IMPROVING THE MEDICAID PROGRAM FOR BENEFICIARIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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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, DC.

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.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

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—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.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chairman will recognize himself for an opening statement.

Today, Medicaid is the world's largest health coverage program. Medicaid plays a critical role in our health care 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, today accounting for more than 25% of state spending in FY 2014.

Given rising federal costs, Congress has a responsibility to ensure that proper incentives are put in place to increase the accountability inclusiveness of Medicaid, while maintaining quality for our nation's neediest citizens.

To that end, the clarification of eligibility limits and thresholds on Medicaid will serve to bring vulnerable populations into the program, while confirmingreassuring existing enrollees as to their eligibility status.

As a result, the creation of certainty in the Medicaid system will allow us to take another step towards providing meaningful access to care, while protecting taxpayer investments and ensuring that care is provided for the truly needy.

That's why I'm so pleased today to be discussing several bipartisan bills that will help boost the accessibility and transparency of the Medicaid program.

First, a bill to be introduced by Reps. Doggett (TX), McGovern (MA), and Marino (PA) would permanently allow individuals with rare diseases who participate in clinical trials to exempt up to $2,000 in compensation for services rendered from their Medicaid eligibility.

Second, Representatives Bilirakis (FL), Lance (NJ), 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.

Next, Ranking Member Pallone (NJ) and Rep. GT Thompson (PA) have introduced a bipartisan bill that would allow for a special needs trust exception to extend to non-elderly, disabled individuals for purposes of Medicaid calculation.

Finally, Representative Collins (NY) will be introducing the Medicaid Directory of Caregivers Act, a bill that would require State Medicaid programs to increase patient accessibility through the publication of an electronic list of Medicaid providers.

It is my hope that through the steps currently taken in these bills, as well as any productive additions that may occur henceforth, this committee can come together to take meaningful steps towards Medicaid certainty, transparency, and accountability.

I look forward to hearing from our witnesses today, and I yield to ————————.

Mr. PITTS. 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.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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.

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.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

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.

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.

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 affects the lung. It causes the body to produce 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 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 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 en-

sure 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:]

September 18, 2015

Michael P. Boyle, M.D., FCCP
Vice President of Therapeutics Development
Cystic Fibrosis Foundation
6931 Arlington Road
Bethesda, MD 20814

Written Testimony for the Hearing: "Improving the Medicaid Program for Beneficiaries"
Committee on Energy and Commerce, Subcommittee on Health

Summary:

- The Cystic Fibrosis Foundation offers its full support for the Ensuring Access to Clinical Trials Act, HR 209.
- The law the Ensuring Access to Clinical Trials Act makes permanent, the Improving Access to Clinical Trials Act, allows people with rare diseases to receive up to $2,000 annually in compensation for participation in clinical trials without that compensation counting toward their income eligibility limits for SSI and Medicaid.
- Unless Congress acts, it will expire on October 5, 2015. We urge swift Congressional action on the Ensuring Access to Clinical Trials Act.
- The Senate passed identical legislation on July 16, 2015.
- The Improving Access to Clinical Trials Act has enabled people to participate in clinical trials who would otherwise have not for fear of losing critical benefits.
- Rare disease researchers face a serious challenge in recruiting participants for clinical trials, especially for those diseases or subtypes of disease with very small populations.
- CF is an expensive disease, and Medicaid is critical for many to afford care.
- A broad coalition of health care organizations support the Ensuring Access to Clinical Trials Act, including NORD, BIO, MDA, Research!America, and over 70 other groups.
- The Congressional Budget Office (CBO) has given HR 209 a minimal preliminary score.

Written Statement:

On behalf of the Cystic Fibrosis Foundation, representing the approximately 30,000 people with cystic fibrosis (CF) in the United States, I am pleased to offer this testimony in support of H.R. 209, the Ensuring Access to Clinical Trials Act of 2015.

We are deeply grateful to Health Subcommittee Chairman Pitts and Ranking Member Green, as well as full Committee Chairman Upton and Ranking Member Pallone, for convening this discussion on an issue that is so important to the rare disease community. As I will discuss in greater detail later in my testimony, the Improving Access to Clinical Trials Act expires on October 5, and swift Congressional action on HR 209 is vital to ensure the continued viability of this critical law.

The Ensuring Access to Clinical Trials Act will permanently remove a barrier to clinical research for rare diseases and allow Supplemental Security Income (SSI) and Medicaid recipients to participate in and benefit from clinical trials. We greatly appreciate the efforts of the bill's sponsor, Congressman Lloyd Doggett (D-TX), and all of those working to pass this important legislation.

Cystic fibrosis is a rare, genetic disease that primarily affects the lungs. It causes the body to produce thick, sticky mucus that clogs the lungs and other parts of body and leads to life-threatening infections and serious digestive complications. In the 1950s, few children with CF lived to attend elementary school. Since then, tremendous progress in understanding and treating CF has led to dramatic improvements in length and quality of life for those with cystic fibrosis. Many people with the disease can now expect to live into their 30s, 40s and beyond.

As a physician, professor, and clinical investigator at the Johns Hopkins Division of Pulmonary and Critical Care Medicine, I have observed the devastating impact of this disease and the importance of clinical research in developing treatments that can change the lives of

individuals with CF. It is for this reason that I am here today to ask that the Ensuring Access to Clinical Trials Act be passed without delay.

The Ensuring Access to Clinical Trials Act of 2015 eliminates the five-year sunset clause from a current law — the Improving Access to Clinical Trials Act (IACT). Signed into law in 2010, 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. Unless Congress acts, this critical law will expire on October 5, 2015.

The Senate has already passed identical legislation by unanimous consent, and we urge similar swift consideration of this bill in the House.

Through my work with the Cystic Fibrosis Therapeutics Development Network and in my own clinical research at Johns Hopkins as Director of the Johns Hopkins Adult Cystic Fibrosis Program, I have seen firsthand how the Improving Access to Clinical Trials Act has enabled people to participate in clinical trials who would otherwise have not for fear of losing critical benefits.

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 did not 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 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 the Medicaid and SSI support on which he was completely reliant in jeopardy. Mike even volunteered to participate in the trial without payment, but this is not allowed by 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. To this day, I still wonder if his outcome may have been different if he had enrolled.

Rare disease researchers face a real challenge in recruiting participants to test new medications. Removing barriers to drug trial participation is particularly important, as recent advances in medical research and technology allow for the development of innovative and promising medications. Securing an adequate number of clinical trial participants is vital for therapies that treat rare conditions, but rare disease researchers in particular often have difficulty recruiting drug trial participants, simply because they have a smaller pool of patients.

If 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 participating in clinical trials to drop out of these trials for fear of losing their benefits. This would put vital clinical research at risk at a time when the medical needs of the majority of people with rare diseases are not being met.

With the advent of precision medicine, it is now possible to customize therapies to treat an individual's specific genetic makeup. As this new concept in drug development quickly becomes a reality, it opens the door for the advance of targeted therapies in many important areas of medicine, including cancer and rare diseases like CF.

For example, the Cystic Fibrosis Foundation has collaborated with pharmaceutical companies to develop targeted therapies that address the underlying cause of the disease in people with specific genetic mutations that cause CF. Two of these therapies are now available to patients; however, they are only effective for some groups of people with cystic fibrosis. Nearly half of those living with CF are still waiting for a therapy to treat their disease.

The mission of the CF Foundation is to find a cure for ALL people with cystic fibrosis — including those with the rarest CF mutations, which might be found in only a handful of people. In order to achieve this goal, we must ensure nothing stands in the way of carrying out this vital research; no one should be excluded from participation.

We are well on the way to our goal. There are currently 18 clinical trials under way for new cystic fibrosis therapies — more than ever before. Many in the CF community are calling 2015 the "Year of the Clinical Trial." Now is the time to ensure that all people with CF — and all rare diseases — have opportunities to participate in clinical trials for potentially life-saving treatments.

The necessity of ensuring an adequate number of clinical trial participants holds true not just for genetically targeted medications, but also for therapies that treat the symptoms of cystic fibrosis, including antibiotics and nutritional supplements like pancreatic enzymes.

It is also important to note that cystic fibrosis is an expensive disease, and individuals who rely on Medicaid for their coverage cannot afford to be without it due to their participation in a clinical trial. According to a 2014 Cystic Fibrosis Patient Survey, nearly 20 percent of those with CF receive Medicaid, and almost one quarter of CF patients delayed getting medical care or skipped treatment because they worried about the costs.

The Improving Access to Clinical Trials Act was the result of the rare disease community coming together five years ago in support of a policy that will help improve clinical research for devastating rare diseases and help people with those diseases keep vital health benefits.

Now, the Ensuring Access to Clinical Trials Act, which would remove the sunset clause from IACT, enjoys similar widespread support. This bill is supported by a diverse coalition of health care organizations, including the National Organization for Rare Disorders (NORD), the Muscular Dystrophy Association (MDA), the Biotechnology Industry Organization (BIO), Research!America, Faster Cures, the Children's Hospital of Philadelphia, the Massachusetts Medical Society, and more than 70 other groups.

This legislation will have minimal cost to American taxpayers. According to a preliminary estimate by the Congressional Budget Office, the Ensuring Access to Clinical Trials Act will cost less than $500,000 over ten years.

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.

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.

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:]

Testimony of Tim Clontz
Senior Vice President, Cone Health and
Chair, Public Policy Committee
National PACE Association

"Improving the Medicaid Program for Beneficiaries"

House Energy and Commerce Committee
Subcommittee on Health
September 18, 2015

Executive Summary

Mr. Chairman, Ranking Member Green, and members of the committee, thank you for hosting today's hearing on the *PACE Innovation Act* and these other important bills. I am Tim Clontz, and it is my honor to testify today on behalf of the National PACE Association, the 115 PACE organizations operating in 32 states, and the 35,000 participants we serve.

The Program of All Inclusive Care for the Elderly (PACE program) is a proven care model that provides high-quality, integrated care to some of our nation's frailest, most vulnerable citizens – those needing a nursing home level of care. Studies show that people receiving care from PACE organizations live longer, in better health, with fewer hospitalizations and more time living in their homes than those receiving care through other programs.

The *PACE Innovation Act of 2015* would allow CMS to test the PACE model with new populations such as younger people with disabilities, individuals at-risk for needing nursing home care and others. This much needed legislation would address serious gaps in our current health and long term care delivery system, and would allow PACE organizations to offer high-quality, fully-integrated care that allows vulnerable populations to maintain their optimal health, receive much-needed services, and to live independently in the community.

This non-controversial, bipartisan legislation was scored as revenue neutral by the Congressional Budget Office, and passed the United States Senate by unanimous consent in August 2015. We thank the bill sponsors, Congressman Christopher Smith (R-NJ) and Congressman Earl Blumenauer (D-OR) for their tireless support of PACE, and applaud the committee for its consideration.

We also commend the committee for its consideration of the Medicaid DOC Act. Giving consumers the information they need to choose the right health care coverage for them helps to move the delivery and finance system in the right direction. We believe this principle should apply to all options equally and applaud the Act's requirement to disclose the primary care and specialist physicians accessible to individuals through Medicaid fee for service and primary care case management programs

We look forward to working with committee leaders to advance these bills through committee, to the House floor, and onto the President for his signature.

Overview of the PACE Program

The Program of All Inclusive Care for the Elderly (PACE) is a fully integrated care model that serves some of the most complex and challenging individuals in our health care system – aging seniors who require a nursing home level of care. The PACE philosophy is centered on the belief that it is better for frail individuals and their families to be served in the community whenever possible. Although all PACE participants are eligible for nursing home care, 90 percent continue to live at home.

PACE organizations provide the entire continuum of medical care and long-term services and supports required by frail older adults, including primary care, specialty care, home care, transportation, therapy services, and other benefits. In short, PACE covers all Medicare Parts A, B and D benefits, all Medicaid-covered benefits, and any other services or supports that are medically necessary to maintain or improve the health status of PACE program participants.

PACE serves some of our nation's frailest and most vulnerable citizens – those requiring a nursing home level of care. The average PACE participant is 76 years old, has 4 to 5 chronic conditions and has difficulty performing at least 3 activities of daily living such as eating, bathing, dressing or moving around. Approximately half of PACE participants have a dementia diagnosis, and ninety percent are dually eligible for Medicare and Medicaid.

Despite their frailty and complexity, PACE participants enjoy a high quality of care and quality of life. Several evaluations of PACE have found that participants experience better health outcomes than beneficiaries served in other care models including fewer unmet needs, better access to preventive services such as immunizations and hearing and vision screenings, less pain, less likelihood of depression, and fewer hospitalizations and nursing home admissions.

Moreover, the PACE program has proven to be a good value to taxpayers. A recent study by Mathematica Policy Research determined that PACE costs are comparable to the cost of other Medicare options but that PACE provides better quality of care. The MPR study determined that PACE enrollees had a lower mortality rate than comparable individuals either in nursing facilities or receiving home and community based services (HCBS) through waiver programs.

Perhaps the best way to describe the PACE program is to tell the story of someone who experienced its benefits:

> Dennis is a 59 year old diabetic who lives in the foothills of North Carolina. Prior to enrolling in PACE, he suffered a massive stroke, fell and hit his head. He was hospitalized for three months and lost 30 lbs. When he was discharged to a skilled nursing facility for rehab, his blood sugars were out of control, he required moderate assistance with activities of daily living, and walked with a walker.
>
> Dennis enrolled in PACE in February 2014 and now lives with his sister. PACE helped Dennis get his diabetes under control, improved his function to the point that he requires minimal assistance with his activities of daily living, and he uses PACE's gym and Otago Balance Program to help maintain his physical strength. Dennis is a robust member of the PACE community, and serves as President to the Participant Advisory Committee.

Opportunities for PACE Growth -- Eligibility

PACE has seen significant growth in recent years, including a 30 percent increase in the number of people receiving services over the last three years alone. That said, we believe that PACE can play an even larger role in the health and long-term services and supports delivery system, and have identified several policy initiatives that could promote PACE growth and innovation.

PACE eligibility is currently restricted to individuals 55 or older who have been designated by their states as requiring a nursing home level of care. It is our belief, however, that others would benefit from the PACE model of care, including younger individuals with physical disabilities, individuals with intellectual or developmental disabilities, and older individuals who have chronic care needs but are not yet nursing home eligible. The current health care delivery system is ill-equipped to meet the needs for these individuals, resulting in myriad physical, social and attitudinal barriers to quality health care. For

example:

- 31 percent of individuals with disabilities rank their health as fair or poor, compared to 7 percent of people without a disability.[i]
- Individuals with disabilities are at far greater risk for chronic diseases such as diabetes, HIV/AIDs and depression. [ii]
- Individuals with disabilities experience higher incidences of unhealthy behaviors, including obesity, sedentary lifestyle, cigarette use, and substance abuse. [iii]
- Women with disabilities experience significant physical and attitudinal barriers to routine gynecologic and reproductive health care. According to one study, women with disabilities were 24 percent less likely to have received a Pap test during the previous year than women without disabilities and were nearly three times more likely than women without disabilities to have postponed needed medical care.[iv]
- Health care providers are poorly trained to meet the needs of individuals with disabilities. They often hold inaccurate or stereotypical perceptions about people with disabilities, make judgments about individuals' quality of life, or fail to make their facilities, clinics, diagnostic tools and exams accessible.

The PACE eligibility restriction is an arbitrary age limit that puts better care out-of-reach for far too many families. To illustrate this point, I wanted to share with you the story, published in a series by the Newport News Free Press, of a family who is struggling at the hands of our inadequate health and long term care system:

> Jim G. is a 54 year old Virginia resident who was diagnosed with early-onset Alzheimer's disease. Although Jim was initially enrolled in clinical trials to combat his illness, he recently ceased all treatment as his memory – and his health – deteriorated. He tried to enroll in the local PACE program, but was unable to because Jim did not meet the age requirements.
>
> Jim was hospitalized in 2014 for a lung infection caused by "silent aspiration", which occurs when the swallowing function is weakened by Alzheimer's. A once vibrant athlete, Jim lost almost 40 lbs.
>
> Initially, Jim stayed 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.
>
> Karen struggled to care for Jim and tend to her school-aged children, while also holding down a full time job, but eventually had to quit her job to care for him full time. Unfortunately, Karen discovered that his needs were more than she could handle. Following a psychotic break and a week as a psychiatric inpatient, Jim was permanently placed in a memory care unit near their home. Karen had to use "crowd-sourcing" to raise funds for Jim's treatment.

This heartbreaking situation might have been avoided had Jim been able to enroll in PACE. Jim could have received day-time 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 silent aspiration and other health complications. PACE has significant experience with dementia, and might have been able to avoid or better managed his psychiatric deterioration. And Karen and her family would have received much needed respite services, emotional and social support, and peace of mind, perhaps helping her maintain her employment.

The PACE Innovation Act of 2015 would help Jim and others like him by allowing CMS to test and adapt the PACE model to support individuals with complex chronic illnesses and disabilities by better integrating the health care and long term supports on which they rely. The following are benefits that this model can offer to consumers, families, and policymakers:

- **Access** to team based, disability competent care for an underserved, high cost population.
- Improved **care coordination with timely and accessible primary care** reducing unnecessary emergency, inpatient and long term care utilization.
- **Reduced nursing home utilization** enabling nursing home eligible individuals to live independently in the community.
- **Compliance with Olmstead** by providing new, less restrictive settings for significantly disabled persons.
- Competent, consistent and **quality attendant care services** for activities of daily living.
- **Social network of care** with innovative physical and virtual day programs to enhance independence and employability.
- **Extensive use of adapted technologies** – computing, telehealth, social networking, environmental controls, mobility – to increase independence, provide enhanced abilities at reduced cost.
- **Significant savings to Medicaid and Medicare** – greater than $20M per year for 300 members of the program.
- **Relocation of individuals from nursing homes** into community setting by partnering with state and local housing organizations to fund development of accessible, affordable and safe housing.

By supporting policies that allow for PACE growth, innovation and expansion, Congress can be assured that they are supporting a proven, cost-effective care model that will help achieve the goal of better care coordination for Medicare beneficiaries with chronic illness.

Opportunities for PACE Growth – Program Development and Operational Flexibility

In addition to the eligibility limitations identified above, PACE's current regulatory framework often stifles PACE development, innovation and growth.

Opening a PACE program involves a lengthy and bureaucratic process, where PACE sponsoring organizations must navigate a complex maze of state and federal requirements and make significant capital investments before it can start enrolling participants. This cumbersome process exists for both the development of new programs as well as the growth of existing programs. In total, the PACE application process takes 18-24 months and can cost $4 - $6 million.

Similarly, PACE organizations must adhere to myriad, cumbersome, sometimes vague regulatory requirements. For example, PACE organizations cannot contract with community-based physicians or Alternative Care Settings to provide services. The requirement that participants see only PACE physicians – and therefore leave their family physician – may discourage some beneficiaries from enrolling in PACE. Similarly, if a PACE organization reaches capacity in one location, it must spend $4 - $6 million to construct a new PACE center rather than contract with a local adult-day health center or senior center. Other regulatory requirement place similar burdens on PACE organizations, often with little benefit to the beneficiary or the taxpayer.

Unfortunately, PACE regulations have been unchanged since 2006. Although NPA and Congress have sought regulatory changes for many years, CMS has not adhered to its own timeline for updating PACE regulations. In its fall 2012 *Regulatory Agenda*, CMS published that a Notice of Proposed Rulemaking to revise the PACE regulation would be issued in July 2013. Since then, this deadline has been extended to December 2013, again to August 2014, then to spring 2015 and is now set for fall 2015. The lack of a revised PACE regulation constrains PACE organizations' ability to grow, increases costs, and limits PACE organizations' ability to offer beneficiaries access to a proven model of care.

Closing

Simply put, helping people get the care they need at home with the love and support of their family members 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 to the care of 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 its effective delivery system to additional people through a pilot program. The PACE Innovation Act does this. Through the act, the PACE model can be adapted to serve people under the age of 55 and people at risk of needing a nursing home level of care. People like a woman with early onset Alzheimer's, or a younger person with physical disabilities, or a person with an intellectual or developmental disability.

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

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

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[i] Seth Curtis and Dennis Heaphy, Disability Policy Consortium: Disabilities and Disparities: Executive Summary (March 2009).

[ii] *Ibid.*

[iii] *Ibid.*

[iv] National Council on Disabilities "The Current State of Health Care for People with Disabilities." http://www.ncd.gov/publications/2009/Sept302009#Health%20Status

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 an associate of arts degree in 3 ½ 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:]

Special needs require special attorneys.

Statement of Richard A. Courtney, CELA* CAP**

President of the Special Needs Alliance

"Improving the Medicaid Program for Beneficiaries"

A hearing by the
Committee on Energy and Commerce
Subcommittee on Health

United States House of Representatives

Friday, September 18, 2015

Statement of Richard A. Courtney, CELA* CAP**
President of the Special Needs Alliance
"Improving the Medicaid Program for Beneficiaries"
Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
Friday, September 18, 2015

Good morning. Chairman Pitts, Ranking Member Green, and members of the subcommittee, I congratulate you on holding this hearing to examine ways that the Medicaid program can be strengthened to better serve its beneficiaries. I appreciate the opportunity to come to Washington, DC, to testify in strong support of the Special Needs Trust Fairness Act, H.R.670, introduced by Representative Glenn Thompson and Energy and Commerce Ranking Member Frank Pallone, and in the Senate, S. 349, introduced by Senators Grassley and Nelson. This legislation has been one of the top public policy priorities of the Special Needs Alliance and the National Academy of Elder Law Attorneys. I am honored to serve as the current President of the Special Needs Alliance and I am a past member of the NAELA Board of Directors and former chair of their Special Needs Law Section. Both organizations wholeheartedly support the Special Needs Trust Fairness Act.

The Special Needs Alliance (SNA) is a national, non-profit organization committed to helping individuals with disabilities, their families, and the professionals who serve them. Many of our member attorneys have family members with special needs; all of them work regularly with public benefit programs, guardianship/conservatorships, planning for disabilities, and special education issues. We volunteer significant time to the special needs community and advocate for legislative and regulatory change to improve the quality of life for individuals with disabilities. The majority of our members are also certified as elder law attorneys (CELAs) by the National Elder Law Foundation and are members of the National Academy of Elder Law Attorneys (NAELA), which has devoted substantial resources to meeting the needs of the special needs community.

As you know, the Special Needs Trust Fairness Act was passed unanimously by the Senate on September 9, 2015, making this hearing and your consideration of the bill very timely. We greatly appreciate your work toward passage.

Personal Background

I have become an "expert" in special needs issues from both personal and professional experience. In 1979, I became the father of identical twin daughters. My wife and I love both our daughters and are very proud parents, but they have led quite different lives. Melissa was in "gifted and talented" education and sports through college and is now a young wife and mother to two elementary school-age boys. Melanie, her twin sister, was genetically the same, but different. She is a wheelchair user with cerebral palsy and learning disabilities. But through her determination and hard work, she completed high school and community college, earning an

Associate of Arts degree in three and a half years. She found a job with our state ARC chapter as coordinator of a project called "My Voice, My Choice" teaching self-advocacy skills to young adults with developmental disabilities. Suffice it to say, she has taught us a great deal as well. She has never wanted help with things she could capably do. She does not easily accept that she cannot do something because she is physically disabled. She does, however, need and is receiving care under a Medicaid waiver benefit. The cost of paying for her care and supportive services is high, and she must rely, as do many persons with disabilities, on programs like Medicaid.

The Problem

For now, my wife and I are here to be supportive of Melanie, but that won't always be the case, and her needs may grow as she gets older. If someday she were to receive some money or property through inheritance or an insurance or litigation settlement, she could lose her Medicaid waiver benefits that pay her attendant to assist her for a few hours each day with certain activities of daily living. In order to keep those benefits, she would need to have those funds placed in a "self-settled" special needs trust (also known as a Supplemental Needs Trusts or (d)(4)(A) trust). That is what Congress intended when it created this and other trust options for those with disabilities in the Omnibus Budget Reconciliation Act of 1993.

Unfortunately, that law included a drafting oversight that seems to assume that a person with disabilities lacks the requisite mental capacity to enter into a contract and therefore is not legally allowed to create her or his own special needs trust (SNT).

These trusts are not complicated. They have a trustee to ensure that funds are used for the sole benefit of the disabled individual. Funds that are placed in such a trust would allow Melanie to pay for additional health care not covered by Medicaid as well as pay for basic daily living items such as clothing, going to the hairdresser, furniture for her home, or a computer. These are things that many of us take for granted, yet many individuals with disabilities don't have the necessary resources to make such purchases without funds from a special needs trust. These are often funded by a family member or secured through a legal settlement.

So, Melanie would not be allowed to create her own SNT, and - believe me - she would question why. She would not understand why, unlike her sister, she could not create such a trust and appoint an independent trustee to manage those funds. She would question why, if her mother and father were deceased, she may be unable to have a judge establish such a trust for her. This has been the result for many under current law, which requires that a trust created with the assets of a person with a disability be established by that person's parent, grandparent, legal guardian or a court, but not by her or himself. Unfortunately, some courts have been unwilling to establish trusts on behalf of an individual with disabilities. So, Melanie's situation is not unique; many others in every state face similar obstacles to creating simple SNTs that will enable them to supplement their care needs beyond what Medicaid provides.

In some states, another trust option called a "pooled trust" run by a non-profit would be available. There is no such trust available within our state, so without the correction of the statute sought in H.R. 670, individuals in many states may be forced to send their inheritance or settlement funds out-of-state to be managed by organizations and entities they know nothing

about. In my practice during the last year, I have informed several clients that this was their only option under current law. While reluctant to do so and confused as to why they could not fund a trust in their home state, they were forced to use the pooled trust to retain essential medical and health care benefits.

Under current law, an individual with a disability and without surviving or cooperative parents or grandparents would be forced to resort to the court for assistance in creating the trust. We have assisted hundreds of persons with court-created trusts over the years. This places an enormous burden on already strained court resources to help a competent (but physically disabled) adult establish a trust while no such burden is placed on the court where a non-disabled adult wishes to do the same. Beyond the degrading presumption of mental incompetence, the effect of the law means that persons with disabilities who have no close family must petition the court and undergo unnecessary legal fees, court delays, and even potential guardianship. In some cases, if the individual does not have the funds to hire a lawyer, then she or he loses access to necessary government benefits.

The Solution: Special Needs Trust Fairness Act

The disparity in the law creates an equality and fairness issue. One should have the right to contract if one has the requisite legal capacity. There seems to be no record of or reason for this disparity in OBRA '93. We believe it was a legislative drafting oversight and not the intent of Congress to deny a basic right to individuals with disabilities.

A statutory change – the Special Needs Trust Fairness Act – would fix this problem with two-words. Simply by adding "the individual" to the current law that describes who can create a SNT would permit Melanie and other mentally-capable adults with disabilities to create a trust. In contrast, the words "the individual" were included in the pooled trusts provisions of OBRA '93. The new ABLE Act program recognized that accounts created under that law are "an account established by an eligible individual, owned by such eligible individual, and maintained under a qualified ABLE program."

We ask that you support and pass the Special Needs Trust Fairness Act thereby removing the misplaced presumption that individuals with disabilities lack mental capacity. This change will save disabled individuals, including veterans, thousands of dollars that can be spent on necessary care, services, and personal items for these individuals to have the best chance for a quality life.

Many disability and aging advocacy organizations have shown support for the Special Needs Trust Fairness Act, including: the American Association of People with Disabilities, Easter Seals, United Spinal Association, National MS Society, National Association of State Directors of Developmental Disabilities Services, Mental Health America, Lutheran Services in America Disability Network, the American Network of Community Options and Resources, Christopher & Dana Reeve Foundation, Pennsylvania Special Olympics, Academy of Special Needs Planners, Iowa Office of the State Long-Term Care Ombudsman, State of New Jersey Office of the Ombudsman for the Institutionalized Elderly,The Florida Bar Elder Law Section, and the Academy of Florida Elder Law Attorneys. I belive it is safe to say that these groups and numerous others believe that many persons with disabilities are quite capable of handling their own affairs and that to presume otherwise is unfair and degrading.

In closing, let me quote a friend and colleague Michael Amoruso, who has worked so hard to correct this inequity in the law. Michael is a leader in the elder and special needs law communities. He is also legally blind and moderately deaf. Under current law, he would not be able to sign (create) his own special needs trust if he ever needed one, even though he has drafted thousands of trusts for clients over the years. In calling us to action to fix this injustice, he wrote "Yet, even to this day, those of us with disabilities must continue to erase the historic, age-old stereotype that a person with a disability is a lesser individual than her or his able-bodied neighbor." The Special Needs Alliance and NAELA ask that you correct this drafting oversight in the law as Michael put it "so that those of us who have disabilities can regain the dignity we deserve and remove the misplaced presumption that we lack capacity due to our disabilities."

On behalf of Melanie, my family, and so many others, I thank you for allowing me the opportunity to testify before you today. I look forward to taking your questions.

Richard A. Courtney, CELA* CAP**
Frascogna Courtney, PLLC
[redacted]

* Certified Elder Law Attorney
** Council of Advanced Practitioners

Mr. PITTS. The chair thanks the gentleman.

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 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. OK. We will send it to you in writing. You can respond in writing.

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 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. OK. 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 we 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. There are not limits on that in the statute that was passed in 1993, because it varies so much. 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 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.

One of the other big problems it deals with of course 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 is really about 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 fewer 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. Yes, 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, OK, 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 not being overcompensated, but they are—the ethics board seems to believe that they need to give them something——

Dr. BOYLE. That is right.

Mr. SHIMKUS [continuing]. 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.

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 appears at the conclusion of the hearing.]

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 benefits 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 it 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 for beneficiaries. These two aspects really should go hand in hand in order to get the country's entitlements under control.

A bill that I recently 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 specialty 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. Yes. 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 youwould 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 on 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. Yes. 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 additional clinical trials, and how many or what proportion of individuals with rare diseases receive 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 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 are 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 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, it's 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, if 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 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—is it the ethics committee that does 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—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 are 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 a reflection of the risk. And then the travel that—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 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. OK. 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 Ph.D. 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. Yes. 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. Yes, 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 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. OK. 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.

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 appears at the conclusion of the hearing.]

Mr. PITTS. OK. The hearing is now adjourned.

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

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. RENEE L. ELLMERS

I want to thank Chairman Pitts and Ranking Member Green, and the Committee for their focus today on improving the Medicaid program for beneficiaries. This vital safety net program has had many successes to date, but as my colleagues know Medicaid faces significant challenges as we work to modernize the program to ensure it is able to provide meaningful access to the most vulnerable patients for decades to come.

While I generally support the bills under consideration today by the Subcommittee aimed at improving Medicaid patient access to care, I very much believe there is a missing component in this discussion.

I found particularly noteworthy the GAO report this committee recently received which found that Medicaid enrollees face particular challenges in accessing certain types of care, such as obtaining specialty care or dental care. Additionally, GAO has previously reported that 38 States experienced challenges ensuring enough participating providers.

These disturbing revelations point to a real policy need to address the holes in this vital safety net program and facilitate improvements to care among our nation's most vulnerable.

With respect to specialty care, Congresswoman DeGette and I have been working on a bipartisan bill to improve Medicaid access to care and improve quality outcomes when it comes to medically necessary foot and ankle care. The HELLPP Act (H.R. 1221) would remove Medicaid patient access barriers to the best trained and best educated physician specialists of the foot and ankle—podiatrists, also known as doctors of podiatric medicine.

Our health-care system increasingly requires the skills of podiatrists because they play a critical role in treating lower extremity complications related to diabetes, peripheral arterial disease, obesity, arthritis, and other chronic conditions, as well as treating and preventing complications from these conditions. Take diabetes as an example: The early-warning signs of diabetes are often found in manifestation of complications in the lower extremity. As such, podiatrists are frequently the first health-care provider to detect, treat, and therefore significantly prevent or reduce complications, such as lower-limb amputations.

Foot and ankle care is already a covered benefit under Medicaid. However, access to that care is jeopardized because currently federal Medicaid law only includes part of the Medicare physician definition which results in not ensuring access to a podiatrist.

The HELLPP Act would remedy this access barrier by referencing the same Medicare definition of physician to ensure that Medicaid patients-who disproportionately suffer from chronic conditions-have timely access to the most appropriate and best trained providers of foot and ankle care.

A strong body of evidence shows that when podiatric physicians and surgeons are delivering foot and ankle medical and surgical care, patient outcomes are better, hospitalizations are fewer and shorter, and our health-care delivery system saves billions of dollars annually.

The Energy & Commerce Committee has voted in favor of this Medicaid access provision in past legislation (2009). And just last congress our Senate colleagues included this podiatry access provision in that chamber's main Medicare SGR reform bills last congress.

While the bills before the Subcommittee are important elements toward improving Medicaid for beneficiaries, there is more we can and should be doing. I very much hope we can take additional steps in the near future and also work to advance the HELLPP Act this congress.

March 12, 2015

The Honorable Lloyd Doggett
United States Representative
2307 Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Marino
United States Representative
410 Cannon House Office Building
Washington, DC 20515

The Honorable Jim McGovern
United States Representative
438 Cannon House Office Building
Washington, DC 20515

Dear Representatives Doggett, Marino, and McGovern,

The undersigned organizations, representing millions of Americans with rare and genetic diseases, advocates, industry, and academic institutions, write to express strong support for H.R. 209, the Ensuring Access to Clinical Trials Act of 2015. This legislation will permanently remove a barrier to clinical research and allow Supplemental Security Income (SSI) and Medicaid recipients to participate in and benefit from clinical trials without fear of losing vital benefits.

The Ensuring Access to Clinical Trials Act of 2015 eliminates the sunset clause from the Improving Access to Clinical Trials Act of 2009 (IACT), legislation signed into law in 2010, making the IACT a permanent law. This will allow patients with rare diseases to continue to receive up to $2,000 in compensation for participating in clinical trials without that compensation counting towards their income eligibility limits for SSI and Medicaid.

Removing barriers to drug trial participation is particularly important as recent advances in medical research and technology allow for the development of new and promising medications. Securing an adequate number of clinical trial participants is vital for therapies that treat rare conditions, but rare disease researchers in particular often have difficulty recruiting drug trial participants, simply because they have a smaller pool of patients.

Further, with the advent of precision medicine, therapies are being customized to treat a patient's specific genetic makeup. These types of trials often require clinical trial participants bearing specific genetic mutations, which necessarily creates an even more complex and exclusive clinical trial recruitment process. Ensuring that all patients with rare diseases are able to participate in clinical trials can help open the door for the advancement of new targeted therapies in many important areas of medicine, including cancer and rare diseases like cystic fibrosis.

Now is the time to ensure that all patients have access to clinical trials for potentially life-saving treatments. We look forward to working with you to secure passage of this bill to enable Social Security beneficiaries to participate in clinical trials so that research into life-saving treatments may to continue to advance.

Sincerely,

Actavis
Adult CF Program - Northwestern University
Adult Polyglucosan Body Research Foundation APBDRF
Alpha-1 Foundation
ALS Association
American Association for Respiratory Care (AARC)
American Autoimmune Related Diseases Association (AARDA)
Amyloidosis Support Groups Inc.
Ann & Robert H. Lurie Children's Hospital of Chicago
Antonio J. and Janet Palumbo Cystic Fibrosis Center, Pediatric and Adult Program, Children's Hospital of Pittsburgh UPMC
Association of Clinical Research Organizations (ACRO)
Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
Batten Disease Support and Research Association
Biotechnology Industry Organization (BIO)
CADASIL Association Inc.
Cardio-Facio-Cutaneous International
CARES Foundation, Inc. (Congenital Adrenal hyperplasia Research, Education and Support Foundation)
CF Care Center at Dayton Children's Hospital
Congenital Hyperinsulinism International (CHI)
COPD Foundation
Cure CMD
Cure SMA
Cystic Fibrosis Foundation
Cystinosis Foundation
Debra of America
FasterCures
First Focus
Foundation Fighting Blindness
Foundation for Prader-Willi Research
Foundation to Eradicate Duchenne
Friedreich's Ataxia Research Alliance (FARA)
Genetic Alliance
Hide & Seek Foundation for Lysosomal Disease Research
Huntington's Disease Society of America
International Fibrodysplasia Ossificans Progressiva Association (IFOPA)
Indiana University School of Medicine, CF Care Center

<more>

International Society of Nurses in Genetics (ISONG)
Lymphangiomatosis & Gorham's Disease Alliance
Lymphedema Advocacy Group
Maine Medical Center CF Program
M-CM Network
MEBO Research, Inc.
Medical College of Wisconsin, Milwaukee Cystic Fibrosis Care Center
MitoAction
MLD Foundation
Moebius Syndrome Foundation
Muscular Dystrophy Association
Myotonic Dystrophy Foundation
National Gaucher Foundation, Inc.
National MPS Society
National Organization for Albinism and Hypopigmentation (NOAH)
National Organization for Rare Disorders (NORD)
National PKU Alliance
National Spasmodic Torticollis Association
Parent Project Muscular Dystrophy (PPMD)
Parents and Researchers Interested in Smith-Magenis Syndrome (PRISMS)
Progeria Research Foundation
ProMedica Toledo Children's Hospital
PXE International
Research! America
Rett Syndrome Research Trust
Stanley Manne Children's Research Institute
Tarlov Cyst Disease Foundation
The Children's Hospital of Philadelphia
The Detroit Medical Reserve Corps
The Massachusetts Medical Society
The National Alopecia Areata Foundation (NAAF)
The State University of New York School of Medicine and Biomedical Sciences
Trimethylaminuria Foundation
Tuberous Sclerosis Alliance
University of Michigan Health System, Cystic Fibrosis Center
University of Pennsylvania Health System, Cystic Fibrosis Center
University of Washington, Cystic Fibrosis Care Center
Vertex Pharmaceuticals
Virginia Commonwealth University Health System, Adult Cystic Fibrosis Program
Wilson Disease Association

House Energy & Commerce Committee
Subcommittee on Health
Title: Improving the Medicaid Program for Beneficiaries
Date: September 18, 2015

Statement for the Record
By the National Academy of Elder Law Attorneys

Dear Chairman Pitts, Ranking Member Green, and Members of the Subcommittee:

Thank you for the opportunity to submit this statement for the record on H.R. 670, the Special Needs Trust Fairness Act, introduced by Representatives Glenn "GT" Thompson (R-PA) and Frank Pallone (D-NJ).

The Special Needs Trust Fairness Act of 2015 corrects a problem in current law that presumes all individuals with disabilities lack the mental capacity to establish their own special needs trusts. This false and unfair presumption imposes unnecessary legal fees and costs, court delays, and uncertainty on people who can little afford it.

The fix is simple: H.R. 670 would add the words "the individual" to 42 U.S.C. § 1396(d)(4)(A) to allow people with disabilities to establish their own individual special needs trusts.

The Senate passed a companion version of this bill (S. 349) by unanimous consent on September 9, 2015. We look forward to working with this Subcommittee to ensure swift passage in the House of Representatives.

Background
People with disabilities who want to live active lives face daunting costs to pay for what others do as a matter of course – from getting out of bed, taking a bath, or feeding or clothing oneself – to more complicated tasks – travel, reading and writing, or working productively. Medicaid may cover the medical and remedial costs for many, but of course there are many more expenses incurred during everyday living. Congress has long recognized the limits of Medicaid; in 1993, it authorized two types of special needs trusts that allow people to set aside funds to pay for supplemental care and meet their non-medical needs while retaining Medicaid. And, just last year, Congress added ABLE Accounts, which provide tax incentives for individuals with disabilities to save funds for their non-medical disability needs without loss of Medicaid.

The Problem: "*The Individual*" is Missing from the Statute
In 1993, Congress authorized two kinds of trusts – individual and pooled non-profit trusts. The law, as drafted, allowed individuals with disabilities to place their funds in a pooled non-profit trust, but in another section left out the words "the individual" thereby failing to allow individuals to establish their own special needs trust:

- Individual trusts "must be established by a parent, grandparent, legal guardian of the individual, or a court." 42 USC §(d)(4)(A).

- Pooled Trusts accounts "must be established by a parent, grandparent, legal guardian of such individual, *the individual*, or a court." 42 USC (d)(4)(C)(emphasis added).

More recently, in the related ABLE Act, Congress permitted these accounts to be "established by an eligible individual." P.L. 113-295

There is no valid public policy reason for prohibiting competent individuals with disabilities from establishing their own individual special needs trusts where all of the other, much more significant requirements are met. These requirements are plainly more important than who signed the document; they are, briefly, that the trust or trust account be:

- Irrevocable.
- Provide payback to Medicaid following the death of the beneficiary for all of its expenditures for the beneficiary.
- Managed by a trustee for the "sole benefit" of the disabled individual.

This legislation would, of course, keep all of these requirements in place.

Why This Common Sense Legislation Should Pass

Current Law Violates the Dignity of People with Disabilities

The presumption in the current statute that all people with disabilities lack mental capacity is false, offensive, and denies a constitutional right to disabled Americans. NAELA Treasurer Michael Amoruso, Esq., a disabled attorney who is both legally blind and has substantial bilateral hearing loss, has drafted hundreds of these trusts as part of his practice for other individuals, and yet the current law does not allow him to sign such a trust for himself.

Ends Unnecessary Judicial Red-Tape

For individuals without parents or grandparents to set up their trust, the law requires court approval. Three examples illustrate this burden:

In Orleans County, New York, a NAELA attorney explained that to get a trust approved, he must draft a petition with all the particular facts about the beneficiary and the trustee, obtain the consent of the attorney for the local department of social services, which can take several weeks in rural counties where the attorney is new to special needs trusts and is part-time, document the consent of each proposed trustee, submit an affidavit for approval of the fees, with a proposed court order, and pay (with client funds) the $210 court filing fee. This normally takes about two months as opposed to two weeks where there is a parent or grandparent willing to establish the trust. In one case, it took from early July to the following April.

A Florida NAELA member says the practice there is to establish a "voluntary" guardianship, starting with a physician's statement that the individual is disabled but competent, then filing a petition for the "voluntary" guardianship. The judge appoints the guardian, at which hearing the

attorney files a separate petition authorizing the special needs trust, which the judge signs. Once the special needs trust is signed, the attorney petitions to dismiss the guardianship.

In Montgomery County, Maryland, a judge denied a petition to establish a special needs trust, notwithstanding the state Attorney General's consent, due to lack of familiarity with these trusts. It was approved at a later hearing, but at additional cost and delay.

Authorizing individuals to establish their own trusts will eliminate reams of such unnecessary complications.

About NAELA
The National Academy of Elder Law Attorneys (NAELA) is a national, non-profit association comprised of 4,500 attorneys who concentrate on legal issues affecting the elderly, people with disabilities, and their families. NAELA members provide advocacy, guidance, and services to enhance the lives of their clients. It is the oldest and largest such association in the United States.

Conclusion
H.R. 670, the Special Needs Trust Fairness Act is a commonsense fix that is sorely needed. We look forward to working with Chairman Pitts, Ranking Member Green, Ranking Member Pallone, and Rep. Thompson on a bipartisan basis to ensure this legislation passes the House of Representatives swiftly.

September 17, 2015

Chairman Joseph Pitts
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Ranking-member Gene Green
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Subject: Support for H.R. 670, the Special Needs Trust Fairness Act

Dear Chairman Pitts and Ranking-member Green:

The undersigned organizations are writing in support of H.R. 670, *the Special Needs Trust Fairness Act of 2015*, which would correct an error in the law that prevents capable individuals with disabilities from creating their own special needs trust. This bipartisan legislation is sponsored by Representatives Glenn "GT" Thompson (R-PA) and Frank Pallone (D-NJ).

Thank you for including this legislation in the upcoming subcommittee hearing, *Improving the Medicaid Program for Beneficiaries.* The Senate recognized unanimously the importance of the legislation by passing it on September 9th. We look forward to its quick passage in the House.

Individuals with disabilities often require public assistance to help cover the impoverishing costs of their long-term services and supports. To avoid destitution, federal law allows individuals to utilize special needs trusts to retain some of their assets for the purpose of supplementing certain costs not covered by these programs.

Unfortunately, current law requires a parent, grandparent, legal guardian of the individual, or a court to establish a special needs trust. *This oversight with respect to special needs trusts has the effect of deeming all individuals with disabilities incapable of handling their own affairs, a patently false and degrading presumption. Moreover, people who no longer have living grandparents or parents must petition the court thereby incurring unnecessary legal expenses and costly delays.*

Thank you for bringing this legislation to the attention of your subcommittee. We hope you will support this legislation and see to it that it passes quickly.

If you have any questions, please contact, David Goldfarb (dgoldfarb@naela.org), the National Academy of Elder Law Attorney's Public Policy Manager.

Sincerely,

Academy of Special Needs Planners
American Network of Community Options and Resources
Christopher & Dana Reeve Foundation
Easter Seals
Justice in Aging
Lutheran Services in America Disability Network
Mental Health America

National Academy of Elder Law Attorneys
National Association of State Directors of Developmental Disabilities Services
National Down Syndrome Congress
National Multiple Sclerosis Society

Statement of the Honorable Glenn 'GT' Thompson (PA-5) Before the House Energy and Commerce Subcommittee on Health
"Improving the Medicaid Program for Beneficiaries"
Friday, September 17, 2015

Chairman Pitts, Ranking Member Pallone, I appreciate the opportunity to have this statement and subsequent documents submitted for the record under Unanimous Consent. While not a member of the House Energy & Commerce Committee, the Special Needs Trust Fairness Act has been a legislative priority for me since its initial introduction in the 113th Congress. Given recent passage of the Senate companion, S. 349, I am very encouraged by the subcommittee adding H.R. 670 to the hearing today.

While Members of Congress are often quick to take credit for bills, the fact of the matter is this issue would have never been elevated to this level, if not for the tireless work an individual from Pennsylvania's 5th Congressional District, H. Amos Goodall, Jr., an elder law attorney from State College, Pennsylvania.

Mr. Goodall, through his association with the National Academy of Elder Law Attorneys (NAELA), helped illustrate the need for legislative action and has played a key role in advocating for the passage of the Special Needs Trust Fairness Act. He is also a devoted member of the Special Needs Alliance (SNA), a national association of attorneys helping individuals with special needs and their families.

Enacting H.R. 670, the Special Needs Trust Fairness Act would tremendously improve the Medicaid program for beneficiaries, as the title of this hearing implies. This simple, bipartisan, bicameral measure would eliminate a current prohibition on a disabled individual from creating his or her own Special Needs Trust, or SNT. These trusts enable assets to be saved on behalf of disabled individuals while protecting their eligibility for means-tested benefits.

Under current law, individuals who are or become disabled must have a parent, guardian, or the courts create their SNT. This places an undue monetary and logistical burden upon individuals who are seeking to secure their financial future, and runs counter to what has already been established by Congress. Individuals with disabilities have always been able to set up their own pooled trust accounts (created by Congress in 1993 and administered by non-profit organizations) and can create their own tax-free savings accounts under the recently passed ABLE Act.

It is through engagement with the National Academy of Elder Law Attorneys and the Special Needs Alliance, particularly the advocacy of Mr. Goodall, that I have been able to engage with individuals who have deep frustration with the current statute and the overall discrepancies under the law. In 2013, I received a letter from Rana McMurry Arnold, Co-Founder and Director of the Sight-Loss Support Group of Central PA, a non-profit organization located in Lemont, Pennsylvania. As a blind individual, Rana helped form this remarkable non-profit to assist others with sight loss, by providing peer counseling, vision rehabilitation referral services, and direct accessibility support for local events.

In her letter, Rana explained that it would never have occurred to her to question her ability to establish a trust on her own behalf simply because she is blind. She stated that while her lack of vision is certainly challenging, she has led a very fulfilling and successful life. In addition to raising a family, Rana established and ran a successful service organization for thirty years. She ended her letter by reminding me that this is a matter of fundamental fairness and encouraging me to work hard to change the law.

As Rana pointed out, individuals facing life changing disease or disabilities will continue to be treated inequitably without action on this bill. This fact alone has been the driving force behind the persistent efforts of advocates in my own district and across the country.

The perspectives of those directly impacted by this legal discrepancy coupled with my experience as a certified recreational therapist, a hospital manager and licensed nursing home administration has solidified my stance on this matter. I have had the honor of working with a number of individuals as they set out to rehabilitate their level of functioning and independence following an accident or illness. As a result, it is hard for me to find a palpable reason why we should continue to complicate their journey to self-sustainability.

As I previously mentioned, the Special Needs Trust Fairness Act of 2015 is a largely bipartisan initiative. For that I thank my colleague and ranking member, Representative Frank Pallone, who has continued to partner with me on this issue. He has consistently acknowledged that individuals facing life changing diseases or disabilities are not being treated fairly and has sought to correct this legal inequity.

In conjunction with Mr. Pallone, I respectfully ask for the support of the Committee of jurisdiction as we approach an opportunity to enable individuals living with a disability to stabilize their financial future, by advancing H.R. 670 through the legislative process, so these individuals facing disability can be treated equally under the law. Thank you.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

October 8, 2015

Dr. Michael Boyle
Vice President of Therapeutics Development
Cystic Fibrosis Foundation
6931 Arlington Road
Bethesda, MD 20814

Dear Dr. Boyle:

Thank you for appearing before the Subcommittee on Health on September 18, 2015, to testify at the hearing entitled "Improving the Medicaid Program for Beneficiaries."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on October 19, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

October 23, 2015

Michael P. Boyle, M.D., FCCP
Senior Vice President of Therapeutics Development
Cystic Fibrosis Foundation
6931 Arlington Road
Bethesda, MD 20814

Answer to a Question for the Record for the hearing:
"Improving the Medicaid Program for Beneficiaries"
Committee on Energy and Commerce, Subcommittee on Health

The Honorable Representative Renee L. Ellmers

1. **I'm concerned that lack of access to appropriate care often times leads to more significant costs to beneficiaries and the program, especially those with chronic conditions such as diabetes. Have you examined and/or do you have experience with the impact of access to care on cost, care needs, and mortality?**

The Cystic Fibrosis Foundation supports a wide range of activities aimed at ensuring that individuals with cystic fibrosis (CF) receive access to appropriate care according to clinical guidelines or standards and without delay.

The CF Foundation has developed clinical practice guidelines for routine care and screening for individuals with CF. These standards guide care for individuals with CF during infancy, childhood, and adulthood. For those over age 6, quarterly office visits and two pulmonary function tests each year are recommended. Guidelines have also been developed for use of chronic pulmonary therapies, which are a major component of the treatment regimen for those with CF; these guidelines govern pulmonary therapies for those who are age 6 or older. Goals have also been set for nutritional outcomes for those with CF. Finally, CF experts follow standards for the management of the complications of CF.

These guidelines and standards encourage the proper use of the many new therapies that have been developed for the management of the symptoms of CF. The CF treatment regimen is complex and therefore poses challenges for patients and their families. Gaps in patient adherence mean that the benefits of CF treatments and treatment guidelines benefit many but not all.

Sixty years ago, the average life expectancy of a child with cystic fibrosis was five years. Because of new CF treatments, constant quality improvement of the CF care system, and strong disease self-management average life expectancy of individuals with CF is 40 years. And for the first time in the history of the disease more than half of people with CF in the US are age 18 or older.

More recently, CF treatments have expanded to include two therapies that address the underlying cause of CF. These treatments were developed for and are effective in patients with specific CF mutations, making them the first "targeted" therapies for CF. The CF Foundation has developed strong initiatives to ensure that those who might benefit from these new medications have prompt access to them.

The Cystic Fibrosis Patient Registry data indicate that CF patients rely on private insurance, Medicare, Medicaid and other state programs, and Tricare or other military plans; and often patients have more than one plan covering their care and treatments. A very small percentage of those with CF are uninsured. The reliance on specific types of health insurance varies by age. For example, a large portion of children with CF use Medicaid or state programs, including over 50 percent of children under age 10. A majority of people with CF ages 18 to 25 received health insurance through their parents' plans in 2014.

While complex, time-consuming treatment regimens have greatly contributed to increasing length and quality of life for people with CF, the financial burden of the disease is a critical challenge for patients and families. Health insurance coverage does not necessarily eliminate all problems in obtaining access to CF care, including medications. There are programs in place that offer financial assistance but even so, CF patients may experience difficulties in obtaining coverage and proper payment for new CF medications. Patients also report burdensome cost-sharing requirements that may force them to forgo treatment or delay or reduce doses of medications. This means that because of financial challenges, patients may receive less than the optimal standard of care. We do not have data on the impact of these changes in care on overall health system costs.

The CF community has observed socioeconomic status-related disparities in CF health outcomes. Investigators have undertaken analyses of the Epidemiological Study of Cystic Fibrosis (ESCF) to determine if a differential use of health services or differential prescription of chronic therapy explains the disparities in CF outcomes. In other words, CF researchers have sought to understand if differential access to care explained SES-related disparities in health outcomes. Studies have found no evidence that disparities in CF outcome are due to discrepancies in care, including treatment of pulmonary exacerbations, use of chronic therapies, and outpatient monitoring. [1] Investigators have suggested that future studies consider the differences in disease management by patients and families and environmental exposures in efforts to understand disparities in CF outcomes.

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[1] Schechter MS, McColley SA, Regelmann W, et al. Socioeconomic status and the likelihood of antibiotic treatment for signs and symptoms of pulmonary exacerbation in children with cystic fibrosis. J Pediatr. 2011 November; 159(5) 819-824. Schechter MS, McColley SA, Silva S, et al. Association of socioeconomic status with the use of chronic therapies and healthcare utilization in children with cystic fibrosis. J Pediatr 2009 November; 155(5): 634-9.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225-2927
Minority (202) 225-3641

October 8, 2015

Mr. Tim Clontz
Senior Vice President for
Health Services
Cone Health
1200 North Elm Street
Greensboro, NC 27401

Dear Mr. Clontz:

Thank you for appearing before the Subcommittee on Health on September 18, 2015, to testify at the hearing entitled "Improving the Medicaid Program for Beneficiaries."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

The Honorable Renee L. Ellmers asked the following question:

I'm concerned that lack of access to appropriate care oftentimes leads to more significant costs to beneficiaries and the program, especially those with chronic conditions such as diabetes. Have you examined and/or do you have experience with the impact of access to care on cost, care needs and mortality?

Response of Tim Clontz, Senior Vice President for Health Services, Cone Health:

When individuals with chronic illnesses, such as diabetes, do not have access to care it reduces their quality of life, and over time leads to increased cost. Programs of All-Inclusive Care for the Elderly (PACE) are designed to address the chronic care needs of individuals by providing timely and appropriate treatments and supports. The level of access to care in PACE results in our participants (those enrolled in our programs) experiencing a higher quality of life, at home in their community, with medical outcomes that meet the highest standards. Moreover, by reducing the incidence of complications associated with chronic illness, PACE programs also reduce the high costs of specialists, emergency rooms, and hospitals incurred in response to these complications.

This has been our experience with the participants in our PACE programs, and it is borne out by studies of PACE programs across the country. In a 2010 study by Chad Boult and Darryl Wieland, PACE is highlighted as one of three chronic care models that include processes to improve the effectiveness and efficiency of complex primary care. [i] An earlier study found that PACE participants experienced better self-rated health status, fewer unmet needs, and improved health care management.[ii] Not surprisingly, the effectiveness of the PACE care model results in reduced hospital admissions and emergency room visits, as evidenced in a number of state-specific (Massachusetts [iii], New York [iv], Wisconsin [v]) and national studies.[vi]

Better care that avoids unnecessary hospitalizations and emergency room visits supports the longevity of people with chronic care and long term service and support needs. A study of PACE participants in South Carolina found that "PACE participants had a substantial long-term survival advantage compared with aged and disabled waiver clients." [vii] This finding is supported by a national study which found that PACE participants had a lower mortality rate than individuals in nursing homes or home and community based services provided by state Medicaid waiver programs. [viii]

Providing effective and timely chronic care helps people live longer, avoid hospitalizations, and experience a higher quality of life with better health outcomes. In the PACE care model we are achieving these results for less than or the same amount of costs as other programs. In Medicaid, states pay PACE programs on average 14% less than the costs of caring for a comparable population through other Medicaid services, including nursing homes and home and community-based waiver programs. [ix] In Medicare, payments to PACE organizations are equivalent to the costs for a comparable population to receive services through the fee-for-service program. [x]

I appreciate the opportunity to provide this information to Representative Ellmers and the committee. I would be happy to provide any additional information that would be helpful. Thank you.

[i] Boult, C. & Wieland, G.D. (2010). Comprehensive primary care for older patients with multiple chronic conditions: "Nobody rushes you through." JAMA, Vol. 304, No. 17, pp. 1937-1943

[ii] Leavitt, M., Secretary of Health and Human Services. (2009). Interim report to Congress. The quality and cost of the Program of All-Inclusive Care for the Elderly

[iii] Division of Health Care Finance and Policy, Executive Office of Elder Affairs. (2005). PACE Evaluation Summary. Accessed on May 25, 2011 at: http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/05/pace_eval.pdf

[iv] Nadash, P. (2004). Two models of managed long-term care: comparing PACE with a Medicaid-only plan. Gerontologist, 44(5), pp. 644-654.

[v] Kane, R. L.; Homyak, P.; Bershadsky, B; & Flood, S. (2006). Variations on a theme called PACE. Journal of Gerontology Series A, Vol., 61, No. 7, pp. 689-693.

[vi] Micah Segelman; Szydlowski, J.; Kinosian, B.; McNabney, M et al (2014). Hospitalizations in the Program of All-Inclusive Care for the Elderly. Journal of the American Geriatrics Society 62:320–324, 2014

[vii] Wieland, D., Boland, R., Baskins, J., and Kinosian, B. (2010). Five-year survival in a Program of All-Inclusive Care for the Elderly compared with alternative institutional and home- and community-based care. J Gerontol A Biol Sci Med Sci. July: 65(7), pp. 721-726

[viii] The Effect of PACE on Costs, Nursing Home Admissions and Mortality: 2006 – 2011 Mathematica Policy Research evaluation prepared for U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy (2014)

[ix] NPA Analysis of PACE Upper Payment Limits and Capitation Rates, July 6, 2012.

[x] The Effect of PACE on Costs, Nursing Home Admissions and Mortality: 2006 – 2011 Mathematica Policy Research evaluation prepared for U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy (2014)

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Minority (202) 225-3641

October 8, 2015

Mr. Richard Courtney
Partner
Frascogna Courtney
4400 Old Canton Road
Jackson, MS 39211

Dear Mr. Courtney:

Thank you for appearing before the Subcommittee on Health on September 18, 2015, to testify at the hearing entitled "Improving the Medicaid Program for Beneficiaries."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

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National Elder Law Foundation

October 22, 2015

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

RE: **Response to Additional Questions**

Dear Chairman Pitts:

Thank you for the opportunity to provide this response to the following question you submitted as addition to the record of the September 18, 2015 hearing on *Improving the Medicaid Program for Beneficiaries*:

Honorable Renee L. Ellmers

"I'm concerned that lack of access to appropriate care often times leads to more significant costs to beneficiaries and the program, especially those with chronic conditions such as diabetes. Have you examined and/or do you have experience with the impact of access to care on cost, care needs and mortality."

As an elder law and special needs planning attorney for the last three decades in Mississippi, a state with the highest rates of diabetes, heart disease and obesity, I have observed the impact you describe. On many occasions, clients have explained that they, their spouses, or their parents have developed acute medical problems and were in hospitals or nursing homes as the result of untreated or poorly treated conditions such as high blood pressure, diabetic conditions and even cancer. Many times we have heard that productive or preventive medical treatments were not available to the ill person, that the individual did not know how to access those services, or that

helpful medical services had taken a back seat to other economic demands for basic housing and support needs.

The Formula for Access

Access = availability + affordability. This seems, to me, to be the fundamental equation for the problem of health care. Without available providers of health care services, the ability to pay is immaterial. And the inability to pay renders selection of services among numerous providers futile. Neither is sufficient without the other. For this reason, the impact of limited access to health care is particularly serious for lower and middle income folk, many of whom live in rural areas where availability is a particular problem.

Affordability

Congress has provided help to Americans on this front in recent years. Several years ago, I counseled a woman in her early 50s who had cancer. Her husband was six months from becoming vested in his company's health insurance plan when she was diagnosed, and she was excluded from insurance. She had applied for Social Security Disability, but even if approved immediately would not become eligible for Medicare for another twenty-four months. She was desperately concerned that her doctor and hospital would stop providing pro bono care at any time, and she would have an accelerating course of illness due to her lack of ability to pay for care. I had to tell her that, while I and my Care Manager had researched all available resources, we had no solution to offer her. However, one popular and extremely helpful provision of the Affordable Care Act – the prohibition against pre-existing condition exclusion by insurers – has made that painful situation a thing of the past. That provision removed a barrier to affordability for health care that has, I believe, improved health outcomes for many. In addition, the requirement that all insurers in the health exchanges provide basic "essential health benefits" and the provision for Medicare coverage of certain preventive health services will promote better health outcomes. Indeed, our clients (regardless of their beliefs or positions about the ACA) have uniformly been pleased at the coverage of their health screenings and have expressed their feelings that it has kept them healthier. Therefore, as you look to modify the ACA please keep these positive aspects in mind.

Availability

While some positive steps have been taken in the health care payment and insurance system, more needs to be done to encourage availability of providers and health services. In Mississippi, there are 21 Community Health Centers for the 82 counties in the state. Some of these provide services to citizens of several counties and may be the only Medicaid-certified providers of services in large geographical areas. Governmental efforts to incentivize primary care providers, such as the recent $240 million HHS grant to help those nurses and primary care physicians committed to serving underserved areas, will be helpful and should be augmented by other solutions to solve the availability problem.

One facet of availability is the individual's ability to reach available health resources. This ability may be impeded by intellectual challenges to understanding and navigating the confusing system, or by logistical challenges to physically getting to those resources. The National Academy of Elder Law Attorneys (NAELA) maintains an on-going Public Policy committee to identify issues and advocate for the elderly and persons with disabilities. NAELA has recently spearheaded an effort, joined by 33 other organizations including the American Diabetes Association, National Association of Social Workers and National Council on Aging, to have the Senate reject a proposed 42% cut in the State Health Insurance Assistance Programs (SHIPs) and level fund the program at $52.1 million, as the House Appropriations Committee has recommended. The primary goal of SHIPs is to advise, educate, and empower individuals to navigate the increasingly complex Medicare programs and to help beneficiaries make choices among a vast array of options to best meet their needs. Making informed decisions among 30+ prescription drug plans, an average of 18 Medicare Advantage plans, as well as various Medigap supplemental insurance policies, can improve access to quality care and saves money for Medicare beneficiaries, and potentially reduces Medicare spending as well.

What Research Says

I have endeavored to understand the forces behind the health problems our clients deal with daily. Among resources we have read are the non-partisan studies conducted by Kaiser Family Foundation. In a November 2013 report on the effect of lack of insurance on health outcomes, it was noted that:

> . . . [U]ninsured patients have increased risk of being diagnosed in later stages of diseases, including cancer, and have higher mortality rates than those with insurance. Wilper et al., 2009, "Health Insurance and Mortality in US Adults." *American Journal of Public Health*, 99(12) 2289-2295; Simard EP, et al. 2012, "Widening Socioeconomic Disparities in Cervical Cancer Mortality Among Women in 26 States, 1993-2007." *Cancer*; Institute of Medicine, 2009, "America's Uninsured Crisis: Consequences for Health and Health Care." Washington, DC: National Academies Press. p. 60-63.

Citing numerous other studies and papers, the report also stated among other conclusions:

> When they are hospitalized, uninsured people receive fewer diagnostic and therapeutic services and also have higher mortality rates than those with insurance.
> . . .
> Uninsured children are significantly more likely to lack a usual source of care, to delay care, or to have unmet medical needs than children with insurance (Figure 12). Uninsured children with common childhood illnesses and injuries do not receive the same level of care as others. As a result, they are at higher risk for preventable hospitalizations and for missed diagnoses of serious health conditions. Disparities exist even among children with special needs, including access to specialists.

http://kff.org/report-section/the-uninsured-a-primer-2013-4-how-does-lack-of-insurance-affect-access-to-health-care/

I hope this response is helpful as you and the Committee consider how to improve the Medicaid and other programs to benefit the growing number of beneficiaries while addressing the growing costs of health care. Please let me know if there is anything additional that I, the Special Needs Alliance, or the National Academy of Elder Law Attorneys can provide for you.

Sincerely,

/Richard A. Courtney/

Richard A. Courtney

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