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LEGISLATIVE PROPOSALS TO MAINTAIN AND IMPROVE
THE PUBLIC HEALTH WORKFORCE, RURAL HEALTH,
AND OVER-THE-COUNTER MEDICINES

WEDNESDAY, JULY 16, 2025

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123, Rayburn House Office Building, Hon. H. Morgan Griffith [chairman of the subcommittee] presiding.

Present: Representatives Griffith, Harshbarger, Bilirakis, Carter of Georgia, Dunn, Crenshaw, Joyce, Balderson, Miller-Meeks, Obernolte, Bentz, Kean, Rulli, Guthrie (ex officio), DeGette, Ruiz, Dingell, Kelly, Barragan, Schrier, Veasey, Fletcher, Ocasio-Cortez, Auchincloss, Carter of Louisiana, Landsman, and Pallone (ex officio).

Also Present: Representatives Latta and Fedorchak.

Staff Present: Jessica Donlon, General Counsel; Kristin Fritsch (Flukey), Professional Staff Member, Health; Sydney Greene, Director, Finance and Logistics; Jay Gulshen, Chief Counsel, Health; Emily Hale, Staff Assistant; Annabelle Huffman, Clerk,

Health; Megan Jackson, Staff Director; Brayden Lacefield, Special Assistant; Molly Lolli (Brimmer), Counsel, Health; Sarah Meier, Counsel and Parliamentarian; Joel Miller, Chief Counsel; Seth Ricketts, Special Assistant; Jackson Rudden, Staff Assistant; Emma Schultheis, Policy Analyst, Health; Lydia Abma, Minority Policy Analyst; Shana Beavin, Minority Professional Staff Member; Keegan Cardman, Minority Staff Assistant; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; La'Zale Johnson, Minority Intern; Elizabeth Kittrie, Minority Health Fellow; and Una Lee Minority Chief Counsel, Health.

Mr. Griffith. The Subcommittee on Health will come to order, and I will take first a brief moment for a point of personal privilege.

This is my first hearing as the new subcommittee chair, but I would be remiss if I didn't recognize the great work that my colleague, Buddy Carter, did.

I understand he is trying to get a demotion and go over to the Senate, and I wish him well in that endeavor. But it made it so that he had to step aside. But that does not mean he is not going to be an integral part of the running of this committee and of the philosophies and policies that he has championed.

I think we are in agreement at least 99.9 percent of the time. And I will look to him for help and guidance on a number of the issues.

So thank you, Buddy. We appreciate your service.

[Applause.]

Mr. Griffith. That said, I now recognize myself for 5 minutes for an opening statement.

Today's legislative hearing is necessary to continue essential programs that are vital to our healthcare infrastructure. Many of the bills before us expire at the end of this fiscal year and must be reauthorized.

One of the bills that will be discussed today is H.R. 4273, the Over-the-Counter Monograph Drug User Fee amendments, led by Mr. Latta and Ranking Member DeGette.

The Coronavirus Aid, Relief, and Economic Security -- CARES -- Act, which passed in 2020, modernized the regulation of over-the-counter monograph drugs and products. It also created a new user fee program to support this new framework, also known as O-M-U-F-A, or colloquially, OMUFA.

And I hope I pronounced the colloquialism right. But it is another one of those fees that we have that make important things happen.

Generally, a company can market an over-the-counter drug if they either submit a new drug application or go through the over-the-counter monograph process. Prior to 2020, that involved a lengthy, burdensome three-phase rulemaking process.

This led to Congress creating a new regulatory framework that allows FDA to issue administrative orders determining a product is generally recognized as safe and effective -- or GRASE -- and simultaneously establishing a new user fee program to help ensure this process is effective and is streamlined.

This is the first reauthorization of OMUFA. We hope to work in a bipartisan way to address any outstanding issues to ensure this program is functioning how Congress initially intended, including minimizing regulatory burdens, supporting innovation, and increasing access to products in a safe and efficient manner.

We will also consider other legislation that will help encourage the FDA to be more flexible in their review process.

H.R. 3686, the SAFE Sunscreens Standards Act, led by Dr. Joyce and Mrs. Dingell, would require the FDA to consider the use of certain real world, evidence-based, and non-animal testing methods when it comes to evaluating new sunscreen active ingredients in the United States.

We are behind other countries in bringing innovative sunscreens to the market, and this bill will help to bridge the gap.

During our last hearing on OMUFA we had a robust discussion about the need for more innovative sunscreens to be available in the United States, and I look forward to the discussion around these policies today.

Along similar lines, the FDA must keep pace with current technological

advancements, which includes greater utilization of non-animal testing methods. H.R. 2821, led by Representatives Carter and Barragan, would help support FDA's efforts to do just that.

Congress gave the FDA the ability in 2022, when FDA Modernization 2.0 was signed into law, but the FDA has failed to fully implement these practices. This legislation would require the FDA to finally update its regulations to account for non-animal testing.

This bill does not require -- does not require -- non-animal testing. It simply provides an option that if companies wish to pursue less costly methods, such as computer AI modeling or organ chip testing.

There are also two important reauthorizations in front of us today that serve a vital role in helping our medical workforce, which are the Title VII and Title VIII reauthorizations.

These programs allocate resources for scholarships and educational assistance so students from underserved backgrounds, who are often from rural areas, can pursue medical careers and help support the medical workforce that Americans widely rely upon.

It is crucial for Congress to take a close look at these programs to ensure resources are going to areas and patients who need it most.

We are also discussing legislation that will continue grants for certain healthcare services in rural areas to help to increase the use of telehealth, so patients can access care more easily.

Reauthorizing the Telehealth Resource Centers Grant Program will support our telehealth infrastructure that has become a lifeline for both providers and patients across the country, especially in rural areas.

Considering each of these reauthorizations is an important step forward to ensure

the program is working as intended.

I look forward to hearing from our witnesses today regarding the importance of these programs and to ensure that they are reauthorized in a timely manner.

That said, I would also say that the Health Subcommittee has great advantages in many ways, one of those being that when somebody is sick or needs healthcare, they don't look at what party they identify with or what their philosophical background is.

This subcommittee has a long history -- and I hope to be a part of continuing that long history -- of doing bipartisan work for the betterment of the American people and the American patients.

And I know that my colleague, the ranking member, Ms. DeGette, feels the same way. We have worked on issues over the years that I have been in Congress.

And I appreciate the opportunity to work with you as the ranking member.

And I now recognize Ms. DeGette for her 5-minute opening.

[The prepared statement of Mr. Griffith follows:]

******** COMMITTEE INSERT ********

Ms. DeGette. Thank you so much. And I want to congratulate you, Chairman Griffith, on your new role as chair of this subcommittee.

We have worked together on the Oversight Subcommittee with Mr. Griffith as chair, with me as chair, and most days we got along. We at least agreed on parliamentary procedure, and there is that.

Mr. Griffith. Absolutely.

Ms. DeGette. So we have worked a lot together over the years. We do have our ideological differences, which we discuss, because we represent very different constituencies.

But as you have heard, we do share a belief in this committee, in this institution, and we believe that we must achieve good things for the American people when it works effectively.

And we want our constituents to live longer and healthier lives. That is what this is about.

So today we are considering important legislation to reauthorize FDA's over-the-counter medicines program, critical health workforce development programs, and more.

I am particularly proud of our past work on over-the-counter medicines, and the chairman mentioned this briefly. Five years in, we have seen early successes.

I want to thank my colleague from Ohio, Mr. Latta -- I don't see him here -- for introducing the legislation with me for this first reauthorization of the over-the-counter medicines program, and I look forward to seeing continued success of the program in the next 5 years.

We were supposed to do this last week, but the Republicans postponed it because I guess they were celebrating the passage of, frankly, the worst piece of legislation, both

in process and substance, that I have seen in my time in Congress.

The Republicans jammed through the Big Bad Bill and its handouts to the wealthiest Americans literally under the cover of night, including in our committee, while real legislating to help our constituents was nonexistent.

Between cuts to Medicaid and the Affordable Care Act and the choice not to extend tax credits for healthcare coverage, 17 million people will now be without health insurance.

I don't see anything beautiful in that. I don't see anything that is going to help the health of Americans.

I think the law rolls back much of the progress that we have made in getting people enrolled early in healthcare when we passed the Affordable Care Act in the first place.

Medicaid expansion was a lifeline to hospitals struggling to keep their doors open, not just for poor people, but for everybody in their community, and now, faced with a financial cliff, many of those hospitals might close.

So just last week, during our unplanned recess, I visited a Planned Parenthood clinic in my district that can no longer serve individuals covered by Medicaid for routine -- not abortions -- but for routine medical exams like Pap smears, breast exams.

They have already had to cancel hundreds of appointments for people coming into these things, and these are people who are not going to be able to find doctors anywhere else.

Frankly, these cuts are just mean. They don't save money. And my colleagues across the aisle have preached for decades about fiscal responsibility. But I guess that giving billionaires more tax cuts and kicking millions of Americans off their healthcare is more important.

The Big Bad Bill makes our mounting national debt even worse, increasing it by trillions of dollars to finance these tax cuts, and now much of it is law.

Much of it won't go into effect for years. So I hope that we could work together in a bipartisan way to clean up this mess of a law before it hurts more people -- and apparently so does Senator Hawley, who after voting for the law just 2 weeks ago, introduced a bill that would reverse many of the cuts in Medicaid that he just voted for.

So, I mean, I pride myself in working in a bipartisan way on bills that will improve the health of our constituents and of all Americans. But I feel, and all of my colleagues on this subcommittee feel, that we have been frozen out of the work of this subcommittee from the beginning of the year, from issues that should be noncontroversial, to the Big Bad Bill that we just passed a couple of weeks ago.

And so let's turn a new page, Mr. Chairman. Let's have a new era in our committee and go back to what we used to do, working together in a bipartisan way.

I yield back.

[The prepared statement of Ms. DeGette follows:]

******** COMMITTEE INSERT ********

Mr. Griffith. The gentlelady yields back.

I now recognize the chairman of the full committee, Chairman Guthrie, for 5 minutes for his opening statement.

The Chair. Thank you, Chairman Griffith. I congratulate you on your new role and excited as you lead your first Health Subcommittee hearing today as chairman.

And I thank all the witnesses for being here before us today.

I think Representative Carter had to run upstairs. There are two hearings kind of going on today upstairs. So I just want to commend him on his excellent work as we talked about yesterday, and point out, I want to say this correctly because I don't want to be misquoted, that he was at the funeral of his granddaughter's cousin -- so it was not his granddaughter -- his granddaughter's cousin who all three of them were at Camp Mystic.

And, fortunately, his granddaughter survived, but so sad for the Hunt family in the loss of their -- and all the others.

Buddy did a great job leading this committee, and he is going to continue to help Americans from a new role he is seeking here in Washington, D.C. I am excited for him.

But we are here today to discuss the reauthorizations of FDA's Over-the-Counter Monograph Drug User Fee Program, known as OMUFA, as well as several health workforce and rural healthcare programs administered by HRSA, which are all set to expire on September 30 of this year.

This is the first reauthorization of OMUFA, and I look forward to hearing from the FDA's Dr. Jacqueline Corrigan-Curay -- I think that is correct -- on the implementation of the program and outcomes of the first 5 years of the program.

The original bill reformed the regulation of over-the-counter drugs, products that so many of us and our constituents use every day, to reduce the bureaucracy, increase transparency, and allow innovation to flourish.

The safety and efficacy of these products is critical, which is why reauthorizing this program in a timely manner is so important.

And I am also looking forward to hearing from our witnesses about ways we can improve participation in the healthcare workforce and increase access to care in rural areas.

Rural areas, like my home State of Kentucky, face a unique set of challenges, ranging from limited access to emergency services and specialized medical care, to higher rates of chronic conditions like high blood pressure and obesity.

It is imperative for lawmakers to understand these nuances and ensure Federal support is targeted to those areas that need it the most.

I am hopeful that this hearing will provide us with an update on how these various programs are operating and any gaps that may need be addressed to streamline and improve healthcare outcomes.

I appreciate my good friend from Colorado as she ended her opening statement saying that it is time for us to find opportunities to work together. I believe this is one of those great opportunities, and we will have others.

Some of the great pieces of legislation that are lasting and standing came out of this committee, like Cures. You worked with Cures with our previous chairman, Fred Upton, and hopefully we can follow some of those pathways and find ways to work together.

When we were on the other side of this majority, on the minority side, we had issues that we didn't support that came out in a partisan way, but we found ways to work together, and I know that we will be able to do that on other issues as well. So, thank you for that.

And I thank the witnesses for your participation today, and I look forward to

today's discussion and working together.

And I will yield back.

[The prepared statement of The Chair follows:]

******** COMMITTEE INSERT ********

Mr. Griffith. The gentleman yields back.

I now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman. Congratulations on your new post. I have always believed that the Health Committee was one of our most important subcommittees.

Now, I know we are here today to discuss several pieces of health legislation, but we can't forget that Republicans just cut more than a trillion dollars from our healthcare system and 17 million Americans stand to lose their health insurance. That is an increase in our Nation's uninsured rate of more than 50 percent.

These are people who will not have access to the healthcare they need, who will get sicker, who will be overwhelmed with medical debt, and, sadly, some may die sooner.

Moreover, hundreds of hospitals, nursing homes, and home care providers will be forced to close.

We heard from hospitals, doctors, the elderly, and people with disabilities who have lined our hallways and this hearing room pleading for their healthcare.

We heard from families who are afraid of falling farther and further behind, from patient groups who fear for people with cancer, substance use disorders, and countless others.

But Republicans ignored these concerns. They will literally do anything, including taking healthcare away from their own constituents, to give giant tax breaks to the ultra rich who do not need them.

And with that said, we are here to discuss several pieces of legislation.

First, we are considering the bipartisan reauthorization of the Over-the-Counter Monograph Drug User Fee Program.

Congress authorized this program in 2020 because of the need to more quickly provide safe and effective over-the-counter drug products to consumers.

I was vocal in my concerns at the time that the FDA OTC program was drastically underresourced. We gave FDA the authorities and resources it needed to allow the program to keep up with evolving science and technology and introduction to new formulizations for consumers.

The authorization also allowed FDA the ability to more swiftly revise or update monographs in response to safety concerns, and this was critical to ensuring the products that consumers use are safe. And that is why I have concerns with the sunscreen bill.

As drafted, the sunscreen bill undermines the existing bedrock safety and efficacy framework set forth in statute.

However, I look forward to continuing bipartisan discussion to get to a solution that provides more options for consumers, while ensuring that those options are safe and effective.

We also consider today the FDA Modernization Act 3.0, which would require the agency to publish a final rule on alternative testing methods. And I am pleased to hear from FDA that we will continue to see guidance come out of the agency, as we have in the past, unimpacted by Trump's 10-for-1 executive order.

We will also discuss important workforce reauthorizations, including the reauthorization of many of the Health Resources and Services Administration's Title VII and Title VIII health professions development programs.

We continue to face nationwide shortages in health providers, and continuing all of the Title VII programs is essential to creating a robust network of providers.

Similarly, the Title VIII programs address all aspects of the nursing workforce, from education and recruitment to practice and retention. As the nursing shortage continues

to grow, it is imperative that we reauthorize all of these crucial programs to support the nursing workforce.

Despite their proven track record in bolstering the health workforce, some of these important programs may be eliminated by the Trump administration because they include words like "diversity" and "representation."

In reality, what these programs are doing is helping us build a health workforce that is actually reflective of our country and is large enough to meet the needs of all of our communities.

Eliminating these programs will only exacerbate the health workforce shortages, and vulnerable communities will suffer the most.

We are also examining a few bills that support parents and infants across the country, including reauthorization of the Healthy Start Program.

This program partners with local providers to improve health outcomes before, during, and after pregnancy, with the ultimate goal of reducing infant mortality and lowering rates of preterm birth, low birth weight, and maternal illness. I am pleased to see it included in this hearing and want to stress the importance of reauthorizing this program for the future.

And relatedly, we are considering legislation that will reauthorize the newborn screening program. While I am concerned the Trump administration is disbanding the advisory committee that supports this life-saving work, by reauthorizing this committee and program we will show that Congress stands with families nationwide who rely on this critical program.

So thanks again to the witnesses for being here. I look forward to the discussion.

And with that, our new chairman of the subcommittee, I yield back the balance of my time.

[The prepared statement of Mr. Pallone follows:]

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Mr. Griffith. The gentleman yields back.

We now conclude with member opening statements.

The chair would like to remind members that pursuant to committee rules, all members' opening statements will be made a part of the record.

We want to thank our witnesses for taking the time to testify before the subcommittee.

Although it is not the practice of this subcommittee to swear in witnesses, I would remind our witnesses that knowingly and willfully making materially false statements to the legislative branch is against the law under Title 18, Section 1001, of the United States Code.

You will have the opportunity to give an opening statement, followed by questions from members.

Our witnesses today are Dr. Jacqueline Corrigan-Curay, JD, M.D., Acting Director for the Center for Drug Evaluation and Research, U.S. Food and Drug Administration.

Thank you for being here.

Dr. Candice Chen, M.D., MPH, Acting Associate Administrator for Health Workforce, U.S. Health Resources and Services Administration;

And Mr. Tom Morris, MPA, Associate Administrator for Rural Health Policy, U.S. Health Resources and Services Administration.

Per committee custom, each witness will have the opportunity for a 5-minute opening statement, followed by a round of questions from members. The light on the timer in front of you will turn from green to yellow when you have 1 minute left.

I now recognize Dr. Jacqueline Corrigan-Curay for 5 minutes to give her opening statement.

The floor is yours.

STATEMENTS OF DR. JACQUELINE CORRIGAN-CURAY, JD, MD, ACTING DIRECTOR FOR THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), U.S. FOOD AND DRUG ADMINISTRATION; DR. CANDICE CHEN, MD, MPH, ACTING ASSOCIATE ADMINISTRATOR FOR HEALTH WORKFORCE, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION; AND MR. TOM MORRIS, MPA, ASSOCIATE ADMINISTRATOR FOR RURAL HEALTH POLICY, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF JACQUELINE CORRIGAN-CURAY

Dr. Corrigan-Curay. Thank you very much.

Good morning, Chair Griffith, Ranking Member DeGette, and members of the subcommittee, and thank you for the opportunity to speak with you today.

I want to talk about something that benefits nearly every American household: over-the-counter medication. These are the products that millions rely on every day -- an antiseptic when your child has a scrape, antihistamines when our pollen count goes up, or an antacid after a large meal.

They are trusted, they are essential, and they must be safe, effective, and up to date. That is where the OTC Monograph User Free Program, or OMUFA, comes in.

Prior to 2020, our ability to regulate OTC drugs hadn't been modernized in decades. It was slow, outdated, and inflexible. Reform was overdue.

When Congress passed OTC monograph reform as part of the CARES Act, it was a bipartisan success that has brought real change. Critically, the user fees that Congress authorized, OMUFA, are what facilitated and supported OTC monograph reform and has set this program up for success.

Now, with congressional support and timely reauthorization, we have the opportunity to realize the full potential of OTC monograph reform, ensuring a more nimble regulatory process, fostering innovation to better serve patients and consumers, and enhancing transparency and accountability from FDA and the industry.

So what have we accomplished?

In just 5 years, OMUFA has helped FDA modernize the OTC drug review process, transforming it from a paper-heavy rulemaking system to a responsive electronic one.

We delivered five key guidances. These provide clarity to manufacturers and enhance public health protection.

We posted 33 final administrative orders and five proposed administrative orders, providing transparency to manufacturers on what is expected to legally market a particular OTC drug.

And I want to highlight one recent proposed order because we believe it can really foster some exciting innovation for children and families.

If finalized, this order would let companies create new, easier-to-take forms of OTC medications, like chewable tablets, tablets that melt in your mouth, and thin films.

These would be for certain medications that currently only come as tablets and capsules and would help people who have trouble swallowing those meds.

OMUFA has also helped us hire 85 dedicated staff members. These are scientists, safety reviewers, and regulatory experts who help ensure that the products on our shelves are safe and effective.

And, importantly, it has opened the door to more innovative products, like new sunscreen ingredients through the new administrative order process.

If Congress does not reauthorize OMUFA this year, that momentum will come to a grinding halt. The impact would be immediate and damaging.

Engagement on development programs and activities to oversee the safety and quality of OTC monograph products would slow or stop as dozens of FDA staff and clinical quality and safety experts would lose their jobs.

Critical progress on the proposed and final orders from our FDA monograph forecast would be shelved, and these include essential updates on labeling drug fact ingredients, including for products intended for pregnant women and children.

No new agreements from the recent commitment letter could be implemented, including important steps like improving meeting management with sponsors and more quickly assessing the quality of facilities bringing new OTC products to the U.S. market.

And perhaps most concerning, we risk sliding backwards, losing the transparency, predictability, and innovation that OMUFA was designed to create.

Without reauthorization, the system that was finally fixed can begin to fail.

The recently negotiated agreement for the next 5 years of OMUFA includes smart, achievable goals. We are going to increase opportunities for industry-FDA interactions to foster innovation, improve transparency of the User Fee Program, invest in product quality and safety, and continue to publish the annual guidance forecast that gives industry and public health stakeholders a clear roadmap for the future.

These aren't just words. They are a commitment to the public, a commitment to keep this progress going.

Every delay in regulation or review affects real people. Without OMUFA innovations are stalled, safety improvements are delayed, and consumers may unknowingly continue to use products that haven't been adequately reviewed with modern science.

In closing, Congress made a smart investment in 2020 when it created OMUFA. That investment is paying off, but we can't stop now. Reauthorizing OMUFA means

continued modernization, supporting innovation, and most importantly, keeping American families safe.

Thank you, and I look forward to your questions.

[The prepared statement of Dr. Corrigan-Curay follows:]

******** COMMITTEE INSERT ********

Mr. Griffith. The gentlelady yields back.

I now recognize Dr. Chen.

STATEMENT OF CANDICE CHEN

Dr. Chen. Chairman Griffith, Ranking Member DeGette, members of the subcommittee, thank you for the opportunity to testify on behalf of the Health Resources and Services Administration and to speak about our critical --

Mr. Griffith. If you could move your mike a little closer so we can get a little bit louder. Yes, thank you.

Dr. Chen. Is that better? Okay.

My name is Candice Chen. I am the Associate Administrator of the Bureau of Health Workforce. I am also a pediatrician, and for most of my career I have practiced primary care in a children's health center about 5 miles from here in Southeast Washington, D.C.

The health workforce faces significant challenges, and when communities face health workforce shortages, access to care, quality, and costs are all negatively affected.

HRSA's National Center for Health Workforce Analysis is the leading Federal entity that collects, analyzes, and reports on the U.S. health workforce. Our National Center conducts workforce projections on over a hundred healthcare occupations, the majority of which are projected to face shortages in the next 10 to 15 years.

These include a shortage of over 87,000 primary care physicians, 210,000 nurses, or RNs, and over 400,000 behavioral health providers.

And we know this workforce is poorly distributed across the U.S., with rural and other underserved communities experiencing the greatest shortages.

HRSA's health workforce programs aim to address these shortages across the U.S. Through scholarship and loan repayment programs, we support the recruitment and retention of critical healthcare professionals in rural and underserved areas.

One of our best known programs is the National Health Service Corps, which offers scholarship and loan repayment to primary care, oral health, and mental health professionals in exchange for at least 2 years of clinical service in a health professional shortage area.

The program has a specific focus on supporting the substance use disorder workforce as well as rural and Tribal communities, and it is in high demand.

In fiscal year 2024, the National Health Service Corps received over 14,000 applications and made nearly 7,000 awards. And due to the multiyear service commitments, the National Health Service Corps is currently supporting over 17,000 healthcare professionals, providing healthcare in every State and the District of Columbia and in the U.S. territories.

The Nurse Corps Program similarly is an important scholarship and loan repayment program that supports nursing students and nurses in practice who commit to work in healthcare facilities in underserved communities. These include primary care clinics, hospitals, nursing home settings, many other settings.

The Nurse Corps Program also provides loan repayments for nurse faculty, an area of the workforce that our schools of nursing have told us is particularly challenging to recruit for. The faculty are essential to train the future workforce.

In fiscal year 2024, the Nurse Corps Program received nearly 10,000 applications and made 1,200 awards.

The Teaching Health Center Graduate Medical Education Program funds 81 primary care residency programs in community-based settings across the Nation.

Seventy-five percent of teaching health centers are in Federally Qualified Health Centers, and this year the Teaching Health Center Program is supporting just over 1,200 medical and dental residents.

The program has a strong track record. Eighty-five percent of graduates go on to practice in medically underserved communities.

HRSA is also focusing on the critical behavioral health workforce needed to address mental and behavioral health disorders, including substance use disorders, that is rising in communities across the Nation.

Behavioral health workforce programs provide grants to support the training of behavioral health professionals. These programs increase the number of students and graduates, they enhance curriculums, they train for rural and underserved communities, and they promote the team-based behavioral health integrated with primary care that is really needed.

Last year, the Behavioral Health Workforce Program supported the training of over 11,000 individuals and graduated over 7,000 new behavioral health providers.

I know at the start of my testimony I shared that I am a primary care pediatrician, but I should also share that I have personally benefited from these HRSA programs which supported my training and career.

And as a healthcare provider and a beneficiary of these programs, I know firsthand how important both the health workforce and these programs are to the health and well-being of American communities.

I and my colleagues at HRSA are deeply committed to strengthening the health workforce, addressing the challenges and gaps, and ensuring that people in all communities across America have access to high quality healthcare providers.

Thank you for this opportunity and for the committee's bipartisan support for the

health workforce programs. I look forward to your questions.

[The prepared statement of Dr. Chen follows:]

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Mr. Griffith. Thank you very much.

I now recognize Mr. Morris for his 5 minutes for an opening statement.

STATEMENT OF TOM MORRIS

Mr. Morris. Chairman Griffith, Ranking Member DeGette, members of the subcommittee, thank you so much for the opportunity to testify today on behalf of the Health Resources and Services Administration, an agency within the U.S. Department of Health and Human Services.

As someone who has worked in rural health for more than 25 years, I am honored to have the opportunity to talk about the importance of reauthorizing congressional programs that provide essential services and telehealth services to rural and underserved areas, addressing important challenges like addressing chronic disease.

The challenges facing rural communities are well known. We see higher rates of mortality, lower life expectancy, higher rates of chronic disease, and also challenges of recruiting and retaining the needed doctors, nurses, and other clinicians in rural communities.

There are also structural challenges, such as geographic isolation, limited clinical infrastructure, and higher poverty.

Despite all these challenges, rural communities are amazingly resilient, creative, and innovative in leveraging the resources they have to develop innovative approaches to address their unique needs.

I saw this firsthand living in rural eastern North Carolina during the early part of my career. I have seen that same dynamic play out time and again in the many rural and Tribal communities I have had the benefit of visiting during my time at HHS. I

appreciate the opportunity to talk to you today about these programs.

It was in the late 1990s that Congress had the foresight to create several new grant and telehealth programs, and they were really worth noting the creativity that you brought to this need, in the sense that there was a lot of flexibility built into all of these programs.

And I think that is really important because you want to make sure the programs can meet the needs of the community in the Upper Midwest and Great Plains as easily as it does in the Deep South or the Mountain West.

This emphasis on flexibility ensures that communities can come up with their own solutions that meet their unique identified needs.

I believe the Rural Health Care Services Outreach Program is a real success story. This program has helped rural communities increase access to primary care, behavioral health, and oral healthcare services. We have seen it improve outcomes for patients with diabetes, heart disease, and hypertension.

We have also been able to help provide funding to help hospitals work with local health departments, community health centers, rural health clinics to form networks of care that better serve their rural regions.

And we have also seen it be used to expand access to services otherwise not available. Examples like this include pulmonary rehab and medication-assisted treatment, just to identify a few.

All told, more than 500,000 rural residents across more than 300 rural communities received services through these grants in our most recent cohort.

Telehealth, as the committee knows, is also an important lifeline for rural communities. It helps bridge time and geographic distances to link rural residents to healthcare otherwise not available in their community.

For more than 30 years, HRSA has been able to invest in telehealth networks thanks to Congress' ongoing support.

These grants bring together all the key partners. That is including the specialists at academic health centers, working with rural hospitals, community health centers, all with an eye towards bringing care to where the patients are.

I have seen this link rural residents to services such as behavioral health, cardiology, neurology, dermatology, that otherwise they would have had to drive long distances to get to.

It has created telestroke programs that provide really important timely care for those at risk of serious stroke damage, and it has helped connect patients getting services in their home.

I think the common link in all of these programs is a commitment to its community partners working collectively to address their unique challenges.

I have seen these programs continue on well after the Federal funding, and I think that is because all the partners have a stake in the ongoing success of the program.

We thank you for your consideration of the reauthorization of these programs. We look forward to working with you on any questions you might have about them. And I thank you for the opportunity to be here today and look forward to your questions.

[The prepared statement of Mr. Morris follows:]

******** COMMITTEE INSERT ********

Mr. Griffith. The gentleman yields back.

We will now begin questioning. I ask that members not begin a new question to our witnesses as their 5 minutes is about to expire. I would encourage members to use that process where they can submit written questions for the record.

I now recognize myself for 5 minutes.

Dr. Chen, in your written testimony you mentioned our country will have a shortage of over 87,000 primary care physicians and nearly 210,000 nurses by 2037. And these shortages are not evenly distributed. They are especially acute in rural areas, like the area I represent.

I understand there are common challenges shared by multiple types of communities.

Given this disparity that you highlighted, would it make more sense to better target our Title VII and Title VIII resources to include geographic need instead of just looking at that based on race or ethnicity as some of the programs are currently operating?

Dr. Chen. Thank you for the question, and it is a very good question, particularly as I sit here next to the head of the Federal Office of Rural Health Policy.

Rural health workforce faces significant --

Mr. Griffith. Yeah, if you could speak up just a little bit

Dr. Chen. I am sorry. Significant and very unique challenges, and it does take intentionality in addressing rural health workforce shortages.

I would say Tom Morris is probably one of the people that I work the most with at HRSA to coordinate some of our programs.

However, there are ongoing workforce challenges in urban and suburban communities. For example, out of that 87,000 primary care physician shortage that we

are projecting, 18,000 of that is in rural communities; 69,000 is actually in nonrural communities.

And so it really does require that we consider all communities and all communities facing those challenges.

Mr. Griffith. I appreciate that. And you mentioned the National Health Service Corps and the Nurse Corps in your opening statement, and I have got one of these curious questions that comes to me when witnesses are testifying.

Did you grow up in the D.C. area?

Dr. Chen. I did. I grew up --

Mr. Griffith. Okay. Because one of the things I love about the, I call it the "Northern Exposure" model that the National Health Service Corps -- for those who don't know, it is an old TV show where a doctor goes to Alaska because he needs to pay off his student loans and he goes up there with a 5-year commitment.

And it was a nice show, but it also shows how sometimes you go to another place and you end up staying. And that is why I was curious as to what area you had originally come from. I was thinking maybe you came to D.C. because of the National Health Service Corps. But we are glad you are here.

That said, do you think we need to authorize more funding for the National Health Service Corps and the Nurse Corps in order to expand those opportunities for rural and underserved areas?

Dr. Chen. We defer funding decisions to Congress, of course. However, as I mentioned, the National Health Service Corps is able to award about 50 percent.

The Nurse Corps is only able to award about 6 percent of all new applications in a year. So there is a lot of opportunity there.

Mr. Griffith. Yeah. And of course this committee only can do authorization.

We can't do the actual expenditure. That goes to Appropriations. But I appreciate that.

Mr. Morris, love you are talking about telehealth. I have always loved telehealth. And, in fact, I carried the House version of the telestroke bill when it first came forward.

The resource centers, the telehealth resource centers, which we are looking to reauthorize in the bills today, serve a vital role across the country, especially in rural areas like my district.

The University of Virginia is currently the resource center for my district and all the Mid-Atlantic. Does HRSA distribute resources based on need or are the allocations the same for each center?

Mr. Morris. For our Telehealth Network Grant Program, like many of our programs, it is a combination of those things. Certainly need is a key factor in it, but we also want to make sure they have a viable work plan to move forward and that they have the personnel necessary to carry it out. So it is a combination.

Mr. Griffith. Okay. I appreciate that.

The University of Virginia has experienced a 24 percent increase in telehealth visits from their program from fiscal year 2024 to fiscal year 2025.

As we look to extend telehealth flexibilities and coverage, do you think that we need to expand the number of centers that we have, thus reducing the geographic footprint that each center serves?

Mr. Morris. Well, thank you for the question.

It is interesting, we have been focusing on telehealth in rural areas for more than 30 years. And your record goes back -- I think I talked to Karen Rubin (ph) yesterday -- back to the mid-1990s when you were advocating for this.

And so with the pandemic, we saw the benefits of telehealth universally. And so

the technology is getting less expensive each year. You can now use a personal computer.

And so we are moving less from a hub-and-spoke model to a distributed. And so the more access points, the better. It can be in your home. It can be in the clinic. It is a continually evolving technology, but it is certainly being tailored more to the patient. So the more access points, the more access.

Mr. Griffith. All right. I appreciate that.

And we all lost friends. I lost a dear friend in the COVID crisis. The one thing that came out of that was healthcare providers suddenly realized that telehealth was not as alien as they originally thought, and it was greatly expanded, and we should continue that.

I see that I am out of time. I was about to start a question and I can't do that. I said that myself.

So I yield back, and now recognize the ranking member of the subcommittee, Ms. DeGette, for her 5 minutes of questions.

Ms. DeGette. Thank you so much, Mr. Chairman.

And, Dr. Corrigan-Curay, I want to thank you for your work on OMUFA and thank you for your testimony today. I do think that this is something -- we have worked on it for many years. And when I would talk to my constituents about over-the-counter drugs, they couldn't believe that we weren't regulating them.

So I am glad the program is working, and I do think this is something that we can absolutely get moving quickly so that it can be reauthorized by the end of the year.

Dr. Chen, I want to talk to you a little bit more about Title VII and the issues that we are having in training new healthcare workers.

The chairman talked about shortages in rural areas, and that is a real problem, but

in districts like mine -- my district is the city and county of Denver -- we have challenges with some of our local community health centers in underserved areas as well.

Is this what we see nationwide, is there can be shortages everywhere?

Dr. Chen. No, absolutely. We are facing, as I said, significant overall shortages in a number of different occupations, but it is almost always in our rural and underserved. And community health centers obviously are designed to serve underserved communities that have the hardest times recruiting and retaining.

Ms. DeGette. Yeah. And I think it is about 75 million people live in a primary care shortage area in this country. So it is a real problem. Is that right?

Dr. Chen. Yes, that is correct.

Ms. DeGette. It is about 22 percent of the country lives in an area without a bare minimum necessary primary care physician. That is not even including the nurses or the mental health professionals, right?

Dr. Chen. That is correct, yes.

Ms. DeGette. So here is my question. How many additional physicians do we need to train to eliminate the primary care shortages and to get to the bare minimum nationwide?

Dr. Chen. As I shared earlier, we are projecting that for primary care physicians by 2037 we are facing a shortage of 87,000.

Ms. DeGette. We need 87,000 by 2037? So that means we have got a lot of work to do.

Now I want to talk about something that is becoming even more of an issue for me and most of the people on this subcommittee.

We have an acute shortage of geriatricians now, which is alarming at how fast the population is aging. Is that correct?

Dr. Chen. Yes, that is correct.

Ms. DeGette. Okay. And that is why Title VII includes programs for education and training in geriatrics. Is that right?

Dr. Chen. It does.

Ms. DeGette. Now, the Title VII geriatrics programs support the career development of junior faculty in geriatrics, and they help train the primary care workforce on issues relating to aging, among other things. Is that right?

Dr. Chen. Yes, that is correct.

Ms. DeGette. In the 2022-2023 academic year, over 67,000 healthcare professionals, students, patients, and caregivers received training under the Title VII geriatrics programs. Is that right?

Dr. Chen. I don't know the numbers off the top of my head.

Ms. DeGette. Okay. Do you know how many people received the training in the 2023-2024 year?

Dr. Chen. It should likely be about the same.

Ms. DeGette. About the same. Okay.

So this year the administration, instead of reporting those numbers in the fiscal year 2026 congressional justification for HRSA, the administration instead proposed to eliminate Title VII geriatrics programs, and I think that is kind of the wrong way to go. I think Congress needs to double down on this work.

So, Mr. Chairman, that is one thing I want to talk to you about, is the geriatrics program.

In academic year 2022-2023, 59 percent of the graduates who received one of the scholarships worked or trained in medically underserved communities 1 year after graduation and 30 percent in primary care settings.

So I want to ask you, Dr. Chen, are students who go to school with this kind of a scholarship more likely to work in a medically underserved area after graduation?

Dr. Chen. We do find that across our programs that students that are supported by either our grant programs or our scholarship programs are more likely to practice in high-need specialties as well as --

Ms. DeGette. Yeah, I am sorry. This is the Scholarships for Disadvantaged Students program.

Dr. Chen. Oh, okay.

Ms. DeGette. I am sorry, I apologize, I skipped a line.

Dr. Chen. Yes, yes, absolutely.

Ms. DeGette. Okay. And how many -- have any Scholarships for Disadvantaged Students grants been awarded this year?

Dr. Chen. We did not award Scholarships for Disadvantaged grants this year.

Ms. DeGette. Why is that?

Dr. Chen. We did have competitions that were cancelled. And with those cancelled competitions, we did not make --

Ms. DeGette. Those were cancelled by the Trump administration?

Dr. Chen. Well, the funding decisions were made across the administration between the agency, the Department, OMB --

Ms. DeGette. And DOGE?

Dr. Chen. I cannot speak to DOGE.

Ms. DeGette. Okay. Thank you.

Thank you, Mr. Chairman.

Mr. Griffith. The gentlelady yields back.

I now recognize the chairman of the full committee, Mr. Guthrie, for his 5 minutes

of questions.

The Chair. Thank you, Mr. Chair.

And thank all of you for being here today.

And, Dr. Corrigan-Curay, first, before I get started on my question, I see Brian Fahey sitting behind you. And I saw him walking around here, and I was just thinking it was normal. Then he goes and sits behind you.

So, do you realize you got one of the top healthcare staffers from Capitol Hill to join you?

So, I really appreciate Brian's service in my office and on our committee and now in his role in the executive branch. So, I appreciate you having great, great -- he is a great -- you will enjoy working with him. He has two beautiful girls too, so they are -- I saw him start his young family in my office.

So, first, I want to start with, I appreciate what FDA has done on the work to implement OMUFA over the last 5 years.

My question, what do you think has been successful with OMUFA, and then what would you like to see different?

Dr. Corrigan-Curay. Under OMUFA I, it was really let's build this program and starting from scratch and getting our electronic system, getting those foundational guidances, getting the staff who could do the work.

And then by year, we started to get meetings with companies to start innovation, and we received our first new OMOR for a sunscreen.

I think OMUFA II really reflects the learnings from OMUFA I. So one is that we need to provide more opportunities for innovation, and we are going to do that by certain meetings need to go longer if it is a complex question. We are going to offer opportunities to look at protocol synopsis.

We understand there are still questions about the GRASE standard, and so we are going to elicit what those questions are and do some more education.

We are going to provide more clarity on when you are doing a proposed order for a new active ingredient, including some clarity on the confidentiality of the data that comes along with that and how we treat that.

We also understand there is room to grow in the quality area of OMUFA. And so one of the things that we are going to do is, we are going to try -- we are going to staff up and get those assessments in new facilities.

So, a facility comes online and starts selling their drug, and we start asking them questions and understand their facility.

And we are also going to release those, what we call information requests -- they are the questions we ask -- because that gives industry more insight into what we are expecting. And of course we will -- any warning letters that might come out, we will.

And we are going to update our risk model. So, when we are deciding where to go for an inspection, it is specific to the kind of risk factors we might see in an OTC facility.

Finally, a lot of transparency we have. So, we got our indexing up of our older documents. We want to further give those documents.

We are going to have transparency not only around those who don't pay their fees, but those who do pay their fees. We are going to give transparency around exclusivity.

And we are generally going to continue to work with those companies on innovative. We have some proposed orders, as I said, the one about changing the dosage forms. So, we are really hoping to move forward on that.

So those are some of the examples. Thank you.

Mr. Guthrie. Thank you. Thank you for your answer.

Mr. Morris, I mentioned in my opening statement about rural health. Can you elaborate on the metrics HRSA uses to measure and improve health outcomes through the rural healthcare services and outreach program?

Mr. Morris. I am sorry, sir. Could you repeat the question?

Mr. Guthrie. Can you elaborate on the metrics HRSA uses on the healthcare program to measure and improve health outcomes on rural healthcare services?

Mr. Morris. And sort of how we measure --

The Chair. In the outreach program.

Mr. Morris. How we measure the impact of our --

Mr. Guthrie. How do you measure the impact of that program?

Mr. Morris. Yes, sir.

For the Rural Healthcare Outreach Program, we look at three main areas.

We track do they improve health outcomes. That is one area.

We also look at whether they are able to continue the grant after -- continue the project after Federal funding. Because these grants are essentially startup funding. They are not ongoing grants in perpetuity.

So, the idea is, we are funding an idea in a community, and the hope is that they are going to keep it sustainable. And we find that about over 90 percent of the grantees continue the project after Federal funding.

And we do find that, like in our most recent cohort, more than 90 percent of the grantees were able to show improved health status for the people they served.

The third area we look at is economic impact, because these dollars have a secondary role in these communities. So, for every dollar invested in our most recent cohort, it generated another $2 in economic activity.

Mr. Guthrie. Okay. Thank you.

And, Dr. Chen, we are estimated to be over 170,000 physicians short in the next decade. Title VII and Title VIII were created to help increase participation in the healthcare workforce.

How can these programs be improved -- I have about 30 seconds -- or streamlined to better meet the need, Title VII and VIII, to help attract more physicians?

Dr. Chen. I think the most important thing is that they are reauthorized.

These programs have been very impactful. We find that our health profession training programs rely on them to support training that is, again, focused on areas of need, whether it is specialties and professions that are in need, as well as integrating content into curriculum and training, for example, behavioral health into primary care, as well as training for rural and underserved communities.

So, we do find that these programs are very effective.

The Chair. Okay. Thank you.

My time is expired, and I will yield back.

Mr. Griffith. The gentleman yields back.

I now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes of questioning.

Mr. Pallone. Thank you, Mr. Chairman.

I wanted to ask a few questions of Dr. Corrigan-Curay.

First, starting with sunscreen, which is an important topic right now at the Jersey Shore, which I represent. For the summer of course, everybody uses sunscreen and worries about the type.

At our stakeholder hearing in April, we heard that the current review system has caused delays in getting new sunscreens to market. We also heard the importance of ensuring safety of the product.

So given those concerns, I don't think that the language in the sunscreen legislation we are considering today is the right approach. In fact, in a statement from the Environmental Working Group, they said, and I quote, that the bill would lower the bar for sunscreen safety.

So, Mr. Chair, I would like to offer the statement from the Environmental Working Group on the sunscreen bill into the record.

Mr. Griffith. Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Pallone. Thank you, Mr. Chairman.

So, Dr. Corrigan-Curay, from what I can tell, because they are regulated as drugs, for sunscreen products to come to market FDA requires rigorous safety data.

What are some of the harms that the agency is concerned about? Briefly, because I have got two more questions for you.

Dr. Corrigan-Curay. Sure. Thank you.

The harms that we are worried about is, if these products are absorbed systemically, they can have systemic effects across.

So that can be the endocrine system, your hormones in development. They can also affect cells and we could have abnormal growth or tumors.

So these are the kinds of tests that any drug that reaches systemic levels we test for, whether it is an over-the-counter or a prescription drug. Those are the kind of tests that we do.

Mr. Pallone. Well, thank you.

So what kinds of studies does FDA need to show products are safe from these risks? In other words, has the FDA worked with manufacturers in getting data that show products are safe from these risks that you just mentioned?

Dr. Corrigan-Curay. Yes. So the first thing we had done was, we published the MUsT studies, which is the first thing you need to do and see what level these are absorbed.

And then once they -- if they are absorbed, then we have studies that, including animal studies, that will tell us whether there are any unexpected toxicities.

And we are very much supportive of what we are doing, the roadmap that Dr. Makary and the work that we have done to reducing, or even eliminating, animal studies.

But at this time for some of those more complex, multi-organ-system toxicities we are using animal studies. We don't have a replacement.

Mr. Pallone. But are these Federal studies, or are these studies that the companies are doing that make sunscreen?

Dr. Corrigan-Curay. These are the studies that the company would do. We did the MUsT studies ourselves to show that they could be done and to provide sort of a roadmap for that.

Mr. Pallone. Okay.

Well, let me go to the provider workforce issue.

HRSA's National Center for Workforce Analysis has said there is a projected shortage of over 187,000 physicians and a projected 6 percent shortage of registered nurses by 2037.

However -- oh, this actually is of Dr. Chen. I am sorry. I want to move to you.

However, Dr. Chen, many of the programs within Title VII and VIII were proposed to be eliminated in the President's budget even though health workforce shortages only continue to increase.

So if I could ask, Dr. Chen, if Congress reauthorizes these programs and appropriates funding for them, can you confirm that HRSA will follow the law and carry out these programs?

We are always worried that we authorize things or we fund things and then the administration zeros them out or just freezes the funding.

Can you comment on that?

Dr. Chen. What I can say is that if Congress authorizes and appropriates for these programs, we will implement them.

Mr. Pallone. All right. Well, that is really important. I really appreciate your

telling me that. Because I do think that these workforce programs are more important than ever, and any attempt to eliminate them is really going to exacerbate the country's workforce shortages.

The other thing I would say too is, I know that we have relied a lot in the past on going overseas to get doctors and to get nurses.

And, I mean, that is fine in theory because we have such a shortage, but I really would much prefer that we train those people here and don't have to rely on other countries, because a lot of times I think it drains the doctors and the nurses in the other countries.

I mean, people tell me that that is not the case, but it is hard for me to believe that it is not the case.

So thank you.

And thank you, Mr. Chairman.

Mr. Griffith. The gentleman yields back.

I now recognize the new vice chair of the Health Subcommittee, Mrs. Harshbarger of Tennessee.

Mrs. Harshbarger. Thank you, Chairman Griffith. I appreciate that. And it is an honor to be the vice chair.

It is the first reauthorization of OMUFA, and it is important that we get it right. And we have made a lot of progress in the first 5 years of this, but I don't think we have realized the full potential of what Congress set out to achieve on behalf of consumers with this.

So we need to work through that to improve the regulatory certainty and minimize regulatory burdens where possible. And I have got a lot more questions for you.

But, anyway, we will start with Dr. Chen.

I represent a very rural area in east Tennessee, and I also co-chair the Congressional Bipartisan Rural Health Caucus. And we continue to hear that patients in rural areas have a much harder time accessing quality healthcare services, which is often due to a lack of providers in the immediate area. And we need to ensure that taxpayer resources are reaching the communities that need it most.

And the term "disadvantaged" is used throughout Title VII and Title VIII of the Public Health Service Act. And my question is, how does the Secretary define such a term?

Dr. Chen. The definition that we use in our programs often is directed by statute, and if there is a particular program that you are interested in, we can follow up with you afterwards with the specifics.

Mrs. Harshbarger. Okay.

Mr. Morris, I joined Representative Emanuel Cleaver to introduce bipartisan legislation to expand the scope of rural health grants to include mobile integrated health and community paramedic grantees, enabling Americans in rural communities to receive centralized mobile and preventative care through local paramedics. And it is an increasingly popular initiative in healthcare known as Community Paramedic.

Currently, EMS is considered a service provider of transportation. However, EMS has progressed over the years to become a crucial part of the healthcare system.

What are your thoughts on reform of the current EMS system, and does HRSA see the value of Community Paramedic as a part of the future of EMS and healthcare as a whole?

RPTR BRYANT

EDTR ROSEN

[11:00 a.m.]

Mr. Morris. Thank you for the question. Yes, the use of community paramedicine local integrated care has been growing for the last 10 years. And it is another example, I think, of the creativity that rural communities can bring to this.

I think what spurred its creation was you had EMTs and paramedics with downtime between calls, and somebody had the idea that they could go do blood pressure checks and home visits, and it extended a somewhat some constrained workforce. So I think it has worked well.

We funded a number of those programs through the Rural Health Outreach over the years, and I am sure we are going to continue to fund them because they really do work.

I think the larger challenges are how to sustain them. There are some pathways forward where it might work well in a value-based care system, but we are also on a fee-for-service system. So part of the challenge is figuring out the best way to cover those services.

Mrs. Harshbarger. Yes, really a lot of different ways to pay for different services. Telemedicine is another.

So they fundamentally believe in the right care at the right place at the right time. And that mentality means that the emergency department isn't always the best place for that patient, and often, those patients can be treated in place or via telehealth.

Do you see how that is not only good for the patients, but also for really the financial portfolio of the healthcare system as a whole?

Mr. Morris. Yes, ma'am.

Mrs. Harshbarger. Dr. Corrigan-Curay, independent pharmacies are the bedrock of our communities. And can you tell us how CDER is operationalizing the OTC-ACNU pathway in order to expand the role of consumer health products and helping consumers manage their health?

Dr. Corrigan-Curay. Sure. You are referring to our additional condition of use, which is a PDUFA program. Yes, there is lots of flexibility in operationalizing. A company will come in and they will establish that the usual sort of drug facts label is not sufficient for selection, and then there will be another condition of use that will be put on. Whether that would be going to a website, whether you could have something within a pharmacy, some questions, electronic kind of questions, but something that you would have to satisfy that condition of use before you access the product.

And we really think that this is going to be key to getting more of those products that we just can't get that self-selection through the label, and perhaps for chronic diseases. And so we will be working with companies on how to innovate in this area.

Mrs. Harshbarger. Okay. That is very, very good. As a pharmacist, that makes me feel good. And then there are certain things that should be kept behind the counter, but we will talk about that later.

Thank you, and I yield back.

Mr. Griffith. The gentlelady yields back.

I now recognize the gentleman from California, Dr. Ruiz.

Mr. Ruiz. Thank you, Mr. Chairman.

I represent a very rural district in southern California, and I am an emergency physician by background. So I have seen the real need for investments and improvements in rural healthcare systems.

Patients experience unique barriers to carry in rural communities, like long

distances to the nearest clinic and transportation challenges; long ambulance wait times that delay critical care; and provider shortages. That is why continued investments in workforce pipelines and programs to improve patients' access to care and quality of care are so important.

The committee is considering a bipartisan bill today that would reauthorize several programs that help strengthen healthcare in rural communities: H.R. 2493, the Improving Care in Rural America Reauthorization Act of 2025 by Representatives Carter and Schrier that I support.

The bill would reauthorize three important programs: The Rural Healthcare Services Outreach Program, the Rural Health Network Development Planning Program, and the Small Healthcare Provider Quality Improvement Program.

Mr. Morris, in what ways have you seen these programs lead to improved access to care in rural communities, and how does HRSA measure the impacts of these grants?

Mr. Morris. Thank you for the question. The programs -- let me speak to the outcomes first. I noted earlier that we have three primary ways that we measure the impact they are having on our community.

The first is we look at whether they are improving health status. And so our most recent cohort, which is around 90 percent of the grantees, were able to show improved health status for the folks they served.

The second way is these are essentially --

Mr. Ruiz. So better health?

Mr. Morris. What is that?

Mr. Ruiz. So better health?

Mr. Morris. Yes, better health.

So these are startup funds. They tend to be the 4-year grant. In the case of the

planning grants, it is a 1-year grant. So they are not grants that somebody gets in perpetuity, but just to get a good idea off the ground.

So one of the things we look at is sustainability. And typically, a little more than 90 percent of our grantees are able to keep the project going after the grant ends.

Mr. Ruiz. So they add new healthcare services.

Mr. Morris. Yes. So the Federal funding got it started, but the community kept it going. And one of the ways that we do that is we don't fund a single entity, we fund a consortium of folks. So we have a health department coming together with a hospital or a clinic. And we find if you have more people involved in the program, they feel more vested.

Mr. Ruiz. So more access to care because there are more services and there are better health outcomes.

What aspects of rural health do you see the greatest need for improvement?

Mr. Morris. Well, I think you look at the five leading causes of death, and in every State in the country, you see people in rural areas tend to die at a higher rate for avoidable or excess death. So cardiac disease, diabetes, injury, pulmonary disease, diabetes, all of those are high-need areas.

Mr. Ruiz. Would access to a hospital nearby affect health outcomes in rural communities?

Mr. Morris. Definitely. I mean a hospital can often --

Mr. Ruiz. So if a hospital would close, it would put in jeopardy the health outcomes of that community?

Mr. Morris. When any healthcare entity closes in a community, you have --

Mr. Ruiz. The big ugly bill is projected to close about 20 percent of rural hospitals. That is a big problem. That is going to take us backwards in improving the

health.

Also vital to the improvement of healthcare quality and access in rural communities are programs to support the physician workforce pipeline. Title VII of the Public Health Service Act promotes education and training for healthcare professionals. Title VII programs help bolster our healthcare workforce. So we must ensure these programs continue to have the resources needed to help our communities.

According to HRSA's own data, our health system is projected to be short by at least 187,000 physicians by 2037. As we face increased provider shortages, I am concerned about recent actions that not only make it harder for those who want to pursue medical education.

The Republicans' big ugly bill capped Federal student loans for professional schools at 200,000, which is far below the average cost of attending medical school, and eliminated, completely eliminated the Graduate PLUS Loan Program that helped them fill the gap between their loans and the cost of medical school.

So this will be particularly devastating for economically disadvantaged students from underserved communities, exactly where we need the physicians the most. As we know, physicians are more likely to practice medicine where they grow up, and we need more providers in underserved communities. To make matters worse, the Trump administration has proposed cutting numerous workforce development programs from Title VII.

Dr. Chen, what impact would cutting these programs have on the healthcare workforce?

Dr. Chen. Well, as I have mentioned, our programs definitely have had positive impacts on all the things that you are talking about, and we recognize that funding decisions have impact.

Mr. Ruiz. So eliminating them would have negative impacts? It is okay to say yes.

Dr. Chen. Yes.

Mr. Ruiz. Thank you. I yield back.

Mr. Griffith. The gentleman yields back.

I now recognize the gentleman from Florida, Gus Bilirakis.

Mr. Bilirakis. Thank you very much, Mr. Chairman. I appreciate it. Congratulations on your chairmanship. I know you will do a great job.

So, Mr. Chairman, thank you again for the opportunity to discuss a number of important reauthorizations to support the public health workforce, rural health, of course, and over-the-counter medicines, all of which reach every aspect of our daily lives. I look forward to learning more from our witnesses on how our committee can improve these critical programs.

First, I would like to highlight the Newborn Screening Saves Lives Reauthorization. Newborn screening is one of our Nation's most successful public health programs, as you know, serving nearly 4 million infants each year and saving thousands of babies' lives.

As co-chair of the Rare Disease Caucus, I am acutely aware of how identifications and interventions significantly improve health outcomes for those born with rare diseases. I remain committed to strengthening the critical program while embracing innovation that allows it to keep pace with the rapid advances in diagnostic science and technology.

I also am interested in learning more about the Over-the-Counter Monograph Drug Reauthorization and promoting innovation in the over-the-counter space for American consumers.

So the question, the first question is for Dr. Corrigan-Curay. I hope I got that

right. As you are well aware, ma'am, the monograph sets the conditions under which the OTC drug products are generally recognized as safe and effective, also known as GRASE. We have heard from stakeholders in our last hearing that more clarity could be provided around the standards for GRASE determinations.

Can you provide a high-level overview of the current standards the FDA uses when making these determinations, and how do you think the FDA can clarify and improve the GRASE standards, please?

Dr. Corrigan-Curay. Yes. Thank you for that question. So the GRASE standard is safe and effective, and it is a standard that is similar to what we use for drugs that aren't over-the-counter. And it is important that they be just as safe and effective, because these are drugs that, of course, are used not under the supervision of a physician.

That being said, each program we look at individually, and we look at the data that we need to establish that. And we will work with a company, and we can have back-and-forth. That is part of our meetings. That is part of things like the protocol synopsis, so that we can have that discussion and determine what is the data that is necessary to meet that standard.

And under OMUFA two, we have committed to do further education in this area, and we will be soliciting from industry where their questions are so that we are most responsive to them.

Mr. Bilirakis. Thank you so much.

Dr. Chen, as you know, Florida has a high and growing population of older Americans, and, simply, we need more healthcare professionals trained in geriatrics in our State or any other State, for that matter.

We are fortunate to have two Geriatric Workforce Enhancement Programs in

Florida that are working hard to train doctors, nurses, social workers and caregivers on how to more effectively care for older adults, especially those with chronic conditions and Alzheimer's disease, and I will add Parkinson's as well.

Would you explain why these programs are important to our ability to provide efficient care to this population, and how effective are these programs in incorporating new and improved technologies and treatments in geriatric care?

Dr. Chen. Thank you. Actually, that was an excellent summary, I think, of what the Geriatric Workforce Programs do. They are grants to organizations, healthcare organizations, who then work to train the workforce. But actually in the training of the workforce, they are also delivering care. So it is a real combination. And as you stated, the aging of our population means that this workforce is needed.

Mr. Bilirakis. Thank you very much.

Anybody else on the panel want to add something to that? Well, I appreciate it very much.

And I will yield back, Mr. Chairman. Thank you.

Mr. Griffith. The gentleman yields back.

I now recognize the gentlelady from Michigan, Mrs. Dingell.

Mrs. Dingell. Thank you, Mr. Chair. Thank you for holding this important hearing on a range of critical public health topics, including the Over-the-Counter Monograph Drug User Fee Program that is expiring this year. I am very proud to have helped write it with my colleague, Diana DeGette, and my colleagues on the other side of the aisle in a bipartisan effort to create the program and its enactment in the CARES Act.

Through discussions involving Members, patients, doctors, pharmacists and advocates, I am glad we were able to take the first step towards reauthorizing OMUFA before it expires this year on September 30th.

But as we work towards a reauthorization that will improve access to safe, effective over-the-counter products, I am very concerned about the ability to implement this reauthorization without a strong FDA workforce. In April, more than 3,500 FDA employees were laid off, a roughly 15 percent reduction in force.

Secretary Kennedy has announced that he would reverse a portion of the broad cuts without specifying how this would occur. Firing key drug safety officials in the name of efficiency I believe is shortsighted. It is not the way that our healthcare system should be run, and that it risks American safety.

The Trump administration has stated that anticipated cuts to the FDA workforce will not affect product reviewers or inspectors. Even if these positions are spared from terminations, gutting the agency workforce leaves them with more responsibility and fewer resources. The idea that they will not be impacted is simply not realistic, especially when the FDA is already understaffed and behind on inspection deadlines.

Dr. Corrigan-Curay, I understand you can't answer questions about RIF, so I won't put you in the position of asking you a question on that specifically. However, we do need to ensure the agency has the necessary staffing to enable product evaluations without compromising FDA's dedication to scientific integrity, public health, regulatory standards, patient safety, and transparency. The user fees are central to that.

So what I will ask is the impact on staffing if this program is not reauthorized on time. For example, what happens to staff in the workflow and availability of patients?

Dr. Corrigan-Curay. Thank you for that question. You are correct. If this program was not authorized on time, approximately 44 percent of the scientists, reviewers and others working in this area would have to be terminated. And what would happen is we would stop meeting on development programs. The proposed orders we have out, including the one on changing the dosage forms, would not get done

and delayed. The new sunscreen that we are trying to work, we would miss those deadlines and we would fall back on the innovation that we are working on.

Mrs. Dingell. Thank you. So my colleagues, we have got to work together on this.

As a co-chair of the Skin Cancer Caucus, I would like to turn to the issue of sunscreen regulation, and recognize we have skin care patients and advocates in the audience today. Thank you for being here and for your advocacy and dedication to the cause of skin cancer prevention.

I have introduced a bipartisan bill, the SAFE Sunscreen Standards Act, alongside my fellow co-chair, Representative John Joyce, which would streamline the FDA review process of the effectiveness and safety of new ingredients for nonprescription sunscreens.

But we do want to make sure everybody is safe. Sunscreen is critical in the prevention of skin cancer, yet there are concerns that the current FDA regulations regarding sunscreen-active ingredients aren't sufficient. There hasn't been an approved new active ingredient in sunscreen since 1999. You can go to Europe, you can get much better product than you can get here.

Dr. Corrigan-Curay, I first want to get your opinion on the current situation of the sunscreen testing requirements. Do you see opportunities for Congress to act to alter the requirements on testing to increase the available active ingredient list?

Dr. Corrigan-Curay. Thank you for that question. I think we are willing to work with you on legislation. We do want new sunscreens on the market. We want to make sure they are safe. We do have a new product, the first OMOR was for a sunscreen. So we hope that perhaps we will break that 1999 record.

But these are drugs, and when we see that they are systemically absorbed at a

rate that they could have systemic effects, we need to evaluate that. And we are willing to look at ways to evaluate it, provided we get the information that will allow us to determine it is safe.

Mrs. Dingell. I am going to submit more questions for the record because I am out of time, but I do think we have got to figure out how the FDA balances health and environmental concerns with the need to access the most updated sunscreen technology and medicine.

So I am going to have questions for the record and yield back, Mr. Chairman.

Mr. Griffith. The gentlelady yields back.

I now recognize the gentleman from Georgia, Mr. Carter.

Mr. Carter of Georgia. Thank you, Mr. Chairman.

And thank all of you for being here.

I am pleased that two of my bills are included in today's hearing, the Improving Care in Rural America Reauthorization Act and the FDA Modernization Act.

Improving rural healthcare is one of the top issues on my priority list. As we like to say in the State of Georgia, there are two Georgias. There is Atlanta and there is everywhere else, and I represent everywhere else. So it is important, particularly in rural south Georgia.

And we know that rural communities have a lot of obstacles. We know they have workforce problems. We know that they have distance and transportation issues.

That is why the Improving Care in Rural America Reauthorization Act will reauthorize the Rural Health Care Services Outreach Programs. And those programs fund locally driven projects that focus on improving access to care and quality improvement and things that we want to improve on.

Mr. Morris, let me ask you, many rural communities have higher rates of chronic

diseases, like diabetes and hypertension. What specific interventions funded through the outreach program have been most effective in reducing chronic diseases in rural areas?

If you will remember, when Secretary Kennedy took over at HHS, he made it clear and he has made it clear ever since then that he really wants to address chronic disease. It impacts over 26 million people in our country, and it is something that he has made as a priority. And we on this Health Subcommittee want to make it a priority as well.

Mr. Morris. Thank you for the question, and thank you for your sponsorship of the reauthorization of this program.

You know, when we review the applicants of this program, it is a good indication of where the greatest needs are, because the communities are able to identify what they want to work on and how they are going to address it. And so we do see a lot of our applicants coming in looking at chronic disease.

I think the things we have seen that have been really effective over the years are early screening, so you can identify somebody who is at risk of a chronic disease and then getting them into a care plan.

So a lot of our grantees include both screening programs and then care coordination as well. We see a lot of use of community health workers to help people pay attention to their meds and keep track of what they need to do to manage their chronic disease.

These grants, because they are essentially startup funding, they can also provide the initial salaries for a new doctor or a new nurse practitioner, and that can help get the project going as well.

Mr. Carter of Georgia. Do you do anything with diets, because we are known as the cardiac belt, because of our diets. We have such good food and such good cooks

down South.

Mr. Morris. I miss that food, sir, but I take your point. And certainly I know of an example in your district in Baxley, Georgia, the Appling Partners in Health. And a big part of what they are doing is looking at how to teach people how to cook more healthy foods as a way to address --

Mr. Carter of Georgia. But it is not as good. I mean it is just -- anyway, Dr. Corrigan-Curay -- thank you, Mr. Morris.

Dr. Corrigan-Curay, I appreciate the administration's focus on reducing animal testing and including FDA's roadmap for reducing animal testing in preclinical safety studies. We all know that millions of animals are being killed unnecessarily, and we want to do something about this.

That is why I have introduced the FDA Modernization Act 3.0, which will allow for the development of safe and effective treatments and therapies without unnecessary animal suffering. We have a law for animal-free testing methods on the books, and it is time we put it to use by expanding testing options.

When does the agency anticipate making updates to its recommendations or guidance on this matter?

Dr. Corrigan-Curay. Thank you for that question. We are committed to reducing, and even eliminating if we can, animal testing. We have been successful in certain areas. We don't test eye irritation or skin irritation with animals, and we will make sure that our guidances and our rules make it clear that we are open to companies coming in with these alternative methods.

We had a very great meeting with NIH, lots of science was discussed, and I think we are really on a good road to move forward in this area.

Mr. Carter of Georgia. Good. Thank you, Dr. Corrigan.

Mr. Chairman, I was very pleased to see OMUFA reauthorization on today's agenda along with my FDA Modernization Act 3.0. One key tenet of the FDA Modernization Act are the provisions on nonanimal testing methods for 505(g) or all monograph drugs. This will open the door for greater innovation and innovation products for consumers.

I look forward, Mr. Chairman, working with you to include this language into the OMUFA. So thank you, and I will yield back.

Mr. Griffith. The gentleman yields back.

I now recognize the gentlelady from Washington, Dr. Schrier.

Ms. Schrier. Thank you, Mr. Chairman. Thank you, Ranking Member. And thank you to all the witnesses for being here today.

As a pediatrician, I first want to talk about newborn screening. I am so happy that our committee is considering the Newborn Screening Saves Lives Reauthorization Act, which is legislation that I co-lead with Dr. Morrison.

The heel prick blood test that every newborn in this country gets is a simple, low-cost, effective tool to identify and treat so many rare diseases. In fact, I was recently at a food bank in my district, and one of the volunteers there was a teenager who I diagnosed when she was born with PKU, phenylketonuria. And she is doing so well and thriving in high school because of this early detection and treatment, which she has been so good about doing.

And I just want to tell you that, or tell everybody that without that newborn screening and early treatment, she would not have been diagnosed until permanent developmental delays and seizures and other just terrible outcomes. So this was really a godsend for her.

And this is the common denominator with all these diseases. They are rare, but

early detection and treatment helps these kids live totally normal lives. And sometimes that is with diet, sometimes medication, sometimes gene therapy.

And I just want to emphasize the importance and say that I really look forward to working with this committee to advance this important bill.

I also wanted to touch on rural health. And we have been talking about the doctor shortage and the Improving Care in Rural America Reauthorization Act, which I co-lead with Congressman Carter.

My district is 10,000 square miles, and so, it includes a lot of rural communities that depend on scarce providers and vulnerable hospitals. And this bill will help expand access.

However, I just would be remiss if I did not point out that almost all House Republicans voted to cut a trillion dollars from Medicaid just a couple weeks ago. And I just want to say that this one big ugly bill will close rural hospitals, and it will impact the very communities that we are talking about helping. And so, this just feels somewhat hollow to be supporting this bill, and at the same time, taking away with the other.

I was wondering if you could just touch on in maybe 30 seconds, Mr. Morris, the impact of Medicaid cuts on rural hospitals and the already existing shortage of primary care doctors.

Mr. Morris. Thank you for the question. I will defer the workforce portion of the question to my colleague. The passage of the bill, we are still reviewing that language and --

Mr. Griffith. Can you move the mic a little bit closer.

Mr. Morris. I will defer the primary care question to my colleague. On the passage of the bill, we are still reviewing the language in the bill. And obviously, it will be implemented by the Centers for Medicare and Medicaid Services, and we are there as

a resource as they work through it.

Ms. Schrier. We anticipate -- the data shows that it will close one in four rural hospitals, just to let you know what you will find when you look at the data.

I also wanted to talk about the physician and nurse workforce, because we are considering the reauthorizations of Title VII and Title VIII health workforce programs. And this ensures that we have the physicians, nurses, dentists that we need to serve patients, particularly in rural areas.

And we do need a bigger pipeline and we need these programs, and I support these programs. And again, though, I just have to say that this feels hollow to hear my colleagues' support for Title VII and Title VIII when they just voted to severely limit financial aid for medical and nursing students, capping the amount that they can take out, making it so that interest starts accumulating immediately, making them more expensive and lengthier to pay off, and that these are the exact students that we are talking about who would benefit from Titles VII and VIII. In addition, the Trump administration has proposed gutting most of the nurse workforce programs within Title VIII.

Dr. Chen, it is great to see you again, a fellow pediatrician. What will happen to our health system if your agency loses funding for nurse workforce programs, like the Nurse Faculty Loan Repayment Program and the Nurse Education, Practice, and Retention program, and loans become more difficult to pay off?

Dr. Chen. I think I can -- I will just reemphasize that we do know that our programs are impactful, that they have made a difference in terms of workforce shortages and distribution of the workforce.

I think what we realize, though, is that the President's budget is the beginning of the conversation, that Congress ultimately makes the final decision. And we are ready to work with you on this.

Ms. Schrier. We think so. I hope that this Congress stands up for bills that we passed in a bipartisan way and does not let this President do a runaround our power of the purse.

Thank you, and I yield back.

Mr. Griffith. The gentlelady yields back.

I now recognize the gentleman from Texas, Mr. Crenshaw.

Mr. Crenshaw. Thank you, Mr. Chairman.

We all know the FDA plays a very critical role in protecting the health and safety of Americans, but we also know some of the systems have not kept up with modern science and consumer needs.

It is one of the reasons I am proud to support the bipartisan reauthorization of the Over-the-Counter Monograph User Fee Program. And it has some smart updates to it. I think it helps the FDA keep everyday medicines, like allergy meds, cold remedies, sunscreens safe and up to date, but without adding red tape.

It brings more transparency, scientific flexibility and accountability to assist in that over 90 percent of Americans rely on. OTC products help people manage their health. They avoid unnecessary doctor visits, and that is good for families, good for our rural communities. It is good for a sustainable workforce. So fixing the system, making it work better for everyone, I think, is in our interest.

Dr. Corrigan-Curay, this legislation formally allows the use of voluntary consensus standards and alternative testing methods for monograph updates. Help us understand that. How does that change the scientific flexibility and efficiency of the review process?

Dr. Corrigan-Curay. Well, I think the voluntary consensus standards, using those, you know, they are known, they are transparent, they can be relied on. And, you know, alternative standards, we have asked in OMUFA two, we want to have a new tier, what

we call a tier two proposed order so that we can update some of the outdated tests that may be in some of the monographs.

So I think we are willing to work with that and try and use -- how do we get -- use the most up-to-date testing that gets us to the answer that we need, and, of course, update some of these testing standards that were in the monographs.

Mr. Crenshaw. We are talking about over-the-counter monographs. What about applying those kind of standards to other pathways in FDA? Do you have any comments on that? I don't want to throw you something out of left field there, but --

Dr. Corrigan-Curay. Sure. And all of us, when we are looking at any alternative method to gather data, for example, the alternatives to animal testing, we are going to use those across the board. So if they can answer a question of safety in an OTC drug, and they can answer it in a prescription drug, then we are going to use it.

I would mention that there are many places we don't use animal studies. For example, in our biosimilar program, when we are approving new biosimilars. Most of our generics don't need animal studies. Those are a lot of medications that are used every day. But any test that is fit for purpose we will use across for other products.

Mr. Crenshaw. Yes. And I will reiterate over and over, and I hope one of our goals in this committee is, while maintaining safety standards for the American people but making the FDA an efficient process, that does not destroy the last remaining innovative industry in the world, which is in the United States. And I hope that is a goal of our administration, and I think it should be a goal of this committee.

Mr. Morris, in many rural communities, access to a physician can be limited to a part-time clinic or a distant hospital. For residents in those areas, how essential is it to have reliable, over-the-counter medications available for managing common health needs?

And to follow up, are you hearing concerns, whether from patients, providers, States, that outdated or ineffective OTC drugs are still in circulation, simply because the FDA hasn't had the resources to review them?

Mr. Morris. Congressman, thank you for that question. It is outside of my knowledge base. I defer to my colleague at FDA on that. I would think the same challenges --

Mr. Crenshaw. Feel free to jump in. That is fine.

Dr. Corrigan-Curay. You know, we are overseeing and looking at the safety/effectiveness. As you know, we have an order to update the acetaminophen safety for a rare side effect. We also have the proposed phenylephrine order we are trying to work through, which would -- you know, on efficacy, the lack of efficacy there.

And so we also, on our agenda, we are going to do some updates in the pediatric dosing for acetaminophen by weight-based, as well as update NSAIDS for some issues for pregnant women. So we are continuing to work through. And I think we are effectively making sure that they are safe and effective.

Mr. Crenshaw. Okay. I appreciate that.

And I will have more questions. I am almost out of time so I yield back.

Mr. Griffith. The gentleman yields back.

I now recognize the gentleman from Texas, another gentleman from Texas, Mr. Veasey.

Mr. Veasey. Thank you, Mr. Chairman.

I want to thank the witnesses for being here today. There is one area of public health where the stakes could not be higher, and that is newborn screening. Every year, nearly 4 million babies are born in the United States, and newborn screening identifies about 14,000 babies each year with potentially life-threatening or life-altering conditions.

For those children, getting an early and accurate diagnosis can mean the difference between a healthy life and irreversible harm or even death.

In 2003, under President George W. Bush, the Advisory Committee on Heritable Disorders in Newborns and Children, or ACHDNC, was established to save lives and spare families from suffering.

Across Democratic and Republican administrations, that committee has determined which conditions belong on the Recommended Uniform Screening Panel, or RUSP, the gold standard that guides States on which conditions to screen for at birth. The RUSP is the reason 14,000 families annually can get a timely diagnosis, early interventions, and have a fighting chance for their children.

Despite this progress, I was saddened to learn from a family in my district in April that HHS quietly and really abruptly dissolved this committee. There were no hearings or no warnings, no consultation with families. And this reckless decision put children's lives at risk, plain and simple. And let me tell you why.

Before the committee was shut down, it was on the verge of voting to add a new condition onto the screening panel, and that is Duchenne muscular dystrophy, or DMD. And DMD is a very devastating genetic disease that primarily affects boys and causes muscles to degenerate and weaken over time. Children often appear very healthy at birth, but without early detection, symptoms like difficulty walking and frequent falls begin to happen at around the age of three or four. Eventually, DMD patients lose the ability to walk. Their heart and breathing muscles weaken, and many die in their early twenties and early thirties from respiratory or heart failure.

Mr. Chairman, I would like to enter into the Congressional Record an NBC article that tells the story of Jennifer McNary and her two sons.

Mr. Griffith. And what is the organization?

Mr. Veasey. I want to enter it into the record.

Mr. Griffith. No, I know you want to enter it into the record of the committee, but I am trying to figure out -- you gave initials or something. What is the organization that printed it?

Mr. Veasey. NBC News.

Mr. Griffith. Oh, NBC News. I am sorry, I just couldn't hear that. And do you have a date on that?

Mr. Veasey. Yes. This article is dated April 17, 2025, sir.

Mr. Griffith. Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Veasey. Thank you. Jennifer is a mother who has lived through both devastation and hope associated with newborn screening. Jennifer's eldest son, Austin, was diagnosed with DMD at age three, when he was already struggling to walk. Austin and his family bravely fought for years, but his diagnosis came too late to change his trajectory of his disease. Sadly, Austin died this past February at age 26.

Jennifer's second son was born into a different world, a world shaped by newborn screening. Max was also diagnosed with DMD at birth, allowing him to receive physical therapy and steroids and to become one of the first patients able to tolerate a new gene therapy treatment.

Max walked until he was 17, 7 years longer than his older brother. Now Max is 23, uses a wheelchair and needs help getting in and out of bed, but he is still alive and he is able to live semi-independently and he is able to go out with friends. And he is here because of newborn screening and early intervention.

That is the difference this committee makes. That is the difference that RUSP makes, and that is the difference this legislation makes. This is not hypothetical. It truly is life or death for many families. And we would be striving to close that gap, not allowing the future of newborn screenings to wither on the vine.

Doctors and advocates across the country warn that dissolving ACHDNC puts us at risk of returning to a patchwork system where children's chances of survival really does depend on their ZIP code. And our newborn screening system saves thousands of lives each year, but it cannot function in the dark.

So I am glad this hearing includes a discussion draft of the Newborn Screening Save Lives Reauthorization Act of 2025, but I am going to be frank. I am really outraged at where we stand today, with no functioning ACHDNC and no roadmap for its reinstatement. This simply cannot wait.

Mr. Chairman, thank you.

Mr. Griffith. The gentleman yields back.

I now recognize the gentleman from Pennsylvania, Dr. Joyce, for his 5 minutes of questioning.

Mr. Joyce. Thank you, Mr. Chairman. And congratulations on your new role as the chairman of the Health Subcommittee. We look forward to working with you.

I would further like to thank you for including the SAFE Sunscreen Standards Act in this hearing. This is my bipartisan legislation, also introduced by Representative Dingell, Representative Ross, and Representative Dave Joyce of Ohio. This represents a year-long work product from the congressional Skin Cancer Caucus aimed at fixing a serious health crisis that we are facing each and every day in the United States.

Today, nearly one in five Americans will develop skin cancer in their lifetime. Squamous cell carcinomas, basal cell carcinomas are estimated at over five million cases each year. In 2025, it is estimated that over 200,000 cases of melanoma will be diagnosed. And in the last 15 years, we have seen that number of new invasive melanomas diagnosed to be increased by almost 50 percent.

We also know that the vast majority of these cancers are caused by ultraviolet damage from the sun. This means that the use of sunscreen decreases the risk of these skin cancers occurring dramatically.

As a dermatologist, the best sunscreen is the one that someone will actually use. And, unfortunately, this is an area that the United States has fallen behind the rest of the world in approving new sunscreen products.

I know that it has been stated before in this hearing but, Dr. Corrigan-Curay, since 1999, over 25 years ago, how many new sunscreen ingredients and formulations has the FDA approved for use in the United States?

Dr. Corrigan-Curay. We have not approved a new one, but we do have a new order.

Mr. Joyce. That is frightening. Zero is the answer since 1999. That was most of my time as a practicing dermatologist in the United States. No new sunscreens.

Mr. Chairman, I would ask unanimous consent to introduce into the record letters of support from the Skin Cancer Foundation, AIM at Melanoma, the SUNucate Coalition, and the and PASS Coalition.

Mrs. Harshbarger. [Presiding.] Yes, sir, without objection.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Joyce. Thank you. These letters represent consensus, consensus support for this bill from physician groups from the American Academy of Dermatology, melanoma research groups, and those involved in actual day-to-day patient care.

The risk for these patients is real. I worked in this area. I saw it every single day of my career as a physician. For children and adolescents who develop just one single blistering sunburn this summer, they will double their chances of developing melanoma in their lifetime. One blistering sunburn, double your chances of a potentially deadly disease.

And the FDA has failed for over two decades to keep pace with innovation in this space. So while I understand the minority does have concerns on environmental issues here, the risk of cancer and ultimately death is something that must be considered in this balance.

Dr. Corrigan-Curay, other countries that regulate sunscreen ingredients as drugs have found ways to ensure high safety standards while ensuring that their populations get access to newest innovative techniques and products. This represents right now a failure at the FDA.

Are you willing to commit to working with this committee and stakeholders on ways to increase access while ensuring the safety for the American consumer?

Dr. Corrigan-Curay. Thank you. We are willing to work. I think we share the same goal of having additional choices. We do have very effective sunscreens. I do want to say that there are sunscreens on the market that are effective. But we understand that having additional options is important, but also understanding the safety of those options.

Mr. Joyce. Thank you. Both Representative Debbie Dingell and I stand ready to work with everyone on this committee to make sure that the text of this policy meets the

stated goals, and have the desired impact at the FDA and account for any patient safety concerns. We respect and understand that.

But American citizens are dying today as we are holding this hearing from metastatic melanoma. We can have that impact. We must take the next step to have that impact. I strongly urge consideration of this bill.

And, Mr. Chairman, I yield back.

Mrs. Harshbarger. The gentleman yields back.

And now I will recognize the gentlewoman from Texas, Representative Fletcher.

Mrs. Fletcher. Thank you so much, Madam Chairwoman.

And thank you to Ranking Member DeGette.

Thank you to all the witnesses for your testimony today. It has been very helpful. And I appreciate that all of you are public servants who care about the health and well-being of people across this country and have dedicated your careers to doing that, and we are here to talk about those things in your recommendations today. So I really want to thank you not only for your testimony but for your work.

At the same time, I have real concerns that once again, even if we reauthorize these programs, we won't have the funding or the staff to carry out these important recommendations and implement the information that we are hearing.

I brought up this concern in April when we first were at our hearing on the Over-the-Counter Monograph User Fees Reauthorization. And I just don't understand why we are having another hearing on this, on reauthorizing a program that supports FDA's work, while simultaneously allowing the Trump administration to gut the FDA's workforce.

This applies to the program reauthorizations under consideration today in these bills that fall under HRSA as well. And if everyone doesn't know, HRSA is slated to be

eliminated completely as an agency under HHS, under Secretary Kennedy. We had him here a couple weeks ago. We need to have him back here, because these are hugely important questions.

This is going to be eliminated as a subagency, and it is all part of the administration's effort to shrink government. And many of the critical workforce programs that we are talking about that HRSA oversees were slashed in President Trump's budget that this Congress is considering and seeming to move through without opposition, without objection to cutting the Federal workforce, to cutting these agencies, to cutting the work that is being done to help people in our communities and to keep them safe and to help them be healthy and healthier.

And it is not included in the authorizations that we are talking about today, but one example of a workforce program that was eliminated in the President's budget that we talked about a little bit earlier is the Children's Hospitals Graduate Medical Education Program, the residents in children's hospitals.

This has traditionally been a bipartisan program with a ton of support, and it is the only Federal program dedicated to training pediatricians. And our resident pediatrician already asked her questions, but we know, we know from people across our districts that this program helps train the doctors who take care of our children. And it is eliminated in the President's budget. It is completely eliminated. The President has decided this is no longer worthy of support.

So my questions, I have questions that I am going to ask the witnesses, but my real question is for the Republicans on this committee. If we reauthorize these programs, and in the next budget the President eliminates them, are you going to vote against them? Are you going to do anything to object and to fight for the programs that everyone here is saying they wanted.

We are introducing bipartisan bills about reauthorizing programs that we are letting the Trump administration -- and when I say "we," I mean half of this body, the majority in this body over the strong objections of the people on my side of the aisle are letting the administration run roughshod, are doing whatever the President wants without question in cutting agencies, in cutting funding, in cutting staff, in saying they want to get rid of all these things.

Will you vote against that? Will you object? Will you stand up for the things that we are talking about today? If we pass the Over-the-Counter Reauthorization and there are no staff to review over-the-counter drugs, are you going to care about firing all of them then?

We can put a stop to this here in Congress. We can do that. We can say no. We can vote no. And I would like to see that happening in this committee and in this Congress.

So, Dr. Chen, I took longer than I thought to ask my questions of my colleagues on the other side of the aisle, so I have a question for you that I am going to submit for the record. You talked a little bit earlier about your experience, and in your testimony, obviously, you talked about the various programs. And I would like for you to speak about how the Children's Hospitals Graduate Medical Education program helps address the pediatric workforce shortages as well. I am out of time, so I will look forward to your answer in writing in the record.

And I will yield back. Thank you so much.

Mrs. Harshbarger. The gentlelady yields back.

And now I recognize the gentleman from Ohio, Mr. Balderson, for 5 minutes.

Mr. Balderson. Thank you, Madam Chair. Good to see you over there.

Thank you all for being here today. And my questions will be directed

predominantly to Dr. Corrigan-Curay.

Thank you for being here. This committee has heard concerns that the FDA moves goalposts in regard to what is asked of sponsors during reviews. Do you believe that this has been an issue within the over-the-counter drug program as well?

Dr. Corrigan-Curay. I would say we don't try to move goalposts. But when we ask for a study, you can ask for a study to answer a question, and those are scientific studies. It is possible that the study doesn't yield the information that is necessary and we need additional information. But we do our best to only ask for the information that we need and to be least burdensome in our approach to the information we are asking to evaluate for safety and effectiveness.

Mr. Balderson. Thank you. Do you think the FDA can provide greater consistency and predictability, moving forward?

Dr. Corrigan-Curay. That is always our goal, and we will take that criticism that we may not be meeting that goal and try and implement greater consistency and predictability.

Mr. Balderson. Okay. I will follow up with you again also, Doctor. Congress has made clear its intent for the FDA to incorporate real world evidence and new alternative testing methods during its review and approval processes.

However, we have heard concerns that the agency has been slow to implement these tools. Can you explain how the FDA is currently using RWE and NAT in sunscreen evaluations and what steps the FDA is taking to ensure that this aligns with both the letter and the spirit of congressional direction?

Dr. Corrigan-Curay. Thank you for that question. We certainly will rely on real-world evidence when it is appropriate and it can answer the question.

You know, in the area of sunscreens, it may seem somewhat counterintuitive that

they are used all the time and so there must be a lot of data and real-world data that we should be accessing in making our determinations.

There are a couple things when you are trying to look for what we are saying causality is here. Does it cause some effect? You need to know what the exposure is. And unlike a prescription drug where we have in medical records exactly how much you took, when you took it, when we are talking about sunscreens, they can be used over many years. It is very difficult for people to quantify or remember which sunscreen, how long. And that can be a key issue that we need, but we will continue to look at whatever data we can.

In terms of the alternative methods, as I said, we are very excited about the roadmap. We are working hard to develop the science that we can replace/reduce animal testing. Skin irritation is no longer done with animals. Eye irritation is no longer done with animals. And we continue to look for other alternative methods, and we certainly will apply them to sunscreens.

Mr. Balderson. Okay. Thank you.

Lastly, 5 years ago Congress worked with the first Trump administration to enact the OTC Monograph Drug User Fee Act program. I know this was a critical step in modernizing the regulation of OTC products for the American people and taking key steps to empower consumers with more choices in meeting their healthcare needs.

A key goal of enacting OMUFA was to improve the regulatory certainty around FDA's OTC work. But, as Congress assesses what has worked well in the first 5 years of this program and where we have opportunities to improve with this year's reauthorization, what suggestions do you have for how there can be more transparency with sponsors to further improve regulatory certainty when it comes to these products?

Dr. Corrigan-Curay. Thank you. We certainly have learned from OMUFA one

and that is reflected in OMUFA two. You know, we are going to provide more guidance or education on the GRASE standard, but we are first going to seek clarity from sponsors in terms of what are the questions they have.

We know we need to provide more guidance on when you are bringing in a proposed order for a new active ingredient, more guidance on how we treat confidential data, also on exclusivity. We are going to do transparency on exclusivity, transparency on fees, who is paying fees and who is not paying fees.

We are going to continue to provide guidance in areas that industry needs to understand that predictability and what our expectations are.

Mr. Balderson. Okay. Thank you very much.

And, Mr. Chairman, I yield back.

Mr. Griffith. [Presiding.] The gentleman yields back.

I now recognize the gentleman from Massachusetts, Mr. Auchincloss.

Voice. I think she was here.

Mr. Griffith. We didn't have that, but that is fine with me. I am just trying to follow the rules. Okay. Then I apologize and I recognize the gentlelady from New York, Ms. Ocasio-Cortez.

Ms. Ocasio-Cortez. Thank you, Mr. Chairman.

And thank you to our witnesses for being here today.

Less than 2 weeks ago, we saw Republicans vote to completely gut Medicaid, which covers nearly half of all births in the United States. And they did this despite the fact that the United States, the richest country in the world, also has the highest rate of maternal deaths among all wealthy countries.

Black women, in particular, in America are dying at more than three times the rate of White women in childbirth. And we also have the highest rate of infant deaths

overall compared to other high-income countries. We are also the only country that doesn't guarantee healthcare as a basic human right.

Dr. Chen, as a medical provider, can you speak to why the United States has such high rates of infant and maternal mortality?

Dr. Chen. This is not actually my area of expertise, so I don't want to speak out of turn. Our Maternal and Child Health Bureau does cover this issue very, very closely, and we are happy to follow up with you afterwards.

Ms. Ocasio-Cortez. I understand. I also think it is important that we talk about the Healthy Start program. Healthy Start is a federally funded, bipartisan program whose sole purpose is to reduce infant deaths and improve the health of pregnant women and new mothers.

There are more than 115 Healthy Start programs across the country in both Republican and Democratic districts. In fact, Healthy Start was actually created by a Republican President, George H.W. Bush, in 1991.

Healthy Start programs, like the ones in my community in the Bronx, provide education for new parents so that they can safely care for their baby and one-on-one support through home visits. They ensure that families are connected to the services they need, like housing, food, transportation and prenatal and postpartum care.

Dr. Chen, your agency oversees the healthy start program, correct?

Dr. Chen. Yes, in the Maternal and Child Health Bureau.

Ms. Ocasio-Cortez. And as I mentioned earlier, it was created under Republican President George H.W. Bush, but since then Healthy Start has been reauthorized several times on a bipartisan basis. The last time it was reauthorized was during President Trump's first administration.

And that is because Healthy Start works. Women in Healthy Start receive earlier

and more frequent prenatal care. Fathers are more engaged, and babies are born healthier under this program.

I am proud to be leading the reauthorization of this with Representative Malliotakis and continuing the bipartisan tradition of this program. I would like to urge my colleagues to support this commonsense, bipartisan effort to reauthorize Healthy Start.

I also want to briefly turn to another bill we are discussing today about sunscreen, which was led by my colleagues, Representatives Joyce and Dingell, which was spoken to earlier today.

With respect to sunscreen, as skin cancer is the most common cancer in the United States, and for people who work long hours outside, like farm workers and construction workers, adequate sun protection is essential. Yet, the Food and Drug Administration, or the FDA, has not approved any new sunscreen filters since 1999. Yet, our counterparts in Europe and Korea and many other markets around the world have been able to bring much more technologically advanced filters to the market.

And the reason this is important is that it is not just a cosmetic issue. The easier sunscreens are to apply and the more elegant these formulations are, then the easier and more commonly adopted they will be for people to use.

If they are uncomfortable, if they smell bad, if they have all of these other issues, folks who work on farms, folks that work in construction, and people who work in the sun are less likely to use them, and it elevates cancer risks for working people.

And so, I am deeply supportive of efforts within the FDA to help streamline a safe process for approving these new filters, ensuring, yes, we want to make sure that there aren't endocrine disruptions or any other kinds of issues, ensuring the safety of these. But surely, we can come to a process where we don't have to wait 25 years between

filters when we are being outperformed by the rest of the world.

So I want to express my support for those efforts and ensure that we can get this moving, because it is just simply unacceptable.

And Dr. Corrigan-Curay, why is the United States so far behind other countries when it comes to available sunscreens?

Dr. Corrigan-Curay. So in some countries, these are regulated not as drugs, but they are regulated as cosmetics. And we regulate them as drugs, and we have done some testing. We know they are systemically absorbed, and we need to look at that data.

If we that data in hand, we would be ready to review as many sunscreens as was submitted.

Ms. Ocasio-Cortez. Thank you very much.

And I yield back to the chair. Thank you.

Mr. Griffith. The gentlelady yields back.

I now recognize the gentlelady from Iowa, Dr. Miller-Meeks.

Mrs. Miller-Meeks. Thank you and congratulations, Chair Griffith.

And I thank the witnesses for testifying before the subcommittee today.

I have the privilege of representing Iowa's first congressional district, which is largely rural, and in many cases, medically underserved. And having been one of the physicians who practiced in these underserved rural areas, I know fully how being an advocate for rural Americans' access to healthcare is a priority for me. And I look to a productive conversation with our witnesses.

RPTR MOLNAR

EDTR CRYSTAL

[11:57 a.m.]

Mrs. Miller-Meeks. Dr. Chen, the Geriatrics Workforce Enhancement Program, GWEP, is a Title VII-funded program that plays a critical role in building a well-equipped healthcare workforce that meets the challenges of an aging population.

At the University of Iowa, the program has reached over 40,000 learners, spanning nearly all of Iowa's 99 counties, promoting age-friendly care to address the complex needs of older Iowans in rural and underserved areas with limited access to specialized care.

Can you speak to the importance of such programs as our demographics continue to shift and older adults are projected to outnumber youth by 2034?

Dr. Chen. Thank you so much for the question and the focus on the geriatric -- on the older adult population and the healthcare workforce that is needed to take care of it.

You are absolutely right. As our population is aging, one of the things that is driving our projected workforce shortages is the aging of the population. As people get older, their need for healthcare tends to increase. And their need for healthcare also changes as they get older. It becomes much more complex.

And so having those specialists, being able to engage in direct care, as well as working on the system to provide better care and access are important, and that is what the Geriatric Workforce Enhancement Programs do.

Mrs. Miller-Meeks. Thank you.

Dr. Corrigan-Curay, earlier this year I sent a letter to the FDA expressing concern with one aspect of the agency's then-proposed rule on additional conditions for

nonprescription use, or ACNU.

The rule went into effect in May, and I am concerned that it contains a provision in the preamble that would allow for simultaneous marketing of otherwise same prescription drug after approval of a nonprescription drug -- I know it is complex -- with an additional condition of nonprescription use.

Historically, when all uses of a product are switched to nonprescription use, FDA has, as required by statute, determined that the prescription product must no longer be available.

Would you support the FDA reconsidering this portion of the preamble to avoid consumer confusion and encourage more prescription-to-nonprescription switches?

Dr. Corrigan-Curay. Thank you for that question.

It is a complicated issue, but in this case, unlike an over-the-counter without a condition of use, that over-the-counter, we have determined, can just be accessed at any store shelf wherever it is being sold.

With the additional condition of use, it means that there is going to be some sort of perhaps technology that is used before you obtain access.

We also realize that there may be consumers who do not want to use that technology, and we want to have the opportunity for them to potentially access that as a prescription drug. That is the rationale underlying that.

Mrs. Miller-Meeks. Thank you.

Dr. Chen, in your written testimony you state that "HRSA serves as the primary Federal agency for improving healthcare access and improving the health of Americans, particularly those in underserved areas, by growing and strengthening the healthcare workforce and connecting skilled providers to communities in need."

For 3 years now I have led an annual bipartisan appropriations letter that in part

advocates for the Public Health Workforce Loan Repayment Program, in addition to which I was the Director of Public Health in Iowa for several years.

Infectious disease doctors additionally collaborate with public health departments, especially in preparation of, and in response to, public health threats.

Do you believe that the workforce programs, such as the Public Health Workforce Loan Repayment Program and the Bio-Ppreparedness Workforce Pilot Program, are worthwhile investments?

Dr. Chen. Well, I can't speak on pending legislation.

The workforce obviously is very important for a number of different reasons, both for the public health side as well as the bioterrorism, infectious disease workforce, and if Congress were to fund those programs, we would aim to implement them.

Mrs. Miller-Meeks. Since you mentioned that you can't speak on them -- and my time is expiring -- if you could respond in writing if there are manners in which the Federal Government can help with our workforce needs, that would be helpful.

With that, I yield back. Thank you.

Mr. Griffith. The gentlelady yields back.

And now I recognize the gentleman from Massachusetts, Mr. Auchincloss.

Mr. Auchincloss. Thank you, Chairman.

We are having this legislative hearing on a number of bills that affect the Food and Drug Administration at a time when the FDA is under unusual and extraordinary strain from the conspiracizing and conflicts of interest of the Secretary of Health and Human Services, and I am hoping to work with the Commissioner of the FDA to help insulate the career scientists at this gold standard agency from political pressures and ideology that is not evidence-driven.

I have been concerned by some of his recent statements. He has praised Calley

Means as a great scientific mind when I think all evidence is to the contrary. He has linked FDA approvals to pricing, which is contrary to the FDA mandate of safe and effective. And most recently has introduced this Commissioner's National Priority Voucher Program, which I don't believe has any statutory authority.

And these are issues that need to be addressed because if the FDA is accommodating purges of career scientists under his leadership and breaching its statutory mandate, it is hard to have confidence in its ability to implement many of these pieces of legislation, including the FDA Modernization Act.

Dr. Corrigan-Curay, could you just briefly give us your experience at the FDA over your career? How long have you worked there and what roles have you had?

Dr. Corrigan-Curay. I have worked there for approximately 9 years. I started as the lead in the Office of Medical Policy. I then moved up into the Office of the Center Director. I was Acting Director of Operations, and then moved into Principal Deputy, and most recently moved into the Acting Center Director role.

Mr. Auchincloss. So it is safe to say that you understand the FDA's mandate and operations pretty well?

Dr. Corrigan-Curay. Yes, I do.

Mr. Auchincloss. And is there any part of the FDA's mandate that has to do with pricing?

Dr. Corrigan-Curay. We do not directly address pricing, but our competition areas -- biosimilars and generics -- we are very aware that the --

Mr. Auchincloss. I understand that the role for generics and biosimilars is to reduce the cost of drugs, and generics have proven very successful in doing that. Biosimilars have made progress. We have got more work to do. I get why we approve those.

But is your approval pathway linked to the price of the drug, or is it linked to safety and efficacy of the drug?

Dr. Corrigan-Curay. Our approval pathway is linked to safety and efficacy of the drug.

Mr. Auchincloss. So when the Commissioner says that the price of a drug is going to influence the approval pathway, does that conform to the mandate?

Dr. Corrigan-Curay. I am not aware of what he said. I don't know whether he is talking about access and competition --

Mr. Auchincloss. Well, what he was talking about was the Commissioner's National Priority Voucher Program and how he might decide to allow drugs to use this fast track.

Before we get into the CNPV, though, give me a brief overview of existing Accelerated Approval pathways. What do they do for companies?

Dr. Corrigan-Curay. So the Accelerated Approval pathway is an approval pathway, and what we do is, we can approve on a surrogate end point that is reasonably likely. It leaves some uncertainty. And then we get the confirmatory evidence after.

We also have a number of programs, like Breakthrough and Fast Track, which are also programs in which we work with companies. We will have more touch points to get them with a drug that is promising either in a preclinical or clinical basis.

Mr. Auchincloss. And these programs are approved by Congress, yes?

Dr. Corrigan-Curay. They are.

Mr. Auchincloss. Explicitly?

Dr. Corrigan-Curay. They are.

Mr. Auchincloss. In your understanding, is there anything within the FDA regulations that would allow for a Commissioner to create a new approval pathway

without congressional statute?

Dr. Corrigan-Curay. My understanding, you know, we can have various times that we approve. We have goals of when we want to approve something. So we can try and approve -- we may say a supplement takes 6 months, but under Breakthrough we can get rolling submissions, we could potentially get that done faster.

Mr. Auchincloss. I understand that you want to, as an agency, you want to have a tight feedback loop. I am saying, is there anything in the FDA's current authorizing statute that allows a Commissioner to create a brand-new Accelerated Approval pathway subject to his discretion?

Dr. Corrigan-Curay. I don't think this is an Accelerated Approval. I think it is a challenge to us to try and move faster in certain areas where there are unmet needs. And I am sure we could get back to you in writing with more detail on that.

Mr. Auchincloss. Right. But as you said, it cannot be linked to price, and it can't be linked to anything that Congress doesn't expressly authorize. So what would be the basis for a National Priority Voucher Program?

I mean, does he just get to decide which drugs get preferred? Is this like fear or favoritism, whatever he thinks is necessary?

Dr. Corrigan-Curay. Well, my understanding is we are going to get more information about this in the process. On our website, I think there are things like unmet medical needs, some of the areas where we typically try and move a little faster.

Mr. Auchincloss. Yes. The challenge here is the biotech companies need to be competing on safety and efficacy, and they absolutely deserve a quick turnaround time from the agency, and you should give them that, and PDUFA should help negotiate that.

But what we can't allow to have happen is the Commissioner's pet projects, or his favorites, or his opinions override preclinical phase 1, phase 2, phase 3 data. And this

program right here, which is without basis in congressional statute, is a fear or favoritism pathway.

Mr. Griffith. The gentleman's time has expired. The gentleman yields back.

I now recognize the gentleman from New Jersey, Mr. Kean.

Mr. Kean. Thank you, Mr. Chairman.

New Jersey is a hub of ingenuity in many industries, including in over-the-counter drugs. A number of OTC companies have a strong presence in New Jersey, where they manufacturer and they develop their innovative products.

Unlike prescription drugs, Americans see these products on store shelves every day and use them for common ailments or to help their kids when they are sick. In fact, many of these products and their active ingredients have been on shelves in some cases for decades.

But this does not mean that these companies are not innovative. Additions of already approved active ingredients to an existing monograph can increase the effectiveness of a product, creating a more convenient route of administration for a product, and also increase a patient's adherence, and therefore their overall health.

Enabling innovation is one of the reasons that 5 years ago Congress, industry, and the FDA worked together to reform the OTC drug approval process.

Now we get the opportunity to evaluate these reforms and make any changes needed to ensure that the OTC monograph program continues to foster innovation.

Dr. Corrigan-Curay, could you please give us a quick summary of the two distinct approval pathways at FDA that were established 5 years ago in the CARES Act and the difference between the two?

Dr. Corrigan-Curay. In terms of the OTC monograph, this was really to change from sort of a rulemaking to a regulatory provision.

I am not sure of the other approval pathway -- I am sorry -- that you are referencing from the CARES Act.

Mr. Kean. So I ask this because I have heard concerns from some OTC manufacturers that when they choose the more streamlined pathway, initiate a change to a monograph through OMOR, their concern is that there is a lack of clarity at FDA on what data they need to determine whether a proposed change is a GRASE.

And this leads to more of a drawn-out and back-and-forth between the FDA and manufacturers that can delay the approval of innovative products.

Wouldn't you agree that knowing at the beginning of the process what the guardrails and expectations are for an OMOR can provide certainty to manufacturers and increase their investment in innovative ideas?

Dr. Corrigan-Curay. Yes. Thank you.

We would, and we are going to give more clarity. That is one of our objectives in OMUFA II, to give more clarity about an OMOR where you are bringing a new active ingredient into the market.

And we definitely are also going to, across the industry, provide more education on the GRASE standard so it is well understood and our expectations are understood under that standard.

Mr. Kean. Thank you.

Dr. Chen, changing gears here, I wanted to highlight one of the bills that we are considering here today, to reauthorize the Title VII public health workforce programs.

I have recently heard from the Virtua Health College of Medicine and Life Science and Rowan University, that is a recipient of the Geriatric Workforce Enhancement Program that is reauthorized in this legislation.

Since there are not enough specialists in geriatrics, this college is adapting by

working with educational institutions in New Jersey, like Rutgers, and health systems, like Hackensack Meridian Health, to educate all members of the healthcare workforce in how to effectively care for New Jersey's aging population.

Can you speak to how this effort in New Jersey to broadly educate healthcare providers instead of relying solely on geriatric specialists will continue to help our seniors?

Dr. Chen. Thank you for your interest, again, I think, in the geriatrics programs.

Taking care of older adults with complex illnesses -- oftentimes multiple chronic conditions, dementia -- takes a real team. And it takes both the combination, I think, of specialists and people who have been trained to provide that specialized care, as well as the integration with primary care and the wider healthcare system. And that is what the Geriatric Workforce Education Program supports.

Mr. Kean. Thank you.

I yield back.

Mrs. Harshbarger. [Presiding.] The gentleman yields back.

And I will call on the gentleman from Ohio, Mr. Landsman, for his 5 minutes.

Mr. Landsman. Thank you, Madam Chairwoman and the Ranking Member, for having today's hearing, and for all of you witnesses for being here today.

When OMUFA was first signed into law -- and we have got 5 years under our belt -- it was aimed at increasing the efficiency at the FDA so that they could update the monographs more quickly, keep up with consumer healthcare needs, and create a simpler pathway to the market for innovative products with safe, established ingredients.

And like everybody else, my constituents rely on these over-the-counter drugs, and they want to be able to have a set of options, lots of options, and the most innovative and best products on the shelves when they go shopping.

The challenge has been that over the course of the last 5 years, despite the attempt of this law to make things more efficient, there have been few sponsor-initiated OTC monograph changes. There haven't been many.

And so the questions here for you, Dr. Corrigan-Curay, as the Acting Director of the Center For Drug Evaluation and Research, have you seen the implementation of OMUFA? I mean, are you watching this? I mean, what can you say?

Dr. Corrigan-Curay. Yes. Thank you for that question.

I think what we have to realize, we do have one, of course, new OMOR for sunscreen, and we have also issued orders to update safety labeling for acetaminophen. We issued an order on phenylephrine and its efficacy or lack thereof.

When you build a program from really scratch -- it is not like when we had the PDUFA, we were approving PDUFA drugs -- there is a time to build, and then we started meeting our meeting goals in year 3, and that is when we start to get the innovation.

So there is a lag in terms of building the first program and then seeing an OMOR come to fruition.

But we have on our agenda, we are going to continue to update labels. We are willing to work with companies. We have told them the data that we need to examine.

And we will continue to work on innovation, including by giving them more opportunities to interact with us. So in OMUFA II, we will expand meetings if needed. We will look at protocol synopsis. We will do more education on the GRASE standard.

Mr. Landsman. I mean, the time to build I get. Three years seems like a long time, but I don't -- I do this, I don't do what you do.

So that piece aside, why have there been so few sponsors? Or is it really just that it took you a while -- I mean, you just named a few, 5 years later.

And, I mean, are you expecting an explosion of approvals now, or are there still -- I

mean, it would be helpful to understand -- for example, folks in my district have said that some of the data required for an over-the-counter monograph change is more rigorous than they would have expected for some products. You mentioned time with your staff.

Is data, the requirements, is that a big part of why we are seeing so few being approved?

Dr. Corrigan-Curay. Well, I think one thing is that we need the data. The standard of safety and effectiveness, the GRASE standard, is one that needs to be rigorous because these products are over the counter. They can be bought anywhere. They are not under the provision of a healthcare provider.

So we need to work with the companies so they understand what that data is. We will work on -- each individual case is different. We will have that conversation.

Mr. Landsman. Do you feel like you have the flexibility -- of course, rigorous data is really important. The question is, when does it become that there is so much data that you are just keeping products from -- there is just too much bureaucracy and it is taking too long?

I mean, do you feel like you have the flexibility, in your reviews of these monographs, to allow for innovation while still ensuring product safety? Or do these applicants have to meet these -- the same stringent standards?

Dr. Corrigan-Curay. They have to meet the standard for safety and effectiveness, but how they get there, we think we can be flexible. We can look at alternative testings. We have the ability to figure out which data is fit for use.

Mr. Landsman. I have run out of time. I will submit my questions. And thank you.

I yield back.

Well, can I -- sorry.

One of the things that would be great -- I am sorry -- is to get a sense -- and we can follow up -- but what can I tell my folks that you all are going to do, or are doing, that will make this process what was envisioned 5 years ago? But I will follow up.

Thank you, Madam Chair, for giving me that. I yield back.

Mrs. Harshbarger. The gentleman yields back.

And now I recognize the gentleman from Ohio, Mr. Rulli, for 5 minutes.

Mr. Rulli. Well, it is good to see Ohio in the house, so God bless you, sir.

I just want to take a second, and I want to thank Mr. Morris for all your hard work at HRSA. It means the world to us. We appreciate it.

I am proud to join, as an original cosponsor, to Chair Carter's bipartisan H.R. 2493, Improving Care in Rural America Reauthorization Act. It extends grants and helps rural residents who have trouble accessing healthcare.

And I think this is a really interesting bill for myself because I think this is one of the first times that I have actually seen on the Hill, versus the State House years that I did, where we have bipartisan support for a cause.

So I think it is really reassuring and refreshing to see such a bipartisan approach to this problem.

And it is a problem. I am going to give two quick examples of personal tragedies that I have seen within my district in the last year.

Directly north of my district in Warren, Ohio, was a hospital called Trumbull Memorial Hospital, where actually my son was born. This hospital got gutted by Steward Health out of Boston, Massachusetts, for some shenanigans they were doing within their financing of the actual hospital.

The hospital closed, so the biggest ER within a 45- to 50-mile radius was shut down.

The problem is with that, when you live in northern Trumbull County or southern Ashtabula, Ohio, which is all in the eastern part of Ohio, you would now have to go to the Cleveland Clinic or University Hospital within the city limits of Cleveland, or you would have to drive down to Youngstown or Pittsburgh.

Some of these areas are an hour away. So if you are having a heart attack or a stroke or another medical emergency, there will not be logistic times to get you to that ER. These are the kind of problems that we are dealing with, with rural hospitals.

Besides that, another example is down in Marietta, Ohio, which is the very southern part of my district, almost a 4-hour drive from Trumbull County.

These are examples of the problem within rural America that we are facing, that both parties can go across party lines and we could join hands together and fix these problems.

In Marietta, they realized that there wasn't a possibility of them having a children's hospital unless you went to Nationwide, which is in the city of Columbus. That is two and a half hours away. In order to get you into Pittsburgh for another emergency is an hour and a half away.

People will die.

There is a major problem in this country with rural hospitals that we have to fix, and it is something that every elected official has brought onto the Hill to try to do.

The reauthorization funds program that provides insulin and blood pressure medications, strengthens telehealth -- and telehealth is going to be incorporated with all this broadband work that we are doing because we have to give them the tools to actually make telehealth work -- and also manages chronic diseases.

Health outcomes should never depend on someone's ZIP Code. I think that is atrocious in a country that is the epicenter of the world, that we have problems just

because we have poor rural America that does not have access.

On the heels of the Big Beautiful Historical Bill, contrary to popular belief, there is a $50 billion investment in rural healthcare.

This is what happens when you get to the finish line of any piece of legislation, and the two parties and everyone starts working together, we realized that there was a hole with the rural hospitals and we got $50 billion in investment in rural healthcare, which will have a profound impact.

I am very happy to support this legislation. I am happy to go across the aisle.

And with that, I yield my time to the chair.

Mr. Griffith. [Presiding.] The gentleman yields back.

We are going to pause for just a minute. I believe we have some other witnesses who are expected -- or some other Members who are expected.

The gentleman from Ohio, Mr. Latta, is recognized for 5 minutes.

Mr. Latta. Well, thank you, Mr. Chairman.

Multiple things here this morning.

Mr. Griffith. Hold the clock for just a second. Let him at least get turned into his page. I just did the same thing upstairs.

I apologize to our witnesses, but we have multiple hearings going on, and we are trying to let every Member who is interested in the subject matter ask their questions.

And I just ran upstairs to the Environment Subcommittee and asked my questions, and ran back down here. And I appreciate my vice chair filling in and helping me out. We both did that at some point today. But I appreciate our witnesses.

And now I believe the gentleman is ready.

Mr. Latta. Well, thank you, Mr. Chairman, and appreciate your indulgence.

And to our witnesses, thank you very much for being here today. This is a really

important hearing, critical to the public health workforce, rural health, and over-the-counter medicines.

The Over-the-Counter Monograph Drug User Fee Program, OMUFA, at the Food and Drug Administration gives consumers access to manage their own care in a safe and affordable manner.

Five years ago I worked with my Energy and Commerce colleagues to modernize how the FDA regulates most OTC medicines with the enactment of the OMUFA program.

These revolutionary changes made the 40-year-old system more efficient, transparent, and open to innovation. I am very proud, once again, to be leading this reauthorization of such a critical program.

The OMUFA program has drastically reduced the burden on our healthcare system by lowering the number of visits consumers need to make to a doctor to obtain a prescription for a simple treatment.

Again, 5 years ago, when Congress initially passed my legislation to reform OTC monographs, I entered into the record a statement of intent on data required for general recognition of safety and effectiveness for nonprescription drugs.

The statement reads: "General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data."

Unfortunately, in the 5 years, I am concerned that the FDA has not fully acted in accordance with the congressional intent by requiring superfluous information. I am concerned that these delays to innovation prevent consumers from benefiting from new and improved products.

If I could ask my first question to Dr. Corrigan-Curay. Hope I pronounced that properly.

In the last 5 years, how has FDA worked to improve the process for expediting the review and administrative order process for monographs?

Dr. Corrigan-Curay. Thank you.

In this first 5 years, what we have done is we have changed this from a paper-based rulemaking to an electronic communication system. We have given fundamental guidances so the expectations are very clear. We started meeting with companies on their programs. We are meeting all those goals.

We had the first OMOR for a sunscreen. We have issued 33 final orders, and we have five proposed orders, to update some of the safety labeling, as well as a new order that we are going to -- proposed order that would allow innovation in terms of dosage forms.

So you could go from tablet or capsule to an oral disintegrating or a chewable, and so that would allow children and those who have trouble swallowing.

So we have done a lot. There is more to do. In OMUFA II, we want to provide more opportunities for interactions with the FDA and companies, so they know our expectations looking at their protocol synopsis.

We will work on issues on quality. We will work on transparency -- transparency in exclusivity, transparency in fees, and who is paying the fees and who is not paying the fees.

So we think we are on a good path to continue this innovation.

Mr. Latta. Just to follow up on that. What is your timeline? Because you said there are more things to do and more to get these things through the process. Is there any kind of a timeline that you are anticipating?

Dr. Corrigan-Curay. Well, right now we are working with companies and we are working on -- or the proposed orders. We need to get the comments finished, the

comments, and put them through.

The sunscreen, that is in, so this would be for a new sunscreen ingredient. We are working along with our timelines that we have in our commitment letter.

The new things under OMUFA II would be really to sort of continue to grow the program in a way that fosters innovation by working -- providing other opportunities to interact with FDA and understand our expectations, provide more clarity and education on the GRASE standard, which I think is what you were saying. There may be some confusion about what our expectations are.

We certainly don't want superfluous studies. We want studies that answer the question. And that is all that we need.

Mr. Latta. Thank you.

And I am interested and I believe this subcommittee would benefit from reviewing the study that was required in my previous OTC modernization legislation.

So, again, it is just -- you brought up one of the issues out there I know we have heard in this subcommittee for a good number of years, is just like on sunscreen. And I am sure it came up, some other members have already brought it up. But the Europeans, they always say, are so much far ahead of us on this, and so we want the United States to lead.

So I look forward to working with you.

And I appreciate the chairman and for the work that is going to be done in this subcommittee.

And I also just want to take a point of personal privilege and congratulate you on the gavel here in the Health Subcommittee.

I yield back.

Mr. Griffith. I thank the gentleman for his congratulatory remarks and for

yielding back.

I see no further Members of Congress wishing to ask questions, so I would like to thank all the witnesses for being here today. We do appreciate it.

Members may have additional written questions for you all. I remind members that we have 10 business days to submit those questions for the record.

I would ask the witnesses to respond to the questions promptly. That, of course, doesn't start until we get them to you.

Members should submit their questions by the close of business on Wednesday, July 30.

Without objection, the subcommittee is adjourned -- oh, I ask unanimous consent, before we adjourn, to insert in the record the documents included on the staff hearing document list.

Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Griffith. And the subcommittee is adjourned.

[Whereupon, at 12:28 p.m., the subcommittee was adjourned.]