportunity to provide testimony to the Committee on Ways and Means as part of its field hearing in Salt Lake City, Utah, entitled *Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity.* My name is Kelvyn Cullimore. I am the President and CEO of BioUtah. I took this position in 2018 to help grow, connect, and raise the profile of Utah's incredibly bold and innovative life sciences industry. From our C-suites, startups, and manufacturing floors to our academic research centers and service providers, we are immensely proud of what we're building here.

BioUtah is the state trade association for Utah's life sciences industry. We are the common voice and flag bearer for the industry comprised of medical device development and manufacturing, diagnostics, laboratories, biotechnology, and biopharmaceuticals. Together we form a community that pushes the boundaries of science, promotes innovation, and delivers technologies and treatments that improve and save lives.

I have personal experience in the industry as a medical device entrepreneur and CEO, so in many ways, the subject of this hearing and how Congress can help power innovation is very important to me personally and professionally. My father and I founded Dynatronics, a Utah-based company that designs, develops, manufactures, and distributes products for physical therapy. Innovation was the key to our success. Whether it was a new electrotherapy modality, ground-breaking ultrasound technology or a better therapeutic treatment table, developing products that benefit patients and practitioners was central to growth and achievement.

At one point, we submitted a new ultrasound product for clearance by the U.S. Food and Drug Administration (FDA). The FDA did not believe our product could do what we represented. They sent a scientist to our facility to validate our claims. Indeed, they admitted we had defied traditional beliefs about how the modality worked and they approved our new product.

Unfortunately, the advent of the medical device tax as part of the *Affordable Care Act* had a significant impact on many businesses, including ours. In the first year of implementation, we paid $160,000 in medical device tax despite an operating loss of $240,000. While the medical device tax was ultimately reversed, it illustrates the negative impacts of bad tax policy.

I've also had a run in public service and chairing hearings – albeit on a local level. From 2005-2018, I served as the first Mayor of Cottonwood Heights, a suburb of Salt Lake City. This was a part-time position in addition to my duties as CEO. I appreciate your willingness to serve in public office and to dedicate your talents and abilities to better governance.

My testimony will focus on Utah's life sciences industry, a view from the trenches, and federal policies needed to help encourage and sustain healthcare innovation.

**Utah's Life Sciences Industry**
A recent study of the top 20 life sciences states revealed that Utah's life sciences industry has been the third fastest growing bio innovation hub in the nation over the last decade. Only Massachusetts and Arizona grew at a faster pace. Moreover, only Massachusetts and New Jersey have a higher concentration of life sciences jobs than Utah. This success is characterized by a strong tradition of entrepreneurship and innovation dating back to medical device manufacturing in the 1950's and including the invention in 1973 of the first artificial heart at the University of Utah. That Utah tradition continues today with a business-friendly government, a can-do spirit of discovery and importantly, a culture of collaboration that seeds startups and supports established companies - producing a vibrant, multifaceted ecosystem that is gaining national and global recognition.

The industry's economic impact in the state speaks volumes. The November 2023 University of Utah Kem C. Gardner Policy Institute report, *Economic Impacts of Utah s Life Sciences and Healthcare Industry,* discusses the substantial reach and economic impacts of Utah's life sciences industry. Key findings include:

**Facilities:** Approximately 1,600 +.

**Jobs:** More than 182,000 Utahns are employed in Utah's life sciences industry directly and indirectly.

**GDP:** Over $22 billion annually - statewide total economic impact.

**Job Growth:** From 2012 to 2022, the number of jobs in Utah's life sciences industry increased by 5.1% per year on average versus 3.5% in other states, and 3.4% in other Utah industries.

**Wages:** Estimated average annual earnings for life sciences workers ($96,000) are nearly 50% higher than earnings for workers in other industries in Utah ($65,000).

It's also important to note that in Utah workers in the life sciences industry are more racially and ethnically diverse than the average for the life sciences industry as a whole.

**Life-Changing Innovation**
In addition to its significant positive economic impacts in the state, Utah's life sciences industry is fertile ground for healthcare innovation. Utah companies large and small have developed or are advancing numerous life-changing medical products.

For instance, one of the first molecular COVID-19 tests to receive FDA Emergency Use Authorization was developed in Utah as was the saliva-based test for COVID-19. Utah companies are also creating life-saving solutions for stroke; advances in genetic-based cancer diagnostics; drug discovery for MS, Alzheimer's and other neurodegenerative diseases; treatment for Parkinson's Disease; regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative diseases of the spine; improved new heart valve replacements; cutting-edge diagnostics for chronic kidney disease; brain-computer interface technology; AI-enabled drug discovery and more are all part of the Utah life sciences world.

Numerous life sciences companies founded in Utah have grown to become engines of innovation, delivering novel treatments and therapies across the globe and employing thousands of Utahns. ARUP Laboratories (diagnostics), bioMeriéux (infectious disease), Merit Medical Systems (invented the first plastic syringe), and Myriad Genetics (first BRCA gene testing), are just a handful of Utah companies whose beginnings trace back decades to visionaries with a passion to transform healthcare.

**Innovation Landscape, View from the Trenches**
In my role as the President and CEO of BioUtah as well as in my personal experience leading a medical device company for years, I have seen first-hand the challenges faced by our industry and more specifically, how government's laws and regulations can impede or promote innovation. My observations on these challenges include the following.

Research and development (R&D) are critical components to finding solutions to medical conditions. Policies such as the federal R&D tax credit that encourage R&D accelerate those solutions. However, policies like the *Inflation Reduction Act* (IRA) or changes to R&D expensing under the *Tax Cuts and Jobs Act of 2017* can negatively impact R&D momentum.

In the same vein, reimbursement policy can incentivize or hamper innovation. Reimbursement policy which recognizes solutions that reduce healthcare costs in the long run encourages development of unique new technologies. Using metrics that measure only the short-term cost without considering the long-term savings is shortsighted. Most progress in medical solutions is iterative in nature. Early coverage and reimbursement approvals not only help patients, but lead to future improvements that further refine medical technology and enhance patient outcomes.

As one of the most regulated industries in the country, it behooves policymakers to balance the need for safe and effective products against the costs and lengthy delays incurred in bringing such products to patients. The need for innovative pathways to market will become even more pressing as technology continues to evolve.

Capital is an essential ingredient of the innovation recipe. Consequently, government policies can increase or chill the flow of capital to innovation. For instance, tax policy related to capital gains can either boost investment in innovation or redirect capital to other investment options. The ability to monetize net operating losses is another example of how tax policy could help early-stage companies not only survive but thrive as such a policy would enable them to generate much needed additional capital. Utilizing some savings from the IRA in support of such a policy could be a way of re-investing in the life sciences.

**Federal Policy and Healthcare Innovation**

In Utah, we are very fortunate to have a state government that supports our industry. Governor Spencer J. Cox has identified Utah's life sciences sector as a strategic economic pillar as has Salt Lake City Mayor, Erin Mendenhall. The state legislature has established the Utah Life Sciences Innovation Caucus to better understand how state policy affects the industry and innovation.

However, no matter how favorable a state's innovation landscape, misguided federal policies can undermine any local advantages and stymie success much like the medical device tax previously mentioned. To that end, we outline several issues for the Committee's consideration.

***Tax Treatment***

Congress should ensure a competitive tax code, including policies such as R&D expensing, R&D tax credits, bonus depreciation, interest deductibility, and small business expensing.

BioUtah supports a provision in the House-passed tax bill, H.R. 7024, the *Tax Relief for American Families and Workers Act of 2024*, that would restore the full and immediate expensing of R&D costs through 2025. Under current law, R&D costs paid or incurred in tax years beginning after December 31, 2021, are required to be amortized over five years. The five-year deduction requirement is especially hard for small companies, given their narrow operating margins and demand for capital. Yet, it is these emerging enterprises that innovate and help improve patient outcomes. Without elimination of

these amortization requirements, small companies could actually owe taxes on grants received that must be recognized as income while the expense associated with the grant would be amortized over 5 years, thus draining much needed cash at a critical stage of company development.

Another favorable tax provision of the bill would reinstate 100% bonus depreciation for property placed in service through 2025. Such favorable depreciation provisions for machinery and equipment would help companies hire workers and expand manufacturing. The Senate must now act on these tax changes to strengthen small businesses and give our life sciences companies the best chance to blossom and give patients hope.

***Medicare Coverage of FDA Breakthrough Products***

It's also critical that Congress prioritizes enactment this year of H.R. 1691, the *Ensuring Patient Access to Critical Breakthrough Products Act of 2023.* BioUtah thanks the Committee for moving this legislation forward last week with overwhelming bi-partisan support and encourages the full House to take up the bill. We also want to thank the committee for agreeing to fix a drafting error that inadvertently omitted diagnostics from the marked-up bill.

Currently, seniors with life-threatening or debilitating conditions often wait years before Medicare provides coverage for FDA-authorized breakthrough medical technologies, which can be a matter of life or death for many patients. Not only does this adversely affect patients, but it discourages the development of new devices and diagnostics.

Research from the Stanford Byers Center for Biodesign found that only 44 percent of novel technologies authorized by the FDA between 2016 and 2019 achieved nominal Medicare coverage by the end of 2022. H.R. 1691 would provide four years of provisional coverage for certain FDA-authorized breakthrough medical products. This temporary transitional coverage will give physicians and their patients access to the most advanced, safe, and effective treatments while facilitating additional clinical data collection to inform the Center for Medicare and Medicaid Services in its development of long-term coverage criteria. It's a "win-win" for patients and the Medicare program.

Let me share a real-world example. PhotoPharmics is a Utah company working on a phototherapy device to treat Parkinson's Disease. They received a "breakthrough product" designation from FDA, opening the door for early coverage under the prior Medicare Coverage for Innovative Technology (MCIT) final rule. This designation and the promise of timely reimbursement attracted the investment PhotoPharmics required to bring this technology to market for the benefit of patients. When MCIT was reversed by the current administration, the resulting uncertainty regarding reimbursement caused investors to pull back, delaying the company's ability to bring the product to market. We have great hope that H.R.1691 will better serve patients by breathing new life into this expedited coverage and reimbursement concept for breakthrough products.

***Mergers and Acquisitions Enforcement***
Finally, given the recent departure from bipartisan mergers and acquisitions (M&A) enforcement policy by the Federal Trade Commission (FTC) and Department of Justice (DOJ), the Committee should take note of the unique value and role that M&A plays in our industry.

M&A are a fundamental tool for medical innovation in Utah and across the U.S. M&A encompasses mergers, partnerships, and licensing collaborations between life sciences companies of all sizes. In Utah, life sciences M&A is a critical pathway that attracts sustained investment, R&D, and growth.

Researchers at the University of Utah and Utah State University were awarded 824 life sciences patents and launched 35 life sciences startups from 2018 to 2022. Small businesses make up the vast majority of Utah's life sciences hub. These companies may rely on M&A to gain the resources and scale needed to bring their innovations to patients.

When it comes to biopharmaceutical companies, 80% operate without a profit, and many are unable to go through the long, complex, and resource-intensive process of developing new medicines alone. Bringing a new therapy to market is like a relay race – and M&A allows companies to "pass the baton" and share existing complementary expertise, manufacturing capabilities, and other forms of support which would otherwise be too costly or overly duplicative.

To that end, BioUtah urges policymakers to take a balanced and bipartisan approach towards life sciences M&A, acknowledging the unique, differentiated, and competitive market dynamics. The FTC and DOJ's current aggressive approach could inadvertently stymie pro-competitive M&A that would spur advances in healthcare in Utah and beyond.

Tolero Pharmaceuticals is a good Utah example of the benefits of M&A. Tolero, founded in Lehi, Utah, developed a technology to address solid tumor cancers. The technology was acquired by Sumitomo Pharma, a large pharmaceutical developer, which enabled the product to be further developed and commercialized. An important side benefit is that the principals of Tolero were able to utilize the proceeds from the sale to seed and incubate many other new companies. The multiplier effect of M&A activity should not be overlooked.

**Summary**
In closing, BioUtah applauds Chairman Smith and members of the Ways and Means Committee for taking the time to come to Utah and learn more about our life sciences industry and challenges to our innovation economy. We also thank Representatives Blake Moore (R-UT), a member of the Committee, and Celeste Maloy (R-UT) for their participation at the hearing.

Fostering a favorable environment for life sciences discovery and expansion requires a pro-innovation tax structure, timely reimbursement, sound regulation, and a reasonable approach to M&A. In Utah, our companies have plenty of ideation, passion, and commitment. What's needed are the right policy tools so they can take root, attract capital, grow, and reinvest in their business to make a difference in patients' lives.

Chairman SMITH. I want to thank each and every one of you for your testimony, and we will now move to questions and answers.

Mr. Shakespear, access to new and innovative treatments can be a challenge in any community, but we know it can be particularly difficult to those living in rural America.

As the parent of a son who was diagnosed with a rare kidney disease, can you talk about the challenges you face coming from a rural area in finding access to necessary innovative therapies and how you are able to manage the logistics today?

Mr. SHAKESPEAR. Thank you, first of all.

When we were diagnosed, it was unknown to the physicians in Utah that the RAFT trial even existed, and so the burden fell on my wife and I to find that treatment. So as I mentioned, if it wasn't for our educational backgrounds, then it would have been impossible to find the treatment to start with.

But managing the back and forth, there is a lot of logistics that go into relocating, you know, 500, 600 miles away and having to stay there consistently. So that was a major challenge, but now that we are back home, there is still a lot of coordinating with physicians.

My wife is a full-time scheduler. She is the care coordinator for my son, and she stays busy all week long and usually has multiple appointments every week. And then we have two older children, so it becomes quite a burden to manage all of the schedules and care for everybody's needs.

But in addition to that, being on a kidney registration list, if you have ever had an organ donation, you know pretty much your entire life is tentative status, hoping to be able to do things but waiting to see if you get that call that disrupts everything.

Chairman SMITH. Mr. Watanabe, many tax provisions have expired or have been phasing down over the past few years, including those which reward innovation right here in the U.S., like research and development. Looking ahead to 2025, this committee is exploring how the Tax Code can help better facilitate innovation, especially in the biotech industry, create new technologies, and encourage domestic manufacturing.

With your experience and understanding of drug development, what would you recommend Congress look at when it comes to supporting healthcare innovation through the Tax Code?

Mr. WATANABE. Thanks for that question, Chairman. Yes, I am glad you asked that question.

I think there are a number of specific provisions. You know, first one is restoring full depreciation, deductibility for R&D investments. You know, the committee has already taken that up. The bill has passed the House. We hope to see that pass through.

You know, the challenge there is that small companies are paying taxes even though they are not making any money because they are not able to fully deduct their R&D expenses, and particularly for smaller companies, that can be crippling.

I think another potential opportunity is looking at monetization of net operating losses. Many small companies have large numbers of NOLs, and an ability to monetize those in the early stages when they can invest in R&D is something that could make a meaningful

difference in capital access for smaller companies, which is becoming increasingly difficult.

Along with that, I think corrections to section 382 would be an important consideration. In some cases, bringing investments into a new company—into your company—new investments in your company causes you to lose your ability to use your NOLs, and correcting that would be an important change.

Section 1202 is a very important tool for early-stage investments. My company benefited from section 1202. Preserving that and potentially even expanding 1202 I think would be another important opportunity to foster investment in especially early-stage R&D companies.

And then also, the passive activity loss rule in the 1986 tax reforms has really significantly impaired the ability of investors to benefit from flow-through losses from their investments. That would be another thing that the committee could address that would particularly foster investment in early-stage companies.

Chairman SMITH. Thank you. I was thinking you were a tax lawyer for a second.

Dr. Soares, you have been at the forefront of innovative treatments in oncology and helping cancer patients navigate what is called the six scariest letters in the English language.

This committee recently approved legislation introduced by Representatives Arrington and Sewell that expands Medicare coverage to multi-cancer early detection screening tests. Can you discuss how having Medicare cover innovative early detection tests can improve the care you are able to provide your patients and ultimately lower healthcare costs?

Staff. We are going to pull pause for 1 second. We are just going to get the mike's working again.

Mr. MOORE of Utah. Your time is still running, Chairman.

Chairman SMITH. Okay. My mike is working.

Mr. MOORE of Utah. Now mine is back.

Dr. SOARES. Oh, yes. Now it is back.

Thank you for the question.

I think novel ways to monitor cancer when it is already diagnosed or detected are key. I think it is important to have that validation.

I can share with you that now there are tests that are available that I can use. There are blood tests that I can monitor the tumor cells that are potentially present after patients receive treatment, and that has been fundamental to potentially helping decrease the need for patients to come to the cancer center. I can alternate between doing CAT scans to monitor recurrence versus these blood tests.

So that has been fundamental to keep patients on surveillance, on monitoring, and then also decreasing the cost of doing these scans and visits if I can do that with blood.

So I think there has been a lot of progress in monitoring and detecting minimal residual disease in cancer patients, and it has been substantially important to keep patients compliant with their care that has been designed for them.

In terms of early detection, I think there are several technologies that are very promised and then they are approved to be safe. They will be fantastic for our patients and for improving their survivals.

Chairman SMITH. Thank you very much.

I recognize Mr. Moore.

Mr. MOORE of Utah. Thank you, Chairman.

Again, I would like to welcome my colleagues. Just appreciate you being here. I appreciate you taking the time out of your busy schedules to be here. I really am honored that the chairman would bring the committee here today so we can showcase what Utahans are so proud of.

I would also like to thank ARUP for hosting us today. Utah has some of the most innovative and fastest growing life science sectors in the country. And as up here, we sacrifice a little bit of our ability to hear, it just showcases there is work to do, and this is a working lab, and, you know, there is a lot to be done. And so we appreciate the productivity that comes from this part of the First District.

As the IRA, Inflation Reduction Act, that was signed into law last Congress is implemented, I remain concerned not only about the law's impact on medical innovation, particularly for rare diseases, but that it may result in increased use of prior authorization in step therapy, fewer covered medicines, narrower pharmacy networks, and fewer plan options for seniors covered under part D.

A lot of times these pieces of legislation get branded as, you know, a way to lower costs and this and that, but the reality of what takes place during this is going to limit all of the important aspects to providing care and getting that care to individuals at a lower cost but at the same time identifying cures and promoting that type of innovation.

There was bipartisan interest in reforming the Medicare Part D benefit for several years prior to the passage of IRA. So I would urge members of this committee particularly to work together towards improving the Part D program for seniors.

So I just want to mention that, because I think it is so important to all the companies and the things they are working on in this area.

I am not going to rehash the fact that tax is going to be important next year. Mr. Watanabe, you have already identified so much of that.

I would ask Mr. Cullimore and—again, Frank, please share—could you speak to net operating losses? You introduced it a little bit. Just the specifics of how it can be beneficial to a company, how they would use it, with some specific examples about some of these tax implications that you have already introduced.

Mr. Cullimore.

Mr. CULLIMORE. I feel inadequate to answer that sitting next to what looked like a tax attorney, but let me take a shot at it.

The NOL monetization concept is very important for early-stage companies because, as they built up losses, as they are doing research, they are building up these losses, but capital becomes so critical to their success. And so the ability to monetize those either through a device of being able to market those like a tax credit could be marketed or to be able to utilize those like an earned in-

come tax credit on a personal tax return, things of that nature, that generates capital that further advances the work.

Now, we recognize there is a cost associated with that, but there are abilities to get returns on those kinds of investments.

Someone asked me, how would you pay for something like that? The IRA, when it was passed, it supposedly generated a lot of savings, they say. Most of those savings are being redirected in other government programs. If even a fractional portion of that were redirected to this, it would fully cover any kind of cost associated with that.

Mr. MOORE of Utah. Thank you.

Anything to add, Frank?

Mr. WATANABE. I was going to say maybe just in terms of putting it into operational practice, you know, our company has been in existence since 2016. We have generated something like a billion dollars in losses trying to get our first product to market before we generated a single dollar of revenue.

You can't use your NOLs until you are profitable. I would hope that maybe sometime in the next 5 years it will be profitable, right, but that is a long time to be sitting in that hole. Our ability to sell our NOLs to another company and bring that money in to invest into R&D immediately would make a huge difference for us and for earlier stage companies.

And, you know, it is not really a cost to the government. It is just a shifting of when those NOLs are used because I have a right to use them eventually. It is just a matter of can I use that money today to invest in research and development versus waiting another 5 years or so until I start generating profits and can start to exploit my NOLs.

Mr. MOORE of Utah. Excellent. Thank you for those specific examples.

Dr. Soares, as I wrap up, there is so much that the Huntsman Cancer Institute does for this community. It doesn't exist without strong private sector involvement in donations and philanthropy. And just thank you for being here. That is what makes this area thrive so much.

But just briefly, as you embrace AI and other types of technologies, what barriers exist for you all that you can't necessarily, you know, find those new next generation innovative technologies that will help you find those cures?

Dr. SOARES. Yeah. Thank you so much for this question.

And I am very proud of living in Utah and being at the Huntsman Cancer Center. As you said, you come here and this place is amazing and you just stay.

There is a need for AI to be able to have data-sharing integration and management. In management, there is a lot of different electronic medical records that are very separate and spread. The AI technology can leverage that. We can integrate this data. We can share them in the proper ways, and that will lead to so much more innovation.

So I think working on ways that we can safely integrate AI and share data will be imperative for us to continue to advance and also use that to identify the patients that will benefit from new treatment options.

Mr. MOORE of Utah. Thank you.

Thank you for your indulgence, Chairman.

Chairman SMITH. Thank you.

Mr. Owens.

Mr. OWENS. Thank you again, Chairman Smith, for coming to this beautiful Salt Lake City and for this important field hearing today. I am so proud to sit next to my good friend Blake Moore. He has been a fierce champion for Utah's unique ecosystem, one that has helped our nation to thrive, our state to thrive.

Today's hearing is highlighting medical innovation. Here in this state, it is the fastest growing state in the union since 2010 and a national innovator in other fields of education, workforce, transportation, IT, and aerospace. I am so proud to see so many Utahans as witnesses today and eager to share our story as a model for the rest of the country.

Mr. Cullimore, what has made Utah so successful in developing in its life sciences industry, and what lessons can we take from the entrepreneurial culture here?

Mr. CULLIMORE. Thank you, Representative Owens.

As you are aware, Utah is a great state for doing business. We have been recognized nationally as the number one state for doing business, the best state to open a business. The entrepreneurial spirit here goes back to the pioneer heritage that founded this state, and that heritage has carried on today.

We have many large companies that operate in the state of Utah, but many of them are here because they acquired technology that was developed here in Utah. We have a phenomenal academic system here with our universities who generate great technology. We also have a great workforce here, and we have the ability to generate great ideas because of the existing critical mass of companies that are here that spin off from other companies. You can trace many of the companies back to other companies that were here, people who have spun off from them.

And so we are very fortunate to have a very high-growth industry in the life sciences here. Most people are unaware of that. We are the number three state in the nation in density of employment in life sciences behind only Massachusetts and New Jersey.

So we are recognized as the life science hub, and that kind of success begets additional success.

Mr. OWENS. Thank you.

You talked a bit earlier, you might want to elaborate, any more on Utah's ability to track funding since the passage of the Inflation Reduction Act in terms of shutting off opportunities for future generic competition?

Mr. CULLIMORE. Well, the Inflation Reduction Act, I don't think we have seen the full impact of that yet. I think as the specifics come forward and we see the impact that can have, it is going to have an even greater chilling effect on research and development in the therapeutics field.

I think we are already seeing—and Frank can testify to this better than me—how investors are very concerned and withholding funding until they see how some of this pans out. And I am afraid what they see will discourage them even further. So that is a challenge.

That is going to be a challenge in the pharmaceutical area for that, and Utah has a lot of early-stage pharmaceutical companies. And so we have some concerns. Some of the things that Frank talked about that could improve it are important steps, but overall, the bill is still of great concern.

Mr. OWENS. Thank you.

Mr. Shakespear, you made some comments earlier. Any additional comments or insight on how to support the rural community for issues that you are having right now in the health arena?

Mr. SHAKESPEAR. Absolutely. Thank you for the question.

I would urge you to put it in the hands of the parents in rural America to decide whether they are willing to pay the price to pursue these innovative treatments. It is difficult to bring them to close proximity to everybody in rural America, and I recognize that. And you have to understand as well that not every urban center is even created equally, because the treatments that saved my son are still not available in Utah.

But in many instances throughout our journey, medical providers at times tried to make the decision for us on whether we would be willing to pay the price to continue with treatment, and I would just urge that in every situation the parent gets the choice in that right. Let the patient choose whether they are willing to pursue that or not, and don't make assumptions about whether the patient is willing to go that distance when making decisions about legislation and things regarding continuing to research and develop these innovative treatments.

Mr. OWENS. Thank you so much.

And I yield back.

Chairman SMITH. Ms. Maloy.

Ms. MALOY. Thank you, Mr. Chairman.

Mr. Shakespear, before I ask a question, I just have to say I am really impressed. We asked you to come here and talk about something really deeply personal and really emotional, and you have been very poised about it, so thank you for that.

You know, I have spent most of my life in really rural areas too. You and I were talking before the start about some of the places that we both know. And we all know, we talk about it all the time in Utah, how we are losing our rural kids to urban areas. They have to leave to get jobs.

And the Governor of Utah has made a big push to bring more jobs to rural areas, and that is wonderful. But your story is a reminder that even when us rural kids grow up and can get jobs in our small hometowns, if anything goes wrong, we still have to move to urban areas where we can get medical treatment or whatever else the problem is.

So thank you for being here and talking about the challenges you are facing and what we can do to better support rural areas because they are important to the economy. I don't even have a question for you. I just want to say thank you.

Mr. Cullimore, you talked about how the state does a good job of supporting the bio-life industries and how we need more federal cooperation. Could you talk about what the state is doing well and how we could support that from a federal level?

Mr. CULLIMORE. Well, the state of Utah has identified the life sciences industry as one of its five target industries for development. To that point, they have taken the approach of providing funding in critical areas that encourage development of these companies.

So, for instance, last legislative session, the legislature passed a life science initiative bill to provide money to develop a workforce specifically for life science needs, which can be very unique. They have also established a fund called the Utah Innovation Fund, which is intended to help bring technologies that are early, early stage at our universities and institutions out to an investable stage. It is really hard to get these early technologies to a point where an investment community will take a look at them. And so that is a key bridge that they have helped to provide.

And they have provided research and development credits and other kinds of incentives for companies.

So from a federal perspective, I think continuing to provide the kinds of tax things that Frank articulated earlier are critical to making sure that we have that, trying to limit the kind of barriers that we face.

The life science industry is probably the most regulated industry in the country, and finding ways to reduce those barriers will help bring products to market a lot faster. Medicare itself could be a great toolbox or a great sandbox for doing some of that.

Ms. MALOY. Thank you.

Mr. Watanabe, you talked about PBMs, and it is something that I hear about a lot. I have independent pharmacists and even, you know, larger chain pharmacies that we have all heard of. They come talk to me about how there is a middleman that is making all the money. You talked about the same thing. I know it is something all of us up here are hearing about. What would your ideal PBM solution look like?

Mr. WATANABE. How much time do I have?

I do think that the intermediaries in the healthcare system have become a real problem and are probably one of the major drivers of growth. The concentration in the PBM sector and now increasingly with the insurance sector is also a problem.

They have immense power vis-&-vis physicians, pharmacies, and the innovators. They now control access to care in many cases, right. They are dictating to doctors what drug their patients can receive rather than the doctor making the decision for themselves what is the best choice. And at the same time, they are extracting large amounts of money from the companies who are innovating, and they are not passing that money on, those savings on to the patients, as it was originally intended.

I think, you know, increased transparency is a very good first step, but I think there are a number of other things that Congress can look at to reduce the power of these intermediaries and ideally to ensure that any savings that are realized in the system are passed on ultimately to the patients who need access and, you know, who are spending an immense amount of their own money caring for themselves or for their loved ones.

Ms. MALOY. Yeah. And we just heard Mr. Shakespear testify he would like to have parents make more of those decisions, not have

them be made by somebody who crunches numbers in an office somewhere. And I agree with him.

Dr. Soares, I am almost out of time, but quickly, what federal policies do you think are acting as barriers to Americans getting their cancer screenings and being responsible upstream for their own health? Is there anything we can do to support you there?

Dr. SOARES. I thank you for the question.

I think there are many things that can be done. Some of them we touched about, step therapy and step therapy in preauthorizations. This hugely affects how I can care for my patients. Patients might elect not to continue treatment, because if I have to start with a medication that I don't think is ideal but step therapy requires me to do, they might have a lot of side effects from that treatment. And they might decide that they don't want to have the treatment anymore because they got traumatized by the side effects.

But I have tools to help the patient. It is just that these issues are limiting my ability of providing the best care that I want.

And it goes also for testing, novel testing and innovations. There are these preauthorizations that are put in place that I cannot give the treatment or do the test that I need for my patients. So that is an issue.

Also, we need to continue telehealth coverage. That is the only way that I will be able to continue to provide the care for my rural population. As you heard, at least 30 percent of the patients that we have in clinical trials at Huntsman are rural. So that is my people. I need to be able to provide care for them. So we need federal support for that.

Ms. MALOY. Thank you.

My time is up, Mr. Chairman. I yield back.

Chairman SMITH. Thank you.

Dr. Wenstrup.

Mr. WENSTRUP. Thank you, Mr. Chairman.

And thank you all for being here today. I really appreciated hearing from each and every one of you.

I want to say to Mr. Shakespear, it was several years ago, probably about 6 or 7 years ago, it was actually a Member of Congress whose daughter was one of the first to receive the treatment that your son treated. And, you know, you mentioned something about the stars aligning, and she was one of the lucky ones where the stars aligned as well.

And, you know, this requires early diagnosis and treatment, which is what we talk about all the time, and improving medicine requires early diagnosis and treatment.

You know, a close acquaintance of my family who happens to be on Medicaid had the same similar situation, but when she was pregnant, she was only offered termination. And that is a sad day in America.

Dr. Soares, you talked about home health and things like that. We are working on that—home health, hospital at home. And I do want to talk—and I will ask you something later—about the delays that you brought up, the delays in care that are offered.

And, Mr. Cullimore, you hit on a few things. You talked about MCIT being repealed by the Biden administration, which held up

then new innovations getting to market. The Biden administration promised they would come out with a new form of it; they did not. And so we have our bill, which you mentioned, and I appreciate that.

So you guys are hitting on all cylinders today, as far as I think this committee is concerned.

You know, I am co-chair of our Doctors Caucus. And, you know, really, one of the themes that we are trying to promote—in Washington, too often, when you bring up healthcare, everyone starts talking about Medicare, Medicaid, Affordable Care Act, Blue Cross Blue Shield; they are not talking about the health of patients. And that is a problem.

And our goal should be to make America the healthiest nation on the planet and work towards that. Besides, that is where the real return on investment is—prevention, cures, all of these things that we are talking about today.

You know, I practice predominantly in an urban area, but I represent urban and rural. So these issues are common throughout, especially in underserved areas.

But one of the things that is a real concern to me in medicine today—and we really need your voice out there so that Congress does act on some of the things. Similar to what we do with semiconductors, we need to do for pharmaceuticals, especially generics. You know, we are reliant on China for our generic medications. We have to turn that around. It is a national security risk. It is a national health security risk. When my daughter can't get amoxicillin for her ear infection, that is a problem.

And so this is something that I would like to address. We talked about, you know, pro-growth tax incentives. We are on board. I have a bill to address the generic issue. Just, can we at least look at our battlefield medicines? If you would have told me when I was a surgeon in Iraq that I relied on China for my protective equipment and my pharmaceuticals, how did we get here? We have to turn this ship around. And we need everybody talking about that and the dangers involved with that. So maybe we can do like we did with semiconductors and address some of those tax issues that would allow us to bring that back.

And I do have a bill up for draft discussion. If we can at least start with our battlefield medicines, will that not tug at some people's heartstrings to say, yes, we have make that domestic? So we need your help in that area too.

But, Dr. Soares, you mentioned step therapy. I have had that bill for years. I don't know why we can't get that through. The Safe Step Act, as it is called, we are going to continue to push that. Same with prior-authorization bills. It is: Speed up care.

You know, you have decisions being made by people that don't see patients, and some have never seen patients. And this is a real problem in patient care. Because it all comes down to that.

So one of the questions I have for you, Dr. Soares, it comes to—you do clinical trials. Thank you for doing that. That is how we get things to market. And you know the problem with getting through FDA approval. But it is even tougher for you, treating patients, when you get something approved by FDA with the indication of something you are treating and Medicare won't cover it.

Can you address that relationship with your patient and how that is affected when someone else is deciding that they can't get something that can make them healthy?

Dr. SOARES. Yeah. Thank you for question.

And this is very upsetting. I had several patients that I would like to have provided a treatment—in this case, we are talking radioligands, radioisotopes. And even though has been approved by the FDA for one niche of what the therapy benefits, it is not really paid by Medicare to all the indications. So my patients die, because I cannot give them the treatment that they deserve.

And, you know, thankfully we have done a lot of innovations and I have many more treatment options for my patients, but that particular treatment is the cornerstone of longer progression for survivors and survival for these patients.

I had personally lost patients because I had not been able to provide the treatments because I have been told they were not covered by Medicare. And that is unacceptable to me.

Mr. WENSTRUP. That seems immoral and sinful to me, and people that aren't standing over patients trying to help them making those decisions.

Thank you. I yield back.

Chairman SMITH. Mr. Estes.

Mr. ESTES. Well, thank you, Mr. Chairman.

And, you know, once again, I want to thank you for holding a hearing outside the bubble in Washington, D.C. I know many Members like myself go home every week and listen to our constituents, but having these hearings around the country is really important for us to be able to talk with people in, I will use the term, the "real world," as opposed to what is going on in Washington. And it is great that we are able to take this information to make sound policy decisions.

I am just going to dive right into questions today. I have a lot of things to go over.

And, Dr. Soares, thank you for your testimony. And I want to thank you for what you do to help advance medical breakthroughs in the country.

And cancer has impacted most of us, if not personally, then a family member or a close friend. And there have been so many innovations in the field of cancer treatment.

Can you talk a little bit about why it is important for the United States to remain the leader in medical innovation?

Dr. SOARES. Thank you for the question.

We are extremely successful in medical innovation. There are so many pathways that are so important for us to continue to lead. It is important for our patients, for our communities, for our economy. The amount of economic revenue that is generated from research, in many aspects, is also huge.

So, from the aspect of healthcare, delivering healthcare to our patients is key. It is also economically important. And, also, if we keep our drugs here, we don't have to depend on other countries to supply. Because, as was mentioned, drug searches, this is a huge issue. And I also have not been able to provide chemotherapy drugs and symptom control management drugs to my patients because they are not here.

So it is such a multilevel importance that we continue to lead all these efforts.

Mr. ESTES. Yeah. Well, thank you.

And, Mr. Watanabe, you have heard—and I know you talked about it, our chairman talked about it—how important research and development is, and the issues there, and just how important that is for medical R&D to help save lives.

I have been a fierce advocate of making sure that the Tax Code encourages U.S.-based research and development. And you talked about it a little bit, but do you want to talk some more about how the Tax Code helps or does impact the R&D that gets developed? And what other points do we need to do in Congress to help make sure that—and encourage innovation in the U.S.?

Mr. WATANABE. I think I mentioned in my comments, I think, first of all, it is important to recognize that most of the innovation that is happening now is happening in small companies, companies like mine, and, you know, not companies who are generating billions of dollars in profits from existing drugs.

And, as a result, capital is probably the most important thing for small companies like mine. It is very expensive to develop drugs. I mentioned my company spent almost a billion dollars getting our first product to market, with no revenue.

So this committee in particular and Congress more generally—you know, policies that foster our ability to acquire capital, like the Tax Code changes that I mentioned but other measures that foster an environment that is friendly to capital formation for small companies, is vital, because that is what gives us the resources to run the clinical studies, to do the basic research that leads to the medical innovation.

And then I think, you know, the other aspect that Mr. Cullimore touched on is M&A. Most drugs are developed—new drugs are developed by small companies, but they aren't marketed by small companies. Typically, the company is bought or the drug is bought by a large company. And that M&A activity is critical to then getting the medication to patients. And some of the steps by the FTC, in particular, against mergers and acquisitions are really actually going to inhibit R&D and the ability for us to deliver new drugs to patients.

Mr. ESTES. Thank you for those comments.

I mean, a lot of times, in my conversations, a lot of folks have said, "Well, research and development only helps big companies," but it is really the small ones that are so much more greatly affected through that.

It is critical that we keep innovation here in the U.S., but it is also critical that we make sure healthcare is affordable. You know, in my home state of Kansas, there are a lot of rural Kansans, as we have talked about today, and we need telehealth to help make sure we have better outcomes.

And, unfortunately, some of the higher costs, driven by the incorrectly named Affordable Care Act a decade ago, have prevented Kansans from getting some of that medical care. And, as we mentioned before, or has been mentioned earlier, the so-called Inflation Reduction Act is only making it worse.

And so we need to make sure that—you know, as we look ahead, CBO, the Congressional Budget Office, is already projecting that premiums are going to go up and that seniors will have fewer drug choices in their drug insurance because of these disastrous pieces of legislation. So I want to make sure, as we look forward, that we can actually implement policy that helps make sure that we have drug treatments and other treatments available to patients.

So thank you all for your time in being here.

And I will yield back.

Chairman SMITH. Mr. Hern.

Mr. HERN. Thank you, Mr. Chairman.

Congressman Moore, thanks for hosting us here in your beautiful city.

I would like to thank the witnesses for being here.

It has been great to work on healthcare in Ways and Means in my 4 years on the committee. And when we talk about healthcare, things usually turn very partisan, with the exception of innovation.

And you probably saw, last week we had a great markup. A lot of bipartisan bills came out of there, a lot of, you know, "kumbaya," "let's go get 'em." And then we had CMS come out and support the mental illness treatment using PDTs, so that is great.

And while I wish everything could be as positive as last week, it is sad that what we are dealing with is stifled innovation and a decrease in patient access due to the Inflation Reduction Act, a bill that had zero Republicans on it.

And one consequence of the IRA that I am extremely concerned with is the harm it is going to do to research of rare diseases treatments, as we have been talking about. I know on a personal level how having a rare disease can affect an individual and their family. I will always advocate for those who are suffering from a rare disease and support efforts to bring treatments for these diseases to market.

Over 90 percent of rare diseases have no FDA-approved treatment. And that is millions of patients across America with no options.

According to the 2021 National Organization for Rare Diseases report, about 25 percent of drugs on the market with an orphan designation are approved for more than one orphan indication. Under the IRA, there is no incentive for companies to investigate these additional uses, because as soon as they receive additional orphan designation, they are eligible for government-mandated price controls.

That is why I am proud to co-sponsor the ORPHAN Cures Act. This bill fixes one of the many IRA consequences that would only hurt individuals who are already suffering enough. The ORPHAN Cures Act would ensure that orphan drugs treating one or more rare diseases are excluded from Medicare price negotiations.

You know, this hearing we are having today, this markup, is exactly what the Chairman wanted to do when he became the Chairman of Ways and Means just almost 2 years ago, was to get out and listen to the experts, listen to the people that are receiving the brunt of, or the lack of, work from Washington, D.C.

And you all have expressed, you know, intimately the issues you are having in order to get to this—not some, you know, politician,

not some person on the Hill that has read something in a book. You are telling us from your heart what is really mattering. And we really need to listen to this.

And it is really sad, quite frankly, that we don't have any of our colleagues from across the aisle that could be hearing exactly what you are saying. This isn't political. This is real. This is people's lives, as Dr. Soares said. This is people's lives that we are not being able to help.

And, you know, Dr. Watanabe—Watanabe—I will get that right in a minute—you know, it is sort of interesting, some of the concepts that you came up with. Monetizing net operating loss, that is interesting. The passive versus non-passive investing. You are not asking for the federal government to give you money; you are asking to have an opportunity for just the timing of the tax.

That is something that, you know, everybody on this committee needs to hear. Everybody—not just us on this side of the aisle, but everybody—needs to hear that. So I really appreciate that.

And can you tell us what is going to happen if there are no fixes to the ORPHAN Cures Act? What is that going to look like for, you know, the support to incentivize research and development for rare disease treatments?

Mr. WATANABE. Yeah. Congressman, thank you for your question.

You know, my own company doesn't work in the orphan disease space, but a number of my colleagues at BIO, on the BIO Board of Directors, do, and I can tell you that it is already having an impact. Exactly as you described, the IRA has set up a disincentive for pursuing any follow-on indications for an orphan drug.

You know, historically, that has been the model, that you get your orphan drug approved for its first indication and then you look to see what other possible rare diseases that drug may treat. And, you know, some of the best cures out there for these rare diseases are repurposed from a different initial indication. Companies are not pursuing those follow-on indications anymore precisely, as you said, because the IRA creates this disincentive for them to do that.

I think your ORPHAN Cures Act is an incredibly important fix to the IRA. And we are really hope that we see passage of that bill very soon, because, you know, every day that this disincentive is in place is days that new innovations aren't being developed for people who are suffering from rare diseases.

Mr. HERN. Thank you for your comments.

We are already seeing, you know, what is happening to Part D. You know, we have lost—you know, prices have gone up 21 percent. We are losing options in the marketplace. People are leaving the market because of what is happening with the price controls. It is something that we on this committee have got to get fixed. It is disastrous for our seniors. And just because, you know, somebody says it is great, the results of the actions are showing something completely different.

So, again, we thank you all so much for your, you know, expert testimony. And, again, we need to have all of our colleagues out here.

And I want to thank the chairman once again for having these field hearings on all the different topics we have had this year related to the American people.

Thank you. I yield back.

Chairman SMITH. Mrs. Miller.

Mrs. MILLER. Thank you, Chairman Smith.

And I would like to thank all of you for being here today so that we can have very good conversations back and forth.

I am from West Virginia. This is my third trip to Utah, and it is incredible. But we have an expression in West Virginia. Our mountains are a lot closer, they are a lot lumpier. And there are areas that—the expression is this—and people will look at me and go, what does that mean? And I will say, it means the sun only shines between 10:00 a.m. and 2:00 p.m., because our mountains are so close. It is just so different.

But, you know, because I represent rural West Virginia, where the access to care and innovation can really be a challenge for all of our patients—and an issue that I am particularly passionate about, of course, is care for patients with end-stage renal disease. Kidney care doesn't often see innovation—which I think you are a living example of—which is an extremely pressing issue for us.

But we also have to consider the very basic challenges rural patients face when they are trying to access lifesaving dialysis services, which, again, we have already mentioned. Many ESRD patients in my district have to travel for hours to a dialysis center to receive the care they need, dialyze for two or three hours, then drive back home those hours. And they must do this three times a week just to survive.

This burden on some of our most vulnerable patients really is unbearable. And, thankfully, the new technology exists for patients to receive home dialysis. Home dialysis can be a godsend for rural patients, people who have jobs or families, or are without access to transportation. And I have worked very hard in Congress to increase that access of home dialysis just for our ESRD patients.

So, Mr. Shakespear, I am a mother, I am a grandmother, and I was so touched by your testimony about your son. You know, everyone here, your heart just aches, understanding, or trying to understand, what all you have been through, and how any parent would go to the ends of the Earth to save their baby.

Unfortunately, for parents like us in rural areas, as you have pointed out, there are some patients that don't get care. And it is just, care is so far away, it makes it difficult.

Can you sort of walk us through—I know you have talked about it, but—what was it like finding the care for Isaac? And, you know, can you explain, was it a pediatric nephrologist or a dialysis clinic, or was it a social worker? How did you work all that to navigate for healthcare?

Mr. SHAKESPEAR. One of the challenges has been that Isaac has received care across many different organizations, and, unfortunately, care coordination across different organizations is very challenging.

So, when we initially found out about his diagnosis, he received care from a high-risk fetal obstetrician, fetal surgeon, with Dr. Chmait. And then we had to coordinate with another high-risk OB

at Stanford in order to transfer Isaac from Los Angeles to Stanford for birth.

And then, throughout the process, in the NICU, he was cared for by a wide variety of specialists—nephrologists, neonatologists, and then lots of -ologists. But each condition that he came across usually required a different specialist. And then it was 24/7 care, and so we were dealing multiple nephrologists, multiple neonatologists throughout the process, and sometimes changing over in the middle of crisis situations.

And so most of the burden for coordinating that care has fallen on my wife and I. But my wife has a bachelor's degree in early childhood education. I have a bachelor's degree in biology and a master's degree in healthcare administration and public health. So, when I say it's because of our education, I understand the system, I understand the biology, she understands the development component. And so you could not have picked a better set of parents to be thrown into that situation. But I know that we are very unique in understanding what is happening and being able to communicate those things across different teams.

And so, throughout the process and every hospitalization, we have had to be advocates for our own child and understand the treatments that he was going through and ask questions and be able to explain in clinical terms to the next provider.

Mrs. MILLER. I need to ask one more——

Mr. SHAKESPEAR. Uh-huh.

Mrs. MILLER [continuing]. Question, so thank you.

Mr. Watanabe, Chairman Smith recently created 10 tax teams, because you all know about the Tax Cuts and Jobs Act, and we are just focused on what we can do for 2025 and how we can put these things in order. I am heading one of the tax teams, and what I am hearing about the most is the corporate tax rate.

And because of President Trump's work and all of that that happened, we tried to create a favorable environment for companies engaged in R&D. And it is disturbing to me that our medical supply chain is heavily reliant on foreign manufacturers.

Could you explain to me the benefits of a 21-percent cooperate tax rate and how that helps you?

Mr. WATANABE. Well, you know, as I mentioned earlier, the smaller companies, most of us are not actually profitable, so we don't pay taxes, at least at the moment, although we all hope to at, you know, sometime in the very near future.

But I think, you know, it is also important to understand that small biotechs exist inside of a much larger ecosystem. And I mentioned earlier, for example, the importance of M&A to finish development and to bring the therapies to patients. So I think that any change that fosters the health of the overall biotechnology sector in America, like the corporate tax code, will have a very positive effect on R&D.

And I certainly don't want to suggest that large pharmaceutical companies—I was employed at Eli Lilly and at Amgen in the past. They invest immense amounts of money in research and development. And to the extent that they have to pay higher tax bills, all of those dollars are dollars that they will not then spend on R&D and develop additional therapies.

Mrs. MILLER. Thank you so much. I apologize.

I yield back my time.

Chairman SMITH. Mrs. Steel.

Mrs. STEEL. Thank you, Mr. Chairman, for having this hearing here in Utah.

When Congressman Blake Moore said that it is over 100 degrees, I couldn't believe it, because I came here only to ski, so I always thought that you have much cooler weather.

But thank you, witnesses, coming out here. Because when we hear from you, then, you know, we know which direction that we have to move. A lot of times, we try to introduce the bills, and you know what? Sometimes those bills actually create more loopholes, and then it is not really helping. So thank you very much for coming out today.

And telehealth—I am so into telehealth. Especially California, during COVID, we were totally shut down for a few years. So telehealth has been a vital lifeline for patients living in urban, suburban, and rural areas across the country.

And, last June, Ways and Means took a proactive step in passing the Telehealth Expansion Act, which would allow 32-plus million Americans with health savings accounts to have a permanent access to telehealth and remote care services without first having to meet their deductible.

This legislation must pass before—it is going to be expired by end of this year.

And thank you, Mr. Shakespear, for, you know, you sharing your personal story. And it is really sad, you know, what you have to go through. Of course, you have happy times too, but, you know, when baby comes, usually you have to be really happy.

Actually, my grandson was just born 2 months ago. Nine-pounds premature, so he was in NICU for 8 days. And I remember that, you know what, those 8 days, that, you know, I hoped that he's going to come out healthy. Fortunately, he is healthy. But, you know, what you are going through I cannot really imagine.

But, you know, could you explain just a little more about—since I know that you are chair of the Utah telehealth advisory board at the same time that, actually, telehealth helped to connect with the specialty care providers for your son. So could you tell us how important it is that, you know, we have to move forward with this?

Mr. SHAKESPEAR. Absolutely.

So understand that when we have to travel to Salt Lake City for an appointment, it is not only 9 hours of our time but it is the cost of gas to travel up here, it is the cost of lodging—typically we have to stay oversight somewhere—it is the cost of food.

And I do want to acknowledge, our insurance programs and Medicaid do assist with us this. But when you look at raising gas prices, inflation for the cost of food and for lodging, those rates that we are reimbursed don't change when those price goes up. And so those exacerbated prices make the problem worse for us personally.

But being able to access telehealth from home just gives us a component of being able to keep a consistent schedule, reduce cost, and really protect our son, because taking him out into public is dangerous until he has a higher immune system.

It has been huge to be able to get in quicker as well. Oftentimes, if we are scheduling an appointment, sometimes it is a month out, but telehealth, we can get in that week.

So it makes a significant difference in a number of ways for us to be able to access that.

Mrs. STEEL. Thank you.

And another concern here is, I am concerned that, under current Biden policies, seniors are seeing fewer Part D plans, increased premiums, and fewer drug options.

I also think this hearing must address the CCP manipulation on American companies. Economic diversification is an important tool to halt our current dependency on the CCP on our healthcare supply chain.

I introduced the Medical Supply Chain Resilience Act, which would allow USTR to establish trusted trade partners, diversify medical devices and pharmaceuticals. This framework can help eliminate barriers to trade, expand supplier networks, and allow for the investment in domestic manufacturing.

So I want to ask Mr. Watanabe and Mr. Cullimore: As the CEOs, can you share your perspectives on the greater issues of sole-sourcing products in China instead of in the United States or with trusted allies? And what does the future hold if we don't change that course?

Mr. WATANABE. So I guess I will start.

Yeah, this is a major issue, I think, that we need to address as a country. And I think it is even more acute than some of the issues that Dr. Wenstrup mentioned.

You know, for example, it is not just generic drugs that we rely on. In fact, most of the drugs that we take in this country are being manufactured with chemicals, starting chemicals, that are coming from China. China manufactures the majority of the starting chemicals. China has our entire biopharmaceutical industry by a stranglehold.

You know, I think one of the challenges has been that, as margins have been squeezed by pharma companies through IRA and through PBMs and through a whole variety of things, we are always looking for ways to reduce costs, and, unfortunately, China typically is the cheapest place to buy supplies, it is the cheapest place to run clinical studies, it is the cheapest place to manufacture your product. And so companies looking at their bottom lines are shifting overseas.

We, as a company, have chosen not rely on China for any purpose, one, because, as a former CIA and former Naval intelligence officer, I think we are in the middle of a cold war with China. But, secondly, you know, we saw in the pandemic, if we rely on overseas sources, particularly overseas sources from a country that is not terribly friendly to us, and something like the pandemic happens, we can't rely on those sources anymore. And it would be far worse if our two countries were to actually come into conflict.

So I fully support the BIOSECURE Act and the broader push by Congress to build resiliency in the U.S. biopharmaceutical sector.

Mrs. STEEL. You know what, my time is up, Mr. Chairman, so I—is it okay?

So, Mr. Cullimore.

Mr. CULLIMORE. Oh. Just briefly, the pandemic shined a bright light on this problem, and many companies have recognized that and are trying to disentangle as much as they can from those kinds of sources in their supply chain.

That said, it is very important, I think, that we be judicious in how we approach it. Because sometimes major tariffs or things of that nature can have an immediate effect on U.S. companies that is very negative.

And so I think, while the concept of bringing and reshoring is important, it needs to be done in a way that doesn't create short-term harm that is very significant.

Mrs. STEEL. Thank you, Mr. Chairman. I yield back.

Chairman SMITH. Thank you.

Mr. Feenstra.

Mr. FEENSTRA. Thank you, Chairman Smith, for having this today.

And I also want to give a special shout-out to my good friend, Representative Moore. Thank you for having this in your district. It is truly impressive, what you are doing here. It really is remarkable.

And I thank each one of you for your witness and testimony.

You think about where the U.S. stands. I mean, in the last couple years, last decade, we have for the most part been number one in the world in innovation when it comes to healthcare. And we are losing that. We are losing that grip on what we can do.

And it just seems like, through IRA, that we want to go back to that European-style government price control, the quick solution to try to bend this curve, which is a false narrative. And it really concerns me.

And, then, when we talk about supply chains, when we talk about the tax ramifications, our tariffs, our regulatory environment, there are so many things that are really pinch points to us just being innovative.

So my question is, we are all sitting here trying to figure out, what are the solutions?

And, Mr. Watanabe, I mean, if you look at the supply chain—and you talked about, obviously, China and things that are going on there—what would be the number-one thing that you could say to us, hey, this is the first thing you need to tackle? I mean, is it the amortization of R&D expensing, or what would you look at and say, this is the key?

Mr. WATANABE. I think probably the single most important thing that Congress can do to maintain our leadership in biopharmaceutical innovation is to address access and reimbursement issues in this country. Because if we don't fix the currently broken reimbursement system in this country, there isn't going to be any money for future innovations.

Mr. FEENSTRA. Boom. Thank you. Exactly. Reimbursement. I am glad you said that. And that hasn't been really talked about today.

Dr. Soares, you have also mentioned in your testimony that, because of the IRA, that a lot of cures are going to be gone. I mean, you talk about biologics, you talk about orphan drugs, all these

other things that are going to be on the sunset or go away because of what is happening.

Can you address that? And what is any type of solution? You know, do we have to roll back this? Or how do we fight against this?

Dr. SOARES. Yeah, there are treatments that will go away, and there are treatments that have already gone away and I have not been able to offer to my patients.

I think continuing federal funds and reforms to allow them to keep—that we can be able to incentivize the companies to still have them, that will be key.

It is very disheartening when we have treatments that are effective and, for reasons that are not in the physicians', in the healthcare control, we cannot offer to them.

I cannot speak necessarily of a given policy. That is not what I am expert on. But I can tell you for a fact that some of the treatments have been going away and I have not been able to offer to my patients with rare cancers.

Mr. FEENSTRA. Yeah.

I want to pivot, Dr. Soares. You and I are sort of kindred spirits on talking about rural healthcare——

Dr. SOARES. Yes.

Mr. FEENSTRA [continuing]. And the rural access points. I have done my research in maternal care. You have done it, obviously, in cancer areas.

Can you talk and give this group here solutions to the deserts that are out there in healthcare? I mean, what do you see—I mean, I have done my research and said, all right, this is X, Y, and Z. But for you, what do you see as the opportunity for us?

Dr. SOARES. Yes. Thank you for that question. That is actually one of my tasks, is to provide care and clinical trials to our patients. And then there are several steps.

A, obviously, access to telehealth is key. And then providers that have multi-license so they can even go outside of their states and provide the care.

Access to being able to get the labs done locally so I can monitor that for the patients, and I can also be coordinating.

Continued support of patient navigations that can be reimbursed and help with all of this navigation of rural care. Really, integration of the EMR systems, that it can talk, and AI can help with that.

And regulations that allow us to send the drugs to the rural patients. Because right now there is a lot of regulation that shipping outside even state lines or farther can be very complex and expensive.

Mr. FEENSTRA. Yes.

Dr. SOARES. We have multiple meetings at the Huntsman Cancer Institute to brainstorm how we are going to give and take and deliver cutting-edge therapies to other patients at their homes. I can monitor them, but there are regulations that are needed to be in place for me to be able to actually get, in an affordable way, the drugs to the patients in their homes.

Mr. FEENSTRA. Yep. Yep.

Dr. SOARES. And I will be forever thankful for help with that.

Mr. FEENSTRA. Yep. Thank you, Dr. Soares. Thank you for those comments. And I will be working on those issues and try to help in those areas.

Thank you very much. I yield back.

Chairman SMITH. Ms. Malliotakis.

Ms. MALLIOTAKIS. Thank you, Mr. Chairman.

I am pleased to be here in Salt Lake City for the first time. And I want to thank our witnesses for sharing their expertise and their personal experiences on the topic of healthcare innovation and access.

Under the Biden administration, we have seen significant barriers for Medicare beneficiaries' access to innovative technologies and bringing new drugs to the market. It can take up to 5 years after FDA approval for medical devices to get Medicare coverage. Innovative treatments see that same lag time.

Furthermore, the Democrats have made their intentions clear to oppose the pro-growth tax policies from the 2017 Trump tax cuts that have created a more competitive tax code, they have created millions of jobs, they have helped encourage and sustain innovation in the United States by giving businesses the tools to grow, conduct research and development, and reinvest back into their companies and employees and their communities.

But even more concerning is the implementation of the so-called Inflation Reduction Act and the harmful impacts the Medicare drug price negotiations program will have on premiums and the development of critical lifesaving drugs.

Mr. Chairman, I would like to submit for the record a study by Milliman titled, "Expected Impact of Inflation Reduction Act Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs."

Chairman SMITH. Without objection.

[The information follows:]

MILLIMAN REPORT

# Expected Impact of Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs

*Commissioned by Pharmaceutical Research and Manufacturers of America (PhRMA)*

June 24, 2024

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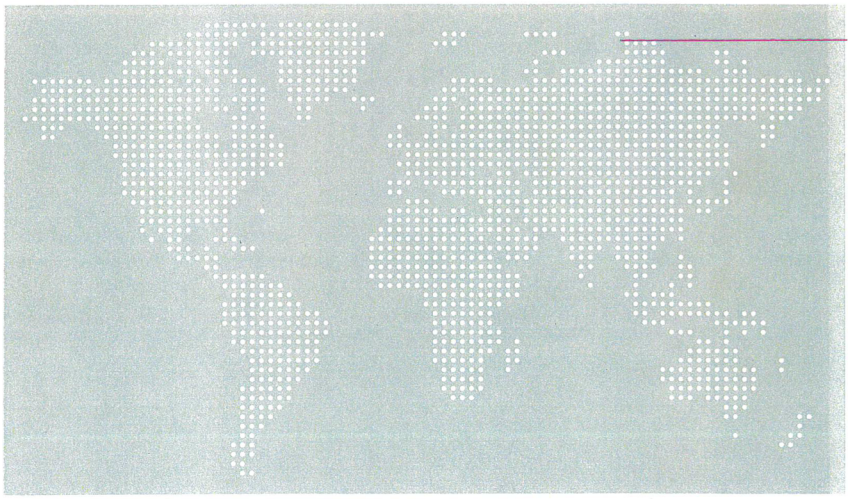

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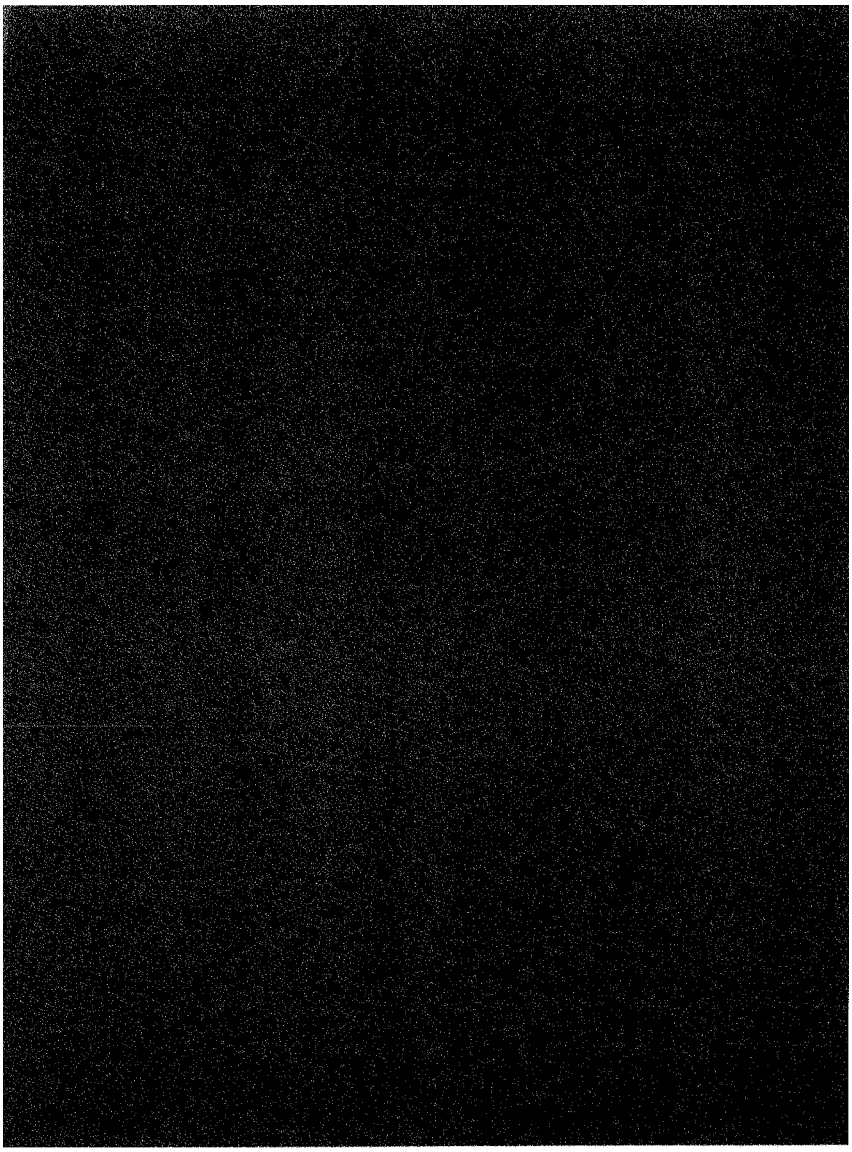

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# I. EXECUTIVE SUMMARY

Pharmaceutical Research and Manufacturers of America (PhRMA) engaged Milliman to analyze the impact of the Medicare Drug Price Negotiation Program (MDPNP) enacted by the Inflation Reduction Act of 2022 (IRA) on Medicare Part D beneficiary out-of-pocket (OOP) costs. The IRA introduces several significant changes to Medicare Part D including the MDPNP, a redesigned Part D benefit, inflationary rebate penalties for pharmaceutical manufacturers, Part D premium stabilization, cost sharing caps on insulins and vaccines, and many others. These changes impact Medicare Part D beneficiaries, pharmaceutical manufacturers, plan sponsors, and the federal government in different ways.

This report focuses on the expected impact on beneficiary OOP costs in 2026 directly attributable to the MDPNP, specifically modeling the incremental impact of the MDPNP after implementation of the 2025 Part D benefit redesign and other provisions that will be in place by 2026. The results in this report include two scenarios, a "baseline" scenario which represents expected 2026 OOP costs without the MDPNP and a "with MDPNP" scenario, which represents 2026 OOP costs with MFPs in place.

Based on the results of our analysis, we estimate the MDPNP will cause average annual beneficiary OOP costs to increase by $70, or 12%, for utilizers of MDPNP selected Part D drugs in 2026. Table 1 displays the results of our analysis in total and by income status (i.e., low-income subsidy (LI) beneficiaries and non-low-income (NLI) beneficiaries). The OOP costs shown in Table 1 represent total OOP costs, inclusive of cost sharing for drugs selected for the MDPNP and all other drugs utilized by these beneficiaries. These values do not include any premiums, medical costs, low-income cost sharing subsidies (LICS), or other reductions for cost sharing paid on behalf of the beneficiary through a supplemental benefit.

**Table 1**
**Impact of Medicare Drug Price Negotiation Program on Annual OOP Costs**
**Utilizers of MDPNP Selected Drugs by Income Status**

| Beneficiary Income Status | 2026 Baseline | 2026 with MDPNP | Impact (%) |
|---|---|---|---|
| NLI | $903 | $1,007 | 11% |
| LI | $43 | $54 | 27% |
| All | $598 | $668 | 12% |

The results in Table 1 are based on key assumptions including estimates of MFPs assigned to each 2026 MDPNP selected drug and benefit designs (i.e., deductibles, copays / coinsurances) of Part D plans in 2026. We modeled results assuming formulary coverage and representative benefits based on current 2024 benefits. However, results are sensitive to benefit designs assumed and benefits in place in 2026 may be different than what is in place in 2024. To sensitivity test the impact of leaner benefits, we replicated our analysis assuming all beneficiaries are enrolled in plans with a defined standard benefit, which includes a full deductible and 25% coinsurance on all tiers. In this scenario, LI beneficiaries experience similar increases in OOP costs, since they are subject to nominal copays, but NLI beneficiaries see OOP savings of 12% on average. Only 2% of NLI beneficiaries are enrolled in defined standard plans in 2024, so the representative benefit scenarios are more likely to reflect what NLI beneficiaries would actually experience. [1]

We assume the prices established by CMS under the MDPNP, called maximum fair prices (MFPs), are equal to our estimates of MFP ceiling prices for drugs selected for the MDPNP. Given the 2026 MFPs are unknown at this time, we are unable to predict actual prices and use this assumption for simplicity, but we expect the findings to directionally hold true at most other prices (provided MFPs are not lower than beneficiary copays). We also assume all 10 drugs selected by CMS for negotiation will be subject to MFPs in 2026.

Increases in OOP costs are driven by beneficiaries paying copays for MDPNP selected drugs. Effective in 2025, as part of the IRA, plan supplemental coverage will contribute to a beneficiary's maximum out-of-pocket (MOOP) limit. As such, lower prices established by the MDPNP will slow a beneficiary's progress toward MOOP, even though the beneficiary continues to pay the same fixed copay. This results in beneficiaries paying additional copays to reach MOOP, resulting in greater total OOP costs. While some beneficiaries paying coinsurance could experience reduced OOP costs, we expect more beneficiaries will experience OOP cost increases, which will outweigh any savings, on average, based on the benefit designs in place as of 2024.

[1] Based on CMS 2024 Part D landscape files: https://www.cms.gov/medicare/coverage/prescription-drug-coverage

- Approximately 3.5 million beneficiaries using MDPNP selected drugs are estimated to experience OOP increases attributable to the MDPNP. These beneficiaries are primarily those with copay benefits, which includes both LI and NLI beneficiaries.

- Approximately 2.2 million beneficiaries using MDPNP selected drugs are estimated to experience no change in OOP costs attributable to the MDPNP. These beneficiaries may have reached MOOP both before and after the MDPNP or may be enrolled in a plan with zero cost sharing.

- Approximately 1.2 million beneficiaries using MDPNP selected drugs are estimated to experience OOP savings attributable to the MDPNP. These beneficiaries are primarily NLI beneficiaries who did not reach MOOP before or after MDPNP implementation.

This report also analyzes the beneficiary OOP cost impacts by Part D plan type, race / ethnicity, aged / disabled status, and End Stage Renal Disease (ESRD) status. We expect average increases in OOP costs for beneficiaries taking an MDPNP selected drug in all three Part D plan types—Medicare Advantage Part D plans (MA-PD), stand-alone prescription drug plans (PDP), and Employer Group Waiver Plans (EGWP). Beneficiaries in EGWPs taking MDPNP selected drugs are expected to see a 29% annual average OOP cost increase, as compared to a 17% increase for those in MA-PDs and 3% for those in PDPs. We find that Black and Asian beneficiaries experience the largest increases in average OOP costs from the MDPNP, likely due to a disproportionate share of LI and MA-PD beneficiaries in these racial / ethnic groups, making these beneficiaries more frequently subject to fixed copays.

# II. BACKGROUND

## MEDICARE DRUG PRICE NEGOTIATION PROGRAM

The IRA[2] authorizes the Department of Health and Human Services (HHS), delegated to the Centers for Medicare and Medicaid Services (CMS), to determine drug prices for select qualifying single source drugs in Medicare Part B and D. Generally, drugs are selected based on their total gross Medicare spending in prescribed data periods. The maximum fair price (MFP) for each MDPNP selected drug cannot be above the MFP ceiling, prescribed by the IRA as the minimum of the applicable percentage of the non-Federal Average Manufacturer Price (non-FAMP) and, depending on whether the drug is covered under Part D or Part B, the plan-specific enrollment-weighted average price net of direct and indirect remuneration (DIR) or the average sales price (ASP), respectively. Once an MFP is finalized, the price will apply to all Medicare beneficiaries (subject to a 340B drug program nonduplication requirement) in the applicable year(s).

### Ten Part D Drugs Selected for Medicare Drug Price Negotiation Program in 2026

For initial price applicability year (IPAY) 2026, CMS announced selection of ten Part D drugs for the MDPNP on August 29, 2023,[3] with MFPs to be announced by September 1, 2024. The selected drugs for 2026 are the focus of this analysis and are displayed in Table 2 below. This table was originally published by CMS in the Medicare Drug Price Negotiation Program fact sheet.[4]

**Table 2**
**2026 Selected Drugs Total Part D Gross Covered Costs and Utilizers[5]**

| Drug Name | Commonly Treated Conditions | Total Part D Gross Covered Costs* (in $B) | Number of Medicare Utilizers* |
|---|---|---|---|
| Eliquis | Prevention and treatment of blood clots | $16.5 | 3,706,000 |
| Jardiance | Diabetes; Heart failure | $7.1 | 1,573,000 |
| Xarelto | Prevention and treatment of blood clots; Reduction of risk for patient with coronary or peripheral artery disease | $6.0 | 1,337,000 |
| Januvia | Diabetes | $4.1 | 869,000 |
| Farxiga | Diabetes; Heart failure; Chronic kidney disease | $3.3 | 799,000 |
| Entresto | Heart failure | $2.9 | 587,000 |
| Enbrel | Rheumatoid arthritis; Psoriasis; Psoriatic arthritis | $2.8 | 48,000 |
| Imbruvica | Blood cancers | $2.7 | 20,000 |
| Stelara | Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis | $2.6 | 22,000 |
| Fiasp / NovoLog | Diabetes | $2.6 | 777,000 |

** Data reported by CMS based on the data period of June 2022 through May 2023.*

Table 3 summarizes the most common Part D formulary tier placement and benefit type for each drug selected for the MDPNP, separately by Medicare Advantage and Part D (MA-PD) and standalone Prescription Drug Plan (PDP), based on the 2024 formulary and benefit information released by CMS. In general, tier 5 is virtually always a coinsurance between 25% and 33% and tier 3 can be a copay (up to $47) or a coinsurance (up to 25%), where the latter is common for many PDPs. The tier and benefit type shown in Table 3, below, are weighted by enrollment.

[2] Inflation Reduction Act of 2022: https://www.congress.gov/117/bills/hr5376/BILLS-117hr5376enr.pdf
[3] HHS Announcement: https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html
[4] CMS Fact Sheet https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf
[5] CMS Selected Drug Negotiation List Fact Sheet: https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf

**Table 3**
**2024 Most Common Part D Benefit Design for Drugs Selected for the MDPNP in 2026**

| | Most Common Tier / Benefit | |
|---|---|---|
| **Drug Name** | **MA-PD** | **PDP** |
| Eliquis<br>Jardiance<br>Xarelto<br>Januvia<br>Farxiga<br>Entresto | Tier 3 / copay | Tier 3 / coinsurance |
| Fiasp / NovoLog* | Tier 3 / copay | Tier 3 / copay |
| Enbrel<br>Imbruvica<br>Stelara | Tier 5 / coinsurance | Tier 5 / coinsurance |

* *Insulins are not subject to the same benefits as non-insulins on the same tier and member cost sharing is subject to a maximum copay of $35 / month.*

### MFP Ceiling Price Calculation

While the final MFP can be lower than the ceiling, the MFP ceiling generally is the maximum price allowable under the MDPNP per 30-day supply of a given drug. In our analysis of 2026 MDPNP selected drugs, we estimate the ceiling price for each drug using the methodology prescribed in the IRA. Given 2026 MFPs are unknown at this time, we are unable to predict final MFPs and use the MFP ceiling in our analysis for simplicity.

To estimate the MFP ceiling, we (1) determine the discount percentage set by statute based on the age of the drug; (2) apply the discount to the drug's estimated non-FAMP; and (3) compare the discounted non-FAMP to the drug's estimated net price. The ceiling price is defined as the lower of the discounted non-FAMP price and the net price (i.e., Part D plan-specific enrollment-weighted amount).[6] The elements of the ceiling price calculation are defined as:

- Non-Federal Average Manufacturer Price (non-FAMP): The average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers, but not taking into account any prices paid by the federal government. Non-FAMP does not reflect rebates paid by the manufacturer to third-party payers for most drugs.

- Length of Time Since FDA Approval and Minimum Discount: The minimum discount for a given selected drug off of non-FAMP aligns with the number of years since approval by the U.S. Food and Drug Administration (FDA) to the first day of the price applicability period. The IRA divides minimum discounts into three categories:

  - Short monopoly: Less than 12 years since FDA approval (25% discount off non-FAMP).
  - Extended monopoly:[7] 12 to 16 years since FDA approval (35% discount off non-FAMP).
  - Long monopoly: More than 16 years since FDA approval (60% discount off non-FAMP).

- Average Net Price: For a Part D drug, the plan-specific negotiated price net of all price concessions received by such plan or pharmacy benefit managers (PBMs) on behalf of such plan for the most recent year for which data is available. The net price is calculated for each plan, and then enrollment-weighted across all plans with non-zero claims for the given drug.

[6] Weathering the Reform Storm: https://www.milliman.com/-/media/milliman/pdfs/2022-articles/8-17-22_weathering-the-reform-storm.ashx
[7] Not applicable for drugs selected for 2026; extended monopoly discounts will take effect for selected drugs beginning in 2030.

# III. RESULTS

## PART D BENEFICIARY OOP COST IMPACTS

We reviewed the 2026 impact of the MDPNP on different cohorts of beneficiaries in this analysis, including:

- Income Status: NLI vs. LI
- Plan Type / Population: Individual MA-PD vs. Individual PDP vs. Employer Group Waiver Plan (EGWP)
- End-stage Renal Disease (ESRD) Status
- Race / Ethnicity
- Aged / Disabled Status

We chose a representative plan design underlying each plan type specific to large national carriers and for all other carriers as well, based on average 2024 Part D plan designs. Whether a plan has a coinsurance or copay benefit on the preferred brand tier is a key determining factor in the magnitude of total NLI patient OOP cost (see Appendix A for more details). There are a variety of benefit offerings in the Part D market, but many PDPs have coinsurance on the preferred brand tier whereas most MA-PDs have historically offered a copay on this tier in almost all cases. This differentiating factor between plan types is a key driver of the results presented in this report. As the IRA introduces new Part D financial dynamics for plans, we may see an increase in the number of Part D plans with coinsurance on brand tiers, though this analysis does not address potential changes in plan designs in future years. In addition to the representative plan designs based on 2024 plan offerings, we also modeled results under a defined standard benefit for comparison. Only 2% of NLI beneficiaries are enrolled in defined standard plans in 2024, so the representative benefit scenarios are more likely to reflect what NLI beneficiaries would actually experience. Results reflect the representative benefit designs except where specifically noted as defined standard.

The results in this report display two scenarios, a "baseline" scenario which represents 2026 OOP costs without the MDPNP and a "with MDPNP" scenario which represents 2026 OOP costs with MFPs (assumed equal to estimated ceilings) in place. We assume all ten selected drugs will have MFPs in place, though it is possible the MFP may not apply if CMS determines that a generic or biosimilar alternative is approved and marketed prior to August 1, 2024. Both scenarios reflect full implementation of the IRA's Part D benefit redesign.

### Patients With OOP Cost Increases

Beneficiaries with the following characteristics are likely to see OOP cost increases:

1. **Utilize a drug selected for the MDPNP:** Beneficiaries must take a drug selected for the MDPNP for their OOP costs to be affected.

2. **MDPNP selected drug is covered on a copay tier and not subject to a deductible:** All LI beneficiaries fall into this category as their cost sharing is exclusively nominal copays with no deductible (as shown in Table A-1). Additionally, NLI beneficiaries with copay benefits are likely to see cost increases as more copays are required to reach MOOP under the MDPNP than prior to its application.

### Patients With No OOP Cost Changes

Beneficiaries with the following characteristics are likely to see no change to their OOP costs.

1. **Not utilize a drug selected for the MDPNP:** Beneficiaries not taking any of the selected products will see no impact to OOP costs.

2. **MDPNP selected drug is not subject to cost sharing, or beneficiary reaches MOOP both before and after application of the MDPNP:** Some beneficiaries utilizing MDPNP selected drugs may see no change to their cost sharing if their drugs are covered on a tier that does not require beneficiary cost sharing. This instance is most common on D-SNPs participating in the Value Based Insurance Design (VBID) program.[8]

[8] LI beneficiaries pay the lesser of the nominal copay in Table 4, the actual benefit (e.g., if a $0 generic copay is the plan benefit, the LI beneficiary pays $0 at the POS), and the POS cost of the drug. In most cases, the LI beneficiary pays the nominal copays displayed in Table 4. Approximately 42% of LI beneficiaries are enrolled in dual-eligible special needs plans (D-SNPs) which can coordinate care between Medicare and Medicaid. A trend in recent years among D-SNP sponsors is to provide a benefit through the Value Based Insurance Design (VBID) program which completely waives LI patient pay, meaning the beneficiary pays $0 for all drugs. In 2024, approximately 82% of beneficiaries enrolled in D-SNPs have this benefit. Cost sharing for beneficiaries with this benefit is unaffected by the MDPNP as they pay $0 for all drugs, including those selected for the MDPNP. We adjust for this benefit by reducing the LI OOP cost to $0 for approximately 82% of D-SNP members in our analysis.

Additionally, beneficiaries who satisfy MOOP by paying the full $2,000 (as is typical for utilizers of specialty drugs) both before and after MDPNP will see no change to their cost sharing as their cost sharing continues to be capped at the same amount.

### Patients With OOP Cost Savings

Generally, to see OOP cost savings as a result of the MDPNP a beneficiary must have *all* of the following characteristics:

1. **Utilize a drug selected for the MDPNP:** Beneficiaries not taking any of the selected products will see no impact to OOP costs. These beneficiaries may have a change in premium, though premium impact was outside the scope of this analysis.

2. **Qualify as an NLI beneficiary:** LI beneficiaries will typically not benefit from MDPNP because they pay fixed nominal copays regardless of a drug's point of sale (POS) costs.

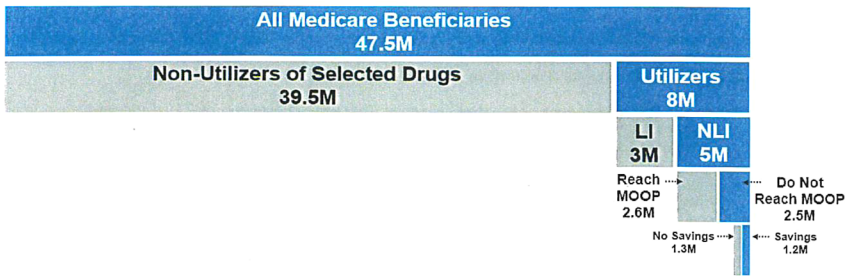
3. **Do not reach MOOP when MDPNP takes effect:** Beneficiaries with gross costs significantly above the MOOP are likely to still reach MOOP after the MDPNP goes into effect. Only those who no longer reach MOOP will have savings attributable to the MDPNP.

4. **MDPNP selected drug is covered on a coinsurance tier or subject to a deductible:** Beneficiaries with copay benefits will typically not see a reduction in OOP costs unless they are subject to a deductible **and** their costs are low enough that they do not reach MOOP. Beneficiaries with coinsurance benefits will generally see more significant savings than those with copays.

There are other less common cases where a beneficiary may see savings, such as cases where a beneficiary only takes one or two scripts of an MDPNP selected product or switches LI eligibility during the year.

Figure 1 below illustrates the estimated number of beneficiaries who satisfy each qualifier.

FIGURE 1: ESTIMATED NUMBER OF BENEFICIARIES BY COHORT




- We estimate approximately 3.5 million beneficiaries will experience cost increases attributable to the MDPNP. These beneficiaries are primarily those with copay benefits (from both income statuses).

- Approximately 2.2 million beneficiaries are estimated to experience no change in cost attributable to the MDPNP. These beneficiaries may have reached MOOP both before and after the MDPNP or be enrolled in a plan with zero cost sharing (such as D-SNPs participating in the VBID).

- Approximately 1.2 million beneficiaries are estimated to experience savings attributable to the MDPNP. These beneficiaries are primarily NLI beneficiaries who did not reach the MOOP before or after the MDPNP implementation. As described above, around 450,000 of these beneficiaries have coinsurance benefits and are expected to see more significant savings than those with copay benefits and a deductible.

## OOP COST IMPACTS BY INCOME STATUS

Table 4 displays the average OOP cost impacts by income status. Both NLI and LI beneficiaries see an increase in OOP costs, on average, due to the MDPNP when modeling with representative 2024 benefits.

The findings of this analysis are sensitive to the underlying benefits assumed. Table 4 displays results using representative plan designs by carrier. For contrast, Table 4 also shows OOP impacts by income status based on a defined standard benefit design where the plan design includes a full deductible and 25% coinsurance on all tiers in the initial coverage phase. Nominal copays for LI beneficiaries still apply under the defined standard benefit design, but we assume reductions in nominal copays from VBID do not apply.

**Table 4**
**Impact of the MDPNP on Annual OOP Costs**
**By Income Status and Benefit Design Scenario**

| | | Utilizers of MDPNP Selected Drugs | | | All Utilizers** | | |
|---|---|---|---|---|---|---|---|
| **Benefits Scenario** | **Income Status** | **2026 Baseline** | **2026 with MDPNP** | **Impact (%)** | **2026 Baseline** | **2026 with MDPNP** | **Impact (%)** |
| Representative | NLI | $903 | $1,007 | 11% | $432 | $445 | 3% |
| | LI | $43 | $54 | 27% | $39 | $41 | 5% |
| | **All** | **$598** | **$668** | **12%** | **$328** | **$337** | **3%** |
| Defined Standard* | NLI | $1,709 | $1,498 | -12% | $716 | $687 | -4% |
| | LI | $64 | $82 | 29% | $60 | $63 | 5% |
| | **All** | **$1,125** | **$995** | **-12%** | **$541** | **$521** | **-4%** |

** Defined Standard projection does not reflect the $0 cost sharing D-SNP benefit offered through VBID. Less than 2% of NLI beneficiaries are enrolled in plans with defined standard benefits in 2024.*
*** Utilizers of any Part D covered drugs.*

In both scenarios, LI beneficiaries will pay higher OOP costs after the MDPNP is in effect. NLI beneficiaries also experience an increase in OOP on average using 2024 representative plan designs, however, NLI beneficiaries consistently pay less in OOP costs when using a defined standard benefit design. Since only 2% of NLI beneficiaries are in plans with a defined standard benefit in 2024, the representative benefit scenarios more closely represent what NLI beneficiaries would actually experience.[9]

Seven of the ten MDPNP selected drugs are typically covered on copay tiers in 2024. Based on our analysis, NLI members with copay benefits for brand drugs will typically experience greater OOP costs once the MDPNP is in effect relative to the baseline. This result is driven by three key factors:

- **The POS drug cost does not change the copay.** The copay amount (e.g., $47 for a preferred brand product) is agnostic to the POS cost of the selected drug. This means the beneficiary is insulated from the POS cost of the drug and will pay $47 whether a drug costs $1,000 or $200, for example, in the initial coverage phase.

- **Plan supplemental coverage counts toward MOOP.** Beginning in 2025, beneficiaries progress through Part D benefit phases according to the "greater of" their plan cost sharing and the defined standard cost sharing. When a plan offers an enhanced benefit, the differential between defined standard cost sharing and the plan's actual cost sharing is called plan supplemental coverage, or non-covered plan paid (NPP). Under IRA, any positive NPP will accumulate toward MOOP (in addition to the patient pay), meaning the beneficiary will hit MOOP on the same script they would have under a defined standard benefit even if every claim had cost sharing less than defined standard (e.g., a lower copay). This dynamic translates into many beneficiaries paying less than $2,000 in actual OOP cost upon reaching MOOP beginning in 2025.

  Because the plan supplemental coverage amount scales up or down with the POS cost of the drug, when the POS cost of a selected drug is reduced in the MDPNP scenario, fewer dollars accumulate to the MOOP, and more scripts are required to satisfy the MOOP. Because the beneficiary requires a greater number of claims to hit MOOP before their OOP liability ceases, the beneficiary must pay more copays which increases their total OOP costs relative to the baseline scenario.

[9] Based on CMS 2024 Part D landscape files: https://www.cms.gov/medicare/coverage/prescription-drug-coverage

- **Many beneficiaries using MDPNP selected drugs will reach MOOP.** Even in cases where a beneficiary benefits from reduced OOP costs from a selected drug, they often do not see savings across all of the drugs they utilize. For example, consider a beneficiary who reached the $2,000 MOOP based on $1,500 in OOP cost from a selected product and $500 from other products. Once the MDPNP goes into effect, if the OOP cost for the selected drug dropped to $1,000, then this beneficiary may still reach MOOP based on their other drugs. This beneficiary would only see OOP savings from MDPNP if they have little enough spending on other drugs, such that they no longer reach the MOOP.

The drivers behind LI OOP cost increasing under the MDPNP scenario are very similar to the drivers affecting NLI beneficiaries described above.

- **LI beneficiaries always pay nominal copays prior to the MOOP.** Because LI beneficiaries only pay nominal copays, they are insulated from the POS drug cost, similar to NLI beneficiaries with copays, though this dynamic exists for **all** LI beneficiaries, even those enrolled in plans with coinsurance benefits.
- **LICS counts toward MOOP.** Similar to the dynamic described above with the plan supplemental coverage amounts being a function of the POS cost, LICS is also often a function of the POS cost. The LICS subsidy pays the difference between the plan cost sharing and the LI nominal copay. Many LI beneficiaries are enrolled in defined standard plans or basic plans with coinsurance on brand tiers which drives the LICS subsidy higher. In the MDPNP scenario, the reduction in POS cost of the selected drugs reduces LICS and therefore more claims are required to reach MOOP. This means the LI beneficiary will incur more claims prior to MOOP, and therefore, must pay more nominal copays, which increases their total OOP costs relative to the baseline scenario.

Three of the ten MDPNP selected drugs are most commonly covered on the specialty tier, which is virtually always a coinsurance benefit. Under a coinsurance benefit, NLI beneficiaries who do not reach MOOP would see savings in OOP costs due to lower POS costs resulting from the MDPNP. However, the vast majority of specialty utilizers reach the MOOP with or without the MDPNP and the impact of supplemental coverage accumulating to MOOP is minimized since virtually all plans offer a specialty coinsurance equal to or leaner than defined standard coverage. Therefore, these beneficiaries do not see any impact to OOP costs.

## OOP COST IMPACTS BY PLAN TYPE

Beneficiaries in all three plan types (MA-PD, PDP, and EGWP) experience increases in OOP costs on average, with EGWP beneficiaries experiencing the largest increase and PDP beneficiaries experiencing the smallest (as a percentage). This is because many PDPs have coinsurance benefits on Tier 3, the preferred brand tier, where many of the 2026 selected drugs are covered (in 2024).

Table 5 displays the average OOP cost impacts by plan type for both benefit scenarios. On average, beneficiaries would see a reduction in OOP costs under a defined standard benefit design, due to a significant portion of NLI beneficiaries underlying each plan type cohort.

**Table 5**
**Impact of the MDPNP on Annual OOP Costs**
**By Plan Type and Benefit Design Scenario**

| | | Utilizers of MDPNP Selected Drugs | | | All Utilizers | | |
|---|---|---|---|---|---|---|---|
| **Benefits Scenario** | **Plan Type** | **2026 Baseline** | **2026 with MDPNP** | **Impact (%)** | **2026 Baseline** | **2026 with MDPNP** | **Impact (%)** |
| Representative | MA-PD | $472 | $551 | 17% | $264 | $275 | 4% |
| | PDP | $743 | $764 | 3% | $385 | $387 | 1% |
| | EGWP | $570 | $735 | 29% | $362 | $388 | 7% |
| | **All** | $598 | $668 | 12% | $328 | $337 | 3% |
| Defined Standard* | MA-PD | $1,001 | $857 | -14% | $480 | $459 | -4% |
| | PDP | $1,132 | $987 | -13% | $517 | $494 | -4% |
| | EGWP | $1,418 | $1,357 | -4% | $781 | $771 | -1% |
| | **All** | **$1,125** | **$995** | **-12%** | **$541** | **$521** | **-4%** |

** Defined Standard projection does not reflect the $0 cost sharing D-SNP benefit.*

While the majority of EGWPs and individual MA-PD plans have copay benefits on the preferred brand tier, the individual PDP market has diverging benefits on this tier. Standalone PDPs are typically categorized into three archetypes: basic plans, low-premium enhanced plans, and high-premium enhanced plans, where benefits are a key differentiator among plans. Focusing on Tier 3:

- Basic PDPs virtually always offer a **coinsurance** benefit on Tier 3
- Low-premium enhanced PDPs typically offer a **coinsurance** benefit on Tier 3
- High-premium enhanced PDPs always almost offer a **copay** benefit on Tier 3

Figure 2 displays the percentage of NLI utilizers of MDPNP selected drugs who have copay or coinsurance benefits for selected drugs covered on Tier 3. Figure 2 excludes utilizers of MDPNP selected drugs exclusively covered on Tier 5 (the specialty tier), given the benefit is virtually always a coinsurance.

FIGURE 2: PERCENTAGE OF NON-LOW-INCOME UTILIZERS OF DRUGS SELECTED FOR MDPNP BY PLAN TYPE AND TIER 3 BENEFIT TYPE

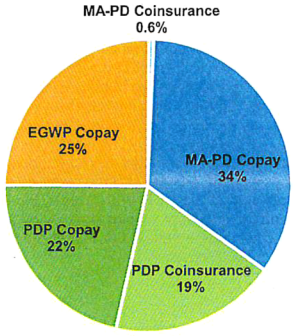
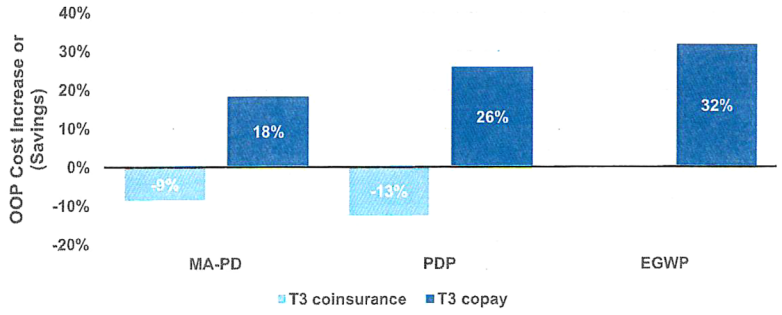



Figure 3 displays the average OOP cost impacts for NLI beneficiaries using MDPNP selected drugs, categorized by the type of Tier 3 benefit (limited to selected drugs covered on Tier 3) in the representative plan design, coinsurance or copay. Similar to Figure 2, above, Figure 3 excludes utilizers of MDPNP selected drugs exclusively covered on Tier 5 (the specialty tier), given the benefit is virtually always a coinsurance.

FIGURE 3: 2026 MDPNP IMPACTS BY PLAN TYPE AND TIER 3 BENEFIT TYPE: NON-LOW-INCOME UTILIZERS



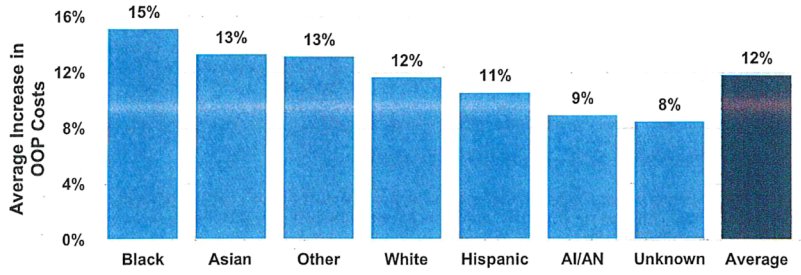
The results above show that OOP cost savings for Tier 3 drugs are only generated for NLI utilizers when the MDPNP selected product is subject to coinsurance, which is the case for 19% of utilizers. In 2024, the PDP market is split between coinsurance or copay Tier 3 benefits, but in aggregate the cost increases attributable to MDPNP selected drug utilizers with copay benefits slightly outweigh the savings generated from those with coinsurance benefits.

As discussed earlier, we assume MFPs are at the estimated ceiling price, but results are directionally similar at other prices. If actual MFPs are lower than the ceiling, beneficiaries with coinsurance benefits would experience greater savings than shown above, while beneficiaries with copay benefits would experience greater OOP increases than shown above, due to a greater number of scripts required to reach MOOP (provided MFPs are not lower than beneficiary copays).

## OOP COST IMPACTS BY RACE / ETHNICITY

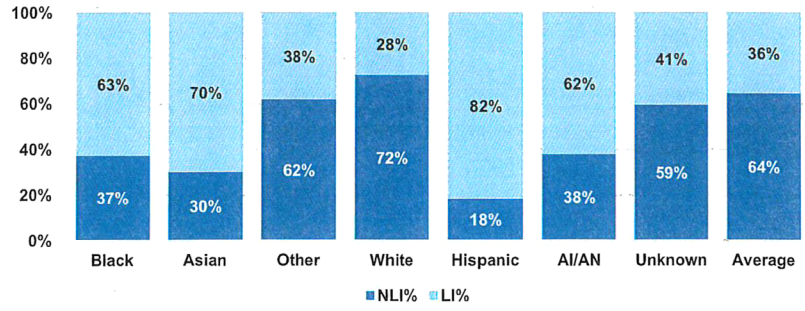
Figure 4 displays the OOP cost impact for MDPNP selected drug utilizers by race / ethnic group. In general, each group sees similar impacts as a percentage of baseline OOP costs, ranging from 8% to 15%. Black and Asian beneficiaries see the largest increases in OOP costs, on average, due to the MDPNP. Approximately 77% of MDPNP selected drug utilizers are white, which is similar to the full Part D population which is approximately 78% white.

FIGURE 4: 2026 MDPNP IMPACTS BY RACIAL / ETHNIC DEMOGRAPHIC GROUP[10]



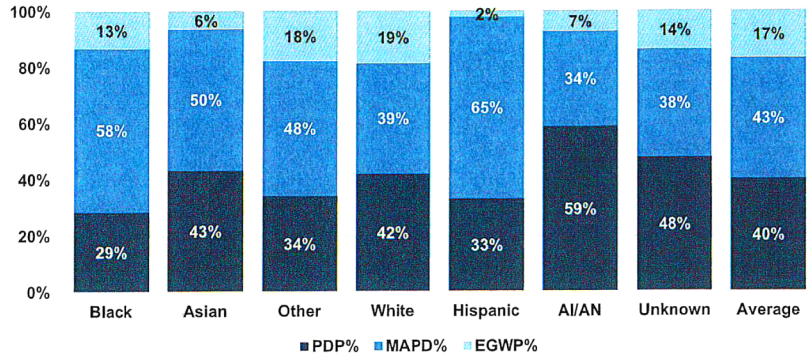

As discussed above, the OOP cost impacts for a particular racial / ethnic group tend to align with the plan benefit design characteristic for the MDPNP selected drug (e.g., copay or coinsurance) and income status. Figures 5A and 5B below show the mix of income status and plan type, respectively, by racial / ethnic group for selected drug utilizers.

FIGURE 5A: INCOME STATUS MAKEUP OF 2026 MDPNP SELECTED DRUG UTILIZERS BY RACE / ETHNICITY




[10] AI / AN refers to American Indian and Alaska Native in Figures 4, 5A, and 5B.

FIGURE 5B: PLAN TYPE MAKEUP OF 2026 MDPNP SELECTED DRUG UTILIZERS BY RACE / ETHNICITY




Among MDPNP selected drug utilizers, Black beneficiaries see the largest percentage increase in OOP costs, on average, due to 63% being LI and 58% enrolled in MA-PD plans, where copays predominate. The combination of these two dynamics leads to this group having the largest OOP cost increases from MDPNP. Asian beneficiaries have a similar pattern, with 70% being LI and 50% enrolled in MA-PD plans. We reviewed OOP cost impacts for each utilizer, plan type, and income status combination and did not observe significant variation by race / ethnicity.

## OOP COST IMPACTS BY OTHER DEMOGRAPHIC GROUPS

We also reviewed the impacts of the MDPNP in 2026 for two other demographic groupings: aged / disabled status and ESRD status. Table 6 shows the OOP cost impacts for aged vs. disabled, as well as ESRD vs. non-ESRD status Part D MDPNP selected drug utilizers.

**Table 6**
**Annual OOP Costs Before and After 2026 MDPNP**

| Part D Status | % of Utilizers of MDPNP Selected Drugs | 2026 Baseline | 2026 with MDPNP | % Impact |
|---|---|---|---|---|
| Aged | 87% | $653 | $730 | 12% |
| Disabled | 13% | $227 | $252 | 11% |
| ESRD | 2% | $373 | $403 | 8% |
| Non-ESRD | 98% | $601 | $672 | 12% |

Both aged and disabled beneficiaries see similar average OOP cost impacts as the overall MDPNP selected drug utilizer average, between 11% and 12%. MDPNP selected drug utilizers with ESRD see slightly lower impacts than those without ESRD, who closely mirror the overall average, likely due to beneficiaries with ESRD being more likely to hit MOOP due to their higher drug costs.

# IV. DATA, METHODOLOGY, AND ASSUMPTIONS

This section outlines the data and methodology underlying the results in this report.

## DATA SOURCE

We relied on the 2021 CMS 100% Research Identifiable Files (RIF) dataset, which includes claims for all Medicare Part D beneficiaries. This includes beneficiaries in standalone PDPs and MA-PD plans, but excludes PACE plan beneficiaries. Our analysis includes beneficiaries in both the individual and EGWP markets.

## CLAIMS PROJECTION AND OUT-OF-POCKET COST CALCULATION

We project claims forward to 2026 using utilization and unit cost trends and calibrated Part D gross costs to values from the 2023 Medicare Trustees Report. We developed a model to adjudicate claims under the 2025 Part D benefit design, using benefit designs derived from average 2024 benefits in the Part D market. For large, national organizations we used formularies and benefit designs based on the particular organization and plan type, whereas all other organizations use an illustrative benefit design based on the most common design by plan type. Because EGWP other health insurance (OHI) wrap benefit designs and formularies are not public, we use MA-PD benefit designs by organization / all other as a proxy. Additionally, because EGWP benefit designs are typically significantly richer than the average MA-PD plan, we reduce the MOOP limit to $1,500 to further reduce the OOP costs for the EGWP members in our analysis.

## MFP CEILING CALCULATION

We estimate MFP ceilings using methodology prescribed by CMS in the Medicare Drug Price Negotiation Revised Guidance.[11] We rely on historical gross costs by product and estimate direct and indirect remuneration (DIR) using data from SSR Health, adjusted to reflect estimated Medicare Part D rebates. We assume a relationship between non-FAMP and the wholesale acquisition cost (WAC) of 0.82, based on a 2021 Congressional Budget Office (CBO) report on federal program drug pricing.[12] We use the ceiling price for simplicity. We do not know actual prices at this time and our use of the ceiling price is not intended to be a signal of what actual prices may be.

[11] Medicare Drug Price Negotiation: Revised Guidance: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf
[12] A Comparison of Brand-Name Drug Prices Among Selected Federal Programs: https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf

# V. CAVEATS, LIMITATIONS, AND QUALIFICATIONS

This report was developed for the Pharmaceutical Research and Manufacturers of America (PhRMA) to understand the 2026 Medicare Part D out-of-pocket (OOP) cost impact of the Medicare Drug Price Negotiation Program (MDPNP) enacted by the Inflation Reduction Act of 2022 (IRA). This information may not be appropriate, and should not be used, for other purposes. We do not intend this information to benefit, and assume no duty or liability to, any third party that receives this work product. Any third-party recipient of this report that desires professional guidance should not rely upon Milliman's work product but should engage qualified professionals for advice appropriate to its specific needs. Any releases of this report to a third party should be in its entirety.

Milliman has developed certain models to estimate the values included in this report. The models are intended to project Part D costs and adjudicate benefits under different benefit designs to estimate 2026 Part D OOP costs. We have reviewed the models, including their inputs, calculations, and outputs for consistency, reasonableness, and appropriateness for the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOPs).

The models rely on data and information as input to the models. We relied upon certain data and publicly available information, for this purpose and accepted without audit, though we reviewed for reasonability. To the extent that the data and information provided is not accurate or is not complete, the values provided in this report may likewise be inaccurate or incomplete. Actual results will certainly vary due to differences in unit cost and utilization trend, 2026 benefit designs, and actual 2026 maximum fair prices (MFPs) determined by the Centers for Medicare and Medicaid Services (CMS).

Maddie Cline, Michelle Robb, and Katie Holcomb are actuaries for Milliman, members of the American Academy of Actuaries, and meet the qualification standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, the information in this report is complete and accurate and has been prepared in accordance with generally recognized actuarial principles and practices. This report outlines the analysis and opinions of the authors and not necessarily those of Milliman.

# APPENDIX A: MEDICARE PART D OOP COSTS

In Medicare Part D, beneficiaries pay a monthly member premium (which may be $0) and cost sharing at the point-of-sale (POS) for prescriptions. This analysis is exclusively focused on cost sharing and does not quantify the impacts of the MDPNP on member premium. Cost sharing, which is set by the Part D plan sponsor, varies by formulary tier.

## LOW-INCOME (LI) BENEFICIARY COST SHARING

LI beneficiaries receive "extra help" in Part D in the form of a waived deductible, cost sharing subsidies, and premium subsidies to curb OOP expenses. As such, LI beneficiaries' actual OOP cost sharing (i.e., patient pay) is limited to nominal copays, which vary based on their LI subsidy (LIS) "level" and by drug type. The 2025 LI beneficiary copays are displayed in Table A-1, below.

**Table A-1**
**2025 LI Part D Nominal Copays (Pre-MOOP)***

| | Full Dual Eligible Beneficiaries 100-150% FPL (LIS level 1) | Full Dual Eligible Beneficiaries >=100% FPL (LIS level 2) | Institutionalized Beneficiaries (LIS level 3) | Beneficiaries with Waived Cost Share via Part D VBID |
|---|---|---|---|---|
| **Generic Drug** | $4.90 | $1.60 | $0 | $0 |
| **Brand Drug** | $12.15 | $4.80 | $0 | $0 |

** 2025 CMS Advance Notice https://www.cms.gov/files/document/2025-advance-notice.pdf. LIS level 1 includes beneficiaries designated as level 4 prior to 2024.*

New in 2025, all beneficiaries have a $2,000 maximum out-of-pocket (MOOP) limit. LI beneficiaries are subject to the nominal copays in Table A-1 on each claim before satisfying the MOOP, which is reached via the combination of these nominal copays, LI cost sharing subsidies (paid by the government), and any supplemental drug coverage (paid by the plan).

## NON-LOW-INCOME (NLI) BENEFICIARY COST SHARING

NLI beneficiary cost sharing follows the plan design as determined by the Part D plan sponsor.

In 2024, a typical NLI member is enrolled in a Part D plan with copays on generic tiers, either a coinsurance or a copay on brand tiers, and a coinsurance on the specialty tier. One way in which standalone prescription drug plans (PDPs) have historically differed from Medicare Advantage Part D (MA-PD) plans is PDPs will typically offer a coinsurance on the non-preferred brand tier (up to 50%), whereas MA-PD plans will typically offer a copay (up to $100). Many PDPs also offer a coinsurance (up to 25%) on the preferred brand tier, whereas MA-PDs very rarely have a coinsurance on this tier and instead have a copay (up to $47). When a beneficiary is subject to a coinsurance on a brand tier, their OOP costs are typically much higher than if there was a copay in place.

## ILLUSTRATIVE PATIENT OOP COST JOURNEY

In the figures below, we provide examples of a patient taking a single MDPNP selected drug under different scenarios to illustrate the cost sharing dynamics we observed in the data. In all three examples, the beneficiary fills one script each month for a $750 brand drug with an MFP of $250 per script.

### LI Beneficiary

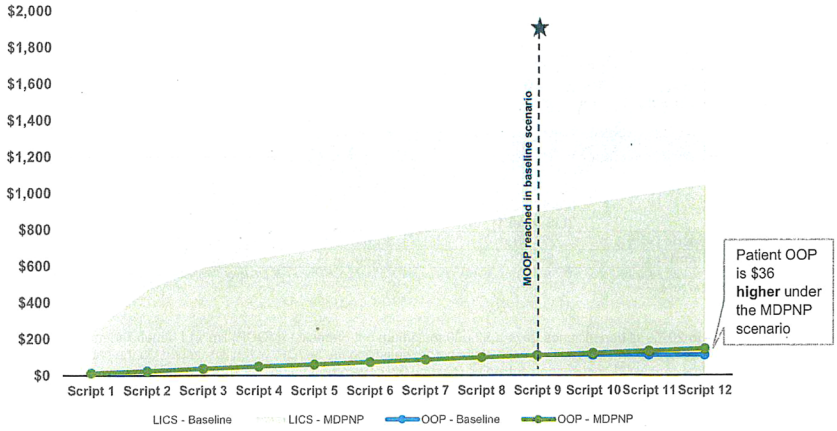
In Figure A-1, we show cost sharing by month for an LI beneficiary. Because the beneficiary is LI, they pay a fixed copay of $12.15 per script regardless of the plan they are enrolled in or what tier the drug is covered on. The plan receives a LICS payment to cover the difference between the plan's benefit design (defined standard[13] in this example) and the LI copay, which is shown as a shaded area.

- At the current cost of $750, the beneficiary pays no deductible, a fixed copay of $12.15 for the first nine months, and then stops paying by the 10th script once their combined OOP and LICS reach the MOOP. Therefore, their total OOP is $12.15 x 9 = $109.35.

[13] The 2025 defined standard benefit design is a $590 deductible, 25% coinsurance, and a $2,000 MOOP. More information on the standard benefit can be found at Weathering the reform storm: The Inflation Reduction Act's changes to Medicare and other healthcare markets (milliman.com)

- At the MFP of $250, the beneficiary still pays no deductible and a fixed copay of $12.15 per script. However, because the drug cost is much lower, the LICS payment is also lower and the beneficiary never reaches the MOOP. As a result, the beneficiary pays their copay for all 12 months, resulting in total OOP of $145.80 ($12.15 x 12) which is an *increase* of $36 over their OOP cost in the absence of the MDPNP.

FIGURE A-1: LOW-INCOME COST SHARING EXAMPLE



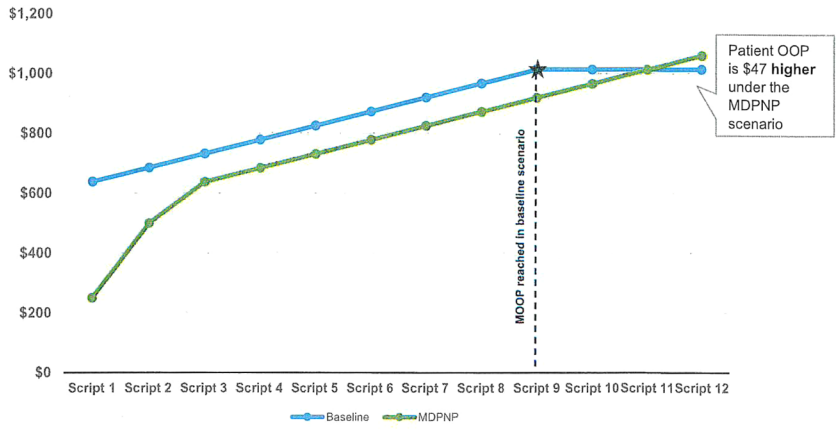

### NLI Beneficiary with Copay

In Figure A-2, we show cost sharing by month for an NLI beneficiary with the selected product covered on the preferred brand tier with a $47 copay. We also assume the beneficiary has a $590 deductible.

- At the current cost of $750, the beneficiary progresses through the deductible and their first copay in the first month and then pays their $47 copay for the next eight months, until they reach MOOP in month 9. This beneficiary reaches the MOOP at the same point as the LI beneficiary because all non-basic plan coverage (i.e., the difference between defined standard coverage and the $47 copay) accumulate to the MOOP under the IRA. Therefore, total paid OOP by the beneficiary is $590 + $47 x 9 = $1,013.

- At the MFP of $250, the beneficiary similarly pays the full deductible and then $47 per script. This beneficiary sees lower costs per script in the deductible phase, now needing three scripts to satisfy the deductible rather than just one. However, because the drug cost is lower, the beneficiary does not reach the MOOP, similar to the LI beneficiary example. As a result, the beneficiary continues paying their copay through the end of the year instead of stopping at month 9. This results in three additional copays and a higher total OOP cost compared to what they paid prior to the MDPNP. The lower per script cost in the deductible phase is offset by three additional copays, resulting in total OOP of $1,060 which is an *increase* of $47 (one copay) over their OOP cost in the absence of the MDPNP.

FIGURE A-2: NON-LOW-INCOME COST SHARING EXAMPLE – COPAY BENEFIT

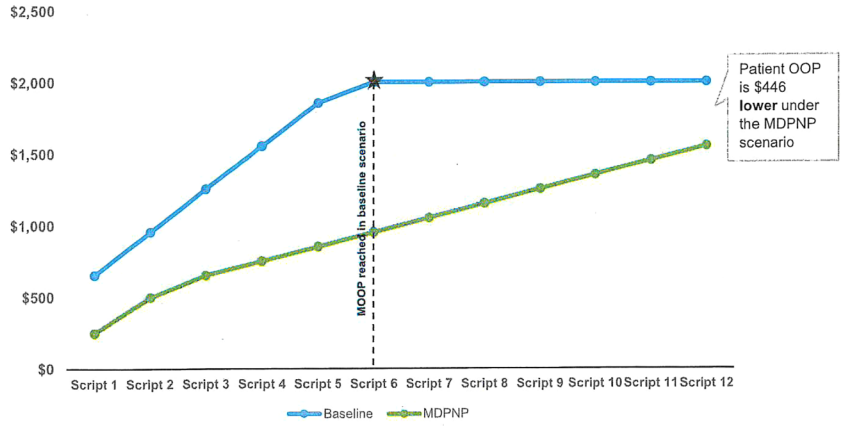



### NLI Beneficiary with Coinsurance

In Figure A-3, we show cost sharing by month for an NLI beneficiary with the selected product covered on the non-preferred brand tier with a 40% coinsurance. We also assume the beneficiary has a $590 deductible.

- At the current cost of $750, the beneficiary progresses through the deductible and then pays 40% coinsurance until they reach MOOP in month 6. Therefore, their total OOP is $2,000. Please note, in this example, the beneficiary pays the full $2,000 to reach MOOP since their cost sharing (40%) is greater than the defined standard benefit (25%).
- At the MFP of $250, the beneficiary similarly pays the full deductible and then 40% per script. However, because the drug cost is lower, the beneficiary does not reach the MOOP. Since this beneficiary has a coinsurance benefit, their OOP costs are reduced in line with the drug cost reduction. The beneficiary pays 40% of the lower drug cost. Therefore, their total OOP cost is $1,554, or $590 + ($250 x 12 - $590) x 40%, which is a *decrease* of $446 over their OOP cost in the absence of the MDPNP.

FIGURE A-3: NON-LOW-INCOME COST SHARING EXAMPLE – COINSURANCE BENEFIT



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Ms. MALLIOTAKIS. According to the study, the IRA's government price-setting scheme will cause Medicare beneficiaries' annual out-of-pocket costs to jump by $70, or 12 percent, for those who utilize these negotiated drugs under part D in 2026. Low-income beneficiaries' out-of-pocket costs will increase by a staggering 27 percent.

And on top of the rise in premiums, the Congressional Budget Office's conservative estimates say that 13 fewer drugs will come to the market over the next 30 years, with outside experts projecting the number will be around 135 new cures.

I will start with Mr. Watanabe.

Thank you for your mention of the impact that this will have on especially the orphan drugs. And I am also proud to be a co-sponsor of the ORPHAN Cures Act.

The President said recently that the Democrats, quote, "finally beat Medicare," unquote, and I am afraid that the data in Medicare Part D would agree.

My question is, do higher out-of-pocket costs lead to patients stopping treatment, perhaps, or maybe trying to ration their medication? What impact would this have as a whole?

Mr. WATANABE. Yeah, there is no question that increased patient co-pays has an impact on patients adhering to therapy or even fulfilling therapy.

I think it is well-known in the biopharmaceutical industry that anytime the patient is paying more than about $35 out of pocket, the rate at which the patient refuses to accept the medication at the pharmacy counter goes up.

And that is leaving aside, you know, conversations between a doctor and a patient when the doctor says, "Hey, I am going to prescribe this medication for you, but the co-pay is going to be X" and the patient walks away.

And this unfortunately is occurring both across commercial and Medicare plans, where there is constant increase in cost-shifting to the patients, which is unfortunately impacting the standard of care.

Ms. MALLIOTAKIS. And I see all your fellow witnesses nodding their heads that they are in agreement that this is a concern.

I want to also talk about manufacturing and R&D. I recently introduced the bipartisan Supply Chain Security and Growth Act, which will onshore critical supply chains in pharmaceuticals, in medical devices, and other manufacturing back to the United States by providing credits to companies who choose onshoring their manufacturing.

Mr. Cullimore, can you speak to the importance of these types of incentives as we work to onshore these particular drug productions and, in particular, reduce our reliance on foreign nations, Communist China, which we unfortunately rely on far too much for APIs and other pharmaceuticals?

Mr. CULLIMORE. Thank you for the question.

It is really important to understand that the reason people have gone to China and other places is because it is cheaper. Now, to bring them back, to reshore those kinds of processes, the investment of dollars to make that happen is significant.

We just met with a company that was looking at doing the chemicals, the APIs, as they call them, that they are doing overseas, bringing them here, acknowledging that it was going to be a significant investment.

A bill like you are proposing would provide incentives and a pathway for those kinds of reshoring activities to occur. Because the biggest problem is not just the lower costs; it is the investment that it requires to reshore and do all of those kinds of things. So you are right on track with that.

Ms. MALLIOTAKIS. Well, thank you very much. I appreciate that.

And, you know, we see shortages, about 250 different drug shortages, things like antibiotics and chemotherapies. We need to onshore this stuff. If COVID taught us anything, it is that we cannot rely on countries, particularly a communist country like China, for this.

And so we, as a committee, are working very closely to try to address this issue, and hopefully we will be able to do it in the near future.

Chairman SMITH. I would like to thank each and every one of our witnesses for your testimony, for answering our questions, for being here, and for your ideas.

I also want to thank each member of the committee. The members of this committee are spread in thousands of different directions, and for them to make it a priority to come up here to hear from real Americans of the issues that you are facing—I admire your hard work, and I appreciate the sacrifice that you have all made.

Please be advised that members have 2 weeks to submit written questions to be answered later in writing. Those questions and your answers will be made part of the formal hearing record.

# LOCAL SUBMISSIONS FOR THE RECORD

| | |
|---|---|
| **Date** | July 12, 2024 |
| **Name (Print)** | Pinar Bayrak-Toydemir |
| **Company** | University of Utah/ARUP Laboratories |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

I am part of the rare disease undiagnosed disease network nationwide. Not only are treatment options available to patients, specifically economic disparity group is a problem, but it is also important to make diagnosis available. I have seen many families have a very hard time getting proper diagnostic tests available for rare disorders. Some of these tests are very expensive and Medicare/ Medicaid does not cover those tests because of cost and rarity.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Cornelia Ulrich |
| **Company** | Chief Scientific Office, Huntsman Cancer Institute, University of Utah |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

The United States needs to remain at the forefront of medical innovation. The National Institutes of Health and National Cancer Institute are the powerhouses of biomedical research in the world. However, funding in post-inflation dollars has decreased over the last decade and many of the brightest minds leave academia, because of the challenges in obtaining research funding. NCI- designated cancer centers give rise to the next cures and reach communities near and far. We have enormous opportunities (e.g. with immunotherapy and AI) but funding constraints for the NIH and NCI are a severe handicap. The research engine needs the resources to maintain the US eminence in biomedical innovation and cancer cures.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Ken Charhut and Ryan Stanfield |
| **Company** | Foldax |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Innovation for medical therapies related to both pediatric patients and women's health issues needs to be a top prioiy in public policy and funding through organizations such as teh National Institutes of Health (NIH). There is a huge need for cardiac therapies for children, specifically replacement of heart valves. The same is true with the female population of child-bearing age (domestically and internationally). Heart valve therapies that are available to patients (currently) either have low durability – resulting in recurrent surgeries – or low quality of life – because patients are required to be on an anti-coagulation medication for life. There needs to be more funding for research & development of low-cost therapies, automated manufacturing and high reliability. Federal support is required to create and sustain heart care therapies.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Ronald Day |
| **Company** | University of Utah |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

I am a Pediatric Cardiologist. I care for children with pulmonary vascular disease. Children need better access to medical devices and medications. The FDA sponsored Pediatric Device Consortia provides an effective way to develop more devices for children. I received an award from the Southwest Pediatric Device consortium. Please continue supporting this FDA program.

Pediatric medications have a barrier with insurances. Children are not covered by insurers when the medications (approved for adults) are needed for children. A treat and monitor approach could be used when adequately large clinical trials cannot be performed in children. I am willing to discuss this idea further.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Charlene Edwards |
| **Company** | Cancer Patient at Huntsman Cancer Inst. |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

I did submit my story by email.

Briefly, I was diagnosed with carcinoid/neuro-endocrine cancer in 2006. I was initially told there was no treatment or cure.

While there is still no cure, there have been some new innovations that have helped me set my clock back during these last 18 years.

I am now involved in a second trial in an attempt to again set my clock back. I was also able to be among first in western US to use an innovation – a nuclear scan. It was the first new technology to help me set that clock back.

As a community of neuroendocrine patients we are often aware of new treatments on the horizon. We sometimes wait years for that treatment to come to the US in trial phase – and then more years to finally have it available. As patients we are always grateful for the hope that is given from new research + technology. Thank you for fighting for us.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Atim Atte Enyenihi, PHD |
| **Company** | Salt Lake City Department of Economic Development |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

1. Diversity in clinical trials is crucial for treatments to benefit everyone in the U.S.A.
2. Representation matters in all aspects of medical innovation from the bench to c-suites of healthcare companies. Let's make companies more inclusive
3. Healthcare providers need to be more coordinated. I had an eye emergency and went to urgent care who sent me to the emergency room. Turns out that I didn't need to be in the ER at all because no ophthalmologist is on site. I waited hours for a doctor from the eye center when I could have referred to the eye center in the first place. I am now left with a huge bill to pay.
4. There should be incentives for companies to innovate in rare/ genetic diseases area which has few patient populations. We must go beyond cancer and diseases with large patient populations.
5. Insurance companies should not dictate what care of treatment to be given to patients. Doctors and patients should do that.
6. Let's work to decrease health disparities in underserved minority populations and the economically disadvantaged.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Craig Mosmay |
| **Company** | Seek Labs |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

One of my concerns is with the language of the BioSecure Act. We are a company that has an opportunity to sell product into China, where our largest market is. We are concerned that opportunity will disappear. I think the Act should not restrict rfee trade with China.

We also think Congress should encourage test to treat. We have developed inexpensive, innovative testing and can help our healthcare system to be more cost effective and efficient.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Debbie Pitt |
| **Company** | bioMerieux |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

It is an honor to be present at this hearing focused on innovation and access to healthcare. One of the biggest threats we face globally is around anti-microbial resistance (AMR) due to inappropriate antibiotic usage. Many physicians outside the hospital do not have access to the appropriate diagnostic tools that identify whether an infection is due to a bacterial or viral infection, therefore they prescribe an antibiotic when the patient may not need it. Payors have limited coverage policies for tests that include pathogens over 5 targets. Testing for larger panels is needed to increase access to unserved patient populations closer to their homes to fight the threat of AMR.

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| **Date** | July 12, 2024 |
| **Name (Print)** | Andrew Roberston |
| **Company** | IONIQ SCIENCES |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Early cancer detection saves lives and money, per published clinical literature. As currently drafted, the proposed multicancer early detection bill narrowly defines allowable technology for reimbursement. This will severely limit innovation on cancer detection by the life science industry. As a result, American many not fully benefit from the unbridled entrepreneurial sprit and bold new ideas. Furthermore, the narrowly defined allowable technologies is an unintended consequence by Congress to limit competition and innovation. I urge you to remove this and allow the life science industry to do what it does best – innovate to save lives and money.

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| **Date** | July 12, 2024 |
| **Name (Print)** | David Sanders |
| **Company** | American Cancer Society |

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## Committee on Ways and Means
## Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Please see my attached statement. Thank you.:

Concerning health innovations

1. Healthcare is needed by all of us. It is a core element of our general Welfare. In our society we have state and federal governments with the same goal of keeping us as healthy as possible. There is no doubt that there have been advances in medical research science and technology. But the level of health literacy is about the same as it has been for decades which by some estimates is less than 35%. Health literacy is generally described as the ability to follow the doctors orders in the absence of the doctor. And such a condition of health-literacy-deficit drives the increase in health care costs and defeats attempts at developing a Health Intelligent Society
2. I would like to close my comments with a request and an example that is personal and yet applicable to everyone. I am a Cancer Survivor who is very fortunate to be alive today in spite of my own lack of health literacy. I currently volunteer with the American Cancer Society Cancer Action Network to help raise awareness and fight Cancer in our society. I am always driven by the story of Henrietta Lacks, the HeLa Cell Woman, whose cells are the backbone and currency of modern medical research including being used to come up with vaccines against COVID. I became aware of her during my Cancer episode at the age of 53 when I learned that her cell were used to create the treatment that saved my life. But I also learned that she was the reason I was able to get my polio shot at age 5 at Fleming elementary School that was just a mere 5 houses down the street from where she last lived before passing and the discovery of her immortal cell. Her contribution has been codified with bipartisan acceptance in the passing of the Henrietta Lacks Enhancing Cancer Research Act of 2019 and I am glad to say that "yes", I have close ties with her family in my efforts to fight Cancer.
3. From my example I hope it is clear that health literacy deficit in our nation can be expensive and deadly. It demands an all hands effort to make a Health Intelligent Society with the benefit of lowering health care costs long term from generation to generation, community to community, family to family. Please consider an innovative approach toward a National Health Intelligence Program and on behalf of the American Cancer Society, I ask this committee to support the following budget requests:

A) National Institute of Health: (Ask $51.3 billion)
B) National Cancer Institute: (Ask $7.934 billion)
C) Advanced Research Projects Agency for Health ARPA-H: (Ask $1.5 billion)
D) Centers for Disease Control and prevention/Division of Cancer Prevention and Control: (Ask $472.4 million)

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| **Date** | July 12, 2024 |
| **Name (Print)** | Kapil K. Sharma, MS. MBA. MSF |
| **Company** | Altitude Lab |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Hello, I am a biomedical engineer and health care entrepreneur, located in Salt Lake City, Utah. I help operate a premier lifescience startup incubator called Altitude Tech that is designed to lower the barrier of launching new health care innovation and startup companies in our mountain-west US region. As a young lifescience startup executive, I feel there is demand and need for more innovation-friendly procedures within the FDA. The FDA has a difficult job of ensuring reliability and efficacy for all medical innnovations and products in the US regulation; however, the agency's current medical device and pharma drug approval pathways are archaic and inadvertently stunt development of new innovations in the US. I feel there should be a set of new regulations or lifescience startup friendly regulations (seperate rom the traditional existing regs) that allow for easier approval process and faster development of normal innovations. Majority of novel medical innovations fail to exist due to the stringent, cost-bearing requirements that are more fit for larger organizations. Thank you!

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| **Date** | July 12, 2024 |
| **Name (Print)** | Lerenzo Smith |
| **Company** | University of Utah |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

I am a cancer researcher at the University of Utah studying a rare cancer of the adrenal gland called adrenocortical carcinoma. Studying a rare cancer in academia is a difficult task as government funding sources prioritize studies with larger impact (i.e. more prevalent in our population). Further, even for researchers that study more prevalent cancers, government (federal funding sources are dismal right now). We need to prioritize federal funding sources for academic labs, as these labs set and establish foundational knowledge for developing novel therapies for diseases. This means increasing the NIH budget! Moreover, we spend so much time and money developing therapies, yet patient access remains a big issue. It is my ask that you also consider policy that makes treatments (that I'm working to help establish) accessible to all Americans. Thank you!

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| **Date** | July 12, 2024 |
| **Name (Print)** | Chad Testa |
| **Company** | Curza, Inc. |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Antibiotics come likely from small companies over recent history, yet funding is sparse. The PASTEUR Act would provide a route for companies to succeed in a market where the products are encouraged to not be used for resistance concerns. This has caused many companies to go bankrupt. If there is a pandemic caused by resistant bacteria, it will make COVID look small. Both chambers of Congress have voiced concern over the lack of attention being paid to bacterial biothreats.

*on Ways and Means website at: https://waysandmeans.house.gov/*

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| **Date** | July 12, 2024 |
| **Name (Print)** | Neli Ulrich |
| **Company** | Huntsman Cancer Institute, University of Utah |

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**Committee on Ways and Means**
**Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

AI offers a new opportunity for a revolution in health care access and providing care to rural populations. We have to overcome distance as a disparity in cancer screening and care. Decentralized trials, AI in monitoring remote symptoms and ways to provide cancer care over a distance through technology/ AI is where we can make a big difference. Huntsman Cancer Institute is happy to serve as a resource of discussion on AI/ healthcare and overcoming distance as disparity.

*on Ways and Means website at: https://waysandmeans.house.gov/*

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| **Date** | July 12, 2024 |
| **Name (Print)** | Robert Wynalisk |
| **Company** | Discgencics, Inc. SLC |

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## Committee on Ways and Means
## Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity

We want to hear your story. Below please provide any personal experiences or general comments about access to health care in America and unleashing medical innovation and economic prosperity that you wish to be included in the official hearing record.

Dear Ways and Means House Committee,

I am COO and Board Director for DiscGenics, a late-clinical stage "privately-funded" startup. Our product is a cell (drug/biologic) regenerative therapy to treat patients suffering from mild-moderate, chronic low back pain. This represents 16M patients in US annually and 2nd largest indication of opioid use. Our therapy has shown compelling safety and efficacy in phase I/II trials. As a 351 drug/biologic, we are challenged to navigate through the FDA (OTST/CBER Branch) through each phase of our journey, from prior pre-clinical, to early clinical, to our current late-clinical phase. We are now allowed to start final preparations for a final phase III pivotal and confirmatory clinical trial. The process of review and obtaining consensus with the FDA took nearly 16 months of multi-interactions with the agency, many without obtaining timely updates. This has limited our ability to fund raise to support foreword operations of the company and to onboard investors required to fund the phase III program. We now look to bring back to executive funding report committee clinical manufacturing to initiate the trials and to support company through next 3-4 years to complete study and go through study date and BLA (biological license) allowable for commercialization. Our polite request is to improve the administrative operations and efficiency of the FDA (OTST/CBER) branch, that would allow for a more effective review of our program in future interactions. Up to and including our phase III study results and for successive BLA reviews.

# PUBLIC SUBMISSIONS FOR THE RECORD

ConnectedHealthInitiative

July 26, 2024

The Honorable Jason Smith
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, District of Columbia 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
Washington, District of Columbia 20515

**RE: Statement for the Record of Brian Scarpelli, executive director of the Connected Health Initiative, on the hearing *Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity***

Dear Chairman Smith and Ranking Member Neal:

Thank you for holding this hearing on modernizing healthcare in America through medical innovation. Digital medicine is foundational to enhancing access to care through innovative methods. Digital tools can connect health practitioners to more patients, empower those patients to better understand their health, and help physicians more effectively diagnose and treat conditions. Digital health and telemedicine modalities are now well-demonstrated to enable efficacious and cost-effective healthcare delivery. I urge you to expand flexibilities and otherwise enable digital health innovations to give patients the care they need.

The Connected Health Initiative (CHI) is a coalition of healthcare stakeholders from across the value chain, including patients, physicians and other types of providers, research universities, and software and device companies. We advocate for policies that enable all patients, and their providers, to harness the power of technology to spur patient engagement, improve health outcomes, and control costs.

**Flexibilities for Digital Healthcare Tools and Services**

During the COVID-19 public health emergency (PHE), the Department of Health and Human Services (HHS), under its emergency authority, provided much-needed flexibilities for providers and patients in several key areas to facilitate efficient and efficacious care. Patients could take telehealth appointments from their homes, reach their doctors more easily online, and take up innovative remote monitoring tools and services with far fewer hurdles (including no copay). From the perspective of physicians and other providers, numerous outdated restrictions on digital health capabilities were set aside, such as the Centers for Medicare & Medicaid Services (CMS) suspending geographic and originating site restrictions for telehealth visits. For physicians, other providers, and patients, the experience of the PHE illustrated the untapped potential of

digital health tools to improve outcomes and save costs across a range of use cases, and highlighted how legacy restrictions in statute and regulation are diminishing that potential without benefit to the public. Despite increased utilization in response to demand, a recent study has shown that there was not any correlated trends of fraud or overuse.[1] Based on the experience during the PHE, we call on Congress and HHS to take the steps needed to fully enable these digital health tools to advance the Quadruple Aim in health care of enhancing patient experience, improving population health, reducing costs, and improving professional satisfaction for physicians and other providers.

Congress has already taken important steps in response to the country's COVID-19 PHE experience that can and should be built on. Thanks to this Committee's work and both chambers prioritizing the issue, restrictions over a quarter of a century old in Section 1834(m) of the Social Security Act, which blocked Medicare coverage of live audio and video visits except in rather narrow circumstances and disallowed access to those services from a patient's home (and which were suspended during the PHE), have been temporarily lifted through the end of 2024. We have long supported the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act (H.R. 4189) as well as the Telehealth Modernization Act (H.R. 7623). CHI also supported H.R. 8261, the Preserving Telehealth, Hospital, and Ambulance Access Act, bipartisan legislation focused on telehealth that passed out of the Ways and Means Committee unanimously in May 2024. Each bill would unlock Medicare coverage for live audio / video visits, including visits conducted at the home of patients, with the most recent version of H.R. 4189 making those changes permanent and the most recent versions of H.R. 7623 and H.R. 8621 extending those changes to the end of 2026.

Virtual care is now mainstream. People in rural and underserved areas benefit most from being able to visit with their caregivers virtually, and they are a major reason why Section 1834(m)'s restrictions must be permanently eliminated. Similarly, the PHE flexibilities allowed for coverage of audio-only telehealth services, recognizing that a video component requirement unnecessarily impedes access to care for individuals without reliable internet access and disproportionately harms rural and underserved populations. Flexibility for audio-only telehealth services was extended to the end of this calendar year, but we encourage its permanent extension.

**Remote Physiologic and Therapeutic Monitoring**

Asynchronous remote monitoring tools and services allow great flexibility for patients to access their care. One member of CHI, Avenue Health, demonstrates the potential of

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[1] Department of Health and Human Servies Office of Inspector General, "Medicare Generally Paid for Evaluation and Management Services Provided via Telehealth During the First 9 Months of the COVID-19 Public Health Emergency That Met Medicare Requirements." https://oig.hhs.gov/oas/reports/region1/12100501.pdf

remote monitoring every day. Nurses employed by Avenue Health remotely monitor patients with conditions like hypertension, and patients can call these nurses when they are feeling poorly. Access to remote monitoring and instruction from these nurses reduces emergency visits by patients, saving the health system money. This care at home—or wherever a patient experiences an issue—is a key means of care for rural communities in particular. Many more patients could benefit from this type of monitoring for a variety of chronic and acute conditions.

We applaud the positive steps taken by CMS to support the use of remote monitoring tools and services, such as allowing remote monitoring at Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs) in last year's Medicare Physician Fee Schedule (PFS), which has provided overdue support for the use of remote monitoring tools by frontline providers serving America's most vulnerable populations. However, several barriers impede the wider adoption of remote monitoring innovations already shown to improve outcomes, reduce costs, and augment providers' experience. For example, remote monitoring services are subject to the 20 percent copay required for Medicare coverage. Too many Medicare beneficiaries are unable to afford a monthly bill for remote monitoring, even if it may greatly benefit their health. Notably, during the PHE, HHS waived this requirement and others; responsibly expanding patient access in this way leads to better management of chronic conditions, ultimately saving money in Medicare expenditures. Over three years of digital health usage during the PHE showed that, without legacy restrictions that have little or no public benefit, it is being used responsibly and appropriately.

The copay requirement is one of many outdated restrictions still in place that no longer has a connection to the public benefit. Eliminating arbitrary barriers like this would help more providers see the benefit of remote monitoring and increase innovation. CHI members already work to innovate in the healthcare sector, but bureaucratic barriers stop them from reaching their full potential.

**Appropriately Categorizing Software-as-a-Medical Device (SaMD)**

CMS must advance Medicare coverage and payment policy changes that appropriately categorize artificial intelligence (AI) through steps like recognizing that AI software as a medical device is appropriately categorized and paid for as a direct practice expense and
responsibly expanding support for AI's use in the prevention and treatment of beneficiaries' acute and chronic conditions. From CHI's perspective, many new innovations are supporting safe and efficacious treatments for patients suffering from a wide range of health conditions, and should be accessible to all Medicare beneficiaries. In light of this, we have urged CMS to clearly acknowledge that it is incorrect to categorize all software, particularly SaMD, as general "Computer Software" with an indirect PE that is non-allocable. We have also called on CMS to propose steps for

collaboration with our community to find ways to leverage opportunities and overcome challenges related to Medicare coverage and payment policies for innovative technologies.

Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute. For instance, CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories and if so, which category. Congress, and the Ways and Means Committee, should encourage CMS to use their existing authority to properly evaluate these innovations.

**The WEAR IT Act**

To further the adoption of digital medicine and improve rural healthcare, CHI supports H.R. 6279, the Wearable Equipment Adoption, Reinforcement, and Investment in Technology (WEAR IT) Act, led by Congresswoman Michelle Steel (R-CA). The WEAR IT Act would allow individuals to access certain wearable health technology through their tax-advantaged flexible spending accounts (FSAs) and health savings accounts (HSAs). Currently the Internal Revenue Service (IRS) allows HSA and FSA funds to be spent primarily on single-purpose devices. In a recent development, the IRS now considers the Oura Ring and the Aura Pulse Comprehensive Health Tracker eligible for FSA and HSA expenditures, two exceptions to the IRS's general rule against such devices. Many cutting-edge wearable health devices have multiple functions such as catastrophic fall detection, heart rate monitoring, and/or blood oxygen measuring. Although these devices outperform covered legacy technology in many cases, they are generally not covered (with the exceptions described above) because of the IRS's historical interpretation of the law, which is outdated. The IRS has recently begun to modernize its approach to HSA and FSA eligibility, but only in unpredictably narrow cases. If Congress enacts the WEAR IT Act, patients, consumers, physicians and other providers will benefit from greater certainty that such devices will be covered by FSAs and HSAs. In turn, healthcare stakeholders will have more choice and additional ways to improve outcomes and control costs. Moreover, the use of wearable health technology in rural and underserved settings will help patients and providers by collecting more detailed information that can improve treatment, especially for chronic conditions. This could be life-changing for patients who live far from their doctors.

**Preventing Overuse and Fraud Using Digital Health Tools**

Digital medicine and telehealth services are a clear value add to the provision of healthcare services, especially in rural areas. Studies have consistently demonstrated that telehealth services are not more susceptible to fraud than in-person healthcare, and that including telehealth services does not lead to over-utilization. According to the Alliance for Connected Care, telehealth usage in Medicare currently accounts for about 5 percent of services, a number which has remained steady since the start of the PHE.[2] Even with the addition of telehealth usage, the overall usage of Medicare services has not increased significantly. Generally digitizing the healthcare system makes utilization and other fraud-related trends easier to track and respond to since automated tools are bing used. And ultimately, restricting telehealth services due to fears of over-utilization will just mean that rural areas continue to lack access to key healthcare supports.

CHI understands that addressing waste, fraud, and abuse is a key goal for the Committee as you look at Medicare spending. We agree that tackling these issues will help bring down the overall costs of healthcare spending, but we stress that telehealth has proven no more prone to fraud than other healthcare modalities. It is important to distinguish between telehealth fraud, the perpetration of healthcare fraud using telehealth modalities, and "telefraud," the use of telemarketing to defraud consumers, including healthcare consumers. This second type of fraud is better addressed through existing authorities at the Federal Trade Commission (FTC). This February, the HHS Office of the Inspector General (OIG) released a report examining the incidence of telehealth fraud in Medicare and found that the telehealth services provided to Medicare beneficiaries did not show signs of fraud.[3] We urge the Committee to recognize that digital health tools are an asset to preventing fraud and overuse.

**Conclusion**

Addressing issues in medical innovation is vital to ensuring a system that benefits all patients. Digital health technology, including wearable and remote monitoring technology, can make a huge difference for individuals and patient groups as a whole. CHI urges the adoption of policies that allow for flexibility to innovate and provide the care that patients need.

Sincerely,

Brian Scarpelli

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[2] Alliance for Connected Care, "Medicare Telehealth Analysis." https://connectwithcare.org/medicare-telehealth-analysis/

[3] Department of Health and Human Servies Office of Inspector General, "Medicare Generally Paid for Evaluation and Management Services Provided via Telehealth During the First 9 Months of the COVID-19 Public Health Emergency That Met Medicare Requirements." https://oig.hhs.gov/oas/reports/region1/12100501.pdf

Executive Director
Connected Health Initiative

CHG Healthcare

July 26, 2025

Committee on Ways and Means
United States House of Representatives
Washington, D.C. 20515

**Re: Salt Lake City Field Hearing: Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity**

Dear Chairman Smith, Ranking Member Neal, and members of the House Committee on Ways and Means:

CHG Healthcare applauds the Committee on Ways and Means (the "Committee") for conducting its recent field hearing in Salt Lake City, Utah. The hearing's topic on access to healthcare in America perfectly aligns with CHG's core business objectives of ensuring that patients maintain access to healthcare providers and ensuring that healthcare providers maintain the flexibility to temporarily see patients where they work and live. In the spirit of the hearing, we urge the Committee to add H.R. 5208, *The Health Care Provider Shortage Minimization Act*, to a future hearing or markup, and eventually advance the bill to the House floor with a favorable recommendation.

CHG Healthcare is headquartered in Salt Lake City, Utah and is one of the largest temporary healthcare staffing companies in the country. We help fill staffing gaps in hospitals, clinics, and healthcare systems to ensure uninterrupted patient care. Our more than 4,000 employees are spread across the country and we place healthcare providers in every state. In 2023, we placed over 10,000 physicians who served an estimated 15 million patients. Many of these patients would not have received care but for our services.

Most of the healthcare providers we place are locum tenens physicians. "Locum tenens" is a Latin phrase meaning "place holding". A locum tenens physician is someone who steps in when a permanent physician is unavailable because of illness, vacation, job transfer, or family leave - among other reasons. Without locum tenens physicians, the healthcare system would be riddled with gaps and vacancies and patient care would be materially disrupted. Physicians do locum tenens work to supplement their income; have more flexibility and control over when, where, and how they want to work; and to temporarily work during short-term life transitions. Locum tenens physicians practice in hospitals, outpatient centers, government and military facilities including the VA and Indian Health Services, and in rural community health centers. Importantly, rural communities are particularly reliant upon locum tenens physicians. By bringing in locum tenens physicians, rural facilities are able to maintain continuous operations, thereby improving healthcare access and outcomes in communities that might otherwise face significant challenges in recruiting and retaining full-time physicians.

Locum tenens physicians have been classified as 1099 independent contractors for more than 40 years. CHG Healthcare operates under a "safe harbor" rule pursuant to Section 530 of the Revenue Act of 1978 (the "Revenue Act") to classify locum tenens physicians as independent contractors. In addition to the safe harbor rule, the Revenue Act specifically exempts certain professions from being treated as employees, such as real estate agents and direct sellers. However, the Revenue Act does not exempt locums tenens physicians. Maintaining and codifying the status quo of locum tenens physicians working temporarily as 1099 independent contractors will ensure that patients maintain access to medical care and promotes the flexibility necessary for a locum tenens physician to do locum tenens work.

Over the past few years, with the emergence of the gig economy, many federal and state legislatures have sought to classify more workers as employees rather than independent contractors. Locum tenens physicians don't need or want to be employees of staffing agencies. Most locum tenens physicians are already employees of the hospitals and healthcare systems where they permanently work. Some are contractually prohibited from working as an employee for anyone else. Requiring them to be employees of temporary healthcare staffing agencies would therefore impede their flexibility to practice. Further, if locum tenens physicians lose their independent contractor status, many will stop the practice due to the administrative complexity of multiple employers and existing employment.

In 2005, California codified the critical function of locum tenens physicians and surgeons by exempting them from being an employee of a staffing agency (Cal. Bus. & Prof. Code § 2418). In 2019, California further confirmed there would be no presumption that California's ABC test would apply to a locum tenens physician (AB 5). Unfortunately, AB 5 did not exclude other advanced healthcare practitioners, which caused some staffing agencies to stop placing healthcare providers in California. Other states have proposed similar legislation, creating confusion and contradictions, justifying a federal preemptive exemption. The Health Care Provider Shortage Minimization Act, H.R. 5208, codifies the status quo of locum tenens working temporarily as 1099 independent contractors.

The Association of American Medical Colleges (AAMC) estimates that the U.S. will face a shortage of up to 139,000 physicians by 2033. We need to make sure physicians have the ability to go to where healthcare services are needed. Efforts to classify locum tenens physicians as "employees" will have severe unintended consequences and could subject the overall healthcare system to significant additional friction.

Highlighting H.R. 5208 in Committee will add a focus on the value locums tenens provide, filling gaps in our healthcare system - especially in rural areas - that otherwise are at risk of becoming "physician deserts." Maintaining independent contractor status for locum tenens is critical to our healthcare system. The legislation has no score, and would ensure that future, sweeping labor legislation does not inadvertently impede the provision of healthcare.

Thank you for your consideration. If you have questions or concerns, please feel free to contact the undersigned at your convenience.

Sincerely,

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United States House Ways and Means Committee
Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity Child Welfare
Response Submitted by: Community Hospital, 2351 G Road, Grand Junction, Colorado 81505
July 25, 2024

Community Hospital is an acute-care hospital located in Western Colorado, licensed for 60 beds. We are an independently owned hospital that serves the largest metropolitan area between Denver, Colorado, and Salt Lake City, Utah. Though our county is considered metropolitan based on population, we primarily serve patients from rural and frontier counties. Community Hospital has been in business and a part of our community since the 1950s. We pride ourselves in being a part of our community and being able to give back and meet the needs of our community in unique ways. Independent hospitals are pivotal in keeping competition in healthcare, creating access, and ensuring affordability.

Mesa County, Colorado was one of the top ten most expensive places in the nation for hospital stays due to monopolies and a large hospital system controlling the market. The study, which looked at Mesa County specifically, found the prices in monopoly markets are, on average, 15.3% higher.[1]

We have been able to address community needs, through partnerships and innovation, including adding multiple primary care providers and specialists, adding clinics in areas that have been healthcare deserts for the last 50 years, and building an on-site childcare center. We were able to build these last two with the help of Congressionally Directed Funds from Senators Bennet and Hickenlooper.[2] This is an amazing example of how federal solutions can help support the needs of communities. Further, we have been able to partner with our rural and frontier neighboring hospitals by sending providers to their communities to provide surgeries, standing up operating rooms in their facilities, and helping with workflow processes and implementation of programs.

Because we are independent, we are able to nimbly move to address needs in our community. We have a board of directors who live in our community; they are bankers, lawyers, business owners, and physicians who live where the hospital they serve is located. This allows them to make decisions where they live to positively impact the lives of their friends and neighbors.

Providing safe and quality care for our friends, families, and neighbors is the most important part of our jobs. Through innovations, creativity of staff, and a supportive board, our hospital has grown and continues to create value in our communities. We have added multiple primary care doctors to our area, clinics, and service lines which has created meaningful competition. 15 years ago, Community Hospital had a market share of 5%, with a large system hospital with a Sole Community Provider status dominating our market. Today, our market share is approximately 30% and the large hospital system has been purchased by an even larger national health system. Our innovative approaches to healthcare continue to benefit our community and the children who live here.

Community Hospital developed an innovative, direct contract with our school district (one of the largest employers in our region) which was losing money on healthcare. Our teachers were paying over half of their income on premiums and deductibles. As partners with the school district, we worked to lower costs and increase access, especially in primary care. By keeping teachers healthy we continue to support the next generation. During the COVID-19 Pandemic, it only took one call from the school district to

[1] "Grand Junction is among the most expensive places for hospital stay," The Denver Post
[2] "Bennet Secures Nearly $121 Million for Colorado Projects in FY22 Funding Bill" [Press Release] Michael Bennet U.S. Senator for Colorado

Community Hospital for us to provide the necessary products to keep the schools safe and open. Even though we have been partners with our school district for the last 12 years, saved the district substantial amounts of money, and created access to both primary and specialty care, the large system just bought that contract for over 30% less. We understand the need for our school district to manage costs, and yet we cannot stay competitive with a large system who can offer vast discounts to secure a contract. The same large system has their own insurance product. They are bringing this product into our community where we anticipate them blocking access to our hospital through non-preferred and tiered products, again driving all patients in our area to their hospital. Our ability to be innovative in response to community needs will be blocked through a lack of competition.

Another innovative partnership Community Hospital has developed is with Mesa County Government and the Mesa County Sheriff's Office (MCSO). The MCSO was experiencing high levels of hospitalizations of their deputies. Through our local partnership, Community Hospital began offering health screenings and programs to promote healthier lifestyles and preventative care.

Community Hospital also partners with Colorado Mesa University. We provide sports medicine to the athletic department and on-campus student health services, including reproductive health services. During the COVID-19 Pandemic, our Chief Medical Officer and Infectious Disease Doctor held daily meetings and worked with the university to implement preventative care and treatment. Our university was one of the only universities that stayed open during the pandemic through a unique wastewater testing protocol.[3] By being independent we can adroitly assess community needs and partner quickly to develop innovative solutions to these needs.

The money that is made at Community Hospital stays in the local community. We are able to support local banks, businesses, and contractors for our building and growth. Over 90% of our building projects have been completed by local contractors and subcontractors. We also support local not-for-profit organizations. We give back locally to programs like Girls on the Run which promotes physical fitness and self-confidence in girls, Little League, Special Olympics, and several other organizations that support local youth.

Healthcare costs in our community have decreased because Community Hospital has created meaningful competition. As an independent hospital, Community Hospital has been at a disadvantage in that we are the only hospital that does not have a Centers for Medicare and Medicaid (CMS) designation. This means that Community Hospital is paid significantly less than a nearby hospital with a designation for the same procedures. This is an area that Congress can help, by creating a CMS designation for independent hospitals, thereby providing a means to help independent hospitals remain financially viable. We are further disadvantaged by the fact that CMS has a lack of parity in reimbursement models in communities such as ours. We are in a remote urban setting but primarily care for patients from rural and frontier counties, including across state lines.

There is a role for both system and independent hospitals in America. Independent hospitals have agility and can quickly maneuver to provide for the needs of their specific populations and communities. In populations such as ours who are not being served by multiple systems, our independent hospital is the last buttress against system monopolies, and how those monopolies drive up the cost of healthcare.[4]

Community Hospital continues to compete against the large system resources, yet continues to find innovative ways to offer care to our patients. We have been able to do this with a very small margin, and

[3] "The Future of Virus Tracking Can be Found on This College Campus," The New York Times
[4] "Care Costs More in Consolidated Health Systems," Harvard Medical School

with an uncompetitive disadvantage with no CMS designation. Independent hospitals are vital to a robust, competitive, and innovative healthcare marketplace. Our ability to be agile, serve the unique needs of the communities where we are located, and serve as a backstop for competition, is needed in healthcare. By first studying the impact that independent hospitals have on the marketplace, then developing a new CMS designation that allows CMS to offer independent hospitals an ability to stay competitive, create innovation, offer increased healthcare access, and help keep the costs of healthcare low, the health of communities will continue to be served.

Re: Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity

In 2006, at the age of 50 - I was diagnosed with what was then called Carcinoid cancer and is now called Neuroendocrine cancer by the medical community. (NETs)

When I was diagnosed, the youngest of my 4 children had not yet started high school.

My outlook felt gloomy! The surgeon told me he had gotten everything he could see in the resection and removal of nearly 3 feet of small intestine, but it was likely the tumors would reoccur. The tumor board he had spoken with said if they did reoccur, more surgery would not represent a cure and therefore would not be recommended. I was feeling terminal and didn't know what kind of a timeline I could expect.

The surgeon told me I should find an oncologist.
As I called nearby offices, receptionists would ask me how to spell Carcinoid — Not what I was hoping to hear. When I did go in for an appointment with a local oncologist, I was told there was no cure, and no treatment.

That was the day I called Huntsman Cancer Institute. The woman I spoke with said she would set me up for an appointment with a doctor who likely knew more about my type of cancer than any doctor this side of the Mississippi. Dr. John Ward (a breast cancer specialist who extended care to carcinoid patients, as there were few specialists in the U.S.) gave me exactly what Huntsman promises patients, HOPE! (Their address is Hope Circle.)

After examining me and looking at my scans in November, Dr. Ward told me I should not cancel Christmas, I should keep wearing my seat belt, I shouldn't take up smoking or drinking; and if I walk when texting, I should wear a helmet. He told me they were now treating patients with better things than they had had available 10 years ago. He also told me it was his job to worry, and my job to live my life. Hope!

Dr Ward was the only contact I had with anyone who knew about carcinoid/neuroendocrine cancer for 7 years. In 2013, that changed, when Dr. Ward's office called and asked if I would be willing to talk with a newly diagnosed patient. Connie and I became friends. She told me of a Utah NET Support Group she had been attending.

My doctors at Huntsman, and the Support Group became my lifeline. Merlynn, the support group organizer, brings in many professionals from various medical fields to speak to us. He also takes point in researching new trials and technologies on the horizon. He researches

things being used in Europe that give us hope for those treatments becoming available in the United States. Things we can discuss with our doctors.

When Merlynn was first diagnosed, he flew out to see Dr Woltering, considered by many to be the foremost authority on neuroendocrine cancer in the U.S. at that time. This doctor, after examining him, drew a rough sketch of a carriage, and a clock, then referencing the story of Cinderella, asked Merlyn what happens to the carriage when the clock strikes 12? We all know the answer - it turns into a pumpkin. He told Merlynn, "You don't want to become a pumpkin. As new treatments come along, take every opportunity to turn your clock back."

Fast forward a few years. A noted specialist and surgeon, Dr Liu, had moved from Vanderbilt University Medical Center to Colorado; and Huntsman Cancer Institute had recruited doctors who are knowledgeable, and focused on neuroendocrine cancer. As my symptoms were worsening in 2017, especially my pain, Dr. Whisenant at Huntsman, in consultation with Dr. Liu, recommended a surgery to de-bulk my liver, in hopes of getting the tumor causing me the most pain.

Dr Liu had recently acquired a newer technology, one used in Europe since 2001, but just becoming available in the U.S. The nuclear scan was called a Gallium 68 or Netspot scan. It did a much better job of identifying NETs than MRI or CT. Dr Liu invited me to come and be scanned the day before my planned surgery. That scan changed the course of my surgery! I lit it up everywhere. Instead of just going in to de-bulk my liver, I was opened up in a different direction. A number of tumors were removed from my liver, and some that would have eventually caused kidney failure. Also removed were what Dr Liu described as a "frosting layer" of tumors on my diaphragm. He removed all he could. My clock had again been set back, largely due to some newer technology found in that nuclear scan I was fortunate to use. At that time, the scans were in the process of being approved by Medicare. I had to pay for it out of pocket. The approvals were taking place, and my insurance followed suit once Medicare was onboard. I was eventually able to be reimbursed. Once again, my clock was set back!

Because of the sheer number of tumors that were not able to be removed surgically, the next step recommended to me was a newer treatment, still in the trial stage in the U.S. called PRRT (Peptide Receptor Radionuclide Therapy), a nuclear treatment. Europe had been using PRRT and their numbers on this looked encouraging. I was placed in that trial at Huntsman in late 2017. I began the four treatments of the nuclear therapy given every 2 months. My clock was set back further! More hope!

After more years, and undergoing several other traditional treatments, (liver embolizations, direct beam radiation to my skull), my symptoms and fatigue were worsening, my quality of life deteriorating. In January, Doctor Soares, who I am grateful to have as my current doctor,

had me do a scan that is a newer nuclear scan than the Gallium 68. The Copper Cu 64 Dotatate scan has a shorter half-life than the Gallium, exposing the patient to less radiation, it also does a better job of detecting tumors. Another blessing of newer technology. After seeing the results of this scan, Dr. Soares helped me get into a trial taking place now. It is a treatment we learned about several years ago and have been watching and hopeful for what it might do. The new treatment in this trial is also a nuclear therapy, referred to as Actinium.

For this trial, the computer did not randomize me to get Actinium yet. Instead, I am in the arm of the trial comparing a standard of care to the Actinium. However, I am scanned more often and when a certain level of progression is seen, I will have the option of trying Actinium. More hope for the possibility of setting my clock back.

Today, 18 years after I started this journey, all 4 of my children are grown and settled into their careers. I have 5 beautiful grandchildren that I absolutely delight in spending time with — and I will add, they love spending time with "Grammy!" I am so grateful for every moment I have had with my family, and for each instance of the setting back of my clock.

My friend, Connie, died before PRRT became available in the U.S, outside of the trials. I have sometimes wondered, if the timing had been different, if her clock could have also been set back.

Since our support group was formed in March of 2013, we have had approximately 145 patients on our roles. We have seen approximately 35 of those, some quite young, leave their families behind, as they have lost their fight.

Every cancer patient is so grateful for every scientist and doctor looking for better treatments, and hopefully, someday for cures. We are all in hopes of new treatments. We know these need to be delivered as safely as possible, but are also anxious to receive them more quickly, especially when there are years of data available from other countries. It seems most insurances let Medicare take the lead on approvals. That can feel like a very long process to those trying to set back their clocks, with the hope of having additional time with their families.

Thank you for your time.

Charlene

SurvivorsFor Solutions

July 26, 2024

The Honorable Jason Smith
Chairman
U.S. House Committee on Ways and Means
1011 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
U.S. House Committee on Ways and Means
372 Cannon House Office Building
Washington, DC 20515

Dear Chairman Smith and Ranking Member Neal,

On behalf of my organization, Survivors for Solutions, and all those advocating for improved access to current medications and breakthrough treatments, I want to thank you for investigating healthcare access in America and protecting medical innovation.

Your recent "Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity" is particularly relevant for patients like me who suffer from rare, chronic, or life-threatening illnesses and rely on the constant development of new treatments and cures. When I was diagnosed with multiple sclerosis (MS) over 30 years ago, I never could have dreamed of the medications that exist today. Throughout my MS journey, I have required four different breakthrough drugs, none of which were available at the time of my diagnosis in 1993. Thankfully, at that time, the federal government allowed innovators to innovate unbridled, leading to the discovery of countless lifesaving treatments that are still in use today.

The hope that medical advancements provide is necessary for patients, no matter what they are surviving. Unfortunately, actions by the current administration have put America's flourishing innovation pipeline at risk and this hope at stake.

The 2022 Inflation Reduction Act (IRA) contains numerous provisions that hurt patients like me. Most notably, the Medicare Drug Price Negotiation Program will significantly hinder critical medical research and development (R&D). Price controls in any industry lead to shortages, reduced quality and innovation, market distortions, and can counterintuitively lead to higher costs. We are seeing the same play out in the Medicare prescription drug market: higher costs, fewer options, and less hope for patients in need. Had the drug price "negotiations" been in place at the time of my diagnosis, it is possible that the treatments I rely on today would not exist.

One particularly problematic component of the program is the "Pill Penalty," an IRA provision that grants small-molecule drugs a shorter exemption window from price control than another type of treatment – biologics. Small molecule drugs are critical for treating a variety of conditions – from bacterial infections to Alzheimer's to brain cancer. Fixing this "Pill Penalty" would spur the continued development of this necessary medication, which is often more affordable and

accessible than biologics. Congress must remedy this discrepancy to protect the incentives for small molecule development.

Another critical issue standing between patients and their medications is pharmacy benefit managers (PBMs). Consolidation in the PBM marketplace gives a few of these corporate giants — which were once valuable to the supply chain — the power to control access to treatments and influence drug prices. They use their market dominance power to line their pockets — all at the expense of patients. Congress should step in to ensure these middlemen do not deny anyone their much-needed medication.

Patients around the world are lucky that America has such a flourishing innovation ecosystem. I urge members of Congress to protect the development of and access to medical advancements that save and improve the lives of patients like me.

Thank you again for holding this hearing. I hope that your committee and all of Congress can take the necessary steps to protect access to medication and foster innovation across the country.

Sincerely,
John Czwartacki
Founder and Chairmen of Survivors for Solutions
www.survivorsforsolutions.org

Cc: Members of the U.S. House Committee on Ways and Means

Chairman SMITH. And, with that, the committee stands adjourned.

[Whereupon, at 11:45 a.m., the committee was adjourned.]

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