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IMPROVING THE MEDICAID PROGRAM FOR BENEFICIARIES

Friday, September 18, 2015

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:01 a.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Shimkus, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Green, Butterfield, Schrader, Kennedy, and Pallone (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Graham Pittman, Legislative Clerk; Michelle

Rosenberg, GAO Detailee, Health; Chris Sarley, Policy Coordinator, Environment & Economy; Josh Trent, Professional Staff Member, Health; Christine Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; and Samantha Satchell, Minority Policy Analyst.

Mr. Pitts. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today, Medicaid is the world's largest health coverage program. Medicaid plays an important role in our healthcare system, providing access to needed medical services and long-term care for some of our Nation's most vulnerable patients.

The Congressional Budget Office estimates that Federal Medicaid expenditures will grow from $343 billion this year to $576 billion in 2025. At the same time, State expenditures have grown significantly, accounting for more than 25 percent of State spending for fiscal year 2014.

Given the scope of the program and its impact on millions of Americans' lives, Congress and States have a responsibility to ensure that the program is modernized to better serve some of our Nation's neediest citizens.

Congress can make incremental improvements to this 50-year-old system in a way that respects taxpayers, empowers patients, and promotes more holistic, patient-centered care. That is why I am so pleased today to be discussing four bipartisan bills that will help strengthen a patient's role in their own care and reduce barriers to accessing health care.

First, the Ensuring Access to Clinical Trials Act of 2015 would permanently allow individuals with rare diseases, who participate in

clinical trials, to continue to be able to receive up to $2,000 in compensation for participating in clinical trials without that compensation counting towards their income eligibility limits for SSI or Medicaid.

Second, Representatives Bilirakis, Lance, and several other colleagues have introduced H.R. 3243, which would authorize the HHS Secretary to waive certain Medicaid requirements in regards to the PACE program. PACE -- the Program of All-Inclusive Care for the Elderly, that is PACE -- is an integrated care program that provides comprehensive long-term services and supports to individuals age 55 and older who require an institutional level of care, many of whom are dually eligible for both Medicare and Medicaid.

The PACE model is limited to those age 55 and older who meet State-specified criteria for needing a nursing home level of care, but other targeted populations could benefit from the successes of the comprehensive PACE model.

Next, Ranking Member Pallone and G.T. Thompson have introduced a bipartisan bill that would extend the special needs trust exception to allow nonelderly individuals with disabilities to establish a special needs trust on their own behalf. If enacted, a special needs trust established by a nonelderly, disabled individual would no longer be considered an asset in determining that individual's eligibility for Medicaid.

Finally, Representative Collins will be introducing the Medicaid Directory of Caregivers Act, or the Medicaid DOC Act. This commonsense proposal would require State Medicaid programs to provide patients in their fee-for-service Medicaid program with a directory of healthcare providers participating in Medicaid.

Medicaid patients in managed care have an identified network of providers. However, too often in fee for service Medicaid patients struggle to find a doctor who will accept Medicaid. And this bill would help solve that problem and effectively reduce a Medicaid patient's barriers to care by cutting down on the time and energy they have to expend to find a doctor to provide care.

I look forward to hearing from our witnesses today. Is anyone seeking time on our side?

If not, I yield back, and at this point I recognize the ranking member of the subcommittee, Mr. Green, 5 minutes for his opening statement.

[The prepared statement of Mr. Pitts follows:]

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

Mr. Green. Good morning. And thank each of you for being here this morning.

We are here to examine four bipartisan bills, each of which makes key improvements in the Medicaid program. I thank the chairman for holding this hearing. It is both an opportunity to advance these worthy legislative proposals, but also build on our committee's record of bipartisan success for this Congress.

As we know, nearly 1 in 10 Americans are impacted by a rare disease. The Ensuring Access to Clinical Trials Act, introduced by Representative Lloyd Doggett, allows patients with rare diseases to participate in and benefit from clinical trials without risk of losing critical benefits. The bill makes permanent the Improving Access to Clinical Trials Act, a law enacted in 2010 that permits patients with rare diseases to receive compensation for participating in clinical trials without that compensation counting towards their income eligibility limits for SSI or Medicaid. This is scheduled to sunset on October 5, so this is timely legislation. Without extending or making IACT permanent, people with rare diseases would be discouraged from participating in clinical trials. At a time when there is such a great need to develop new therapies, promoting access to clinical trials for patients in need of treatments is something we should all support.

H.R. 670, the Special Needs Trust Fairness Act, was introduced

by Ranking Member Frank Pallone and Representative Glenn Thompson. This important legislation will correct an error in the law that prevents capable individuals with disabilities from creating their own special needs trust.

People with disabilities often need help covering the high cost of long-term services and support. Federal law allows individuals to use special needs trusts to retain some assets for the purpose of supplementing expenses that are not covered by public assistance programs. Unfortunately, an oversight in current law makes it incredibly difficult for an individual with disabilities to set up a special needs trust on their own. This has the impact or effect of deeming all individuals with disabilities incapable of handling their own affairs, which is blatantly false and discriminatory.

The Special Needs Trust Fairness Act will correct this injustice. I want to thank our ranking member for his long history of leadership on this issue.

The Program of All-Inclusive Care for the Elderly, or PACE, is a community-based, long-term service and support program designed to provide quality integrated care for some of our Nation's most vulnerable citizens. Under this proven care model patients who are eligible for nursing homes are able to remain in their homes and receive medical support services through the adult daycare centers. The PACE Innovation Act of 2015 will allow the Centers for Medicare & Medicaid

Services, CMS, to pilot the PACE care model with new populations where high-quality, fully integrated care is likely to be effective.

Finally, the Medicaid Directory of Caregivers Act is a draft proposal that responds to recent reports which highlighted challenges patients have with provider directories in their health systems. Too often it is difficult for patients to see if a doctor is affiliated with their health plan and providers are uncertain if they have been included in a newly established insurance network.

Confusing or misleading provider directories have led to a rise in surprise billing where a patient faces unexpected, costly out-of-network medical bills. This timely draft legislation requires States that participate in fee-for-service Medicaid to publish a provider directory on a regular basis.

I look forward to working with my colleagues to advance all these legislation. I look forward to working with my colleagues on the committee to further strengthen Medicaid programs in key areas and build on past success. Each of these bills is the product of thoughtful, bipartisan consideration and work. And I want to thank our witnesses for being here today and look forward to discussion on the legislation proposals.

And I yield back.

[The prepared statement of Mr. Green follows:]

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Mr. Pitts. The chair thanks the gentleman, and now I recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman.

Obviously, we have four pieces of legislation in the Medicaid program that are having a legislative hearing today, and three of the bills have both bipartisan and bicameral support and have already passed the Senate.

In particular, one of the bills under consideration, the Special Needs Trust Fairness Act of 2015, would correct an unfair anomaly in Federal Medicaid law to allow nonelderly individuals with disabilities to establish a special needs trust on their own behalf, and this legislation is a proposal that I have sponsored for many years. I am happy to see this commonsense policy moving forward.

There is no reason why we should prevent competent individuals from establishing their own special needs trust, and it is time we fix this unintended problem that undermines the rights of those with disabilities.

I am also pleased to see a proposal with wide bipartisan support to promote innovation in the PACE program. The Program of All-Inclusive Care for the Elderly, or PACE, is an integrated care program that provides comprehensive long-term services and supports to individuals age 55 and older who require an institutional level of

care, many of whom are eligible for both Medicare and Medicaid and of course are known as dual-eligible beneficiaries.

This legislation would allow PACE programs to waive certain requirements, like expanding to the under-55 population, that limit the ability of this successful program to grow. And I recently learned that a new PACE program is in my home district and I look forward to supporting the continued success of the program.

I also look forward to hearing testimony regarding H.R. 209, the Ensuring Access to Clinical Trials Act, a bill with 49 bipartisan cosponsors and one that should be of considerable interest to this committee given its rare disease focus.

This legislation would permanently remove the sunset clause that was in the original Improving Clinical Trials Act that was signed into law in 2009. It also builds on a 2014 GAO report finding that clinical trial compensation for travel to a rare disease trial location and time away from work actually acts as a deterrent for vulnerable SSI and Medicaid beneficiaries who are fearful of losing eligibility for their benefits when they need them most.

The legislation would make certain that beneficiaries can disregard up to $2,000 of compensation per year that an individual may receive for participation in a clinical trial investigating a rare disease.

And finally we have a draft bill on the agenda that I would like

to have more time to review, but that shows great promise as a bipartisan initiative to improve access to care in Medicaid. The draft legislation proposed would require States that participate in fee-for-service Medicaid to publish up-to-date provider directories. And I want to ensure that we go about drafting such a requirement in a way that is streamlined with managed care provider directory requirements in Medicaid, but I feel certain that we will all share the same goal with this legislation.

Let me thank you, Mr. Chairman and our ranking member, Mr. Green, for holding the hearing on these legislative initiatives in Medicaid with broad bipartisan support from our committee members and look forward as we move these bills in the subcommittee and full committee. Thank you.

[The prepared statement of Mr. Pallone follows:]

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Mr. Pitts. The chair thanks the gentleman.

As usual, all the written opening statements of the members will be made a part of the record.

[The information follows:]

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

Mr. Pitts. That concludes the opening statements of the members.

I would like to thank our panel, the witnesses, for coming today. I will introduce them in the order that they present their testimony.

And you will each be given 5 minutes to summarize your testimony. Your written testimony will be made a part of the record.

First of all, we have Dr. Michael Boyle, vice president of therapeutics development, the Cystic Fibrosis Foundation.

Welcome.

Then Mr. Tim Clontz, senior vice president for health services, Cone Health.

Welcome.

And Mr. Rick Courtney, president, Special Needs Alliance.

Thank you all for coming. And we will begin with Dr. Boyle.

You are recognized for 5 minutes for your summary.

STATEMENTS OF MICHAEL BOYLE, M.D., VICE PRESIDENT OF THERAPEUTICS DEVELOPMENT, THE CYSTIC FIBROSIS FOUNDATION; TIM CLONTZ, SENIOR VICE PRESIDENT FOR HEALTH SERVICES, CONE HEALTH; AND RICK COURTNEY, PRESIDENT, SPECIAL NEEDS ALLIANCE

STATEMENT OF MICHAEL BOYLE

Dr. Boyle. Thank you, Mr. Chairman.

My name is Dr. Mike Boyle. I am a professor of medicine from Johns Hopkins, where I have run the Adult Cystic Fibrosis Program for the last 15 years, and I am vice president at the Cystic Fibrosis Foundation, where I oversee clinical trials. And on behalf of the CF Foundation and representing the 30,000 people with cystic fibrosis in the United States, I am really grateful for this opportunity to be able to testify in support of H.R. 209, the Ensuring Access to Clinical Trials Act. We are particularly grateful to Health Subcommittee Chairman Pitts, Ranking Member Green, full committee Chairman Upton, and Ranking Member Pallone, the bill's sponsor Congressman Doggett, and all of those who are working to pass this very important legislation.

Remember, cystic fibrosis is a rare genetic disease that primarily effects the lung. It causes the body to produce thick large

amounts of thick mucus that congest the lungs and leads to life-threatening infections and serious digestive complications. In the 1950s, few children with CF lived to attend elementary school. But since then tremendous progress and understanding and treatment of CF has led to dramatic improvements in length and quality of life for those with CF so that many people with CF now can expect to live into their thirties, forties, and beyond.

As a physician, professor, and clinical investigator at Johns Hopkins I have seen the devastating impact of this disease and the importance of clinical research in developing treatments that can change the lives of individuals with CF, I am privileged to have played a role in several pivotal trials. It is for this reason I am here today to ask that the Ensuring Access to Clinical Trials Act be passed without delay.

As you know, the Ensuring Access to Clinical Trials Act of 2015 eliminates the 5-year sunset clause from our current laws, the Improving Access to Clinical Trials Act, or IACT. It was signed into law in 2010, and IACT allows people with rare diseases to receive up to $2,000 annually in compensation for participating in clinical trials without that compensation counting toward their income eligibility limits for SSI and Medicaid. But unless Congress acts, this critical law will expire on October 5 of this year. The Senate has already passed identical legislation by unanimous consent, and we urge similar

swift consideration of this bill in the House.

The particular individual that comes to mind when I think of the Ensuring Access to Clinical Trials Act is a young man with cystic fibrosis by the name of Michael that I was caring for in 2009 prior to the original passage of this law. Mike had significant lung disease from CF, but for many years had made time to participate in clinical trials to help speed the development of desperately needed new therapies.

Yet, in 2009, when a trial of a very promising new therapy called ivacaftor started and was looking for CF clinical trial participants, Mike didn't participate, not because he didn't want to -- in fact, he desperately wanted to enroll in the trial of a drug which was later found to be the most effective drug that has ever been developed for his type of CF -- but because he had evaluated his finances and was afraid that the modest payment of approximately $750 associated with participation in the trial would put his Medicaid and SSI support, on which he was completely reliant, in jeopardy. He did not enroll. Mike even volunteered to participate in the trial without payment, but this is not allowed by most hospital review boards for the vast majority of clinical trials, including this one.

Approximately 4 months after deciding not to enroll because of financial concerns, Mike died unexpectedly from complications of CF. And to this day I still wonder if his outcome may have been different

if had he enrolled.

Rare disease researchers face a real challenge in recruiting participants to test new medications. Securing an adequate number of clinical trial participants is essential to testing new therapies, so we can't let any obstacles stand in the way of being able to let these patients enroll.

If is the Improving Access to Clinical Trials Act were allowed to expire and this barrier were reinstated, it would not only affect future trial enrollment, it could cause those with rare diseases who are currently participating in clinical trials to drop out of these trials for fear of losing benefits. This will put vital clinical research at risk at a time when the medical needs of many people with rare diseases are already not being met.

The advent of precision medicine has allowed specific medications to be developed which target the specific genetic makeup of patients. Two of these therapies are now available in CF, but they only treat a subset of patients. We need to have availability of patients for additional trials to treat the other half of these patients.

The mission of the CF Foundation is to find a cure for all people with CF, including those with the rarest CF mutations. Even then, there might be only a handful of people with those mutations who can enroll in these trials. In order to achieve this goal, we must ensure that nothing stands in the way of carrying this out and developing these

breakthrough medications. All of these things make the support of this act essential.

Again, I am deeply grateful to the committee for this opportunity to offer testimony in favor of the Ensuring Access to Clinical Trials Act and I ask for your support of it. The Cystic Fibrosis Foundation stands ready to work with this committee and congressional leadership to ensure passage of this bill to enable those with rare diseases to access life-sustaining treatments and enjoy the best health and quality of life possible. Thank you.

[The prepared statement of Dr. Boyle follows:]

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Mr. Pitts. The chair thanks the gentleman.

I now recognize Mr. Clontz for 5 minutes for your opening statement.

STATEMENT OF TIM CLONTZ

Mr. Clontz. Mr. Chairman, Ranking Member Green, and members of the subcommittee, thank you for holding this hearing --

Mr. Pitts. Can you pull it closer? Hold the mike closer. Yeah, pull it. Go ahead, you may proceed. If you can get it closer, that is better.

Mr. Clontz. My name is Tim Clontz, and I am senior vice president at Cone Health, a large regional health system in North Carolina and a joint venture partner in three PACE programs. It is my distinct privilege to testify on behalf of the National PACE Association in support of a PACE Innovation Act 2015.

Programs of All-Inclusive Care for the Elderly, or PACE programs, serve some of our most frail and most vulnerable populations, those needing nursing home level of care. By integrating medical care and community-based, long-term services and supports, PACE allows seniors to get the care they need at home and with the love and support of their family members and friends.

PACE is a proven high-quality program. Studies show that PACE

enrollees live longer, with fewer hospitalizations, and live at home longer than those receiving care through other programs.

Unfortunately, many individuals cannot access the PACE benefit because of arbitrary age restrictions or because they are not yet quite sick enough to qualify. These limitations have real consequences for real people, their families, and for the delivery system.

Take, for example Jim G., a 53-year-old Virginia resident with early onset Alzheimer's disease. He lived at home with his wife Karen and school-aged children. Jim tried to enroll in PACE but was unable to because he was not old enough.

Initially, Jim stayed at home alone during the day where he was isolated and struggled with activities of daily living, such as personal grooming, household chores, and child care. As his memory deteriorated, so did his health. Jim was hospitalized in 2014 for a lung infection caused by silent aspiration, which occurs when the swallowing function is weakened by Alzheimer's.

His wife Karen struggled to care for Jim and her school-aged children and hold down a full-time job, but eventually had to quit her job for Jim. Unfortunately, she quickly discovered that his needs were more than she could handle, and following a psychotic break and a week in a psychiatric facility, Jim was permanently placed in a memory care unit near their home.

To add to her stress, Karen had to crowd source to raise money

for his care as this particular facility was not covered by Jim's VA benefits. This is no way to treat a 23-year veteran.

This heartbreaking situation might have been avoided had Jim been able to enroll in PACE. He could have received daytime support that would allow him to continue to live at home with his family. He could have received therapies to help him stay physically strong and primary care to help avoid the silent aspiration and other complications.

PACE has significant experience with dementia and might have prevented or managed his psychiatric deterioration. And Karen and her family would have received much needed respite services, emotional and social support, and peace of mind.

The PACE Innovation Act of 2015 would help Jim and many others like him by allowing PACE to serve younger individuals with disabilities, at-risk populations, and others who would benefit from the fully integrated services offer by PACE.

This legislation is revenue neutral, bipartisan, and has been endorsed by many national organizations. Simply put, helping people like Jim get the care they need at home with the love and support of their family and friends makes sense. Integrating medical care and community-based, long-term services and supports also makes sense.

These are two truths that the PACE program has known and applied for over 25 years for people age 55 and older who need a level of care comparable to a nursing home but who wish to continue their lives at

home. It is time to build on this foundation and extend this effective delivery system to additional people through a pilot program.

The PACE Innovation Act does this. Through this act, the PACE model can be adapted to serve people under the age of 55 and people at risk of needing nursing home level of care. People like a man or a woman with early onset Alzheimer's or a younger person with physical disabilities or a person with an intellectual or a developmental disability deserve the same options.

While the differences in each of these individual needs may be significant, the shared challenge of accessing effective, integrated, and coordinated medical and long-term services and supports is compelling. We can build a more effective delivery and financing systems to serve these vulnerable populations. With your support, the PACE Innovation Act and the pilot programs can help show the way.

Thank you for the opportunity to address the committee on these vital matters.

[The prepared statement of Mr. Clontz follows:]

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Mr. Pitts. The chair thanks the gentleman.

And I now recognize Mr. Courtney 5 minutes for your summary.

STATEMENT OF RICK COURTNEY

Mr. Courtney. Thank you, Chairman Pitts and Ranking Member Mr. Green and members of the subcommittee. I am glad to come to Washington and testify in strong support of the Special Needs Trust Fairness Act, H.R. 670, introduced by Representative Glenn Thompson and committee Ranking Member Frank Pallone. Their leadership on this has been steadfast and outstanding, and we appreciate that.

I am honored to serve as president of the Special Needs Alliance, a nationwide organization of special needs planning attorneys. And I am also a member and former member of the board of directors of the National Academy of Elder Law Attorneys. Both organizations devote substantial resources to serving the needs of the special needs and disability community and strongly support the Special Needs Trust Fairness Act.

In 1979, I became the father of twin daughters. My wife and I love both our daughters and we are proud parents, but they have had very different paths. Melissa was in gifted and talented education through secondary school and college, and is now the young wife and mother of two elementary school-age boys. Melanie, her twin sister,

was genetically the same, but different. She has cerebral palsy and learning disabilities. She is a wheelchair user. But through her determination and hard work, she got through high school and community college and obtained and associate of arts degree in 3-1/2 years. She found a job with our State art chapter after college. She was the coordinator of a project called My Voice, My Choice, teaching young adults with developmental disabilities self-advocacy skills.

Suffice it to say she has taught us a lot too. She has never wanted help with things she could capably do, and she has never easily accepted that she can't do something because she is physically disabled. She does, however, need and is receiving services through a Medicaid waiver program in our State. The cost of attendant care and medical services is high and she must rely, like many people with disabilities, on essential programs like Medicaid.

For now, my wife and I are here to be supportive of Melanie, but it won't always be so, and her needs my grow as she gets older. If she were to receive some money through an inheritance or an insurance settlement, she would lose her Medicaid waiver benefits that pay her attendant for a few hours a day to help her with those activities of daily living she requires help with.

In order to keep those benefits, she would be required to put those assets into a special needs trust, also known as a supplemental benefits trust or a (d)(4)(A) trust. Under the Omnibus Budget Reconciliation

Act of 1993, funds held in these trusts are not counted as assets or resources for a person's SSI or Medicaid eligibility determination, and the trust provides a way to provide funds for other life essentials that are not covered by Medicaid, such as clothing, furniture, telephone, or computer access.

Unfortunately, that law included a drafting oversight that penalizes physically disabled, mentally capable adults in the creation of these trusts. By requiring that such trusts can only be established by that individual's parent, grandparent, legal guardian, or a court, mentally capable adults are forced to rely on others to do this for them. The effect of current law is they are treated as though they were mentally incapable or mentally incompetent and cannot legally act for themselves.

So Melanie would not be allowed to create a special needs trust for herself, and believe me, she would question why. She would not understand why, unlike her sister, she can't establish a trust to hold funds that come to her. She would question why, if her mother and father were deceased, she would have to hire a lawyer to go ask a judge to create a trust for her, which, unfortunately, some courts have been unwilling to do.

In addition to being demeaning to the individual, this barrier places an enormous burden on already strained court resources. The individual may be forced into an imposed guardianship and even a loss

of Medicaid or SSI benefits.

The barrier in the law creates an equality and fairness issue. One should have the right to contract if one has the mental capacity to do so. We believe it was a legislative drafting oversight that caused the problem and not the intent of Congress to deny this basic right to mentally capable adults with disabilities.

The Special Needs Trust Fairness Act would fix this problem with two words. By simply introducing the words "the individual" into the current statute that describes who can create a special needs trust, it would permit Melanie and other mentally capable adults with disabilities to create such trusts.

On behalf of Melanie and my family and so many other clients that we have worked with, I thank you for the opportunity to testify here before you today and look forward to taking any questions.

[The prepared statement of Mr. Courtney follows:]

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Mr. Pitts. The chair thanks the gentlemen.

We will begin the questioning. I will recognize myself 5 minutes for that purpose.

Dr. Boyle, in your experience as a researcher, how has the Improving Access to Clinical Trials Act affected recruitment for clinical trials since it was implemented in April of 2011?

Dr. Boyle. Well, the easy answer to that is it has allowed an increasing number of patients to be able to participate that otherwise either wouldn't have been able to or wouldn't have because of fear of exceeding their income limits. We actually keep pretty close track of this in terms of talking with research coordinators around the country, and the overwhelming feedback has been that this has removed a barrier which has allowed patients who otherwise, like I said, would have been hesitant to participate.

The reason this is particularly important is obviously not just for the individual, but for actually advancing science. As we look at some of this precision medicine and we need small, specific populations of patients to study that have specific genotypes, sometimes a few patients can make a difference. And so it has been helpful extremely helpful both for the patients, but also for advancing the science.

Mr. Pitts. Now, you mentioned in your written testimony, Dr. Boyle, that many in the cystic fibrosis community consider this the

year of the clinical trial, with 18 clinical trials underway this year. Can you speak to what is on the horizon in cystic fibrosis research and how the Ensuring Access to Clinical Trials Act might play a role?

Dr. Boyle. Well, thank you for that question. In some ways it follows onto that previous question where we have been -- it is a great success story, right? We have seen some of this recently. It featured by President Obama in the State of the Union, talking about precision medicine, in which we are starting to actually develop medications which treat different types of cystic fibrosis based on their underlying genotype, their genetic characteristics.

Again, this gets a little hard because you can't just group everybody together. And so one of the exciting things in CF has been these new transformative medicines that just don't treat the symptoms, that just don't treat cough or mucus, but actually treat the underlying cause. So that is a big thing. At the same time, we have other trials that are treating the ongoing infection, the ongoing inflammation, and nutritional problems.

So it is the year of the clinical trial. We are going to have a talk called that in our upcoming national meetings, but because it is such an exciting time for advances in CF.

Mr. Pitts. Thank you.

Mr. Clontz, I am happy that Pennsylvania leads the country in the number of PACE programs, with 19 programs serving individuals

throughout the State. So I think that PACE expansion is a great idea. But serving younger individuals with disabilities who are still in the prime of their lives would likely be different than serving older adults who are in the twilight of their lives. Would PACE be able to adapt to serve these new populations? Would younger people be served alongside older adults? How would it all work?

Mr. Clontz. It is important to note that the legislation authorizes CMS to do a demonstration project to determine how best to serve younger individuals through PACE. So we can test a couple of different approaches to figure out what will work best for new populations.

One of the programs in Philadelphia is interested in exclusively serving individuals with physical disabilities. They want to adhere to the PACE model in some ways, using the interdisciplinary team and capitated financing, but incorporate other services and benefits that are unique to the needs of the individuals with spinal cord or cerebral palsy or other issues. So in that case it would be a very unique and distinct program.

In other areas we will have to be more creative. For instance, in remote rural counties there might not be enough potential participants to warrant the construction of a program exclusive to these individuals. In that case, an existing PACE program could leverage its existing care team and resources to provide primary care

and therapy services while partnering with other organizations to provide home-based services and supports, employment services, and other services required by a younger population.

Mr. Pitts. Thank you.

Mr. Courtney, we will start with you on this, but any of you can jump in here. Do you have any additional ideas, other than the ones presented to us in these bills today, about approaches that would improve Medicaid patients' healthcare outcomes, curb program outlays, and possibly be bipartisan. I think today's hearing and last week's hearing on other Medicaid bills demonstrate this committee is ready to work together to make some improvements to the program. Would you please comment?

Mr. Courtney. I have looked at the testimony of both the gentlemen who have testified today and believe that their programs, what they are asking for, is going to help a lot of people and benefit the Medicaid program. I don't know that I am aware of any additional initiatives to take at this point.

Mr. Pitts. Mr. Clontz or Dr. Boyle, do you want to continue to add?

Dr. Boyle.

Dr. Boyle. The answer is, I am a little afraid to shoot from the hip on this, but I would love to be able to think about this with our team and to be able to submit further to you.

Mr. Pitts. Okay. We will send it to you in writing. You can respond in writing.

[The information follows:]

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

Mr. Pitts. My time has expired. The chair recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman. I am pleased with this committee's continuing commitment to advancement in medical science. Although we passed the 21st Century Cures, our work is not complete. I believe H.R. 209 highlights another area in which the committee must work research on rare diseases.

Mr. Boyle, what makes clinical trials for rare diseases like cystic fibrosis more difficult than a common disorder like blood pressure?

Dr. Boyle. It is all about the numbers. There are only 30,000 individuals with cystic fibrosis in the United States. Most clinical trials, particularly for early development of drugs, require adults, so that is about half that number. Then you splitting down into specific characteristics of those patients that you want to study. There are certain types of infections, there are certain types of genetics. So those pools get smaller.

At the same time, we are making sort of amazing advances. It is really held up as a disease that is seeing some of the most exciting advances in medicine recently. So the biggest difference in this for rare disease population is we need those numbers because we don't have large numbers like hypertension or COPD, other diseases.

Mr. Green. The GAO report from last year found that the average

amount of compensation for rare disease clinical trials is $568. Is it fair to say that when you factor in travel, time off of work, and other expenses, that most patients afflicted by rare diseases may in fact lose money in order to participate in a clinical trial? And in a smaller group, I know it is difficult. I am happy that we are able to shed the spotlight on the important issues, and 209 is a good bipartisan piece of legislation and hopefully we will pass it on.

H.R. 670. Mr. Courtney, your biography shows that you were the first attorney ever in the State of Mississippi to receive the designation of certified elder lawyer attorney. In almost 40 years of providing legal advice for elderly and disabled there are probably very few individuals in the country as much experience with you as you need in special needs trust.

Having practiced probate law in Texas before I got elected to Congress, there is obviously a need. Can you recall any particular client where passage of this law would have made a notable difference in their health and livelihood?

Mr. Courtney. Yes, sir, we have had several. There was a young woman who was injured and she relied on Medicaid waiver services to provide care. And she received a settlement, and she had to do a special needs trust, but she had no parent or grandparent living, she had no legal guardian because she was mentally capable. She had to resort to a court. And there were some problems with the court that

she would have to go to, understanding that they had to step in and create the trust. So it caused delays for her and also a temporary loss of benefits because of the delays of getting to court to establish a trust. We don't feel it was Congress' intent in the initial statute to put that burden on her or on the court.

Mr. Green. When I was practicing law I found out, and it wasn't through law school, but it was practice, that in Texas we have what I think was called a Miller trust, that a senior, Alzheimer's, debilitating illness would sign that trust and then they would be eligible for Medicaid because they would put whatever income they had and that would be assumed by the State. Is that something that is based on State to State?

And, frankly, it was hard to get that information. The State agency did not share it with most of their -- with questions. But thank goodness I had a great law professor who explained it to me. Is that common in other States to have something like that?

Mr. Courtney. The Miller trust that you refer to is in subsection (b) of the statute that we are talking about. H.R. 670 seeks to amend subsection (a), which is the individual special needs trust that would hold resources or funds, property, and not be counted as assets for Medicaid eligibility.

The Miller trust is one in which someone who needs nursing home care or some institutional level of care for Medicaid can place income,

and the income can go into the Miller trust. But that is a separate type trust, and we are not seeking to any revision of that statute.

Mr. Green. Okay. Thank you.

PACE innovation program remains a successful asset in our community since 1971. PACE advocates are proud to stand behind over 100 programs that help. Mr. Clontz, although PACE has consistently grown over the years, unfortunately, it is not available to all patients who wish to enroll. What is the existing barriers preventing the program from spreading further?

Mr. Clontz. We would love to see more PACE programs as well. There are a couple of factors that really affect PACE growth and NPA has identified several regulatory and process changes that would assist.

First, PACE is a very capital intensive program. Programs must build a day center and hire their full interdisciplinary team many months before opening. This investment can run up to $4 million to $6 million prior to opening, all to serve 150 or so individuals. If CMS would allow programs to leverage existing community resources by contracting with adult day centers and family physicians, it would allow us to grow more efficiently.

Additionally, the PACE application process is lengthy, time consuming, and bureaucratic. The PACE application typically is about the size of a phone book. But if CMS was to move to a more

attestation-based model where programs could assure they meet all of the major program requirements it would expedite the process.

Finally, CMS needs to dedicate staff resources to support PACE management and growth. PACE responsibilities are split across multiple divisions with CMS and we need a dedicated staff for PACE.

As for Houston, there is a program under development in Houston that is working with the State on an application, yet it has struggled to align PACE with managed care in the State. This is a perfect example of how better technical assistance and leadership from CMS would be helpful.

Mr. Green. If you could get me that group in Houston, be glad to work with them.

Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

And I now recognize the vice chair of the subcommittee, Mr. Guthrie, 5 minutes of questioning.

Mr. Guthrie. Thank you.

My first is for Dr. Boyle. In this position, when I was in the State legislature, there are a lot of families that come to advocate, and we get to know them and get to know families, particularly personally a lot of times. And there were a couple of people that I knew that had cystic fibrosis and they said that our child is probably going to live to be in their late twenties, maybe thirty. I think one

lived to be late twenties, one early thirties, so they are no longer with us.

And yesterday I actually was in a discussion with someone about the new innovations, a pharmaceutical that has been approved, and so there is a lot of promise.

And we spent a lot of time in this committee this year and bipartisan, unanimously passed the 21st Century Cures Act, and trying to get cures to the market quicker. And then how will the Ensuring Access to Clinical Trials Act help advance the discovery, development, and delivery of cures?

Dr. Boyle. Well, I think in a couple ways. Really the way that we make progress at the end of the day is by scientific clinical trials. Right? So we have a lot of good ideas, and actually the 21st Century Act and those things have opened up some possibilities for doing new testing.

But the biggest thing is we need access to patients. We have to partner with them to test these therapies to figure out if they are going to really make a difference. And so we can test in dishes with cells, we can do all kinds of tests in the lab, but at the end of the day, all of these trials have to go through patients.

And so this act enables us to be able to partner with patients and make sure that some of the newest, most needy patients -- remember, over a third of our patients are on Medicaid with cystic fibrosis. And

so if those patients have a barrier to participate, we have lost two things, one, the ability to be able to make those advances, but also in some ways some of the people who are most needy are missing out.

Mr. Guthrie. Thank you very much.

And, Mr. Courtney, I certainly appreciate your testimony. Mrs. Eisenhower was always asked, always answered, they said: "You must be proud of your son." And she would always say: "Which one?" So it sounds like you are very proud of both of your daughters. But I can tell you when were talking about Melanie and said if she was told she wasn't able to do something, I can see a little pride, and I guess she has a little fight in her. So I could just see that in your face. I don't know if the people back behind there can see it in your face. So that is great that you are advocating.

I just want to ask you about the difference between the special needs trusts. Of course there are pool trusts, and we created ABLE. As a matter of fact, I don't know if it is your Representative, but a Representative from Mississippi was real involved, Greg Harper, in the ABLE accounts. And could you explain the difference in those for the populations for which they are created?

Mr. Courtney. We want to thank Congress for passing the ABLE Act earlier this year, because it is a wonderful tool for people with disabilities. But in certain circumstances, because of some limitation based on CBO scoring, it is limited to those people who have

a disability that occurred prior to age 26. So a 28-year-old young woman who becomes disabled from an injury would not be able to have an ABLE account.

It is also limited in the amount of money that can be placed into an ABLE account. So $14,000 per year is the maximum at this point that could fund the account. So even if my daughter Melanie, who had a disability prior to age 26, were to receive money and want to open an ABLE account, if she got a life insurance settlement from an aunt who left her as beneficiary for $50,000, she could only put $14,000 of that in. The other money would disqualify her for Medicaid.

So that is why the ABLE Act is a wonderful tool, but it works in coordination with special needs trusts in many situations because there are other assets a person with a disability may acquire or have that would need to be in a special needs trust and could not go into an ABLE account.

Mr. Guthrie. So the H.R. 670 will still be needed because in your daughter's situation the ABLE account wouldn't cover the situation you just described?

Mr. Courtney. Yes, Mr. Vice Chairman, that is true, because she would have some assets that would need to be placed in the trust so they would not disqualify her for benefits. And at this point the deficiency in the act is that she is not able to create that trust.

Mr. Guthrie. Well, are there limits in the amount of money that

can be put into in a special needs trust and what the funds can be used for?

Mr. Courtney. Three are not limits on that in the statute that was passed in 1993, because it varies so much. I mean, someone may get an inheritance of a few thousand dollars, someone may get more.

Mr. Guthrie. Were there limits in the way the funds can be spent?

Mr. Courtney. There are limits because the act itself says that there is a Medicaid payback from that trust, a payback reimbursement to Medicaid of any funds left in the trust at the beneficiary's death. So that is one protection of the Medicaid program. But also State agencies and Social Security's POMS policies place criteria on those trusts, special needs trusts. And many States have very restrictive rules and policies about how disbursements may be made and for what from a special needs trust.

So, yes, there are protections of those moneys. It is an irrevocable trust. The beneficiary can't revoke it and undo it once they create it or once it is created. We hope they will be able to create it.

Mr. Guthrie. Appreciate it.

Mr. Courtney. And they also have to appoint an independent trustee.

So those are all protections of the money to protect it both for the needs of the beneficiary that are credible and reasonable needs

based on State policies and also that the trustee can monitor.

Mr. Guthrie. Well, thank you.

My time has expired, and I really appreciate you guys being here.

Thank you. I yield back.

Mr. Pitts. I thank the gentleman, and I recognize Mr. Schrader from Oregon, 5 minutes for questions.

Mr. Schrader. Thank you, Mr. Chairman.

Mr. Clontz, I am very interested in the PACE program. We have one, obviously, in Oregon that seems to work very well. I think most people realize that in-home care gets you better results at the end of the day. Even in my little corner of the veterinary medical world my patients do a lot better at home.

Could you talk about a little bit about research that has compared health care delivery, health care outcomes with folks in PACE versus going to, say, a nursing home?

Mr. Clontz. Absolutely. Several studies have explored the cost effectiveness and quality of PACE. A recent study by Mathematica Policy Research determined that PACE costs are comparable to the cost of other Medicare options and provide better quality of care. The study determined that PACE enrollees had a lower mortality rate than comparable individuals either in nursing facilities or receiving home and community-based services through waiver programs.

Mr. Schrader. Very good. I would like to get a copy of that,

if that is possible. That would be really interesting.

[The information follows:]

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

Mr. Schrader. One of the other big problems it deals of course with is the dual eligibles, folks both on Medicare and Medicaid, very expensive population to take care of, multiple doctors, multiple needs. The coordination becomes difficult. Can you talk a little bit about how PACE handles that coordination compared to a traditional situation?

Mr. Clontz. Yes. At least in North Carolina the vast majority of the participants, in fact 95 percent or more, are dual eligible. So it is the population that we work with predominantly.

It really is about the integrated nature of PACE in terms of coordinating care, having these individuals on a regular basis, typically three times or more a week in the adult day center, being able to put eyes on these folks, having direct access down the hall from a physician, having therapy when they are in the facility. These folks are picked up at their homes, drivers go in the homes. They can see whether there are subtle changes in their living arrangements. All of this about really an integrated care model.

Mr. Schrader. Very good. Well, we have enjoyed the same good results in Oregon.

With that, I will yield back, Mr. Chair.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. Shimkus. Thank you, Mr. Chairman. And I appreciate the

comments from my colleague from Oregon. And I had it out in efficient order, but I think I am going to continue with Mr. Clontz for a second.

One of the big concerns is how the high-cost population, as we were talking about, the duals, are driving Federal healthcare spending. Can you follow up, you were talking about this is with Mr. Schrader, but can you, again, talk about how PACE programs are reimbursed and what is known about the cost effectiveness of these programs?

Mr. Clontz. PACE programs are essentially on the Federal side a Medicare Advantage plan. We received capitated payments on a monthly basis for each of our individuals. On the Medicaid side, it is obviously different from State to State, but we have received an amount that is less than what -- a PACE program receives less dollars than they would receive if they were actually in a skilled nursing facility. The payment model is actually designed that way.

Mr. Shimkus. Thank you very much.

Now, Mr. Courtney, in a follow-up to a hearing we had last week, we heard testimony about individuals taking advantage of loopholes in Medicaid eligibility policies, such as through the use of annuities and promissory notes, to obtain Medicaid coverage when they could afford to pay for their own care. Can you explain how a special needs trust differs from some of these other financial instruments?

Mr. Courtney. Well, a special needs trust is a creature of Federal statute, OBRA 1993 created that and recognized that Medicaid

does not provide everything that a person with a disability may need. It provides what Medicaid pays for for medical services, but there are other life needs, like clothing and access to the community.

So the special needs trust is a method and an effective method that the law recognized to hold excess resources that would not be countable, but subject to a Medicaid reimbursement payback to meet other needs that are supplemental to what Medicaid would cover.

Mr. Shimkus. Yeah, I have been a member for quite a long time, and every once in a while we will then reinvestigate, because I know in your opening statement you talked about elder law issues.

There is a concern by many of us of the squirreling away of assets for seniors then to become Medicaid qualified when they can obviously -- I used to tell a story of my grandmother. She was in long-term care, 10 years. Every penny of her assets were used for the first 3 years. And then the rest came. She then qualified for Medicaid, and thank God it was there, and it took care of the 7.

There is a concern that there is ways to avoid people paying down their assets to the care before they qualify, and, Mr. Chairman, we still need to investigate, because Medicaid and Medicare are still going broke, okay, there are still programs that have structural actuary problems that we need to address.

My last question for Dr. Boyle. In your experience, is it common practice for clinical trial participants to receive compensation for

participation?

Dr. Boyle. Yes, it is actually a good question, because I think one of the common things when you look at this act is to say: Well, why don't patients turn down the money. Compensation in clinical trials is actually a really scrutinized area. Every trial that we submit there is an ethics review board for the local hospitals, as well as our network that looks and sort of stipulates how much a patient gets paid.

And there is a sweet spot. If it is too much, then it feels like you are enticing them to participate in a trial that maybe we don't know if it is beneficial. Right? So too much actually feels that is not ethical.

On the other hand, almost every ethics review board says you can't give patients the option of paying nothing, being paid nothing, because they feel like they might feel some pressure from the physicians to say: Oh, why don't you not take payment?

So they always set what is considered to be sort of a fair amount of payment. It is a modest amount, it covers travel, it covers some of their time. The fact that this is only a $2,000 limit that we are talking about shows how modest it is.

So, yes, patients get paid. It is way less than the amount of time they spent. And they really don't have any choice. The amount is stipulated by an ethics board that looks at each clinical trial.

Mr. Shimkus. And if I may, I have another question, Mr. Chairman. But I just want to follow up on his response.

So you are telling me that the payment is designed to make sure that they are legitimately -- they are not being overcompensated, but they are -- I still -- I don't understand the -- the ethics board seems to believe that they need to give them something --

Dr. Boyle. That is right.

Mr. Shimkus. -- and that is why they are paid.

Dr. Boyle. Well, that is right. And so really it is designed, it is supposed to basically compensate them for their time. It is actually not supposed to be an enticement with too much. The too little part, they are a little afraid of treating patients differently, as well as the patients who participate in trials feeling pressure to decline payment when they may need it.

Mr. Shimkus. Thank you very much.

Thank you, Mr. Chairman. I yield back.

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[9:59 a.m.]

Mr. Pitts. The chair thanks the gentlemen.

Now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questioning.

Mr. Lance. Thank you, Mr. Chairman. First I request to enter into the record a letter from over 50 organizations in support of the Ensuring Access to Clinical Trials Act.

[The information follows:]

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

Mr. Lance. As Republican co-chair of the rare disease caucus, I meet with patients almost weekly who suffer from conditions for which there are few or no treatments. These disease populations are so small, the challenges for drug development are significant. Disease populations with greater numbers often struggle to maintain adequate participation in clinical trials, but the challenges are far more acute in the rare disease space. The Ensuring Access to Clinical Trials Act seeks to address this challenge by helping to move clinical research forward and to ensure that rare disease patients on Medicaid and SSI can participate in clinical trials without fear that their compensation will count toward their eligibility limits.

To demonstrate the importance of participation in clinical research, I briefly share the story of a young man named Alex who lives in the district I serve. As an 8-month-old infant, Alex was diagnosed with cystic fibrosis, and his parents were told he would live to be about 20 years old. Today Alex is 20, and in his lifetime, a life expectancy for a patient with cystic fibrosis has more than doubled, due largely to the successes of clinical research.

Clinical trials have brought about cutting edge therapies which have made it possible for Alex to live his life, attend college, and hope for a brighter future. These benefit from the clinical trials that lead to a number of treatments, including hypertonic saline, which was brought to market after a 10-year study, and continues to benefit

Alex as he struggles daily to clear his airways of the life threatening mucous and bacteria that cystic fibrosis produces. Most recently other drugs have been brought to market, Kalydeco and Orkambi, two drugs that address the root causes of cystic fibrosis. These new therapies have been heralded as historic breakthroughs for the treatment of cystic fibrosis and have potentials to address decades to the life of Alex and others. And I certainly want to work with everyone on this committee as we move forward on these important issues. And I thank all on the panel in that regard.

Now, Mr. Courtney, I used to practice law, and I was very much interested in your remarks. The Special Needs Trust is Federal legislation, obviously, and I would imagine, as you state, it was merely an oversight. Certainly anyone who is competent, regardless of physical disability should be able to document this without having to rely on someone else. And I would imagine that legislation would pass easily. Glenn Thompson is a very able member of the Congress. He and I are classmates, coming in on the same day.

I do share Congressman Shimkus' concern, and I do not attribute this to you or to anyone whom you represent. What is the typical amount that is placed in the Special Needs Trust in your opinion based upon your experience in the practice of law for almost 40 years?

Mr. Courtney. Thank you, Mr. Lance. I don't believe there is a typical amount because as you might understand from having practiced

law, there might be a small inheritance from a family member.

Mr. Lance. Sure.

Mr. Courtney. Or there might be a large insurance or litigation settlement.

Mr. Lance. Or a large inheritance, I presume. It is possible. Isn't it?

Mr. Courtney. Yes, sir.

Mr. Lance. And when the person passes on, then the Federal Government and the State government are reimbursed for Medicaid payments if there are funds in that trust?

Mr. Courtney. Current statute does not provide for reimbursement to the Federal Government for SSI payments, but to Medicaid, the State Medicaid agency where they have received Medicaid benefits will get reimbursed.

Mr. Lance. And is it only the percentage that the State pays under the Medicaid, or is the full 100 percent?

Mr. Courtney. It is the full amount that Medicaid has paid for that individual's care even prior to the Special Needs Trust implementation.

Mr. Lance. I see. So, for example, as I read the figures in your great State, Mississippi, which I know because I went to Vanderbilt Law School right next door, you have a share -- Mississippi, 74 percent is funded by the Federal Government and roughly a quarter by the State

government. Is that accurate?

Mr. Courtney. That math is correct, yes.

Mr. Lance. That is certainly not true in New Jersey where it is 50/50. I have never understood that, but certainly others can explain that to me. And so the full 100 percent would be reimbursed through the State agency. Is that how it would work?

Mr. Courtney. Yes. An individual in Mississippi receives Medicaid benefits. Then at the death, any assets in the Special Needs Trust would go back to reimburse the State in full for those benefits the State had paid.

Mr. Lance. Thank you very much. My time has concluded. I yield back, but this reminds me that I did once practice law, and it is a very interesting conversation. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman for New York, Mr. Collins, 5 minutes for questions.

Mr. Collins. Well, thank you, Mr. Chairman, for holding this hearing. It has been very educational and interesting. I want to thank also the committee's taking a balanced approach to Medicaid reform. And your testimony is very helpful.

Last week we held a hearing focused on curbing waste, fraud, and abuse in the program, and this week we are addressing how we can improve the program beneficiaries. These two aspects really should go hand

in hand in order to get the country's entitlements under control.

A bill that I recent drafted, have not quite dropped yet, but we are talking about it today, the Medicaid Directory of Caregivers or Medicaid Doc Act. This bill is an example, I would like to think, where commonsense meets good government. The Medicaid Doc Act would require that States who operate a fee-for-service or primary care case management program would include on the Medicaid program's Web site simply a directory of physicians who have served Medicaid patients in the prior 6 months.

Today some States have this service; others don't. The bill came as a result of hearings by this committee and GAO reports that have been citing access to care of primary physicians, a problem with Medicaid fee-for-service programs. If beneficiaries can't find a doctor who will treat them, what is the point in having this kind of insurance?

So I would welcome any of you to comment on this. Again, I like to call it commonsense meets good government, and, again, for this hearing hear some opinions or thoughts you might have.

Dr. Boyle. Well, I can comment, and I can probably comment wearing two hats. First of all, as a cystic fibrosis physician, a good number of our patients, as we said, over a third are on Medicaid, and frequently, although we take care of the majority of their CF needs with a CF team, there is specialty care and other cares that they need

outside of our team. And you are right, it is a barrier sometime to be able to identify those other caregivers who would accept Medicaid.

So that list would be helpful, and, actually, as previously practicing in primary care for a few years before doing speciality training, I think it is true not just for CF patients, but for all individuals on Medicaid. So --

Mr. Clontz. I would add that it is a very commonsense approach and another tool for individuals to find a physicians.

Mr. Collins. Yeah. I have to think as we have expanded Medicaid, in many cases, certainly in New York, it is just must be the most frustrating thing to say: I finally got insurance and you are going up and down, and, you know, there is no guarantee that someone on the list would maybe accept new patients, just kind of a start.

Do you have any other suggestions you would like to share with the committee, that is the purpose of a hearing, that you think and any kind of other commonsense approach to help these patients find a primary care physician? I know you must have thought it through at some point.

Mr. Clontz. As a health system who serves a very large population of Medicaid recipients and other disadvantaged, economically disadvantaged individuals, it is a constant process for us to identify physicians, not only who are taking Medicaid, but are taking new Medicaid patients.

One of the things that we have done in addition to having a federally qualified health center in our community, we have also opened up a pediatric clinic for Medicaid and self-pay patients, and an adult clinic as well. So it is a constant battle for us, and any tool we can get would be welcomed.

Mr. Collins. I want to thank you all for those comments, and certainly would urge all my fellow members here to support the bill as we do move this forward and intend to drop this very soon. And with that, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it so much.

Mr. Clontz, thank you for testifying today on the PACE Innovation Act. I am proud to be a cosponsor of this great piece of legislation. The Program for All-Inclusive Care for the Elderly, or PACE, is a unique program that many people may not know about. So I appreciate you testifying today.

In Florida we have four PACE providers that serve 900 participants in six counties. One of these providers happens to be located near me, Suncoast Pace in Pinellas County, the county where I reside and I represent part of the county.

Mr. Clontz, who is eligible for the program currently, and under this bill how will that change?

Mr. Clontz. A potential participant in PACE is eligible if they are 55 years of age or older, have been qualified by the State as needing skilled nursing facility care, and reside in a service area for a PACE organization. So all of those qualifications have to be met.

Mr. Bilirakis. Very good. Thank you.

Again, as I understand it, the majority of PACE beneficiaries are dually eligible for Medicare and Medicaid. Is there any data and the extent to which the program's effectiveness varies based on whether or not the beneficiaries are dual eligibles?

Mr. Clontz. I am not aware of any that is specific to dual eligibles versus those that are Medicare only or private pay, if that is your question. We can certainly reach that.

Mr. Bilirakis. Yeah. Please do. Thank you very much.

Dr. Boyle, again, thanks for your testimony. I am a cosponsor of the Access to Clinical Trials bill, and it is an important provision for patients, in my opinion. What proportion of rare diseases still lack appropriate treatments and thus could benefit from the additional clinical trials, and how many or what proportion of individuals with rare diseases received Medicaid benefits?

Dr. Boyle. So I am not sure if I know the exact percentage of all rare diseases that receive Medicaid benefits, but I can tell you

that the needy population number is high. Like I said, our number is over 30 -- over a third of our patients rely on Medicaid. I think that is probably reflective of that population in general. And the other thing is that is a particularly needy group in terms of new therapies. I think you asked about what proportion still needed additional clinical trials.

Mr. Bilirakis. Exactly.

Dr. Boyle. I would say there is almost no rare diseases right now that we say don't need any more clinical trials. Right? So even those who have therapies we know we can continue to make progress if we have access to these patients for trials, and that the vast majority of them are in early stages needing trials to have any type of therapy.

Mr. Bilirakis. Thanks so much.

One last question, Mr. Chairman. I guess I have time.

Dr. Boyle, if FDA allowed the use of biomarkers, would it permit for more diverse patient populations in clinical trials and make the clinical trials easier to fill? How important are biomarkers to future drug development particularly for rare diseases of patients?

Dr. Boyle. Well, that is a very good question and a particular area of interest of mine. So biomarkers, as you know, would allow us to potentially look at other outcome measures for clinical trials that maybe aren't the typical things such a lung function which require large populations.

So I think it depends on the disease how good those biomarkers are, but certainly we know that in the future we want to be able to try to look at the whole picture and not just one measurement in patients but also to use the other weapons we have, the other tools that we have to assess a drug. So being able to look at tests in the lab, being able to look at other markers of how patients are going to do, would allow us to have a little smaller cheaper trials to get some of the same answers.

So I think this is -- the FDA is already doing a lot and discussing with this, but I think that we are looking forward to working with them, working with you, on new strategies to incorporate that in the whole approval process because it would expedite it in getting new therapies to patients.

Mr. Bilirakis. Very good.

Thank you, Mr. Chairman, for calling this very important hearing. I yield back.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions.

Mrs. Brooks. Thank you, Mr. Chairman. During the 21st Century Cures debate, is when I personally learned that we had -- we know there are over 10,000 known diseases and conditions with cures and treatments, but there are only a cure for 500 of them. And that was

somewhat shocking to me.

And so then to know that we have difficulties with the rare disease populations, I would like to ask you if this act sunsets, what will actually happen to the patients who are in clinical trials who are receiving payments now?

Dr. Boyle. Thank you for that question, because you are right, it is not just -- if this act were to -- or this law were to sunset, it wouldn't just affect the future. It would affect today --

Mrs. Brooks. Right.

Dr. Boyle. Or actually October 6 probably. And that is because people who are currently in trials and getting and receiving payments would suddenly have to recalculate. Right? And they would have to look and say: Can I afford to stay in this trial. That could actually sort of have a devastating effect for trials if they feel like they are getting close to getting some answers when suddenly patients are pulling out. That is actually one of the biggest nightmares of researchers when you start losing patients because it is hard to assess outcome.

So you are right. It is not just a down-the-road issue. It would be an October 6 issue in terms of advancing therapies for those other thousands of rare diseases you discussed.

Mrs. Brooks. Are clinical trials run differently for pediatric therapies versus adult therapies, and where does the payment go?

Dr. Boyle. So they are, and, again, this is a big topic of discussion in trying to make sure this is done well. The majority of higher risk trials early on are in adults. But once there is a little bit of establishment of some safety, then we do want to move down to pediatric patients because we want to be able to treat those patients early on before they have all those diseases. But we need to be able to demonstrate effect on those.

So pediatric trials often times have their own separate entity that we run. In some ways they are almost more challenging to enroll because obviously as a parent of three teen daughters, I would have the same feeling of: Hey, do I really want to put my child through this, or can I let some adults do it. So it is a particularly needy group to enroll.

The payment above the age of 18 goes to the individual. Below that it actually goes to the parents. Obviously they can work with the child to decide about that, but there is a whole area of assent after the age of 12. So patients who are 13 or 14, they can't sign consent themselves to participate, but they do have to sign something that says: I understand this. I have talked about it, and I do want to participate, even though they are not legally able to sign. I hope that that answered your question.

Mrs. Brooks. I am curious about the payments because I have read in your testimony people can get paid anywhere -- the committees or

ethics committee -- is it the ethics committee that do the reviews? How is the payment determined what patients get for clinical trials? Because I have read from $50 up to $2,000.

What is $50? And why would -- why is that even -- that doesn't pay for time and travel, I wouldn't imagine, and so why is there that minimal of a payment in any case?

Dr. Boyle. So it all depends on the design of the trial and it is supposed to reflect the amount of time spent. So it is not supposed to reflect risk. Right? If you are paying people more to take more risk, that actually feels like you are enticing them to do something unwise.

So what happens is there is some standards set -- in the CF community, the Cystic Fibrosis Foundation has played up a large part of this with our therapeutic development network. So we actually say: Calculate the number of hours that this individual is going to be participating, and this is the amount that they can be compensated based on the amount of hours.

It is not, again, a reflection of the risk. And then the travel that -- you know, being reimbursed for travel is a separate issue. That is actually not part of the pay -- I can tell you nobody gets rich doing this. This is basically just trying to be able to make sure that they have enough to, you know, sort of pay for their time that they have because it is affecting all the rest of their lives, whether it

is in school or it is having a job, it is a way to be able to cover them even when most of the time they are just volunteering out of altruism.

Mrs. Brooks. Okay. Thank you all for all of your work. This has been very helpful today. I yield back.

Mr. Pitts. The chair thanks the gentlewoman.

I now recognize the gentleman from Missouri, Mr. Long, 5 minutes for questions.

Mr. Long. Thank you, Mr. Chairman. And thank you all for being here today.

Mr. Courtney, currently an individual with a disability cannot set up his or her own Special Needs Trust. If this individual does not have a parent, grandparent, or legal guardian available to set up a trust, what are the next steps?

Mr. Courtney. Well, the other option in current law is to go to a court to do that. And some courts have been reluctant or even unwilling to allow a competent person with no guardianship to come into court and ask to create a trust or have the court create the trust.

Mr. Long. And if they did allow that, how long does it take to petition the court?

Mr. Courtney. Well, it can takes months or up to a year depending or court delays and getting an attorney that would understand how to go forward and look at the statute, Federal statute, and understand

those benefits to be able to approach the court. So it can take a lot of lawyers' fees and time and court resources for months.

Mr. Long. So it might take a PhD from MIT to be able to sort it out?

Mr. Courtney. Yes, right. Or an experienced elder law attorney that understands those things.

Mr. Long. Are there any additional costs that would be incurred?

Mr. Courtney. Certainly there are court fees, there are lawyers' fees that would have to be paid to hire the lawyer to go to court and do that. And then there also might even be the need for that individual to pay for their own care during the interim if the benefits were cut off because they were determined to have too much money yet but not yet in a trust.

Mr. Long. Can you give specific examples of an individual with a disability who has been unable to set up a Special Needs Trust without petitioning the court?

Mr. Courtney. Who has been able to set up a Special Needs --

Mr. Long. Yeah. Do you have any examples of individuals that have been able to do this without having to petition the court?

Mr. Courtney. Those individuals who have a surviving parent or grandparent, the parent or grandparent could sign the trust and --

Mr. Long. Yeah, but I am saying if they don't have the parent, the grandparent, or legal guardian.

Mr. Courtney. No. They can't set up a Special Needs Trust if they don't have one of those four entities or people that can establish the trust.

Mr. Long. That is kind of what I was thinking. Do you believe that current law which precludes individuals from setting up their own Special Needs Trust creates a presumption that these individuals lack the mental capacity to create their own trust?

Mr. Courtney. That is exactly how the current law treats them, as though they were mentally incapable and incompetent to set up their -- to manage their own affairs.

Mr. Long. And how would making this technical correction in the law provide more equitable treatment for individuals with disabilities?

Mr. Courtney. It would allow mentally capable adult with physical disabilities to create the trust that Congress has recognized as an effective vehicle to hold assets and allow that person to do it without the complications of having to go through the court process as we mentioned and give them the same equity and fairness that other non-disabled adults are accorded by law.

Mr. Long. Without going through this long arduous court process that we have ascertained is made to take forever and a day.

Mr. Courtney. That is correct.

Mr. Long. And it is hard to sort out.

Mr. Courtney. Yes, sir. That is correct.

Mr. Long. Okay. Thank you all. Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman.

That concludes the questions from members who are present. We will have follow-up questions. We will send them to you in writing, other members who were not able to attend I am sure will send them. Please we would ask that you respond promptly. And that means that members, they have 10 business days to submit questions for the record. So members should submit their questions by the close of business on Friday, October 2.

[The information follows:]

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

Mr. Pitts. Thank you for your testimony. It has been very clear. You have been very, very excellent witnesses in this very important issue as we move forward.

Without objection, the subcommittee is adjourned.

Let me just add, I have a UC request here to submit the following documents for the record: letters from the National Academy of Elder Law Attorneys, collection of organizations in support of H.R. 670, Special Needs Trust Fairness Act, and a statement from Representative G.T. Thompson of Pennsylvania.

Without objection, so ordered.

[The information follows:]

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

Mr. Pitts. Okay. The hearing is now adjourned.

[Whereupon, at 10:22 a.m., the subcommittee was adjourned.]