

**THE FINANCIAL AND SOCIETAL COSTS OF
MEDICATING AMERICA'S FOSTER CHILDREN**

HEARING

BEFORE THE

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT
INFORMATION, FEDERAL SERVICES, AND
INTERNATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
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THURSDAY, DECEMBER 1, 2011

U.S. SENATE,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES,
AND INTERNATIONAL SECURITY,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:37 a.m., in Room SD-342, Dirksen Senate Office Building, Hon. Thomas R. Carper, Chairman of the Subcommittee, presiding.

Present: Senators Carper, Brown, Collins and Coburn.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Good morning, everyone. Welcome to this hearing today. And I am delighted especially to welcome our lead-off witness, Ke'onte Cook and his mom and dad.

Ke'onte, in a few minutes, each of us are going to make some statements, and then we will turn it over to you to say whatever you would like to say to us.

Over the past few years, this Subcommittee has been focused almost exclusively on how our Federal Government can achieve better results for less money. Among other things, we have examined cost overruns in major weapons systems and overpayments for additional spare parts that we do not need. We have focused on how to manage our Federal property, on bloated information technology projects that waste millions of dollars and, most notably for today's hearing, on how we can spend taxpayer dollars on prescription medications in our Nation's public health care system. In fact, today marks the third in a series of hearings over the past several years examining this particular subject.

Nearly 2 years ago, our Subcommittee asked the Government Accountability Office (GAO), to look into the potentially improper prescribing of mind-altering medications, also known as psychotropic drugs, for children in foster care whose health care is paid for through Medicaid and managed by the States.

We learned through various media reports and medical articles that many foster children, may have been receiving these medications at alarming and potentially dangerous rates. If these reports were true, not only were taxpayer dollars being misspent on these medications, but more importantly, the health and well-being of these children was very likely in danger.

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We wanted an independent government audit from the GAO. In asking them to look at this issue, we wanted to know if overprescribing, or improper prescribing, of these powerful mind-altering medications was occurring and if it was, how prevalent was that and what were the costs. The report we are releasing today confirms some of our worst fears.

GAO's findings reveal that foster children in the five States that were examined are receiving mind-altering medications at between 2 and 4½ times the rate of other children under Medicaid. In 2008, the five States combined spent over \$59 million on mind-altering medications for foster children. Beyond these rates, the GAO found three alarming patterns in their data.

First, thousands of children were prescribed mind-altering medications in excess of the maximum doses for the child's age as recommended by the Food and Drug Administration (FDA) and by medical literature. Furthermore, for the medications for which there is no FDA recommended dosage for their age, the GAO found a number of children receiving dosages beyond those even recommended for adults.

Second, more than 600 foster children in these five States were found to be receiving five or more mind-altering medications at the same time. According to medical experts, one of whom is with us today as a witness, there is no evidence supporting the use of five or more mind-altering medications in adults, much less for children. In fact, I am told that there is only limited evidence that supports the use of even two mind-altering medications being prescribed to a child at the same time.

Finally, and perhaps most disturbingly, dozens of foster care children under the age of one year in these five States and over 3,500 non-foster children in those States, were prescribed a mind-altering medication. According to medical experts, there are no established medical health uses for mind-altering medications in infants and providing them these drugs can result in serious health effects for them over both the near term and the long term.

We look forward to hearing more about the GAO's findings today. Greg Kutz from GAO has joined us to discuss them. He has appeared before this Subcommittee many times before, and we welcome him back today.

Along with him is Dr. Jack McClellan from Seattle Children's Hospital. He is one of the medical experts hired by GAO to review their report. Mr. Bryan Samuels is here from the Department of Health and Human Services (HHS) to give us the Federal Government's perspectives, and while Matt Salo is here on behalf of the State Medicaid Directors. We welcome all of you.

I am probably most interested, however, to hear from our first witness today, Mr. Ke'onte Cook, who joins us all the way from McKinney, Texas. Ke'onte, I would like to say you are the one who came the furthest for this hearing. Mr. Cook is here with his mom and dad. I was fortunate to spend some time with all of them here earlier this morning, and we look forward to hearing a little more about him and his experience in just a few minutes. I also hope that today's hearing and what comes from it will end up helping kids like him from all across the country. So something very good may happen because of your appearance here today.

In anticipation of today's hearing, the Department of Health and Human Services sent a letter last week to all 50 States regarding the proper use and monitoring of mind-altering medications for children in the foster care system. The letter promises that the Department will convene a meeting of all 50 States in the next few months to discuss this issue further.

It is my hope the Department's letter also serves as a signal to States that more detailed guidance is coming, guidance that reflects the best practices from States across the country with regard to the use of mind-altering medications to treat children.

It is also my hope that this letter will lead to solutions, solutions that will help to improve the health and welfare of some of our Nation's most vulnerable children, foster kids, while also saving taxpayers' dollars at the same time.

I believe there is plenty of blame to go around in this report. Unfortunately, it appears that the Federal Government, State and local governments, doctors, nurses and perhaps others have not kept up with the increased frequency with which mind-altering medications have been prescribed over the past decade for children.

There also appears to be a lack of cooperation between the Health and Human Services Department and the State Medicaid programs throughout the country concerning this issue. States have worked out piecemeal solutions based on their own experiences, and frankly, in at least some cases, those solutions were not arrived at until after young lives were damaged or lost.

As I mentioned and as we will hear in testimony today, the children discussed in GAO's report are some of the most vulnerable members of our society. It is our responsibility to take up their cause. As a former governor, I know that the foster care system is complex. But that complexity is no excuse for not dealing with this issue head-on. We all have a responsibility to ensure that the Medicaid program works for all children that it serves, whether they are in foster care or not.

I oftentimes describe the 50 States as laboratories of democracy. And what this report reveals is that some States are managing their program better than others. That should not come as a surprise. There are best practices in use in some States that really do work in helping foster children. Every State should be adopting those practices or tailoring them for adoption. In addition, the American Academy of Child and Adolescent Psychiatry (AACAP) has promulgated some very good guidelines which both the GAO and others site. And if they are not already doing so, most States should follow those guidelines. What we cannot do is wait for another tragedy to happen before we make the right decisions. We cannot stand idly by while children's lives or health are potentially put into danger.

Now to be clear, it is important to realize that these drugs we will be talking about this morning are often used in dire, or even tragic, situations. In most cases, they are prescribed as intended and used in an appropriate manner, to help children who have experienced significant trauma in their young lives. In these cases, there is no doubt about their value.

What is in doubt are the patterns and practices identified in GAO's testimony today. What is in doubt is the effectiveness and

necessity of having children take five or more mind-altering medications at the same time. What is in doubt is an infant being given anti-psychotic medication. In these cases, I do not see any gray areas. What I do see is more black and white—what is appropriate and humane, and what is not.

We need to begin the process now of developing a consensus about what is appropriate and humane when it comes to prescribing mind-altering medications to children and end the bad practices that are putting children in danger. We need to act quickly before one more child's life or health is placed in jeopardy or before one more taxpayer dollar is spent inappropriately. Senator Brown.

OPENING STATEMENT OF SENATOR BROWN

Senator BROWN. Mr. Chairman, that was a very good opening statement, and I want to commend you and your staff for identifying this issue. One thing I have enjoyed about being on this Subcommittee is the wide range of topics that we investigate and try to understand and try to do it better. So thank you for bringing this up.

And a lot of what you said is, quite frankly, unacceptable—to think that infants are getting drugs one year or younger and that somebody is getting five or more mind-altering drugs at once.

And foster children, often being removed from neglectful and abusive homes, are one of the country's most vulnerable populations. When tragic and traumatic circumstances obviously define their early lives, it is no wonder the studies show the tendency for more mental health conditions than in other children.

I was especially concerned in reading the results from Massachusetts, and it is something that I can assure you, Mr. Chairman, we will not be taking lightly. We are going to immediately try to figure out why Massachusetts in particular was much higher than other States that were reviewed.

And as our witnesses will discuss today, there are few options facing folks. For example, the challenges surrounding foster care, State authorities, caseworkers, and parents, they do not have a lot of options on treatments. I understand that, but we know basically from the study that including prescribing heavy-duty psychotropic drugs such as antidepressants, and in some cases even antipsychotics, are sometimes given first rather than as the last option.

And with the use of these medications, although they have been shown to effectively treat mental disorders, the side effects and risks that they pose oftentimes outweigh the benefits, specifically to children. I, quite frankly, note that I do not believe they are well understood.

That is why we have asked GAO to look at this issue more closely, and their investigation has produced some alarming results. Not only are foster children being prescribed these drugs at a higher rate than the nonfoster kids in general, but also in ways that hold significantly higher risks, such as multiple medications at once, as you have noted, exceeding the Federal FDA recommendations.

And in Massachusetts, nearly 40 percent of the foster children population analyzed in the report were prescribed at least one psy-

chotropic drug at a rate almost four times that of nonfoster children in my home State. In over 900 cases in Massachusetts, foster children were being prescribed three or more drugs at once. And while the scope of the report does not address the appropriateness of these prescriptions in a case-by-case basis, it does reignite the debate over whether the rates of prescribing match the scientific evidence behind the medical conditions.

So regrettably, the concerns raised in this report are not just limited to foster children. Though high risk prescribing practices for foster children were found at higher rates than nonfoster children in most cases, the significantly larger population of nonfoster children covered by Medicaid makes these statistics just as alarming. For instance, thousands of prescriptions, a total of 5,265 according to the report, were filled for infants under one year old.

When I read that, Mr. Chairman, I said to myself, what? How can you do that?

This is just the data from five States. So we just imagine what it is like nationwide.

And considering that experts have found no mental health indications for the use of psychotropic drugs in infants, this is particularly shocking and disturbing. As our witnesses will testify today, providing these powerful drugs to infants could result in serious adverse effects that will potentially affect them for the rest of their lives. And the risks seem to me, and I believe every member of this Committee, simply too great.

Medicaid, which is run by the States and administered by the Department of Health and Human Services, reimburses the costs of these drugs to foster children. And as of today, HHS has limited authority to adequately oversee State monitoring programs. Well, Mr. Chairman, maybe we need to change that, to be that check and balance that they need. As a result, States' comprehensive oversight policies are a mishmash of programs of various effectiveness, as you also noted.

Although HHS provides informational resources such as best practices to help inform State monitoring programs for children in State custody, each State is responsible for designing and implementing its own program. GAO has examined five States. And many of these programs, quite frankly, fall short, and comprehensive oversight is desperately needed.

It is obvious that consistent and comprehensive guidelines in this area are needed to ensure and effectively treat and reduce harmful risks to children in the Medicaid program, and particularly with foster children. In addition, better oversight in this area can have a broad impact in reducing the fraud, waste and abuse that we have noted for the last year and identified in the Medicaid program in general. And every dollar we save there can be used in a more effective and cost conscious way.

The Child and Family Services Improvement and Innovation Act that recently passed Congress was a good step, but it, quite frankly, does not go far enough. I encourage HHS to rapidly endorse guidelines and best practices and use its current authority to push State Medicaid and child welfare agencies to improve as quickly as possible.

So once again, Mr. Chairman, thank you for holding this hearing.

I look forward to hearing your testimony, young man. I know we spoke briefly. Thanks.

Senator CARPER. Thank you, Senator Brown.

Ke'onte, the way this works, I have the privilege of chairing this Subcommittee. I am a Senator from Delaware. Senator Brown the senior Republican Member of this Subcommittee, and he is from the State of Massachusetts. And sitting next to him is Senator Susan Collins from Maine, and she is the senior Republican Senator on the entire Homeland Security and Governmental Affairs Committee, and she is going to make a statement next. Susan.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman. Let me thank you for holding this hearing to examine the potential overuse of psychotropic drugs by children in foster care, who are covered by the Medicaid program.

On any given day, more than a half a million children are in foster care in our country. Typically, these children have been placed in care because they have been abused or neglected by their parents. Children in foster care also tend to have more serious mental, emotional or behavioral disorders than other children. As a consequence, they are exceedingly vulnerable.

I am very troubled by recent reports that the use of powerful psychotropic drugs to treat depression, anxiety and other mental health disorders is particularly high for children in foster care, especially in certain States like Texas. The statistics that the GAO found in analyzing Texas are truly astounding. In that State, foster children were 53 times more likely to be prescribed five or more psychiatric medications at the same time than nonfoster children.

While some children with behavioral and mental disorders may benefit from taking these drugs, children in foster care appear to be at particular risk of being given too many of these drugs and often concurrently. They often experience frequent changes in their foster placements and, as a result, are much less likely to receive the careful medical and psychological oversight that would normally be exercised by a parent.

State agencies also appear to do far too little to monitor the use of these medications. That is why I was pleased to join my colleagues on this Committee in requesting that the Government Accountability Office compare the rates of psychotropic prescriptions for foster and nonfoster children on Medicaid. We also asked the GAO to review State efforts to monitor the prescription of these powerful medications for children in foster care.

According to the GAO, foster children in the five States examined were prescribed these powerful drugs at more than two to more than four times the rate that these drugs were prescribed to nonfoster children who were also participating in Medicaid.

I am alarmed that the GAO found that in hundreds of cases five or more psychotropic drugs were prescribed at the same time. Moreover, in thousands of cases, the prescribed doses exceeded the maximum guidelines.

Of greatest concern was the finding that my two colleagues have already alluded to, and that is that these powerful drugs were prescribed to thousands of infants who were less than one year old.

Given the possibility for serious adverse side effects, I find it hard to imagine any scenario that would justify the prescription of five or more of these powerful drugs to a child, and I find it impossible to imagine that it would ever be appropriate to prescribe them for an infant. The scientific literature supports this skepticism.

We have a moral responsibility to provide for the health and welfare of these children. We provide funding for their medical care, for the foster systems that support their welfare and for the schools that they attend. Our responsibility, however, does not end with just writing the check. That is what this hearing is all about. The GAO report suggests that we have a long way to go before we have fulfilled our responsibilities to these children and young people.

Earlier this year, Congress did pass legislation to require States to establish protocols for the prescription of psychotropic drugs to children in foster care as a condition of eligibility for Federal child welfare funds. This new law, however, does not specify what these protocols should be. As a consequence, we found that there is tremendous variation from State to State, and none of the States examined by the GAO met the standards established by the American Association for Child and Adolescent Psychiatry.

While my first concern is obviously for the welfare of these children and for short and long-term impact on their health, I am also concerned about the costs involved. Many of these drugs are very expensive. If they are being overprescribed and needlessly prescribed, it not only has an adverse impact on the health of these vulnerable children, but it also costs our Medicaid programs a lot of money.

Clearly, more needs to be done to strengthen the oversight of the care provided to children in foster care. The GAO has recommended that the Department of Health and Human Services endorse best practices guidelines.

And I think it is not a coincidence, Mr. Chairman, that the Department appears to now be acting in light of your calling this hearing.

I look forward to hearing the additional recommendations and particularly the testimony of our first witness, and I thank you for allowing me to give an opening statement today.

Senator CARPER. We are delighted that you are here. Thank you for your comments.

Ke'onte, those of us who serve in the Senate today have our own families in many cases. We have careers that we have spent years of our lives on. Senator Brown and I spent some years in the military. He was in the Army. I was in the Navy.

Senator Collins, in addition to serving as a U.S. Senator, she did a great job of telling other Senators what to do for a number of years, and how to do it well, and she is from Maine, as I said earlier.

One of us, Senator Coburn, who is about to speak next, is from Oklahoma, and he is also a physician. Until just a few years ago, he still—even as a member of the House and as a member of the Senate—still delivered babies. He is what is called an obstetrician and gynecologist (OB-GYN) and he has done a lot of good work in his life, and he still does. Senator Coburn.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. I am anxious to hear Ke'onte's testimony. I will just make one point. Access to a government health care program is not access to real care, and we are seeing that in this hearing today.

Senator CARPER. Let me now introduce our lead-off witness, and his name, as you have gathered by now, is Ke'onte Cook. Ke'onte is 12 years old and is a former foster care child. He has recently been adopted by Mr. and Mrs. Scott Cook.

And Scott and Carol, we welcome you two today.

Mrs. Cook is actually joining Ke'onte at the witness table, and I believe Mr. Cook is seated right over Ke'onte's right shoulder.

Ke'onte and his family live in McKinney, Texas, where he is now attending middle school. His many interests include volunteering, competing in cross country meets, playing the clarinet and spending time with his family.

On behalf of all my colleagues and myself, Ke'onte, we want to thank you for being with us here today, and we want to thank your mom and your dad for joining us as well. Thank you for bringing them with you. All right.

And with that, you are recognized to say whatever is on your mind. Please proceed.

**TESTIMONY OF KE'ONTE COOK,¹ MCKINNEY, TEXAS,
ACCOMPANIED BY CAROL COOK, MOTHER**

Mr. COOK. Thank you, Mr. Chairman. Chairman Carper, Ranking Member Brown and Members of the Subcommittee, thank you for allowing me to share part of my life with you today, and my experiences with medications during foster care.

My name is Ke'onte Cook. I am 12 years old and in the 7th grade. This year, I participated in cross country with my middle school in which I ranked in the top 15 of my class, allowing me to go to regionals. I am currently first chair for clarinets in my band, and I have three small roles in my school play, *Cinderella*, that was showed this month on December 15th—also, the date for my second year anniversary in my adopted home. One of my favorite things to do is dance for fun, especially hip-hop and the robot.

I was adopted 2 years ago in 2009, and I was in foster care from ages 6 to 10½. Besides the medicines, foster care was all right to me except for my third foster home. The first two foster homes seemed more like they cared about me, but the third home always felt awkward, and I felt pressured by them when I chose my adoptive home.

I was pretty ignorant about the medicines I was on at the time. I also did not know what type of drugs I was on during foster care or how many drugs I was on since I was put into foster care at age six. All I knew was that if I did not take them like I was told I could not watch TV, play video games or play with my toys.

About a year after I was adopted, I found out I was on 20 different drugs total and sometimes I took up to five drugs at one time. At one point, I was on Vyvanse 70 milligrams for attention deficit hyperactivity disorder (ADHD); Seroquel 200 milligrams as

¹The prepared statement of Mr. Cook appears in the appendix on page 48.

a mood stabilizer; Guanfacine 2 milligrams for impulse control and ADHD; Buspar for depression; and Clonidine, 0.2 milligrams for insomnia. I have also been told that the amounts of some of the drugs I was given were more than most adults take.

Some of the things I was diagnosed with were post-traumatic stress disorder, insomnia, ADHD, depression, but I was never told I was diagnosed with anything other than the ADHD. They seemed way too much for a regular kid, which I am, and I was very confused when my adoptive parents told me what I was on and why.

I have been in the mental hospital three times during foster care, and every time I had to get on more meds or new meds to add to the ones I was already taking. Some of the meds were for bipolar and seizures, and I am not bipolar and never had a seizure. Sometimes the meds they gave me made me easy to get irritated, which I feel is not good for a kid to experience. The meds made my appetite go away, too, for a long time. I would barely eat anything. I remember having a bowl of spaghetti, and I ate about three bites, and then I was done. I had side effects no one told me about, no one told me I would have or talked with me about before taking a new med. I was so out of it when I had the side effects sometimes it seemed like it did not bother me at all.

One time I went to visit my youngest sister in her adoptive home. Her mom told me that she did not want to give me my meds because it made me glazed and tired. My adoptive parents said that when I stayed for my trial weekend with them in October 2009, my meds put me in a lights-out mode 15 minutes after I had taken them. Some of the meds I took made me have stomachaches. I would get so tired all of a sudden. It felt like I would collapse wherever I was in the house. My foster parents would tell me something, and I would not be able to process it like a normal person would. Sometimes I would even try turning my head away and then closing my mouth to refuse taking the meds, but I had to take them eventually.

I think putting me on all these stupid meds was the most idiotic thing I have ever experienced in foster care and was the worst thing someone could do to foster kids. I was upset about my situation, not bipolar or ADHD, and I think therapy is a better choice over meds if meds are not a necessity in that moment. And I should know because I went to therapy with my adoptive parents for 1½ years with Dr. Jason Mischalanie, an attachment therapist who helped me understand why I acted the way I did and to figure out how to react in a better way to the things that upset me rather than the way I was doing them. Now I am not only more focused in school, succeeding above other classmates in reading, band, athletics, not going to the office anymore for bad behaviors, and I am happy.

Chairman Carper, Ranking Member Brown and Members of the Subcommittee, thank you for inviting me to Washington, D.C. to tell my story.

Senator CARPER. Ke'onte [Applause.]

We have a lot of witnesses that come before this Subcommittee. I do not ever remember having one as young as you. And it is rare that we have one as eloquent as you have been this morning. Thank you for just an amazing statement.

Mr. COOK. Thank you too, Mr. Chairman.

Senator CARPER. How long have you been in Washington, D.C.—you and your mom and dad?

Mr. COOK. A day and a half.

Senator CARPER. Have you done anything that was fun?

Mr. COOK. At the Lincoln Memorial, there is something that looked like a slide, and I slid down it and ran into the sign that says do not touch. [Laughter.]

Senator CARPER. It turns out I got up early this morning. I usually go home to Delaware at night, but I got up early this morning. Senator Brown and I like to run and work out, and I ran down to the Lincoln Memorial today. It is my favorite run. It is 5 miles down there and back.

And so you are right. I saw a sign that looked like somebody knocked it over. [Laughter.]

I wonder who might have done that, Scott.

Well, we are glad you are here—

Mr. COOK. Thank you.

Senator CARPER [continuing]. And hope you have had a little bit of fun as well. And thank you for preparing and for joining us here today.

You mentioned in your testimony that you had lived in three foster homes before finding the Cooks, or before they found you, and you became their adopted son and they became your adoptive parents. And I think I understood you to say that your experience in the first two foster homes was generally pretty good and not so good in the third one.

Do you recall whether it was in the first home, the second home or the third home when you first began taking these drugs? Do you have any recollection of that?

Mr. COOK. It was the first home.

Senator CARPER. And were you taking a lot of them or some of them?

Mr. COOK. I was taking about three a day.

Senator CARPER. Do you recall why the doctors or someone thought you should be taking those?

What was it about your behavior that people thought, well, he should be taking some kind of mind-altering drug? What was it?

Mr. COOK. I would throw tantrums because I was upset and I could not let it out in the way that I needed to. So then they thought, well, let's just put him on meds so he will basically be quiet.

Senator CARPER. Ok. And it sounds like you kind of like zoned out. Is that what you said? You sort of zoned out?

It is hard to do well in school when you are zoned out. It is hard to do well in the Senate when you are zoned out. [Laughter.]

But somewhere along the line somebody figured out, and maybe it is when you came to live with your mom and dad, that this was not working and there was a better way to help you deal with whatever behavior problems you were having. Who helped figure that out?

And what turned out to be more helpful than taking those medicines?

Mr. COOK. Therapy with an attachment therapist.

Senator CARPER. Can you talk just a little bit about that for us, please?

Mr. COOK. I would go every Saturday, and we would talk about how I was doing in school, and we would talk about deep conversations about my mom, and that would help me get over my anger about my mom.

Senator CARPER. Right. But it worked?

Mr. COOK. It did.

Senator CARPER. Yes, it worked.

I have a fellow that—Senator Coburn and I serve on the Finance Committee together, and we had a witness. A bunch of witnesses came to see us a couple months ago, and they were talking to us about how to reduce this big budget deficit we have. We are spending more as a government than we actually take in, in taxes.

And one witness was talking to us about how do we get better health care results, and he said here is what we should do. He said we should find out what works and do more of that. That is all he said. Find out what works and do more of that.

And in this case, we need to find out what works and do more of that.

We have 50 States across this country. In some of those States, they are figuring out what works. We need to find out what works and, throughout the country, do more of that.

I said when we had a chance to meet earlier today and talk; I said to Ke'onte, you have been—for a guy 12 years old, you had a pretty rough ride. It sounds like you have ended up in a really good place for yourself and for your mom and dad, but you had a rough ride. And a lot of foster kids do in life.

But I think because of your presence here today a whole bunch of kids, thousands of kids across this country, kids that are foster kids and kids that are not, are going to have a chance for a better life, a more productive life, to be better students and to go on and be a real success.

I just want to ask if I do not know if there might be one thing that you would like to pass or share with us, like advice. This is like a child advises the elders. So maybe one piece of advice you have for all of us here today, one thing that you think maybe we could take away from your testimony to help more children across the country—what would that one thing be?

Mr. COOK. That meds are not going to help a child with their problems. It is just going to sedate them and make them tired, make them forget it for a while, and then it comes back and it happens again.

What I learned in therapy is that when you are taking therapy you talk about the deepest thing, it hurts, then it comes back, but you can handle it better.

Senator CARPER. Well, that is a mouthful. Thank you for those words of wisdom.

And with that, let me turn to Senator Brown. Thank you.

Senator BROWN. Thank you, Mr. Chairman.

Mr. Chairman, I have seen you run, OK, and I know how fast he does a mile, and I think he can beat us both. All right? [Laughter.]

Senator CARPER. He can run us into the ground.

Senator BROWN. And that loop is only 3½ miles, not 5. [Laughter.]

Senator CARPER. It is 5. Trust me.

Senator BROWN. OK, I feel better then.

Well, thank you. Everyone is in a good mood because this is obviously a nice young witness.

And I am curious actually, Mrs. Cook and Mr. Cook. How did you identify, obviously, the overprescription? Was it the fact that he, in his own words, was zoning out?

I mean, what led you to take that proactive step to get your child back?

Ms. COOK. We have had about 3½ years of experience in foster care and lots of training, including a little bit of training from Nancy Thomas. She actually came and helped teach kind of a course at our foster care community, for attachment therapy.

And stemmed from that, we learned. We just got really educated fast about how foster kids, they do; they come with a lot of baggage. They are sad. Why would they not be sad? Their situation is not a happy one.

And it is so easy to just find something to help them feel better for the moment, and that is not the right thing. And there are so many ways to help them through consistency and just not letting them down and being there for them.

So really, it was right from the time when we had foster care. When we got him, we knew something was off. We knew that. The medications—that is terrible. He was just lights-out. That was it. You can just tell that there was more to the situation.

But we only had him a weekend. So of course, we had to give him his meds correctly that weekend. But when we got him, we asked the physician at his new pediatrician. We said, what can we do to start getting him off these things? We need to start seeing how he really reacts.

And he was very interesting for the first few months. He gave us some fun times, but that is it. It took a few months, and he was already a different child.

Senator BROWN. Well, I could only imagine. Of course, it is going to be interesting. He was on some very serious medications, affecting a young man. So I want to commend you and your husband for taking that step.

Is this your first adoption from foster care?

Ms. COOK. Yes, this is our first actual adoption.

Senator BROWN. So what made Ke'onte so special?

Ms. COOK. Well, we were looking.

Senator BROWN. Get out the earmuffs. [Laughter.]

Ms. COOK. I have told him this so many times because I really want him to know that I really feel like God brought him to us because we were originally looking for a little girl, but we were not necessarily picky. We really prayed that God would bring us who he wanted us to have. And after not having our foster kids, it was really hard. So when we moved to Texas.

Our caseworker, she was amazing. From a refuge house, an adoption agency in Dallas, she sent this video, this little book. She goes, I know you said you were looking for a little girl, but you

know, just something about this hit me, and I think you should look at it.

And we did. And it was a Wednesday's Child feature on him, and it was actually the second time that he was Wednesday's Child. He had been on it 2 years prior.

And there was a possible adoption from the first time he had been seen on it, but it fell through. It did not happen.

And so, they let him come back 2 years later and do it again, and we saw that and his story. He just wanted a home. He wanted somewhere to belong. And you could tell from the first time to the second time he had a little less hope in his tone.

And we had looked at some of the other Wednesday's Child just because we were on that Web site at that time, and no one else hit us like Ke'onte did.

And we just knew. After the situation of not having the girls that we had in Florida, we knew he needed someone and we needed someone to need us back. It was just perfect in the way that he was brought in so quickly, right before Christmas. It was amazing.

Senator BROWN. Great.

And Ke'onte, I see you are giving the thumbs-up there. That is great.

When you were going through your transition and you were being medicated, what are your thoughts or memories about transitioning from being highly medicated to where you are now?

Obviously, I am presuming it was filled with some real struggles and battles. So what gave you the strength to actually become the young man that you are now and be where you are here today, testifying before the U.S. Congress?

Mr. COOK. It was basically that I had hope that it would soon be over and I would not have to go through the same struggles that we did during those few months ago. So that drove me to get through it, and that is why.

Senator BROWN. Great. Well, thank you for testifying. Good luck to you and your family. God bless.

And I look forward to hearing the rest of the testimony. Thank you, Mr. Chairman.

Senator CARPER. Thank you, Senator Brown. Senator Collins.

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

Ke'onte, that must have been a wonderful Christmas present, when you went to live with the Cooks and when they became your parents. I bet that was one of your best Christmases ever.

Mr. COOK. Hm. [Laughter.]

Ms. COOK. You can say it.

Mr. COOK. It was awkward.

Senator COLLINS. It was hard?

Mr. COOK. I kind of love my DS more, but you know. [Laughter.]

But then I grew attached. So I cannot say anything now.

Senator COLLINS. Well, they probably will get better and better. That, I am sure of. I bet when you look back you will consider it as being a great Christmas present.

I am curious, when you were put on these medications, whether any of the doctors explained to you what the medications were for and how you might feel when you were taking them. Did they talk to you about that?

Mr. COOK. They did not say anything.

Senator COLLINS. They did not say anything? They just said, here is your medications; take it?

Mr. COOK. Basically.

Senator COLLINS. Did your previous foster parents explain to you what the medications were for or how you might feel?

Mr. COOK. Only one. And then they did not tell me how I would feel. They just told me what it was for, and it was for ADHD.

Senator COLLINS. That had to be really scary, not to know what you were taking or why you were taking it. And I just cannot imagine the doctors piling on drug, after drug, after drug without explaining to you what it was for, how long you should take it, what the impact might be, how you would feel and what you should do if you did not feel well taking it.

Did any of them ask you—did any of the doctors tell you to be sure to come back to see them or call them if the drugs made you feel zoned out?

Mr. COOK. They did, but the foster parents did not go back like they were supposed to.

Senator COLLINS. I see.

Ms. Cook, what kind of differences after the very difficult transition period did you notice in Ke'onte's behavior once he was off most of those medications?

Ms. COOK. His behaviors were it was just a light and day difference. He went from break-dancing on the principal's conference room desk in her office to not even going to the principal's office for a whole month, in just a short period of time. When he started school, it was January to May. He was almost a different child altogether.

He was happy. He was always smiling. I mean even to this day he smiles all the time. He is happy. You can tell. Even if I give him a consequence—he has to do chores for forgetting his homework—he is happy. I mean not to do the chores, but he is there with us, doing the chores, almost like you are not supposed to enjoy that.

No, he is happy, and you can tell. And he does not have the tantrums. He is not upset for no reason. If he is upset, he is upset, and it is a real reason and not just for no reason.

His tantrums—he would be on the floor and just be wailing, or he would tear things up in his room. It was like he did not know how to be a real kid. He had been kind of doped up for 4 years. It was almost like we had to show him what a kid his age is supposed to be like.

Senator COLLINS. Thank you.

Ke'onte, I just want to thank you so much for coming here today. I think it is very brave of you to tell your story, and it is going to help a lot of other children, and it is going to help us make sure there are better policies in place.

So I thank you very much for coming forward

And Ms. Cook and Mr. Cook, I think you are a great family. Thank you.

Mr. COOK. Thank you.

Senator CARPER. Amen. Dr. Coburn.

Senator COBURN. Ke'onte, you have a great smile.

Mr. COOK. Thank you.

Senator COBURN. It is infectious. Are you on any medicines now?

Mr. COOK. No, not at all, just a couple of vitamins.

Senator COBURN. Think about that. As a physician, I can tell you three of the medicines you were on are contraindicated for a child your age, and were not approved, never been studied.

The other thing, looking at these medicines, is each one interacts with the other one. In other words, two out of the five work against three out of the five.

So probably the most important question I would have for you is about this therapy that you had on Saturdays; did you ever experience anything like that while you were in foster care?

Mr. COOK. Not exactly. We would go to a therapist. It would more be like a psychiatrist, and basically what we would do, we would talk about how the week was going. If we were good, we would get donuts or chips, and then we would just quit and then play.

Senator COBURN. But nobody spent the time talking to you about the disappointment with your birth mom? Nobody allowed you an opportunity to express your feelings about some of your anger?

Mr. COOK. Not at all.

Senator COBURN. Yes. Has there ever been a time—and maybe Ms. Cook, you can answer this. Were you ever on Social Security disability?

Was Ke'onte ever on Social Security disability as a consequence of being on these medicines?

Ms. COOK. Not that I am aware of, no.

Senator COBURN. OK. All right.

What would be the message, Ke'onte, that you would have for other kids who are not yet adopted that are in foster care that are on medicines? What would your experience tell them?

It is a tough question, I know.

Mr. COOK. My experience would tell them that there is someone coming. You just have to wait for them and sit tight.

Senator COBURN. That is a great answer. All right. Thank you, Mr. Chairman.

Senator CARPER. Well, as we approach Christmas, that thought of someone is coming, all you have to do is hold on and sit tight, is probably in the minds of a lot of kids your age and across the country.

Fortunately, for a lot of kids your age and younger across the country, they have never had to go through what you have gone through. They are lucky they were born on third base, if you will, and pointed to a home where they had loving, caring parents who took wonderful care of them and made sure that they had what they needed and, frankly, were not subjected to what they did not need and was not good for them.

I, too, want to thank you very much for joining us today and for speaking with the wisdom of someone well beyond your years.

And I just want to say to your mom and dad it is just a joy to be here with you, and I think Ke'onte is here representing all the good that can come from kids when they have the kind of home that you have provided for him. He has received the kind of treatment and care that really has helped him. So we thank you for being role models on your own.

And finally, I would say as I said at the beginning, Ke'onte, some real good is about to come out of what was not so good in your life and the lives of a lot of other kids. Some real good is going to come, and not just in Texas, and not just in Delaware or Massachusetts or Maine or Oklahoma but in all 50 States. So you can feel, I think, good and proud of that.

And as we think about gifts that we are going to send to our friends and family this Christmas, I can think of few gifts of greater value than that.

And with that having been said, Mr. Cook, you are excused from the witness table and you are free to take your mom and dad with you. I understand you have not had any breakfast yet maybe, or at least not enough, and so we are going to excuse you and you can head out and get some chow.

And then I guess do you head on back to Texas today?

Mr. COOK. No, New York. We go talk to Diane Sawyer.

Senator CARPER. Diane Sawyer. Oh, how about that? All right. Well, give her our best.

Mr. COOK. I will.

Senator CARPER. All right. Good luck. God bless. Thanks so much.

Well, we welcome our second panel, all accomplished witnesses, some of whom have been good enough to join us before.

I will just say to Senator Collins and Senator Coburn, ole Ke'onte is going to be a tough act to follow, but I think this panel might be up to it. So I am going to take just a moment and introduce each of them and then ask them to go forward with their testimony. Thank you all for coming today.

The first witness on our second panel, Mr. Greg Kutz, Director of GAO's Forensic Audits and Special Investigations Unit, Mr. Kutz has spent over 20 years at GAO, working to uncover abuse of any number of things—government credit cards, Hurricane Katrina/Hurricane Rita fraud, problems with U.S. border security among any other issues. He has testified before us on any number of times. We thank him for agreeing to join us, to be here again today.

If we had to pay you on a per witness basis, our Nation's debt would probably be a little higher. So thanks for coming and doing this.

Our second witness is Mr. Bryan Samuels. He is the Commissioner of the Administration on Children, Youth and Families at the Department of Health and Human Services.

Prior to his current position, Mr. Samuels served as the Chief of Staff for Chicago Public Schools, the third largest school system in the Nation.

Who was the head of Chicago Public Schools when you were there?

Mr. SAMUELS. I think it is a guy by the name of Arne Duncan.

Senator CARPER. Would you say that again?

Mr. SAMUELS. A guy by the name of Arne Duncan.

Senator CARPER. What ever happened to him?

Mr. SAMUELS. I think he moved to Washington.

Senator CARPER. Yes, he did. He is doing a good job.

Before that, Mr. Samuels served as the Director of the Illinois Department of Children and Family Services where he worked daily with the Illinois foster care system.

Our next witness is Matt Salo, good to see you—Executive Director of the National Association of Medicaid Directors which represents Medicaid directors across our country.

And prior to being named executive director, Mr. Salo worked on reform and issues at the National Governors Association, an organization I am very familiar with. Actually, it is an organization I loved being a part of for 8 years.

And you served there as Health Policy Analyst for State Medicaid Directors. Thank you very much for that service too.

Our final witness today is Dr. Jon McClellan. I understand that you go by Jack. A child psychiatrist at Seattle Children's Hospital and a professor in the Department of Psychiatry at the University of Washington, his research focuses on the identification of genes vital to the study of psychiatric diseases and the diagnosis and treatment of severe mental health disorders in youth.

Dr. McClellan is a member of the American Academy of Child and Adolescent Psychiatry and spent many years on the committee there that develops treatment guidelines for patients.

And again we thank you.

We thank all of our witnesses for being here. Your entire testimonies will be made part of the record. And if you can summarize your testimonies, or give your testimonies, within 5 minutes or so, that would be fine. If you go way beyond that, I will have to ask you to sum it up and we will turn it over to the next witness.

Mr. Kutz, you are lead-off witness. Welcome. Please proceed.

TESTIMONY OF GREGORY D. KUTZ,¹ DIRECTOR, FORENSIC AUDITS AND INVESTIGATIVE SERVICE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. KUTZ. Mr. Chairman and Senator Coburn, thank you for the opportunity to discuss the use of psychotropic drugs for foster and other children paid for by Medicaid.

My testimony has two parts. First, I will discuss our analysis of psychotropic prescriptions for these children, and second, I will discuss state programs to oversee the use of these drugs to treat foster children.

First, as you have mentioned, foster children in the five States that we analyzed were prescribed psychotropic drugs at rates that were 2.7 to 4.5 times higher than nonfoster children in Medicaid in 2008.

Federal and State officials, academic studies and the child psychiatry experts that we contracted with pointed to several factors to help explain these differences. For example, greater exposure of foster children to neglect and physical abuse often leads to mental health conditions that need treatment. Other factors include frequent foster placements and varying state oversight programs, which I am going to discuss in a moment.

These higher rates do not necessarily indicate inappropriate activity. However, we did identify a number of high risk indicators

¹The prepared statement of Mr. Kutz appears in the appendix on page 52.

in both groups but more prevalent, as you have mentioned, for foster children.

For example, over 1,700 children were prescribed 5 or more psychotropic drugs at the same time. Our experts said that no clinical evidence supports this practice, which can increase the risk of adverse reactions and long-term side effects such as diabetes.

Over 20,000 children had doses above those set by the FDA, which also can increase the risk of side effects without providing additional benefit.

And over 3,500 infants were prescribed antihistamine drugs, and a small number were prescribed other psychotropic drugs. Whether used for mental or nonmental health conditions, our experts expressed significant concern over adverse reactions for these babies.

We will investigate a number of high risk cases and report the results back to you next year.

Moving on to my second point, we found that State programs to oversee the use of these drugs for foster children can be improved. We reviewed programs in these six States that you mentioned against guidelines from the American Academy of Child and Adolescent Psychiatry.

States have no requirements to follow any specific guidelines although the recent legislation mentioned requires protocols in this area. All six States have programs that cover some or many of these guidelines, but none address them all.

For example, AACAP says that States should identify caregivers who can give consent for drug treatment, which all States do. However, three States do not require caregivers to seek input from the child who is actually taking the drugs, which we heard from the first witness.

Five States have fully or partially established guidelines for the use of psychotropic drugs. However, none have fully implemented guidance and programs to monitor the rates of adverse reactions.

And AACAP recommends consultation programs that involve child psychiatrists meeting with consentgivers, physicians and children.

One State covers all of these guidelines, at least partially, while another States covers none. The remaining States fall in the middle.

In conclusion, psychotropic drugs can be an important tool to treat mental health conditions. However, evidence supporting the effectiveness and safety of these drugs for children is limited. We recommend that HHS endorse guidance to the States for monitoring the use of these drugs for foster children. More consistent and comprehensive guidance should better protect these vulnerable children.

Mr. Chairman, that ends my statement, and I look forward to your questions.

Senator CARPER. Thanks very much. Excellent statement.

Mr. Samuels, please proceed. Welcome.

TESTIMONY OF BRYAN SAMUELS,¹ COMMISSIONER, ADMINISTRATION ON CHILDREN, YOUTH AND FAMILIES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. SAMUELS. Welcome. Chairman Carper and Senator Coburn. I want to express appreciation for the invitation to be here and to talk to you today.

This is obviously a serious issue. HHS clearly shares the concerns that this Committee has, and we really do look forward to working with Congress to address the issues and reform a system that cares for the most vulnerable children in our society.

I have to say to you, however, that the issue of psychotropic drugs in foster care is not a new issue. It is not a new problem.

I was the Child Welfare Director in the State of Illinois between 2003 and 2007. During my tenure, on a regular basis, foster parents, adoptive parents, biological family members approached me to express their concerns about the impact of psychotropic medications on the well-being of their children. I can also describe for you examples of visiting residential treatment programs where well over 50 percent of these young people were being prescribed psychotropics, and I can provide you one example in which 100 percent of children in a residential treatment program were on a psychotropic drug. So again, unfortunately, this is not a new problem.

I can tell you that when I was the director what I did was to put in place a comprehensive oversight process. We had strict processes related to informed consent. We trained all of our caseworkers and social workers on all of the necessary procedures. We established an independent review of all prescriptions made for children who were in foster care, and we established an electronic database that captured every child in the State that was on a psychotropic. That electronic database allowed us to also review patterns of prescription and to look at particular prescribers to identify whether they were engaged in practices that we believed to be inappropriate.

Now I would like to try to tell you, or convince you, that I took these steps because of my great child welfare expertise. I cannot tell you that. The first day on the job as Director of Child Welfare was the first day I had ever worked in child welfare. However, I can tell you that I spent the last 26 years of my life on high dosages of psychotropic medications. So I both appreciate the benefits that come from being on a psychotropic as well as the side effects.

I also have the same challenge that has been mentioned earlier, which is I, too, worry about the long-term effects of psychotropics on my own health and well-being. So I do appreciate the challenge that we are talking about here, and I really do believe that there are things that States can do to correct their practices and to operate more effective programs.

And I have to tell you part of our response to psychotropics also involved expanding the array of services that children had. We found that there were many children in the State of Illinois that were being misdiagnosed with a mental illness and being prescribed psychotropics that were intended for adults. In reality, much of the behavior that these prescriptions were being made for were behaviors that were better explained by the trauma that

¹The prepared statement of Mr. Samuels appears in the appendix on page 94.

comes from abuse and neglect and the trauma that comes from a child being removed from their homes. And so, instead of continuing to focus on an acute approach to intervening in the lives of these young people we put in place more therapeutic interventions that had the basis of evidence to demonstrate that they were both appropriate and safe for children in foster care.

So again, unfortunately, this is not a new problem.

If you go to the Internet, any Web site—try Google—and type in child welfare and psychotropics, you will see hundreds of articles that pop up. They go back to the mid-90s, and they articulate even in the mid-90s that there were more than 13 percent of children in foster care that were prescribed psychotropics. So it is an important point to be made.

I provided you three slides. I will not go into them in great detail, but what I will tell you is that this data comes from the National Survey of Child and Adolescent Well-Being. It is a study that has been funded by Congress for the last 8 years. From this study, there have been articles published beginning in 2004 that document that more than 12 percent of all children in foster care were prescribed psychotropics.

More recent data from this study demonstrate that about 16 percent of children between the ages of 11 and 17 known to child welfare are being prescribed psychotropics. More than—almost 20 percent of children who are between the ages of 6 and 11 known to child welfare are being prescribed psychotropics. And most importantly, almost 50 percent these of children who are being prescribed psychotropics are being prescribed more than two psychotropics.

The other slide also intends to show you that this issue of prescriptions cuts across all placement types so that the children that are remaining in their home but being provided child welfare services (CWS) versus children that are being removed from their homes and placed with foster care parents, in both instances, the rate of psychotropic prescription is almost identical. So this issue cuts across all placements in child welfare.

So I am going to summarize by just making five quick points about the steps that HHS is prepared to take to address this issue.

First, we do support the recommendation of the GAO, and we will take steps in the next 90 days to provide specific guidance to States about putting into place the appropriate protocols and procedures to oversee psychotropics.

We also are committed to doing consumer education. We want to make sure that foster parents, adoptive parents and biological parents understand the drugs that their children are being prescribed, and we want the young people to understand the prescriptions that they are being prescribed.

We also will put in place, and will work with States to put in place, the kind of oversight activities that actually make them better, that put them in the possession of real data so that they can make good decisions.

We also are prepared to provide support so that States are much more effective at screening, diagnosing and treating issues related to trauma and exposure to violence.

And we already know—we know this from the Centers for Disease Control (CDC), we know it from the Substance Abuse and Mental Health Services Administration (SAMHSA) and we know it from the National Institute of Mental Health (NIMH) that there are evidence-based practices, therapeutic practices, psychosocial interventions that work for almost all of the issues that children in foster care have.

We are prepared to take these steps. We welcome the opportunity to have further conversations with Congress about additional steps that we can take to meet the needs of children who are absolutely the most vulnerable young people in our society.

So thank you, Chairman.

Senator CARPER. Thank you for sharing that testimony and for giving us a glimpse into your own life and the relevance. I think it is especially appropriate that you are a witness here today. Thank you.

Mr. Salo, please proceed.

**TESTIMONY OF MATT SALO,¹ EXECUTIVE DIRECTOR,
NATIONAL ASSOCIATION OF MEDICAID DIRECTORS**

Mr. SALO. Great. Thank you, Chairman Carper and Senator Coburn. We appreciate being invited to testify here today. I wish it were on a happier issue, but I do think that the silver lining is we are laying the groundwork for trying to do better, which clearly is what we need to do.

Medicaid is the Nation's health care safety net. It is jointly financed by the States and the Federal Government and will spend more than \$400 billion this year providing health care to more than 60 million people. And it is administered by the States under broad Federal guidelines, which leads to enormous variation across the States. We have talked about that a little bit. But it is also a very complex program within any given State.

But the one piece that obviously we are talking about here is the fact that Medicaid is essentially the sole funding source for health care for kids in the foster care system.

Now pharmaceutical coverage and expenditures have been a large and growing concern of the Medicaid directors for a number of years. Psychotropics, in particular, pose a unique concern because the trends in the costs and utilization are far outstripping every other baseline. And analysis of the data shows us that this is due to a variety of reasons, some of which are legitimate, some of which, less so.

And clearly, we have talked a little bit about overutilization and misutilization, and the challenge is we are seeing this everywhere. We are seeing this in adults. We are seeing this in seniors. We are seeing this in kids. And as clearly noted in the GAO report, it is particular true for, quite frankly, some of the most vulnerable kids in our country—kids who are in foster care.

Psychotropics show an enormous amount of promise in treating very serious concerns. But obviously, there are clear concerns with how current prescribing patterns can negatively impact this very

¹The prepared statement of Mr. Salo appears in the appendix on page 113.

vulnerable population. And the report pointed out several potential problems, and they must be taken very seriously.

And I want to be very clear that there is no question that subjecting the most vulnerable people in our society to bad medicine is unacceptable and that we can and should and will do better by them.

But I also want to sort of lay out that this is not just a Medicaid challenge, that this is, quite frankly, a result of a number of serious flaws in the broader U.S. health care system:

The prescribing patterns in this country today, from physicians and others;

The serious shortfalls in clinical research to tell us how are we supposed to treat kids as opposed to adults let alone children in the foster care system.

Quite frankly, as talked about, a lack of effective oversight from a variety of levels of government, and on behalf of the State agencies, we accept that and we take that on and we will try to do better;

But also includes the lack of widespread health information technology which can try to really put a hold on questionable prescribing patterns.

And then at the end of the day, the fragmented nature of the relationship between acute care and behavioral health care in this country.

And so, the solutions that we need to embrace are going to have to involve all of these pieces—a variety of levels of government, mental health professionals, primary care practitioners, researchers and others.

I want to highlight a couple of sort of unique challenges and then talk about a couple of quick solutions.

One of the things that States face in trying to do proper oversight of this is resistance in the community. It is no surprise that trying to do things like prior authorization, a common-sense tool for very serious medications like this, is sometimes completely prohibited at the State level. This is due to influence of the manufacturers. This is due to the influence of advocates. This is due to the influence of the general public who do not like to see government get in between a patient-physician relationship. These are all legitimate issues, but they do lead to challenges in trying to lay out some oversight here.

And as has been mentioned, the unique situations that these kids face in the foster care system and the reasons why they are in the foster care system to begin with really is a result of a variety of traumas which are under-diagnosed and really do require specialized treatment approaches.

So in light of time, I would just sort of lay out a couple of different solutions.

The GAO recommended additional Federal guidance. We absolutely welcome that and are going to work with all of the different parts of HHS, whether it is the Medicaid side, the Administration for Children and Families (ACF) side, SAMHSA, to try to work with that. We embrace that.

But we clearly need more clinical research on how these drugs affect kids. We need to do more to break down the barriers to try-

ing to do coordinated care for the most fragile and vulnerable people in this country, whether it is the dual eligibles, whether it is adults with chronic conditions or whether it is kids in the foster care system. And whatever Medicaid can do and should do, we also need to make sure that the medical community and their representative associations are also at the table. And then finally, I pledge that through our association we will work to try to not only develop—identify, develop, disseminate best practices in this area across the country.

So I look forward to answering your questions, and thank you for having me.

Senator CARPER. Thank you, Mr. Salo.

Dr. McClellan, I am going to slip out just for a minute to say goodbye to Ke'onte and his family. You go right ahead. I will be back within less than minute. OK. Thank you.

**TESTIMONY OF DR. JON MCCLELLAN,¹ CHILD PSYCHIATRIST,
SEATTLE CHILDREN'S HOSPITAL**

Dr. MCCLELLAN. Thank you, Mr. Chairman and Senator Coburn. Thank you for inviting me today to participate in this important discussion regarding the use of psychotropic medications in foster children.

As noted, I am a child psychiatrist at Seattle Children's Hospital, a professor at the University of Washington. I am also the Medical Director of Child Study and Treatment Center which is the State psychiatric hospital for youth in Washington State.

The high risk practices identified by the GAO study raise significant concerns regarding the treatment of severely mentally ill and vulnerable youth. Although the focus of the study is on foster care, the concerns raised are relevant to all children and adolescents prescribed psychotropic drugs.

Children in foster care often have emotional and behavioral difficulties. The high rate of medication used in this population is not a new discovery nor does the use of these drugs always imply bad practice. Several psychiatric medications have been studied and approved for use in children and adolescents. When used correctly, these treatments can help reduce suffering and enhance the functioning of young people.

However, it is also well documented that many children in the child welfare system do not receive high quality psychiatric services. Treatment too often occurs during times of crisis without adequate support or access to skilled clinicians and programs capable of providing effective social and behavioral interventions. In these situations, the medications become stop-gaps used to prevent the child from hurting themselves or others, or to help control disruptive behavior that threatens the child's foster placement. The lack of effective long-term treatment exacerbates the risk for excessive an inappropriate medication use.

This problem is evident in the problems of high risk prescriptions identified by the GAO study. As a group, children in foster care were more likely than other children to be treated with multiple psychiatric drugs and were also more likely to be treated with dos-

¹The prepared statement of Mr. McClellan appears in the appendix on page 119.

ages that exceed recommended standards of care. These practices impacted thousands of children. Some young people were prescribed as many as 10 different psychotropic drugs at the same time per the data. Some children younger than 5 years of age were prescribed as many as five different medications concurrently.

Unfortunately, these practices are not uncommon. In my State hospital, kids are often admitted taking four or more medications. A few years ago, one young boy admitted to Seattle Children's Hospital was taking 13 different psychotropic drugs. There is no research that justifies these practices.

The most troubling finding of the GAO study is the use of psychotropic drugs in infants. Most of the prescriptions in babies were for antihistamines, some of which may have been used to treat other types of medical problems. Regardless, there is little research supporting the use of these medicines in very young children and the prescriptions remain concerning.

Furthermore, dozens of babies were prescribed antipsychotics, antidepressants, Clonidine or Lithium. Some infants were prescribed more than one drug. The use of psychotropic medications in babies defies both standard of care and common sense.

The findings of the GAO study strongly suggest the need for better oversight. The best principles outlined by the American Academy of Child and Adolescent Psychiatry provide a useful set of monitoring guidelines.

Washington State had implemented a model system to oversee psychotropic drugs. Criteria were developed to identify prescriptions that exceed safety thresholds based on dose, number of medications and age of the child. For prescriptions flagged by this process, a second opinion by a child psychiatrist is required before the medication is dispensed. This oversight system has reduced high risk prescriptions and over a two-year period saved the State \$1.2 million.

The results of the GAO study also strongly call for more research. A hodge-podge of prescribing practices occurs in part because none of our current treatments work well enough. Genetics and neurobiological sciences have advanced substantially over the last decade, in large part due to the leadership of the National Institute of Mental Health. Nonetheless, given the marked complexity of brain functioning, the underlying causes of most psychiatric illnesses remain unknown. Without known causes, research on intervention inevitably struggles. We need continued investment, both fiscal and intellectual, in order to develop safer and more effective treatments and to eventually find cures.

Thank you for listening and look forward to questions.

Senator CARPER. Dr. McClellan, thank you. Senator Coburn.

Senator COBURN. Thank you.

I am going to have to leave, and I am going to submit some questions to the record for each of you.

Dr. McClellan, thank you for being here. Your expertise is important in what we are talking about here, for a lot of our foster kids do not have true organic disease outside of the trauma they have experienced. Not many of them are schizophrenic. Not many of them have true bipolar disease. But what they have is situational disease based on what has happened.

In your opinion, is it a shortfall in what we have set up through Medicaid that we do not have the type of psychotherapy versus drug therapy to work on some of these problems, and what would be your recommendation if we had the resources available?

What would you do to change this to where we actually put the resources not just in the research but in the actual treatment? Because what we heard from Ke'onte is he is not on a drug now and yet he had all these diagnoses which probably psychotherapy has helped cure. Plus, the situation has helped.

Can you help me with understanding this?

Dr. McCLELLAN. No, it is an excellent point. The system of care is not adequate built around—it is not just kids in foster care or the welfare system. The entire system of psychiatric services for kids is not well organized, they are not organized enough.

There are a number of evidence-based care, evidence-based psychosocial treatments that have been shown to work in kids. It is hard to access them. It is hard to find providers that can do them. There is a long waiting list, and many communities have no one in the area that can provide it.

Senator COBURN. So we have a shortage, first of all, of child psychiatrists?

Dr. McCLELLAN. Child psychiatrists.

Senator COBURN. And child therapists?

Dr. McCLELLAN. Well, child therapists capable of providing these kinds of psychosocial interventions.

Senator COBURN. Right.

Dr. McCLELLAN. And so, accessing them, finding skilled providers and then finding consistent providers over time with a wrap-around team that stays with the kid over time is really what is needed. It takes an investment in the front end, but you will not only have better outcomes, but you will keep kids off the medicines that they do not need.

Senator COBURN. Yes, and you will have continuity of care which is probably one of the most important things.

Dr. McCLELLAN. Yes.

Senator COBURN. The Cook family actually got continuity of care to Ke'onte in terms of his therapy. It was consistent. I guarantee you they had him there. They had the same therapist working with him all the time. They built a relationship and trust which allowed the therapy to actually work.

There is no evidence that psychotropic drugs, not antihistamines but true psychotropic, are effective or indicated in infants, correct?

Dr. McCLELLAN. There are absolutely, that I know of, no studies at all that have ever—it would not make any sense to study it.

Senator COBURN. So that is one thing that can be fixed tomorrow. That can be a ruling coming out of HHS—this will not happen, and we will not pay for it. So that is something that could be fixed tomorrow.

I will have a couple of other questions for you.

Again, you all do not know how valuable Dr. McClellan is and how few of him there are.

Dr. McCLELLAN. You should tell my children that.

Senator COBURN. I will.

In my practice, finding a child psychiatrist when it is really needed is so difficult to get. And it is not just in a foster home. It is in an insurance-paying patient, to find that. So one of the things we have to do is create the funds so there are more Dr. Jack McClellans. We have to do that because we have a need.

The second point I will make before I run—most of the time, are symptoms of a greater problem, which is the family destruction in our country. And we are treating symptoms rather than some of the underlying problems. So we have to bear that in mind. Although we address treating the symptoms, we also need to go back and see what we can do in terms of firming that up. That is our biggest cultural problem, which we are paying a tremendous amount to do.

Dr. McCLELLAN. It is true that the best intervention Ke'onte got is from his new parents.

Senator COBURN. Yes. Mr. Samuels, thank you for your testimony. HHS—the law states HHS says the States have to have a plan.

Mr. SAMUELS. It does.

Senator COBURN. But there is no regulation at HHS that says you all have to oversight that plan and look at it and do the oversight. Is that correct?

Mr. SAMUELS. What we are required to do, again by statute, is to make sure that a State has a plan.

Senator COBURN. Yes.

Mr. SAMUELS. We do not have authority to intervene or to determine whether a plan is consistent or inconsistent with best practice.

Senator COBURN. OK. But that does not mean you cannot create a regulation that says you are going to submit your plans, we are going to look at the plans and then do the oversight to compare what their performance is against their plan.

Mr. SAMUELS. That is correct. And in our response to the GAO report we indicated that we would put out an HHS-endorsed protocol and we would do that in the first 90 days. But the larger consideration is whether you start a regulatory process today that would lead to a single standard for which all States would have to meet.

And the reality is—and again, it is the right thing to be talking about, but the reality is the Federal regulatory process would require about a year and a half's period of time in order to have that single confirmed standard that we could apply to all. And so, we are going to start with the guidance but move in as specific a direction as we can as it relates to holding States accountable.

Senator COBURN. OK.

And Mr. Kutz, thanks for the study. You guys do great work.

Mr. KUTZ. Thank you.

Senator COBURN. I am for you. I think you all know that.

Mr. KUTZ. We are aware of that.

Senator COBURN. I have lost my thought. I am having a Rick Perry moment. [Laughter.]

I think what I would like to know is in terms of where we have all these medicines used and the costs associated with the medicines and how that impacts, not just in terms of child psychiatry,

is there—I guess the point is did you look at who were writing the prescriptions because my guess is the people with the qualifications to write a prescription were not necessarily the people with the qualifications to actually give the prescription and make the judgments. Somebody untrained in child psychiatry, like me, might have been writing the prescription because that is who was available. So the expertise in terms of making that judgment did not follow.

Did you look at who was writing the prescriptions?

Mr. KUTZ. No, but as I mentioned in my opening statement we are planning to delve into some of the high risk cases and we will look at that as part of that, along with the diagnoses and whether the State controls worked, et cetera. So any input you have into that—

Senator COBURN. I think what you are going to find is people like Dr. Jack McClellan were not the ones writing the vast majority of these prescriptions. It was people not trained in child psychiatry, not clinically, did not have the clinical expertise to be doing what they were doing. And what they were doing was treating a symptom rather than a disease. What can I do to solve this problem for this foster parent.

We have such a shortage of qualified people to actually address these, and so, I would love to make sure that you do that so we end up getting to see—

Mr. KUTZ. Yes, any input you have—

Senator COBURN [continuing]. What the source was.

Mr. KUTZ. OK. Any input you have into that with your expertise, we would be happy to meet with you to go over that, but that would be something we can build into our plan at this point, yes.

Senator COBURN. OK.

Mr. SAMUELS. Senator Coburn, it is worth noting that through the National Survey of Child and Adolescent Well-Being (NSCAW), the study that I described earlier that Congress funds, we actually do track who is making the prescription, and so it could be an important database for GAO to consider in terms of trying to get their arms around that data specifically.

Senator COBURN. Yes. I would just tell you my practice wasn't limited to delivery of babies. I did a wide family practice. And I never once felt comfortable giving an adolescent any psychotropic drug. So I did not because I did not feel competent to do it, and so I always tried to get a referral to somebody that was more competent than me.

And in our work day today, that is not happening. So we are not deferring to somebody of better training and more qualification as we treat. What we are doing is throwing a medicine at a symptom rather than treating the underlying problem.

And I apologize for having to leave. Thank you, Mr. Chairman.

Senator CARPER. Those were great questions and points.

As Mr. Kutz knows, what we do here in this Subcommittee, week after week, month after month, is to try to drill down on how to get better results for less money. And today, we are especially focused on better health care results for less money.

Dr. Coburn raised in his comments and questions the notion of whether or not any infant, any child under the age of one, should

be taking these psychotropic or mind-altering drugs and suggested that is something that is inappropriate, that it should not be allowed, that we can stop that fairly easily.

Let me ask—and I will just start with Mr. Samuels if I could—is it that easy?

Mr. SAMUELS. It is not that easy. In many respects, what we could do today is to provide States the guidance that they would need to make their own decisions. We do not currently have the authority to either prescribe a specific set of steps that they take nor do we have the authority to intervene on any particular patterns of psychotropic prescriptions that we might find in the data. And so, it would require an act of Congress if you wanted us to be able to immediately intervene and stop the practice of making prescriptions to infants.

Senator CARPER. Let me just ask anyone on the panel. Mr. Salo, do you want to comment on that, please?

Mr. SALO. Sure. I think Bryan is right. I mean one of the challenges is in the law itself. One of Medicaid's challenges is we are required by law to cover essentially every drug that is approved by the FDA, with very few exceptions.

We can do prior authorization, and I think that is a key best practice that we have talked about in certain circumstances.

Senator CARPER. Talk about that. How would it work?

Mr. SALO. So in an instance where you have a prescriber who is looking at prescribing a psychotropic for a child under one, which in most cases sounds horrible although I do know that there are some instances in which that turns out to be Benadryl, that might be—

Senator CARPER. I am sorry. In some instances, that turns out to be what?

Mr. SALO. Benadryl.

Senator CARPER. Benadryl, OK.

Mr. SALO. That might be more legitimate. So just sort of doing a blanket "you cannot do any of this" may not work.

But under the current system, if a prescriber chooses to do something more, a stronger medicine for a young child, some States are putting in place things called—they have a variety of names, but prior authorization or red flags, in which the system sort of says: Wait a minute. You just dinged. You prescribed this perhaps inappropriate drug for this patient.

And then, that sets off sort of a warning at which point a couple of different things can happen. Either the physician then has to say: No, I really know what I am doing. This is the right thing.

And they push it through.

Or, you have sort of a more kind of comprehensive peer review team where the State agency or other peers will sort of give feedback back to that prescriber to say: You just did X. Are you aware that maybe Y or Z might be more appropriate?

So those kinds of things can work. I think those are key best practices. Probably easier to do those than just outright prohibitions under the current law, although, as I had mentioned earlier, you do run into challenges at the State level sometimes, trying to do those types of controls. Some State laws just outright prohibit you from doing that for a variety of reasons that I mentioned.

Senator CARPER. You say that some State laws actually prohibit—

Mr. SALO. So some State laws actually prohibit prior authorization—

Senator CARPER. Oh, really?

Mr. SALO [continuing]. For example, for atypical antipsychotics because it is the view of the State legislature that this is for a variety of reasons, whether driven by the manufacturers of the drugs who do not want people saying you should put any barriers up or whether it is just sort of a community sense that you know what, we should not have government involved in this patient-physician relationship.

So State legislative laws are not set in stone. They can be changed, but they require a different kind of tactic than some of the best practices we have been talking about here.

Senator CARPER. All right.

Dr. McClellan, any comments on this point?

Dr. MCCLELLAN. I do not know anything about the State laws other than the State of Washington. We did set up a system where if you want to prescribe an antipsychotic to a child underneath the age of six it requires a second opinion. And there is a process in place where there is a group of child psychiatrists mostly through the university. And there is a form. There is a phone call.

And sometimes they are approved, and sometimes they are not. But that process has definitely helped with high risk prescriptions, and it has reduced the use of antipsychotics in younger children.

Senator CARPER. OK. Thanks.

Does the introduction of electronic health records (EHRs) have the potential for being a valuable tool in ensuring that children at very early ages are not administered these drugs and particularly in ensuring that children at younger ages, whether they are foster kids or not, do not receive a toxic mixture of these drugs?

My mom, who is now deceased, passed away about 3 or 4 years ago, and she had Alzheimer's disease. She had heart disease, arthritis, all kinds of problems in a lot of years of her life.

With my sister in Kentucky and me in Delaware and my mom in Florida, what we did over time is we increased the around-the-clock care for her within her home.

We kept her medicines in what looked like one of my dad's old fishing tackle boxes. Some of you have probably seen these before. And it was divided into medicines before breakfast, at breakfast, between breakfast and lunch, at lunch and so forth throughout the day. We kept it under lock and key because she would forget what she had taken and what she had not.

And she had about five different, maybe six, doctors down there. About every other month, my sister and I would take turns going down to be with her, go visit her doctors and all. It turned out none of the doctors ever talked to each other, and all the doctors were prescribing these different medicines and did not know what the other doctors were prescribing.

My guess is if it happened with my mom it is probably still happening with a lot of these kids. And my sense is that we did not have electronic health records for my mom, but we ought to have them for a lot of patients today, including a lot of children.

Would you all, whoever wants to, just talk about how this can help us in this particular concern, how to address this particular concern?

Mr. SAMUELS. What I can say is that at HHS we did bring together a broad group of entities within the umbrella of HHS to look at this issue, and the Centers for Medicare and Medicaid Services (CMS) did identify electronic records as a potential solution to part of this issue so that you could in real time monitor the decisions that were being made by clinicians. It would provide a great resource.

As I indicated, in Illinois, we created a system where we had an electronic database that had all of the children in foster care who were on psychotropics. It also had what psychotropics they were on, and who was prescribing them. So it allowed us to see where there are going to be interactive effects, where there are going to be issues of that child being on multiple psychotropics from different doctors, and it also allowed us to flag doctors who were clearly exceeding what would be best practice and intervene specifically with them.

So it was a great tool for us. Electronic records represent a real resource and asset in trying to address this issue in real time.

Senator CARPER. Right.

Mr. SALO. Yes, no question. That is absolutely right. It is a key ingredient. It is not the panacea. It is not a silver bullet. It has to be a part of trying to look more holistically at how we are delivering care because you cannot just have a health record and then continue to treat behavioral health issues as completely separate from physical acute care. It is a part of that mix.

And I think one of the things that it could help resolve, one of the States that I talked to in preparing for this, one of their frustrations was in trying to build the capacity of the child welfare caseworkers and staff in this particular issue.

These are really hardworking folks, but for the most part they are college educated. They have a Bachelor of Arts (BA), a Bachelor of Science (BS) and in many cases, a Master in Social Work (MSW). But if they are put in situations where they are having to countermand decisions made by practicing physicians, PhDs, et cetera, there are identified, clear liability issues for the State staff, and so they had to back away.

If you build that kind of thing into an electronic system, you do not really have that kind of problem. So, yes.

Senator CARPER. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman.

I think there are issues. Reading the report, I really was shocked at the results, especially as it affects Massachusetts as I referenced earlier.

I look at it as there are a couple of different tiers here. One is what is the best interest of the child. In listening to the witness, the young man who spoke before us, and recognizing—I think he indicated he was on 20 different drugs at one point. It is abuse. It is child abuse. It is medical malpractice. And it is also; if you take the reason that we are here, it is the cost to the government too, the taxpayer dollars that are paying for this abuse and this malpractice.

In listening to you, Mr. Samuels, you indicated that there is no authority to kind of fix it. Well, I mean, do you want the authority to fix it? Do you want that authority?

Is it something you want us to start working on, or what?

Mr. SAMUELS. Sure. So let me be clear. I am not suggesting that we cannot go a long way in fixing the problem, and I think we have articulated some of the steps that we could take.

But clearly, yes, this is a problem that we are all concerned about, and it is something that we need to fix. And if Congress was given the opportunity or we were given the opportunity by Congress to fix this problem, we would move aggressively to do so.

Senator BROWN. That being said, Mr. Chairman, I would ask that you—Mr. Samuels—that you actually provide us with the tools that you need to do your job. If that is something that we can get to the Committee Chair, we will look at it and see if we cannot get support because, I mean, I felt heartbroken listening to the previous testimony.

And I am saying to myself: OK, now. So how does something like that happen? Where is the breakdown?

If you do not have the authority to fix it, who has the authority? Are you saying the States have the authority?

In the State of Massachusetts, I have already sent out the letter today, based on this hearing, saying how does this happen and who is responsible and how do we fix it? That is one of the things that we have always tried to do here.

So could I ask that you and whoever else would have an interest in this get this information to us?

Mr. SAMUELS. We would both put together a set of recommendations as well as work with your staff to craft a solution that this body could support and move forward.

But can I make one other point which I think is really important here?

Senator BROWN. Sure.

Mr. SAMUELS. I think it is really important to recognize in the larger child welfare context that over the last 14 years most of the energy, both in terms of Congress as well as the States, has focused on the issue of reducing the size of the foster care system. So we have focused more on trying to resolve issues of permanency and get kids home than we have focused on what is their social and emotional well-being and what contribution does the child welfare system have to make to it when it removes them from their home or validates that they have been abused or neglected.

So another strong message that this Subcommittee could send, both to the other Members as well as the broader country, is that we have an obligation to do more than just do safety and permanency. We have an obligation to affect the mental and physical well-being of children and that means addressing the exact issues that you see before because in many instances the assumption is well, if we can just get them medicated long enough and stabilize them long enough we can find a solution, move these children to that solution and then somebody else will make sure that they are OK.

And I think we have a Federal obligation to say that this is unacceptable and that all of us should be working toward their well-

being. Whether they leave the system through adoption, guardianship or they age out, we all have an obligation to work to their well-being.

Senator BROWN. In listening to the testimony and reading the reports and referencing other reports that have been done, how do you consider it in the best interest or the well-being of the child when you are basically overmedicated to the point as was referenced in our earlier testimony as being a zombie and being glassed over and having no knowledge of what is going on really and having no ability to function as a young child?

Do you even have any ability to get out of that cycle of abuse and neglect. Are you talking stabilizing, or are you talking about just overly drugging to the point where they are just vegetables and they are going to do whatever they are told?

It is basically, hey, here is another pill. Just go in the corner and shut up. Play with your Nintendo or whatever.

But at that point, they cannot even do that they are so drugged up.

So I do not disagree with you, I think it is important to get that information.

And Dr. McClellan, you are the expert here, I mean, and we obviously have Dr. Coburn who is an expert on everything apparently.

Dr. MCCLELLAN. It is a good job. [Laughter.]

Senator BROWN. That is going to cost me. That will be on the front page of something, I am sure. But all kidding aside, he is a great man and has a working knowledge of everything.

That being said, I enjoyed listening. I am bouncing back and forth because we are dealing with the defense authorization.

But in hearing his testimony, in hearing him up here speaking to Senator Collins, it is clear that the drugs were counter-productive. They were reacting to each other. No wonder Ke'onte was taking insomnia pills, sleeping medication, because the drugs that he was taking were firing him up so much.

Is there any instance at all that some child under one year old would be given the medication that is referenced in this report? Is there any instance at all that you are aware of?

Dr. MCCLELLAN. I have not looked at the actual medical records for the kids in this report.

Senator BROWN. In your experience then.

Dr. MCCLELLAN. I think before you say about any case you would have to look at it, but I cannot think of a situation where it would be indicated. I just cannot think of one.

Senator BROWN. So how do they do it? How do they get away with it?

Where is the check and balance?

Where is somebody raising a red flag and saying hey, why are you giving this 6-month-old this drug when it is absolutely not appropriate to be prescribed for it? Where are the so-called red flags?

I mean, is it a State-by-State issue? Is that the problem, that there is a complete lack of the ability for us to go in and monitor that stuff?

I am still trying to zero in on where there is the breakdown, and I will take an answer from anybody.

Dr. MCCLELLAN. I cannot speak from a policy standpoint. I mean oftentimes pharmacies—physicians sometimes just write—

Senator BROWN. Where is the doctor's responsibility? Where is the doctor's responsibility to say hey, this is not right?

Dr. MCCLELLAN. Oh, I agree with that, but at some level the oversight has to then pick up on for clinicians, and it is either doctors or nurse practitioners who are writing the prescriptions.

I mean, again, the number of prescriptions that were for babies for psychotropics other than antihistamines were very small. So you are talking a very small number of prescribers compared to all the other work that was done.

Senator BROWN. Right.

Dr. MCCLELLAN. There are outliers in every field, and there does need to be some checks and balances to pick up when someone is just not doing their job very well.

Senator BROWN. Mr. Salo, I think you wanted to jump in.

Mr. SALO. Yes. I would just add that I think there are a lot of breakdowns, and some of it is in medical practice. There are certain things you just should not be doing.

And some of it is in failure on our part as States or as HHS to red-flag it and to catch it and to stop it. There are reasons why there are different practices out there. But we need to do better, clearly.

And I would just make one final point, that clearly we need to do better for these kids, but this is a problem throughout the system too.

Senator BROWN. Oh, yes.

Mr. SALO. And let's keep that in mind.

Senator BROWN. Yes, I know. Well, we are focused on the kids right now, but I do not disagree with you.

What I would hope, Mr. Chairman, is that certainly, my staff would be ready whenever you are ready, but I would hope that we could get the guidance from our witnesses to let us know what we can do. OK, we have identified it. Now where do we go from here?

As you have said, we need to learn—I am paraphrasing—we need to learn how to do it better, and I do not disagree on this issue.

So Mr. Chairman, I mentioned I am back and forth. I have to get down on the floor and work on some issues

Senator CARPER. Sure.

Senator BROWN [continuing]. Affecting our soldiers.

Senator CARPER. Good luck.

Senator BROWN. So thank you all for your testimony.

Senator CARPER. Yes, thanks very much for being here today.

One of the things that witnesses before us hear almost every time we have a hearing is I mention one of my core values—if it is not perfect, make it better. And I think that certainly applies here too today. Obviously, this is not a perfect situation. I do not know that we ever can make it perfect, but we sure can make it better.

What do we need to do as members of the Senate and members of the Congress, members of the Legislative Branch? What do we need to do to make this better, Mr. Kutz.

Mr. KUTZ. We have talked about reimbursement, and what Senator Brown was saying is this is all paid for by the Federal Government and State governments. Medicaid is matching, mostly Federal in some cases, otherwise, 50–50.

But the issue of whether in some cases the government should reimburse legally under current law is one we are looking. We are still looking to get answers from HHS about drugs that are not FDA-approved and in these drug compendia, et cetera. What is the legal authority right now that the government is reimbursing those drugs?

And then we have heard here some of these other high risk practices. Should there be some restrictions of whether the Federal Government reimburses for infants getting these drugs, or 5 or more, 10 or more or whatever the case may be?

So I think reimbursements. As you have mentioned at the beginning of the hearing, we are talking about taxpayer dollars here. Is there something better that can be done to help taxpayer dollars and protect the children at the same time?

Senator CARPER. Thank you. Mr. Samuels.

Mr. SAMUELS. I would rattle off two or three issues that I think are really important.

The first one that I would really push hard for is the recognition that we need to build capacity to provide therapeutic interventions, that there simply are not enough clinicians and not enough clinicians trained in effective interventions to really meet the needs of these children, and so we have to build capacity in this area.

We certainly would support that. We have put some ideas forward. We would be glad to continue to talk to you about that issue.

The second one that I would really recommend is even if we cannot have an electronic record system that allows us to look at this more closely in the immediate future I think that there are probably opportunities for us to look more closely at the Medicaid data from a national perspective. Most of the reports that you see, including the GAO report, are based on Medicaid data. However, the data does not allow us to differentiate foster children from other children in a way that allows us to see patterns that are troubling and concerning.

And so, instead, what we do is rely on academic researchers or the good work of folks at the GAO to go look at this data and then come back and tell us something. We ought to have a national overarching ability to know who is doing what in prescribing psychotropics for kids in foster care.

And then, the last point that I would make is that—in my earlier comments and echoed by Senator Coburn—much of the challenges that young people in foster care have are related to behavioral issues that they need help on. And instead of recognizing issues of trauma we are overdiagnosing children with mental illness, and we ought to build the capacity in child welfare to be able to differentiate children who are expressing traumatic symptoms because of stuff that has happened to them versus children that are showing symptoms of a mental illness. If we can make those separations, then we can reduce the use of psychotropics and target effective interventions for the children who would benefit most.

Senator CARPER. OK. That was a very good summation. Mr. Salo.

Mr. SALO. Yes, I would agree with that last point wholeheartedly, and I think just a couple of other things.

The easy thing to do is just to continue to use the bully pulpit and to shine through the use of the GAO and others.

Senator CARPER. Through hearings?

Mr. SALO. Through hearings and just shine light on little-known problems like this.

I think there is also clearly a role for helping build capacity, not just for electronic health records and HIT, building capacity for the research, the clinical research that is out there, so we know so little about how these drugs interact with each other and how they work with kids in general, and we know very little about how the unique challenges faced by kids in foster care interact with all those.

And then, I think the last piece is just continue to demand accountability. I think that is certainly something that we are talking a lot about with Medicaid. Medicaid is a very process-driven system, and in many ways Medicaid is less of an entitlement to the beneficiary than it is an entitlement to streams of revenue for a bunch of different providers.

And I think there is a way to kind of think more holistically about how we use Medicaid, not just to reimburse for things but to drive better health outcomes, and I think that is an ongoing conversation we would love to have with you.

Senator CARPER. OK. Good.

Dr. McClellan, how do we make it perfect? How do we make it better, if not perfect?

Dr. MCCLELLAN. Yes, I will have to send you that in writing, I think. I mean it is a very complicated system. I agree with what has been said.

I go back to your point about figure out what works and do more of it. We actually know a lot of psychosocial interventions that are effective for treating trauma problems and treating behavior problems. And yet, most kids cannot access them, and many of the people who are out there providing do not use them. And the system has to be more reinforcing for those that do and urging those that do not to change their ways.

Senator CARPER. All right. Good. Thank you all for your responses. I appreciate that.

I have one more question. I am going to read it. I am not going to ask you to answer, but I will ask you to answer it for the record, and we will follow up in writing on this.

In the testimony today from GAO, they reported that the State of Maryland did not have reliable data for its foster children, I believe, in 2008. I am told that this is why we only had five States examined and not six.

I am also told that the data that the GAO received from Maryland was—I think this is a quote—“materially different” than the data that Maryland provided to Health and Human Services. I find that troubling, and the fact that they do not have a good accounting for the children under their care.

I am going to ask Mr. Samuels and Mr. Salo to respond for the record. And basically, we will be asking you were you aware that Maryland could not account for all of its foster children apparently

in its records in 2008, and we will ask if you are aware of any other States that have similar difficulty in accurately maintaining data for foster children under their care.

And finally, we will ask, does this lack of accountability by a State have adverse effect on its foster care and Medicaid Federal grant funds?

So those will be for the record. There will be some other questions, I expect, for the record from me and my guess, from others as well.

Let me ask John Collins who has done a lot of work on this hearing. John, how long do our colleagues on the Subcommittee have to submit questions?

Mr. COLLINS. Two weeks.

Senator CARPER. Two weeks. So we will get our questions in to you within two weeks. We just ask that you respond promptly.

I will close just by saying this; I mentioned this to Ke'onte when I slipped outside to say goodbye to him, and his mom, and dad, after he had a bite to eat. We talked a little bit about Christmas coming up.

And I said to him at Christmas time a lot of us, especially young kids—I remember when we were all kids, especially when I was a kid—we really look forward to what we are going to get. And it was a source of great joy to go down on Christmas morning and find out what was under the tree for us, my sister and me.

But I have learned over time that the real source of joy is not what we get but what we give, and that is a valuable lesson that hopefully all of us learn somewhere along the line, hopefully, sooner rather than later.

I also learned along the way that in adversity lies opportunity. These kids, these foster kids especially, have gone through a lot of adversity in their lives, and there is also some opportunity here. The opportunity we have is to use really the gift of Ke'onte's testimony, and yours, and the good will of, I think, a lot of us to be able to help a whole bunch of kids to end up having a better—not just a better childhood but a better life and a more productive life. And that is a gift for us to give back to others.

I am one of those people who have these core values. One of them is to figure out is there a better way to do everything. How do we get a better result?

But I do not give up on stuff. When I can see that there is a wrong that needs to be righted, I just do not give up. I am pretty persistent. With that in mind, we are going to stay on this one, and we invite all of you to stay on it with us.

We did not invite anyone today to come from the pharmaceutical industry. I think a conversation with the representatives from the pharmaceutical industry and from the pharmacies, pharmacists themselves, probably would be helpful. If we really want to help a bunch of kids, we will be reaching out to them and asking them to meet with us, probably not in a hearing—maybe—but probably at least to have a good conversation and feel how they can be part of the solution here as well.

Again, my thanks to each of you for sharing your time, especially to our friends from GAO and those who work with you on your

study. We are deeply grateful for the work that you have done here as well as in so many other areas.

With that having been said, this hearing is adjourned. Thank you all. God bless.

[Whereupon, at approximately 12:34 p.m., the hearing was adjourned.]

APPENDIX



FOR RELEASE: Dec. 1, 2011
CONTACT: Emily Spain (202) 224-2441 or emily_spain@carper.senate.gov

**U.S. SENATE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION,
FEDERAL SERVICES, AND INTERNATIONAL SECURITY**

HEARING: "The Financial and Societal Costs of Medicating America's Foster Children"

Opening Statement of Senator Tom Carper, Chairman
As prepared for delivery

Over the past few years, this subcommittee has been focused almost exclusively on how our federal government can achieve better results for less money. Among other things, we've examined cost overruns in major weapons systems and overpayments for additional spare parts at the Department of Defense that we don't need.

We've focused on how we manage our federal property, on bloated information technology projects that waste millions of dollars, and – most notably for today's hearing – on how we spend taxpayer dollars on prescription medications in our nation's public healthcare system. In fact, today marks the third in a series of hearings over the past several years examining this particular topic.

Nearly two years ago, our subcommittee asked the Government Accountability Office (GAO) to look into the potentially improper prescribing of mind-altering medications, also known as psychotropic drugs, for children in foster care whose health care is paid for through Medicaid and managed by the states.

We learned through various media reports and medical articles that many foster children may have been receiving these medications at alarming and potentially dangerous rates. If these reports were true, not only were tax dollars being wasted on these medications but, more importantly, the health and well-being of these children was very likely in danger.

We wanted an independent, government audit from the GAO. In asking them to look at this issue, we wanted to know if over-prescribing, or improper prescribing, of these powerful mind-altering medications was occurring and, if it was, how prevalent was it and what were the costs? The report we are releasing today confirms some of our worst fears.

GAO's findings reveal that foster children in the five states that were examined are receiving mind-altering medications at between 2 and 4 1/2 times the rate of other children under Medicaid. In 2008, the five states combined spent over \$59 million on mind-altering medications for foster children. Beyond these rates, the GAO found three alarming patterns in their data.

First, thousands of children were prescribed mind-altering medications in excess of the maximum doses for the child's age as recommended by the FDA and medical literature. Furthermore, for the medications for which there is no FDA recommended dosage for their age, the GAO found a number of children receiving dosages beyond those even recommended for adults.



Second, more than 600 foster children in the five states were found to be receiving five or more mind-altering medications at the same time. According to medical experts, one of whom is with us as a witness today, there's no evidence supporting the use of five or more mind-altering medications in adults let alone children. In fact, I'm told there's only limited evidence that supports the use of even two mind-alerting medications being prescribed to a child at the same time.

Finally, and perhaps most disturbingly, dozens of foster care children under one year of age in these five states, and over 3,500 non-foster children in those states, were prescribed a mind-altering medication. According to medical experts, there are no established mental health uses for mind-altering medications in infants, and providing them these drugs can result in serious health effects for them over both the near term and long term.

We look forward to hearing more about the GAO's findings today. Greg Kutz from GAO has joined us to discuss them. He's appeared before this subcommittee many times before, and we welcome him back today.

Along with him is Dr. Jack McClellan from Seattle Children's Hospital. He is one of the medical experts hired by GAO to review their report. Mr. Bryan Samuels is here from the Department of Health and Human Services to give us the Federal government's view, while Mr. Matt Salo, is here on behalf of the State Medicaid Directors.

I'm probably most interested, however, to hear from our first witness today – Mr. Ke'onte Cook, who joins us all the way from McKinney, Texas. Mr. Cook is here with his Mom and Dad. I was fortunate to spend some time with all of them earlier this morning. I look forward to hearing a little more about him and his experiences in a few minutes. I also hope that today's hearing, and what comes from it, will end up helping kids like him from all across our country.

In anticipation of today's hearing, the Department of Health and Human Services sent a letter last week to all 50 states regarding the proper use and monitoring of mind-altering medications for children in the foster care system. The letter promises that the Department will convene a meeting of all 50 states in the next few months to discuss this issue.

It's my hope that the Department's letter also serves as a signal to states that more detailed guidance is coming, guidance that reflects best practices from states across the country with regard to the use of mind-altering medications to treat children.

It's also my hope that this letter will lead to solutions, solutions that will help to improve the health and welfare of some of our nation's most vulnerable children – foster kids – while also saving taxpayers' dollars, too.

I believe there's plenty of blame to go around in this report. Unfortunately, it appears the federal government, state and local governments, doctors, nurses and perhaps others, haven't kept up with the increased frequency with which mind-altering medications have been prescribed over the past decade.

There also appears to be a lack of cooperation between Health and Human Services and the state Medicaid programs throughout the country concerning this issue. States have worked out piecemeal solutions based on their own experiences and, frankly, in at least some cases, those solutions were not arrived at until after young lives were damaged or lost.



As I mentioned and as we'll hear in testimony today, the children discussed in GAO's report are some of the some of the most vulnerable members of our society. It's our responsibility to take up their cause. As a former governor, I know that the foster care system is complex. But that complexity is no excuse for not dealing with this issue head on. We all have a responsibility to ensure that the Medicaid program works for all the children that it serves, whether they're in foster care or not.

I oftentimes describe the 50 states as laboratories of democracy. What this report reveals is that some states are managing their programs better than others. There are best practices in use in some states that really do work in helping foster children. Every state should be adopting them or tailoring them for adoption. In addition, the American Academy of Child and Adolescent Psychiatry has promulgated some very good guidelines, which both the GAO and others cite. If they're not already doing so, more states should be following them. What we can't do is wait for another tragedy to happen before we make the right decisions. We can't stand idly by while children's lives or health are potentially put into danger.

Now, to be clear, it's important to realize that these drugs we'll be talking about this morning are often used in dire and even tragic situations. In most cases they're prescribed as intended and used in an appropriate manner to help children who have experienced significant trauma in their lives. In these cases, there is no doubt about their value.

What is in doubt are the patterns and practices identified in the GAO's testimony today. What is in doubt is the effectiveness and necessity of having children take 5 or more mind-altering medications at the same time, or an infant being given an anti-psychotic medication. In these cases, I don't see any grey areas. What I see is more black and white: what is appropriate and humane - and what is not.

We need to begin the process now of developing a consensus about what is appropriate and humane when it comes to the prescribing of mind-altering medications to children and end the bad practices that are putting children in danger. We need to act quickly before one more child's life or health is placed in jeopardy or before one more taxpayer dollar is spent inappropriately.

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STATEMENT OF SENATOR SCOTT BROWN, RANKING MEMBER**SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES AND
INTERNATIONAL SECURITY****COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL
AFFAIRS****“The Financial and Societal Costs of Medicating America’s Foster Children”****December 1, 2011**

Senator Carper, thank you for holding this important hearing today.

Foster children, often being removed from neglectful or abusive homes, are one of the country’s most vulnerable populations. With the often traumatic circumstances that define their early lives, it is no wonder studies show their tendency for more mental health conditions than other children. Facing these and other significant challenges surrounding foster care programs, state authorities, caseworkers, and parents, are given few options on appropriate treatments. As our witnesses will discuss today, these options often include prescribing heavy-duty psychotropic drugs such as antidepressants and, in some cases, even antipsychotics – drugs which have little research available supporting their use in children.

While the use of psychotropic medications has been shown to effectively treat mental disorders, the side-effects and risks they pose, specifically to children, are not well understood. This is why we asked GAO to look into this issue more closely and their investigation has produced some alarming results. Not only are foster children being prescribed psychotropic drugs at a higher rate than non-foster kids in general, but also in ways that hold significantly higher risks, such as multiple medications at once or in amounts exceeding FDA recommendations. In Massachusetts, nearly 40% of the foster children population analyzed in the report was prescribed at least one psychotropic drug -- a rate almost four times that of non-foster children. In over 900 cases in Massachusetts, foster children were being prescribed three or more drugs at once. While the scope of the report does not address the appropriateness of these

prescriptions on a case-by-case basis, it does reignite the debate over whether the rates of prescribing match the scientific evidence behind these medical conditions.

Regrettably, the concerns raised in the report are not just limited to foster children. Though high-risk prescribing practices for foster children were found at higher rates than non-foster children in most cases, the significantly larger population of non-foster children covered by Medicaid makes these statistics just as alarming. For instance, thousands of prescriptions -- a total of 5,265 according to the report -- were filled for infants under one year old. This is just the data from five states! In Massachusetts 49 infants were found to have been prescribed psychotropics, in some cases even antipsychotics. Though 49 is a small number compared to the total, one child infant found on these drugs should invite serious scrutiny considering that experts have found NO mental health indications for the use of psychotropic drugs in infants. As our witnesses will testify today, providing these powerful drugs to infants could result in serious adverse effects and the potential risks are simply too great.

Medicaid, which is run by states and administered by the Department of Health and Human Services, provides prescription drug coverage to foster children. As of today, HHS has limited authority to adequately oversee state monitoring programs for youths in state custody. As a result, states' comprehensive oversight policies are a mishmash of programs in various stages of maturity. Although HHS provides informational resources such as "best practices" to help inform state monitoring programs for children in state custody, each state is responsible for designing and implementing its own program. As GAO has examined with the five states it reviewed, many times these programs fall short of providing the comprehensive oversight that is desperately needed.

It is obvious that consistent and comprehensive guidelines in this area are necessary to more effectively treat and reduce harmful risks to children in the Medicaid program, and particularly foster children. In addition, better oversight in this area can have a broader impact in reducing fraud, waste, and abuse in Medicaid in general. I encourage HHS to rapidly endorse guidance on best practices and use its current authority to push state Medicaid and child welfare agencies to improve these programs as quickly as possible. The government has been charged to protect these children and it is not acceptable to fail them any further.

I thank the witnesses for their attendance today and look forward to a helpful discussion on how we can prevent just that. Thank you Mr. Chairman.

**Statement by Senator Chuck Grassley
November 29, 2011**

Mr. Chairman,

I appreciate being able submit a statement in support of today's hearing to discuss the use of psychotropic drugs and the over-prescription of these drugs on youth in our foster care system. Today's discussion is a good first step in finding ways to better monitor how psychotropic drugs are being prescribed to foster children, and thus, improve outcomes for this disadvantaged, neglected, and vulnerable population.

As a co-founder and co-chairman of the Senate Foster Care Caucus, I have taken a keen interest in improving ways to help children who enter the system and expedite their route to a better, more permanent family placement. Foster youth have had to endure hardships on their way into the system, and it's just not right that once placed in foster care, that they then face additional challenges, such as over-use and various side effects that come with psychotropic drugs. I have worked to make improvements to the foster care system and to make it easier for children in foster care to be adopted into permanent, loving homes, including the Fostering Connections to Success and Increasing Adoptions Act of 2008. This law requires states to strengthen oversight of medical treatment and ensure that foster children receive high-quality, coordinated services when their placement changes.

My colleagues and I asked the Government Accountability Office to compare the amount of psychotropic drugs prescribed to foster care children versus non-foster care children. The GAO studied five states, and the children in these states who were on Medicaid in 2008. The report, which will soon be finalized, is startling. You will hear testimony from GAO that will show that foster children were prescribed psychotropic drugs over two to four times higher than non-foster children. The GAO cites three main reasons for these higher rates, including greater exposure to trauma before entering state care; frequent changes in foster placements; and varying state oversight policies. Children in the foster system are about as vulnerable as children can be, so more should be known about the degree to which foster children are given psychotropic drugs and the rationale for doing so, especially given the dramatic findings of this report.

The preliminary work of the GAO shows that some foster youth have been prescribed five or more concomitant psychotropic drug prescriptions, and that some doses exceed maximum levels in FDA-approved drug labels. The GAO will also report that many infants under one year old have been prescribed psychotropic prescriptions. Unfortunately, this GAO report will not get into detail about each foster youth case, so I look forward to the follow-up report that will go into greater detail about specific and high-risk cases.

I am glad to have been an original requester of this report, and agree that we must do more to better track the prescription of psychotropic drugs to foster youth. The Department of Health and Human Services must better work with states, provide guidance and develop best practices

so that there's better oversight of psychotropic prescriptions. Prescribing patterns and adverse effects need to be tracked for the well-being and protection of these children. An environment needs to be established where there's accountability for the degree to which these drugs are used in order to make sure it's not just for convenience and at the children's expense. There's also a public interest in making certain Medicaid isn't being abused through over prescribing. We must consider ways to ensure that caregivers who are responsible for foster children are better educated and are administering psychotropic drugs appropriately. Physicians have a responsibility to make sure that these drugs are not being overprescribed, and then to monitor the side effects in children. Moreover, through the Physician Payments Sunshine Act, which was implemented through health care reform, we will be able to see if the physicians prescribing these medications have any improper relationships with the manufacturers of these products. So, we must act as soon as possible and continue a discussion on this topic even after we leave the hearing.

Again, thank you for allowing me to voice my thoughts on this matter with the committee. It's extremely important that we do all we can to protect America's most vulnerable children. I am committed to improving the process so that foster youth can live stable and healthy lives, and are not burdened with issues that come with wrongful prescribing patterns of psychotropic drugs.

MARY L. LANDRIEU
LOUISIANA

United States Senate

WASHINGTON, DC 20510-1804

December 1, 2011

<p>The Honorable Thomas Carper Subcommittee on Federal Financial Management Senate Homeland Security Committee Hart Senate Office Building, Room 432 Washington, D.C. 20510</p>	<p>The Honorable Scott Brown Subcommittee on Federal Financial Management Senate Homeland Security Committee Hart Senate Office Building, Room 439 Washington, D.C. 20510</p>
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Dear Chairman Carper and Ranking Member Brown,

As Co-Chair of the Congressional Caucus on Foster Youth, I want to commend the Senate Homeland Security Subcommittee on Federal Financial Management for holding today's hearing, which highlights the Government Accountability Office's (GAO) recent report on psychotropic drugs prescriptions for children in foster care. I look forward to the testimonies of the expert witnesses and learning more about the details of GAO's investigation. I appreciate your dedication to our country's youngest and most vulnerable residents

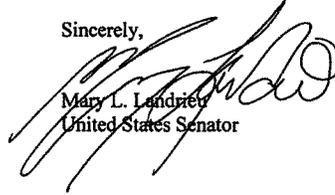
As you know, many states lack efficient records management and adequate oversight of foster care, contributing to a pervasive lack of medical continuity for foster children. Foster children are often shunted between families and prescribed anti-psychotics from doctors unfamiliar with their medical histories. Without a case history, experts and foster care alumni say doctors are more likely to add medications than to reduce them. The GAO report verifies that foster children are more often victims of potentially dangerous and improper prescribing practices, taking psychotropic drugs at a rate "two to over four times higher" than non-foster children in Medicaid. Though children who enter the foster care system are more likely to have significant health concerns, psychotropic drugs are being used as a first line of treatment for foster children who exhibit any signs of behavioral instability—a practice that is careless and unacceptable.

Until now, statistics on psychotropic drugs in foster care have only been available in scattered reports, mostly from investigations of foster care failures by individual states. The GAO report marks the first independent, federal government audit of the rates and costs of psychotropic drug prescribing for children in foster care. Its findings shed light on our government's urgent need to allow foster children greater access to their medical files in order to curb instances of over-medication. I am hopeful that today's hearing and the GAO report will spur states to strengthen their oversight and control over the effective management of psychotropic medications prescribed to youth in foster care.

Again, thank you for holding this important hearing. I look forward to continuing our work together to protect the millions of children around the world who lack stable, loving, and permanent homes. I welcome the opportunity to be a resource to you as you strive to serve the vulnerable children in our country.

With warmest regards, I am

Sincerely,



Mary L. Landrieu
United States Senator

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee, thank you for allowing me to share part of my life with you today and my experiences with medications during foster care.

My name is Ke'onte Cook. I am twelve years old and in the 7th grade. This year, I participated in cross-country with my middle school in which I ranked the top 15 of my class allowing me to go to regionals. I am currently first chair for clarinets in my band, and I have 3 small roles in my school play, *Cinderella*, that will show this month on December 15th, also the date for my 2-year anniversary in my adoptive home. One of my favorite things to do is dance for fun, especially hip-hop and popping.

I was adopted 2 years ago 2009, and I was in foster care from ages 6 to 10 1/2. Besides the medicines, foster care was alright to me except for my 3rd foster home. The first 2 homes seemed more like they cared about me, but the 3rd home always felt awkward, and I felt pressured by them when I chose my adoptive home.

I was pretty ignorant about the medicines I was on at that time. I also didn't know what type of drugs I was on during foster care or how many drugs I was on since I was put into foster care at age 6. All I knew was that if I didn't take them like I was told to, I couldn't watch TV, play video games or play with my toys. About a year after I was adopted, I found out I was on about 20 different drugs total! And sometimes, I took up to 5 drugs at one time.

At one point, I was on Vyvanse 70mg for ADHD, Seroquel 200mg as a mood stabilizer, Guanfacine 2mg for impulse control and ADHD, Buspar for depression, Clonidine 0.2mg for insomnia. I've also been told that the amounts of some of the drugs I was given were more than most adults take.

Some of the things I was diagnosed with were Post Traumatic Stress Disorder, Insomnia, ADHD, depression, but I was never told I was diagnosed with anything other than the ADHD. They seem way too much for a regular kid, which I am, and I was very confused when my adoptive parents told me what I was on and why.

I have been in the mental hospital 3 times during foster care, and every time, I would get on more meds or new meds to add to the ones I was already taking.

Some of the meds were for bipolar and seizures, and I'm not bipolar and have never had a seizure. Sometimes, the meds they gave me made me easy to get irritated, which I feel is not good for a kid to experience. The meds made my appetite go away, too, for a long time. I would barely eat anything. I remember having a bowl of spaghetti, and I ate about 3 bites when I was done. I had side effects no one told me I would have or talked with me about before taking a new med. I was so out of it when I had the side effects sometimes that it seemed like it didn't bother me at all.

One time when I went to visit my youngest sister in her adoptive home, her mom told me that she didn't want to give me my medicines because it made me glazed and tired. My adoptive parents said that when I stayed for my trial weekend with them in October 2009, my meds put me in a lights-out mode 15 minutes after I'd taken them. Some of the meds I took made me have stomach aches. I would get so tired all of a sudden. It felt like I would collapse where ever I was in the house. My foster parents would tell me something, and I wouldn't be able to process it like a normal person would. Sometimes, I'd even try turning my head away and closing my mouth to refuse taking the meds. But I had to take them eventually.

I think putting me on all of these stupid meds was the most idiotic thing I experienced in foster care, and the worst thing someone could do to foster kids. I was upset about my situation, not bipolar or ADHD.

And, I think therapy is a better choice over meds if meds are not a necessity in that moment. And I should know because I went to therapy with my adoptive parents for 1 1/2 years with Dr. Jason Mischalanie, an attachment therapist, who helped me understand why I acted the ways I did and to figure out how to react in a better way to things that upset me rather than the way I was doing them. Now, I'm not only more focused in school, succeeding above other classmates in reading, band, athletics, not going to the office anymore for bad behaviors, and I'm happy.

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee, thank you for inviting me to Washington, DC today to tell my story.

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Federal Financial Management,
Government Information, Federal Services, and
International Security, Committee on Homeland Security
and Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 10:30 a.m. EST
Thursday, December 1, 2011

FOSTER CHILDREN

**HHS Guidance Could Help
States Improve Oversight of
Psychotropic Prescriptions**

Statement of Gregory D. Kutz, Director
Forensic Audits and Investigative Service



GAO-12-270T



Highlights of GAO-12-270T, a testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

Foster children have often been removed from abusive or neglectful homes and tend to have more mental health conditions than other children. Treatment may include psychotropic drugs but their risks to children are not well understood. Medicaid, administered by states and overseen by the Department of Health and Human Services (HHS), provides prescription drug coverage to foster children.

This testimony examines (1) rates of psychotropic prescriptions for foster and nonfoster children in 2008 and (2) state oversight of psychotropic prescriptions for foster children through October 2011. GAO selected Florida, Maryland, Massachusetts, Michigan, Oregon, and Texas primarily based on their geographic diversity and size of the foster care population. Results cannot be generalized to other states. In addition, GAO analyzed Medicaid fee-for-service and foster care data from selected states for 2008, the most recent year of prescription data available at the start of the audit. Maryland's 2008 foster care data was unreliable. GAO also used expert child psychiatrists to provide a clinical perspective on its methodology and analysis, reviewed regulations and state policies, and interviewed federal and state officials.

What GAO Recommends

In our draft report, GAO recommended that HHS consider endorsing guidance for states on best practices for overseeing psychotropic prescriptions for foster children. HHS agreed with our recommendation. Agency comments will be incorporated and addressed in a written report that will be issued in December 2011.

View GAO-12-270T or key components. For more information, contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov.

December 2011

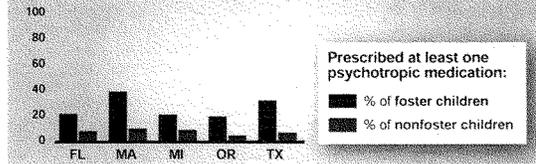
FOSTER CHILDREN

HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions

What GAO Found

Foster children in the five states GAO analyzed were prescribed psychotropic drugs at higher rates than nonfoster children in Medicaid during 2008, which according to research, experts consulted, and certain federal and state officials, could be due in part to foster children's greater mental health needs, greater exposure to traumatic experiences and the challenges of coordinating their medical care. However, prescriptions to foster children in these states were also more likely to have indicators of potential health risks. According to GAO's experts, no evidence supports the concomitant use of five or more psychotropic drugs in adults or children, yet hundreds of both foster and nonfoster children in the five states had such a drug regimen. Similarly, thousands of foster and nonfoster children were prescribed doses higher than the maximum levels cited in guidelines developed by Texas based on FDA-approved labels, which GAO's experts said increases the risk of adverse side effects and does not typically increase the efficacy of the drugs to any significant extent. Further, foster and nonfoster children under 1 year old were prescribed psychotropic drugs, which GAO's experts said have no established use for mental health conditions in infants; providing them these drugs could result in serious adverse effects.

Psychotropic Prescription Rates for Foster and Nonfoster Children Age 0-17 in Medicaid Fee-for-Service in Five States



Source: GAO analysis of state Medicaid and foster care data.

Selected states' monitoring programs for psychotropic drugs provided to foster children fall short of best principle guidelines published by the American Academy of Child and Adolescent Psychiatry (AACAP). The guidelines, which states are not required to follow, cover four categories.

- Consent: Each state has some practices consistent with AACAP consent guidelines, such as identifying caregivers empowered to give consent.
- Oversight: Each state has procedures consistent with some but not all oversight guidelines, which include monitoring rates of prescriptions.
- Consultation: Five states have implemented some but not all guidelines, which include providing consultations by child psychiatrists by request.
- Information: Four states have created websites about psychotropic drugs for clinicians, foster parents, and other caregivers.

This variation is expected because states set their own guidelines. HHS has not endorsed specific measures for state oversight of psychotropic prescriptions for foster children. HHS-endorsed guidance could help close gaps in oversight of psychotropic prescriptions and increase protections for these vulnerable children.

United States Government Accountability Office

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee:

Thank you for the opportunity to discuss psychotropic drug prescriptions provided to foster children under state care. Children placed in foster care are among our nation's most vulnerable populations. Often having been removed from abusive or neglectful homes, they tend to have more numerous and serious medical and mental health conditions than do other children.¹ Treatment of mental illness may include prescribing psychotropic drugs, such as antidepressants and antipsychotics. Because foster children are under state care they typically receive prescription drugs and other medical services through Medicaid, a joint federal-state program that finances health care coverage for certain low-income populations.²

This testimony discusses, for selected states, (1) rates of psychotropic drug prescriptions for foster children compared with nonfoster children covered by Medicaid in 2008, including indicators of health risks, and (2) federal and state oversight policies as of October 2011 for psychotropic drugs prescribed to foster children. We have received comments on a draft of the report this testimony is based on from the Department of Health and Human Services (HHS) and relevant state agencies. We plan to incorporate their comments into the report that we will issue in December 2011. We contracted with two child psychiatrists with clinical and research expertise in the use of psychotropic drugs in children to provide a clinical perspective on our methodology and data analysis. To compare rates of psychotropic drug prescriptions, we reviewed calendar year 2008 fee-for-service prescription claims and foster care data for

¹GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*. GAO-09-26, (Washington, D.C.: February 6, 2009).

²Medicaid programs vary from state to state.

Florida, Maryland, Massachusetts, Michigan, Oregon, and Texas.^{3,4} At the start of our audit, 2008 data were the most recent calendar year prescription claims data available from the Centers for Medicare & Medicaid Services (CMS). These states were selected primarily for geographic diversity and the size of their foster care populations. However, we then excluded Maryland from our analysis due to the unreliability of their foster care data.⁵ To identify potential health risk indicators, we consulted with our experts, performed literature searches, and reviewed state guidelines. The final indicators of potential health risks were: concomitant prescriptions of five or more drugs, prescriptions exceeding dosage guidelines in the Psychotropic Medication Utilization Parameters for Texas Foster Children based on Food and Drug Administration (FDA) approved labels, and psychotropic prescriptions to children under 1 year old. In addition, we evaluated gaps of 7 to 29 days in prescriptions of a drug to identify nonadherence to drug regimens, which can pose significant risks to a patient.

To determine federal and state oversight policies, we interviewed officials from CMS, the Administration for Children and Families (ACF), and the six selected states' Medicaid and foster care agencies. We also reviewed policies and regulations related to the prescribing of psychotropic drugs to foster children. Based on a literature review and discussions with officials

³Some states' prescription drugs are covered by Medicaid managed care plans in which drug payments are included in the capitated payments that plans receive from states. For this review, we selected states that cover psychotropic medications largely under fee-for-service programs so that individual drug claims could be analyzed. In Michigan, Oregon, and Texas, psychotropic medications were primarily paid on a fee-for-service basis. In Florida and Massachusetts, psychotropic prescription claims for most foster children were paid on a fee-for-service basis, with the remaining children largely covered by managed care. In these states, since we examined only fee-for-service data, we were more likely to identify psychotropic prescriptions to foster children during calendar year 2008 than to nonfoster children.

⁴In addition, the Medicaid prescription claims data do not include diagnosis codes, and therefore, we cannot be sure that all the drugs in our analysis were prescribed for mental health purposes.

⁵We performed data checks to determine the reliability of the MSIS prescription claims data provided by CMS, state Medicaid files provided by Medicaid agencies in the six selected states, databases of children in foster care provided by child welfare agencies in the six selected states, and Thomson Reuters Redbook. While a small number of Medicaid and foster care records may contain inaccurate personal data or prescription information likely resulting from data entry errors, based on our discussions with agency officials and our own testing, we concluded that the data elements in five of the six states used for this report were sufficiently reliable to address our audit objectives.

from HHS, we selected the American Academy of Child and Adolescent Psychiatry's (AACAP) guidelines as a basis for assessing the extent to which selected states were implementing recommended practices.⁶

We performed this audit from February 2010 through November 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Our full scope and detailed methodology will be provided in our report that will be issued in December 2011.

Background

Foster care begins when a child is removed from his or her parents or guardians and placed under the responsibility of a state child welfare agency. Removal from the home can occur because of physical abuse or neglect. It can also occur when a child's own behavior or condition is beyond the control of his or her family or poses a threat to their community. Foster care may be provided by a family member, caregivers previously unknown to the child, or a group home or institution. Ideally, foster care is an intermediate step towards a permanent family home. When reuniting the child with his or her parents or guardian is not in the child's best interest, caseworkers seek a new permanent home for the child, such as an adoptive home or guardianship. However, some children remain in foster care until they reach adulthood. As we have previously reported, children in foster care exhibit more numerous and serious medical conditions, including mental health conditions, than do other children.⁷

States are responsible for administering their Medicaid and foster care programs; the programs are overseen at the federal level by HHS through CMS and ACF, respectively. HHS may issue regulations, provide guidance on some issues, or simply provide informational resources for

⁶ AACAP guidelines are available at http://www.aacap.org/galleries/PracticeInformation/FosterCare_BestPrinciples_FINAL.pdf

⁷ GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*, GAO-09-26 (Washington, D.C.: Feb 6, 2009).

states to consider for their programs, the latter being the case for psychotropic drugs provided to children in state custody. Among these resources are best principles developed by AACAP, a nonprofit professional association. While HHS does not require states to follow these guidelines, AACAP developed them as a model to help inform state monitoring programs for youth in state custody. AACAP guidelines point out that, "as a result of several highly publicized cases of questionable inappropriate prescribing, treating youth in state custody with psychopharmacological agents has come under increasingly intense scrutiny," leading to state implementation of consent, authorization, and monitoring procedures. More recently, Congress passed the Child and Family Services Improvement and Innovation Act in September 2011, requiring states that apply for certain federal child welfare grants to establish protocols for the appropriate use and monitoring of psychotropic drugs prescribed to foster children.⁸

The use of psychotropic drugs has been shown to effectively treat mental disorders, such as attention deficit hyperactivity disorder (ADHD), bipolar disorder, depression and schizophrenia. While many psychotropic drugs that have been approved by the FDA as safe and effective in adults have not been similarly approved for children of all ages, prescribing them to children is legal and common medical practice in many instances. According to the National Institute of Mental Health (NIMH), some children with severe mental health conditions would suffer serious consequences without such medication.⁹ However, psychotropic drugs can also have serious side effects in adults, including irreversible movement disorders, seizures, and an increased risk for diabetes over the long term. Further, additional risks these drugs pose specifically to children are not well understood.¹⁰

Psychotropic drugs affect brain activity associated with mental processes and behavior. These drugs are also called "psychotherapeutic" drugs.

⁸Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369.

⁹National Institute of Mental Health, *Treatment of Children with Mental Illness*, NIH Publication No. 09-4702, (Bethesda, MD.: Revised 2009).

¹⁰For example, see Medicaid Medical Directors Learning Network and Rutgers Center for Education and Research on Mental Health Therapeutics, *Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study*, MMDLN/Rutgers CERTs, Publication 1 (July 2010).

While psychotropic drugs can have significant benefits for those with mental illnesses, they can also have side effects ranging from mild to serious. Table 1 highlights the psychotropic drug classes studied in this report and provides examples of drugs within those classes, as well as conditions treated and possible side effects.

Table 1: Psychotropic Drug Classes

Drug class	Examples of drugs	Types of conditions treated by drug class	Examples of possible adverse side effects
ADHD drugs	Atomoxetine (Strattera) Lisdexamfetamine dimesylate (Vyvanse) Methylphenidate (Ritalin, Concerta) Amphetamine (Adderall) Dextroamphetamine (Dexedrine, Dextrostat)	Attention deficit hyperactivity disorder	Decreased appetite Tics Psychosis
Anti-anxiety	Clonazepam (Klonopin) Lorazepam (Ativan) Alprazolam (Xanax)	Generalized anxiety disorder Post-traumatic stress disorder Social phobias	Dependence Drowsiness and dizziness Blurred vision Nightmares
Antidepressants	Fluoxetine (Prozac) Citalopram (Celexa) Sertraline (Zoloft) Paroxetine (Paxil) Escitalopram (Lexapro) Venlafaxine (Effexor) Duloxetine (Cymbalta) Bupropion (Wellbutrin)	Depression Generalized anxiety disorder Obsessive-compulsive disorder Social phobia	Suicidal thoughts Sleeplessness or drowsiness Agitation Sexual dysfunction
Antipsychotics	Chlorpromazine (Thorazine) Haloperidol (Haldol) Risperidone (Risperdal) Olanzapine (Zyprexa) Quetiapine (Seroquel) Ziprasidone (Geodon) Aripiprazole (Abilify)	Bipolar disorder Schizophrenia Tourette's syndrome	Rigidity (muscular tension) Tremor Tardive dyskinesia (uncontrollable movements) Diabetes High cholesterol Weight gain Neuroleptic malignant syndrome (a life-threatening, neurological disorder most often caused by an adverse reaction to antipsychotic drugs)
Hypnotics	Quazepam (Doral) Zolpidem (Ambien) Eszopiclone (Lunesta)	Insomnia Anxiety	Dependence Sleep-walking

Drug class	Examples of drugs	Types of conditions treated by drug class	Examples of possible adverse side effects
Mood stabilizers	Lithium Divalproex sodium (Depakote) Carbamazepine (Tegretol) Lamotrigine (Lamictal) Oxcarbazepine (Trileptal)	Bipolar disorder	Suicidal thoughts Loss of coordination Hallucinations Kidney, thyroid, liver and pancreas damage Polycystic ovarian syndrome Weight gain

Source: NIMH, NIH, and our experts.

Note: The drug class categorizations and the corresponding examples of medications used in this analysis are intended to capture the common uses of psychotropic drugs and were reviewed by our experts. However, some of the drugs may have been developed and used for different purposes. For example, certain anti-anxiety drugs, such as benzodiazepines, may also be prescribed for insomnia. Similarly, some medications developed to treat depression, such as selective serotonin reuptake inhibitors (SSRI) and tricyclic antidepressants, may also be used to treat anxiety disorders.

Foster Children Have Higher Rates of Psychotropic Drug Prescriptions and Indicators of Potential Health Risks

Foster children in each of the five selected states were prescribed psychotropic drugs at higher rates than were nonfoster children in Medicaid during 2008.¹¹ These states spent over \$375 million for prescriptions provided through fee-for-service programs to foster and nonfoster children.¹² The higher rates do not necessarily indicate inappropriate prescribing practices, as they could be due to foster children's greater exposure to traumatic experiences and the unique challenges of coordinating their medical care.¹³ However, psychotropic

¹¹We also examined Maryland, but found that its 2008 data on foster children were not sufficiently reliable for this study. State officials told us that Maryland's transition to a new records system in 2007 resulted in incorrect and missing data for foster children. A state audit in 2008 reported duplicate records with different identifying numbers for the same child, records showing children who had exited foster care as still enrolled in the program, and personal information for the mother recorded as that of the child. Our analysis of the data Maryland provided to us identified 8,869 children in foster care as of September 30, 2008—about 16 percent more than the 7,613 children that Maryland reported to ACF that year. However, audit reports for Maryland indicated that the state had taken some corrective actions as of March 2011.

¹²Based on our analysis of Medicaid fee-for-service claims data, these five states spent over \$317 million on psychotropic drugs for nonfoster children and about \$59 million on psychotropic drugs for foster children (in care 30 days or more) during 2008. This amount paid includes only claims paid for by a fee-for-service program and does not include manufacturer rebates or costs such as managed care (e.g., health maintenance organization (HMO)).

¹³For example, see Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010)

drug claims for foster children were also more likely to show the indicators of potential health risks that we established with our experts. According to our experts, no evidence supports the concomitant use of five or more psychotropic drugs in adults or children, yet hundreds of both foster and nonfoster children were prescribed such a medication regimen. Similarly, thousands of foster and nonfoster children were prescribed doses exceeding maximum levels cited in guidelines based on FDA-approved drug labels, which our experts said increases the potential for adverse side effects, and does not typically increase the efficacy of the drugs to any significant extent.¹⁴ Further, foster and nonfoster children under 1 year old were prescribed psychotropic drugs, which our experts said have no established use for mental health conditions in infants and could result in serious adverse effects.

Higher Rates of Psychotropic Drug Prescriptions among Foster Children

Foster children in Florida, Massachusetts, Michigan, Oregon, and Texas were prescribed psychotropic drugs at rates 2.7 to 4.5 times higher than were nonfoster children in Medicaid in 2008.¹⁵ The rates were higher among foster children for each of the age ranges—0 to 5 years old, 6 to 12 years old, and 13 to 17 years old—that we reviewed. See figure 1 for rates by state. Although a higher proportion of foster children received psychotropic drug prescriptions compared with nonfoster children, the vast majority of children receiving psychotropic drug prescriptions in these states were nonfoster children because the population of nonfoster children is much larger. In addition, according to our experts the higher rates of psychotropic drug prescriptions among foster children do not necessarily mean that the prescriptions were inappropriate; determining so would require, at minimum, a full review of each child's medical

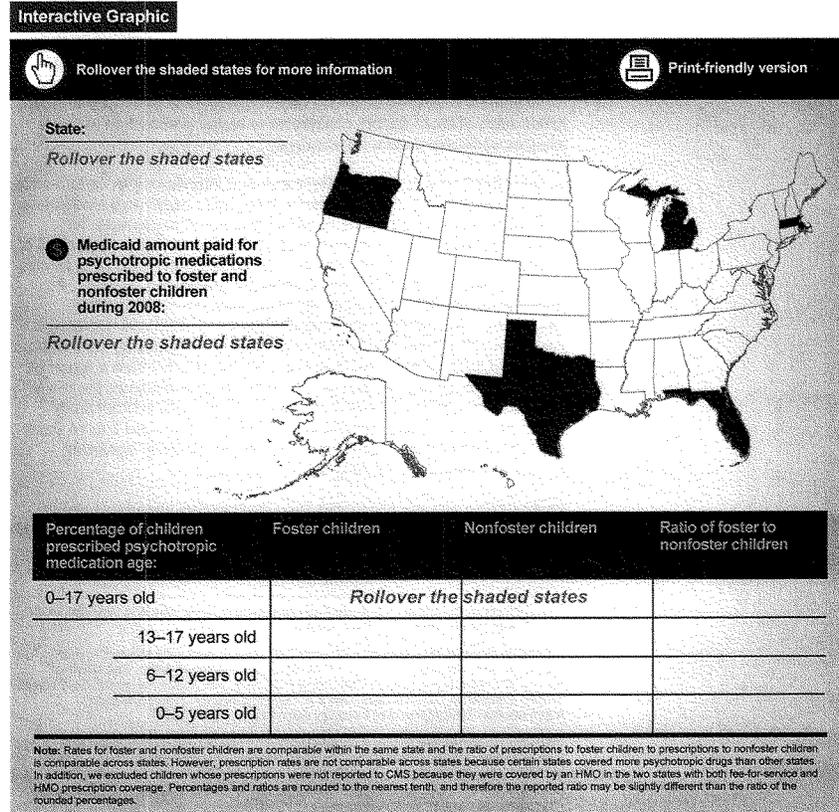
¹⁴According to our experts, medications are approved based on therapeutic research and doses above the recommended level have generally not been shown to be safe or effective.

¹⁵The kinds of drugs included in prescription data reported to CMS in 2008 varied by state. Because the claims data we obtained from CMS contained fewer types of medications for Michigan and Oregon, we may understate the rates of psychotropic prescriptions for both foster and nonfoster children in those states. While rates of psychotropic prescriptions are not comparable across states, they are comparable between foster and nonfoster children within the same state. Similarly, the ratio of prescriptions to foster children to prescriptions to nonfoster children is comparable across states.

history.¹⁶ Figure 1 shows prescription rates for children in each state for various age ranges.

¹⁶In Florida, nonfoster children were in fee-for-service Medicaid an average of 2 months less than foster children. Therefore, the number of nonfoster children with psychotropic prescriptions may be understated.

Figure 1: Psychotropic drug prescription rates for 5 selected states



Source: GAO analysis of state Medicaid and foster care data.

Through our interviews with state and federal officials and our experts, and our review of academic studies, we identified several factors that may contribute to these higher rates of prescribed psychotropic drug regimens. These factors included the greater exposure to trauma before entering state care, frequent changes in foster placements, and varying state oversight policies. However, our literature search identified a relatively small number of studies that have been conducted to determine to what extent each of these factors contributes to higher prescription rates, or whether additional factors are involved.

Greater exposure to trauma. Research and interviews with certain state officials suggest that children entering foster care have more emotional and behavioral issues than do nonfoster children. For example, an analysis of 1996 service claims in one county revealed that 57 percent of foster children were diagnosed with a mental disorder—nearly 15 times that of nonfoster children receiving Medicaid assistance. ADHD, depression, and developmental disorders were the most common diagnoses.¹⁷ According to the National Survey of Child and Adolescent Well-Being (NSCAW), 46 percent of children investigated by child welfare services (CWS) primarily came to the attention of CWS from a report of neglect, while 27 percent had experienced physical abuse as the most serious form of recorded maltreatment.¹⁸ According to another study based on NSCAW data, approximately half of youths aged 2 to 14 years with completed child welfare investigations had clinically significant emotional or behavioral problems.¹⁹

State officials and our contracted child psychiatrists stated that higher levels of psychotropic drug prescriptions may be appropriate to deal with

¹⁷S. dosReis, et al., Mental health services for youths in foster care and disabled youths, *Am J Public Health*, 2001, 91(7): pp. 1094-9.

¹⁸Children in states that required CPS to initially contact the family before the study's field staff were excluded from the study. Those states are not represented. See National Survey of Child and Adolescent Well-Being (NSCAW), No. 7: *Special Health Care Needs Among Children in Child Welfare*, Office of Planning, Research and Evaluation, Administration for Children and Families. (Washington, D.C.: 2007).

¹⁹Children in states that required CPS to initially contact the family before the study's field staff were excluded from the study. Those states are not represented. See B. J. Burns, et al., *Mental health need and access to mental health services by youths involved with child welfare: A national survey*, *Journal of the American Academy of Child and Adolescent Psychiatry*, 43, (2004), pp.960-70.

the increased prevalence and greater severity of mental health conditions among foster children. Further, Dr. Naylor noted that past trauma creates unique treatment challenges for those with multiple severe symptoms. In some cases, their symptoms do not clearly fit into existing diagnoses, which may cause them to receive multiple diagnoses that change with time, foster care placement, and medical provider. Dr. Naylor also noted that very little research has been done on the use of psychotropic drugs in foster children with severe symptoms. This limits the information available to providers on how best to treat their conditions.²⁰

Frequent changes in foster placements. Foster children who change placements often do not have a consistent caretaker to plan treatment, offer consent, and provide oversight. As we have previously reported, changes in placement pose significant challenges for agencies, foster parents, and providers with regard to providing continuity of health care services and maintaining uninterrupted information on children's medical needs and courses of treatment.²¹ Several studies of the utilization of psychotropic drugs have also noted that multiple foster care placements over short periods prevent an individual familiar with the child from coordinating and overseeing his or her long-term medical care.²² Children entering foster care may lack medical care prior to entry, while children with prior medical care may have experienced disruptions in care and have missing or incomplete records. (We discuss how each of the six states oversee psychotropic drug prescriptions in the next section of this testimony that discusses federal and state oversight over psychotropic drugs prescribed to foster children.)

²⁰As we have previously reported, some steps have been taken to address the lack of drug research in the pediatric population. For example, as part of the Food and Drug Administration Amendments Act of 2007, Congress reauthorized two laws, the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA). The PREA requires that sponsors conduct pediatric studies for certain products unless the FDA grants a waiver or deferral. See GAO, *Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA*, GAO-11-457 (Washington, D.C.: May 2011).

²¹GAO, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care*, GAO-09-26 (Washington, D.C.: Feb 6, 2009).

²²For example, see Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010).

Varying state oversight policies. States surveyed by the Tufts Clinical and Translational Science Institute in 2010 reported on several challenges that may affect prescribing patterns for foster children. These included a lack of collaboration among state agencies, professionals, and organizations responsible for the care of foster children; the consent process for foster children, which may require the input of multiple individuals or organizations; and the need for access to up-to-date guidelines on clinical practices regarding psychotropic prescriptions for foster children across stakeholder groups, including caregivers, child welfare agencies, schools, and prescribers. For example, the study found that 34 of 48 states had not implemented a system to identify prescriptions with dosages exceeding current maximum recommendations set by the product manufacturer, professional or federal standards, or state expert panels.²³

Higher Rates of Potential Health Risk Indicators among Foster Children

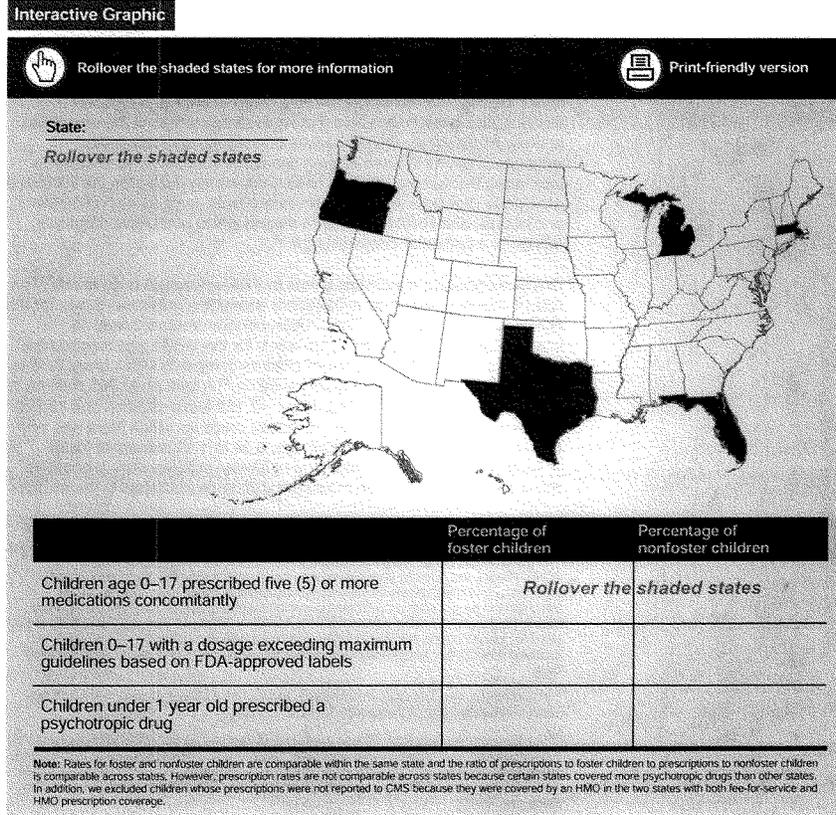
In each of the five states analyzed, psychotropic prescription claims data for foster children showed higher rates of potential health risk indicators than those of nonfoster children in Medicaid. According to our experts, the following three prescribing practices carry increased levels of risk for children, concomitant prescriptions of five or more medications,²⁴ doses exceeding maximum levels in FDA-approved drug labels, and prescriptions for infants.²⁵ Figure 2 provides more information on these indicators by state.

²³Leslie et al, *Multi-State Study on Psychotropic Medication Oversight in Foster Care*, Tufts Clinical and Translational Science Institute (Boston, Mass.: 2010).

²⁴According to one of our experts, this may be justified in rare cases of children with serious, complex mental health issues.

²⁵These indicators are similar to those used by Texas to identify cases for further review, and were cited by our experts as indicators of potential health risks.

Figure 2: Psychotropic drug potential health risk indicators for 5 selected states



Source: GAO analysis of state Medicaid and foster care data.

Concomitant psychotropic drug prescriptions.²⁶ Across the five states, the rate of children prescribed five or more psychotropic drugs concomitantly ranged from 0.11 to 1.33 percent among foster children compared with a lower 0.01 to 0.07 percent rate among nonfoster children. This translates to 1,752 children with such prescriptions in the five states—609 foster children and 1,143 nonfoster children. According to our experts, the use of five or more drugs at once is a high-risk practice. Our experts also said that no evidence supports the use of five or more psychotropic drugs in adults or children, and only limited evidence supports the use of even two drugs concomitantly in children. Increasing the number of drugs used concurrently increases the likelihood of adverse reactions and long-term side effects, such as high cholesterol or diabetes, and limits the ability to assess which of multiple drugs are related to a particular treatment goal.²⁷

Doses exceeding maximum levels in FDA-approved drug labels. The rate of children prescribed medications exceeding maximum doses for the child's age, as cited in the Texas Utilization Parameters based on information in FDA-approved drug labels for the child's age ranged from 1.12 to 3.27 percent among foster children compared with a lower 0.16 to 0.56 percent rate among nonfoster children.²⁸ A total of 20,965 children in the five states had such a prescription—2,165 foster children and 18,800 nonfoster children. Of children prescribed drugs for which there was no FDA-recommended dose for their age, 0.34 to 1.52 percent of foster children and 0.05 to 0.16 percent of nonfoster children were prescribed dosages that exceeded the maximum standards published in the medical

²⁶In our analysis of rates of psychotropic prescriptions, we included stimulants (e.g., ADHD drugs), anti-anxiety drugs, antidepressants, antipsychotics, hypnotics, mood stabilizers, and medications containing combinations of these drug classes. Other psychotropic drugs, such as anticonvulsants and alpha agonists, may be used to treat both physical and mental health conditions. However, because they are more likely to be used for mental health indications when combined with another psychotropic drug, we included them in our concomitant analyses when combined with a second psychotropic drug.

²⁷For example, see Zito et al, *Psychotropic Medication Patterns Among Youth in Foster Care*, *Pediatrics* 2008; Volume 121; 157-163.

²⁸For this analysis, we used dosage guidelines developed by the state of Texas based on FDA-approved drug labels, where available, for 33 drugs. For additional information, see Heiligenstein, *Psychotropic Medication Utilization Parameters for Foster Children*, Office of the Commissioner, Texas Department of Family and Protective Services (Austin, Tex.: December 2010).

literature. According to our experts, taking drugs at dosages exceeding levels recommended by the FDA and medical literature increases the potential for adverse side effects. Although there may be cases in which such doses are clinically justified, in general, there is a lack of research demonstrating that high dosages are more effective. In addition, our experts said that for some drugs, a higher dose may be less effective than the more moderate recommended dose.²⁹

Psychotropic prescriptions for infants. The rate of children age under 1 year old prescribed a psychotropic drug ranged from 0.3 to 2.1 percent among foster children compared with a lower 0.1 to 1.2 percent rate among nonfoster children. This translates to 76 foster children and 3,765 nonfoster children under 1 year old in the five states—a total of 5,265 prescriptions.³⁰ Our experts said that there are no established mental health indications for the use of psychotropic drugs in infants, and providing them these drugs could result in serious adverse effects. According to our data, fewer than 10 infants in foster care and 22 nonfoster infants were prescribed clonidine—with dosages generally used in older children—which one of our experts said could result in significant sedation and potential cardiac problems including, on rare occasions, sudden death. Fewer than ten infants in foster care were prescribed an antidepressant or an antipsychotic, compared with 44 and 12 infants not in foster care, respectively. According to our experts, antidepressants and antipsychotics have significant potential side effects, including cardiovascular and metabolic problems. Anti-anxiety drugs such as antihistamines and benzodiazepines accounted for the vast majority of the prescriptions for infants. Our experts noted that these drugs could

²⁹According to one of our experts, the effect of psychotropic medications has not been proven to be safe or effective above the maximum recommended dose by an FDA review. At lower dosages, psychotropic medications generally show an increase in efficacy with an increase in dose, but this dose-response relationship changes as the dose increases. At higher dosages, increasing doses of medications are often accompanied by an increased risk in adverse effects with little or no added benefit.

³⁰While the data we used for this analysis were generally reliable, the date of birth field was blank for some records. The number of foster infants, in particular, captured in the claims data may be underreported. It is also possible that a small number of Medicaid and foster care records may contain inaccurate personal data or prescription information likely resulting from data entry errors.

have been prescribed for nonmental health conditions.³¹ For example, the antihistamines could be prescribed to treat allergies, itching, and skin conditions such as eczema, the benzodiazepines for seizures or as sedation for a medical procedure. While physicians may use their discretion to prescribe these drugs to infants, these nonmental health uses still carry the same risk of adverse effects, including, for antihistamines, diminished mental alertness and excitation in young children. According to our experts, these cases raise significant concerns because infants are at a stage in their development where they are potentially more vulnerable to the effect of psychotropic drugs. See table 2 for more information.

Table 2: Children age 0-1 year old prescribed psychotropic drugs in five selected states^a

Drug category (subclass)	Foster children	Nonfoster children
Anti-anxiety (antihistamines) ^b	55	3,454
Anti-anxiety (benzodiazepines)	17	254
Other anti-anxiety drugs	0	<10
ADHD drugs	<10	37
Antidepressants	<10	44
Antipsychotics	<10	12
Hypnotic	0	<10
Mood stabilizer	0	<10

Source: GAO analysis of state Medicaid and foster care data.

^aNote: A total of 76 foster children and 3,765 nonfoster children, or 3,841 children age 0-1, were prescribed a psychotropic drug. The totals in the table above do not add up to 3,841 because some infants were prescribed more than one psychotropic drug.

^bOf children prescribed antihistamines, 26 foster children and 2,169 nonfoster children had prescriptions covering fewer than 20 days. According to one of our experts, this more likely represents a non-mental health use, such as for allergies or rashes.

Claims data also raise concerns about patient adherence to prescribed drug regimens, which our experts noted as a patient safety matter. Although foster children as a group were 1.7 to 3.3 times more likely to have three or more gaps of 7 to 29 days between prescriptions than nonfoster children, this is likely related to their overall higher rates of

³¹Experts also noted that some of these prescriptions may have been written with the intention of treating an uninsured parent or sibling. It is not possible to determine from the data whether this was the case.

psychotropic prescriptions. When comparing only those prescribed psychotropic drugs, nonfoster children were 1.2 to 2.0 times more likely to have three or more gaps than foster children, suggesting that adherence is higher among foster children. Frequent gaps of 7 or more days in prescription claims have a number of potential causes, including a parent or the caretaker's failure to fill prescriptions on behalf of a child in a timely manner or a lack of consistent access to care.³² Gaps in drug claims do not indicate that the drugs as prescribed have potential health risks. However, nonadherence to drug regimens can pose significant risks to a patient, such as reduced efficacy from undertreatment, rebound of symptoms, and withdrawal symptoms. For example, the sudden discontinuation of benzodiazepines such as alprazolam can cause seizures³³ and the sudden discontinuation of SSRIs³⁴ such as paroxetine can cause a variety of problems, including dizziness, headaches, fatigue, and nausea.³⁵ Nonadherence to a drug regimen can cause the drug to appear ineffective even though it was not taken for a full trial. For example, antidepressants generally take 3 to 6 weeks to have a beneficial effect on the patient's symptoms.³⁶ Failure to take the antidepressant medications for a sufficient length of time may be interpreted as a lack of response to the treatment, which can result in the premature switch to or addition of other drugs. Table 3 provides more information on gaps in prescriptions for foster and nonfoster children by state.

³²In frequent gaps may also be caused by a serious illness that prevents the patient from taking the medication as prescribed, or patients who choose to discontinue a medication because of side effects.

³³G. Chouinard, *Issues in the clinical use of benzodiazepines: potency, withdrawal, and rebound*. *J Clin Psychiatry*. 2004; 65 Suppl 5:7-12.

³⁴Selective serotonin reuptake inhibitors (SSRIs) are antidepressants.

³⁵S. Hosenbocus, R. Chahal, *SSRIs and SNRIs: A review of the Discontinuation Syndrome in Children and Adolescents*. *J Can Acad Child Adolesc Psychiatry*. 2011 Feb; 20(1): 60-7.

³⁶National Institute of Mental Health, *Mental Health Medications*, U.S. Department of Health and Human Services. (Bethesda, Md.: Revised 2008).

Table 3: Percentage of Children Age 0-17 Prescribed a Psychotropic Drug with Three or More Gaps of 7-29 Days in Drug Claims in 5 States

State	Percent of children who had three or more gaps in drug claims		Percent of children prescribed a psychotropic drug who had three or more gaps in drug claims	
	Foster Children	Nonfoster Children	Foster Children	Nonfoster Children
Florida	1.8	1.1	7.8	12.1
Massachusetts	3.4	1.8	8.4	16.4
Michigan	1.7	0.9	7.9	11.3
Oregon	1.6	0.5	7.7	9.5
Texas	2.2	0.7	6.6	8.6

Source: GAO analysis of Medicaid and foster care data for Florida, Massachusetts, Michigan, Oregon, and Texas.

*Since we used both primary and secondary lists in our gaps analysis, the number of foster and nonfoster children prescribed a psychotropic drug is slightly higher than reported in our overall prescription rates, which were based on primary drugs only.

Selected States' Psychotropic Drug Monitoring Programs Fall Short of AACAP-Best Principles Guidelines

Comparing the selected states' monitoring programs for psychotropic drugs provided to foster children with AACAP's guidelines indicates that, as of October 2011, each of the state programs falls short of providing comprehensive oversight as defined by AACAP. Though states are not required to follow these guidelines, the six states we examined had developed monitoring programs that satisfied some of AACAP's best principles guidelines to varying degrees. Such variation is not surprising given that states set their own oversight guidelines and have only recently been required, as a condition of receiving certain federal child welfare grants, to establish protocols for the appropriate use and monitoring of psychotropic drugs prescribed to foster children.³⁷

HHS has provided limited guidance to the states on how to improve their control measures to monitor psychotropic drug prescriptions to foster children. Without formally endorsing specific oversight measures for states to implement, HHS conducts state reviews and provides other online resources, including the AACAP guidelines, to help states improve their programs. ACF performs Child and Family Services Reviews (CFSR) of states to ensure conformity with federal child welfare

³⁷Child and Family Services Improvement and Innovation Act, Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369 (2011).

requirements—which include provisions for safety, permanency, and family and child well-being—and to assist states as they enhance their capacity to help families achieve positive outcomes.³⁸ These reviews include the examination of a limited number of children's case files, in part to determine whether the state foster care agency conducted assessments of children's mental health needs and provided appropriate services to address those needs. However, these reviews are not designed to identify specific potential health risk indicators related to psychotropic medications, and since they occur every 2 to 5 years, states cannot rely on these reviews to actively monitor prescriptions. In addition, ACF operates technical assistance centers and provides online resources such as links to state guidance on psychotropic drug oversight, academic studies on psychotropic drugs, and recordings of teleconferences related to the oversight of psychotropic drugs.³⁹ While HHS makes a variety of resources available to states developing oversight programs for psychotropic drugs, it has not endorsed any specific guidance. In the absence of HHS-endorsed guidance, states have developed varied oversight programs that in some cases fall short of AACAP's recommended guidelines.

The AACAP guidelines are arranged into four categories, including consent, oversight, consultation, and information sharing, that contain practices defined as minimal, recommended, or ideal. The following describes the extent to which the selected states' monitoring programs cover these areas.

Consent: According to interviews and documentation provided by state Medicaid and foster care officials, all six selected states have

³⁸CFSRs, which occur on a regular and recurring basis in every state (generally every 2 to 5 years depending on the results of the prior review), are the central and most comprehensive component of federal efforts to determine state compliance with federal child welfare requirements. ACF also reviews states' progress related to areas found not to be in substantial conformity with federal requirements based on the last CFSR, generally on an annual basis.

³⁹In order to be eligible for certain federal child welfare grants, state child welfare agencies are required to develop a plan for ongoing oversight and coordination of health care services for foster children, including mental health, in coordination with the state Medicaid agency, pediatricians, other health care experts, and child welfare experts. See 42 U.S.C. § 622(b)(15). Among other things, the state plans must also include the oversight of prescription drugs, and how the agency actively consults and involves physicians and other professionals in assessing the health and well-being of children in foster care in determining appropriate medical treatment for the children.

implemented some practices consistent with AACAP guidelines for consent procedures, though in varying scope and application. According to AACAP, the consent process should be documented and monitored to ensure that caregivers are aware of relevant information, such as the child's diagnosis, expected benefits and risks of treatments, common side effects, and potentially severe adverse events. Thus, states that do not incorporate consent procedures similar to AACAP's guidelines may increase the likelihood that caregivers are not fully aware of the risks and benefits associated with the decision to medicate with psychotropic drugs, and may limit the caregiver's ability to accurately assess and monitor the foster child's reaction to the drugs. Table 4 lists AACAP's guidelines relative to consent and illustrates the extent to which states have implemented those guidelines.

Table 4: State Consent Laws and Policies Compared with AACAP's Best Principles Guidelines

Guideline		FL	MD	MA	MI	OR	TX
Minimal	Identify the parties empowered to consent for psychotropic drug treatment for youth in state custody in a timely fashion	■	■	■	■	■	■
Minimal	Establish a mechanism to obtain assent for psychotropic medication management from minors when possible	■	■	■	■	■	■
Recommended	Obtain simply written psycho-educational materials and medication information sheets to facilitate the consent process	■	■	■	■	■	■
Ideal	Establish training requirements for child welfare, court personnel and/or foster parents to help them become more effective advocates for children in their custody ¹	■	■	■	■	■	■



Source: GAO analysis of information collected through interviews with, and various documentation provided by the selected states' Medicaid and Foster Care officials, and the AACAP's best principles guideline.
¹AACAP Best Principles Guideline states this training should include the names and indications for use of commonly prescribed psychotropic medications, monitoring for medication effectiveness and side effects, and maintaining medication logs. Materials for this training should include a written "Guide to Psychotropic Medications" that includes many of the basic guidelines reviewed in the psychotropic medication training curriculum.

Florida and Michigan provide examples of how states vary in their approach to monitoring consent procedures used for psychotropic drugs prescribed to foster children. For example, Florida requires all prescribers

to obtain a standardized written consent form from the parental or legal guardian, or a court order, before a psychotropic drug is administered. The consent form includes the diagnosis, dosage, target symptoms, drug risks and benefits, drug monitoring plan, alternative treatment options, and discussions about the treatment between the child and the parent or legal guardian. Florida law identifies who is authorized to give consent, and obtains assent for psychotropic drug management from minors when age and developmentally appropriate. Florida provides required training to caseworkers, but the names and indications for use of commonly prescribed psychotropic drugs are not included.

In contrast, Michigan has policies identifying who is authorized to give consent to foster children, but does not use a standardized consent form that can be used to help inform consent decisions. Instead, Michigan requires that caseworkers maintain in their files the consent forms used by individual prescribers, which likely vary in content and may thus vary in helpfulness to consent givers. Moreover, Michigan does not have training requirements in place to help caseworkers, court personnel, and foster parents become more effective advocates for children in their custody. Training for caseworkers is optional, but according to an agency official, the training was unavailable because no trainer had been hired as of September 2011. Michigan does not have policies for obtaining assent from minors when possible, thus meeting only one of AACAP's guidelines for consent procedures.

Oversight procedures: Each of the six states has developed some procedures similar to AACAP's guidelines for overseeing psychotropic drug prescriptions for foster children, as evidenced by interviews and documentation provided by state Medicaid and foster care officials.⁴⁰ According to one study, states that implement standards to improve oversight of the use of psychotropic drugs may create enhanced

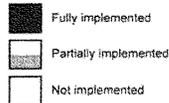
⁴⁰Each of the six states reviewed performs a drug utilization review during the prescription claims process to promote patient safety, reduce costs, and prevent fraud and abuse as required by the Omnibus Budget Reconciliation Act (OBRA) of 1990 (Pub. L. No. 101-508, § 4401, 104 Stat. 1388, § 1388-143). States were encouraged by enhanced federal funding to design and install point-of-sale electronic claims management systems that interface with their Medicaid Management Information Systems (MMIS) operations. The annual report requirement is used to assess patient safety, provider prescribing habits and dollars saved by avoidance of problems such as drug-drug interactions, drug-disease interactions, therapeutic duplication, and overprescribing by providers. However, the extent to which states' DUR process included reviews of psychotropic drugs varied across our states and the DUR process is not focused on the foster child population specifically.

continuity of care, increased placement stability, reduced need for psychiatric hospitalization, and decreased incidence of adverse drug reactions.⁴¹ As such, states that do not incorporate oversight procedures similar to AACAP's recommendations limit their ability to identify the extent to which potentially risky prescribing is occurring in the foster care population. Table 5 lists AACAP's guidelines relative to oversight and illustrates the extent to which selected states have implemented those guidelines.

⁴¹M. W. Naylor, et al, 2007. *Psychotropic Medication Management for Youth in State Care: Consent, Oversight, and Policy Considerations*, Child Welfare V 86, 5 (2007) p.175-192.

Table 5: State Oversight Laws and Policies Compared with AACAP's Best Principles Guidelines

Guideline	FL	MD	MA	MI	OR	TX
Minimal Establish guidelines for the use of psychotropic medications for children in state custody	Partially implemented	Not implemented	Partially implemented	Fully implemented	Not implemented	Not implemented
Ideal Oversight program includes an advisory committee to oversee a medication formulary and provide medication monitoring guidelines to practitioners who treat children in the child welfare system ¹	Partially implemented	Not implemented	Not implemented	Partially implemented	Not implemented	Partially implemented
Ideal Oversight program monitors the rate and types of psychotropic medication usage and the rate of adverse reactions among youth in state custody	Partially implemented	Not implemented	Partially implemented	Partially implemented	Partially implemented	Partially implemented
Ideal Oversight program establishes a process to review non-standard, unusual, and/or experimental psychiatric interventions with children who are in state custody	Partially implemented	Not implemented	Partially implemented	Fully implemented	Partially implemented	Fully implemented
Ideal Oversight program collects and analyzes data and makes quarterly reports to the state or county child welfare agency regarding the rates and types of psychotropic medication use. Make this data available to clinicians in the state to improve the quality of care provided	Partially implemented	Not implemented	Partially implemented	Not implemented	Not implemented	Fully implemented
Ideal Maintain an ongoing record of diagnoses, height and weight, allergies, medical history, ongoing medical problem list, psychotropic medications, and adverse medication reactions that are easily available to treating clinicians 24 hours a day	Partially implemented	Fully implemented	Partially implemented	Fully implemented	Partially implemented	Partially implemented



 Fully implemented
 Partially implemented
 Not implemented

FL Florida
 MD Maryland
 MA Massachusetts
 MI Michigan
 OR Oregon
 TX Texas

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states' Medicaid and Foster Care officials, and the AACAP's best principles guideline.
¹AACAP describes advisory committees as composed of agency and community child and adolescent psychiatrists, pediatricians, other mental health providers, consulting clinical pharmacists, family advocates or parents, and state child advocates.

Texas and Maryland provide examples of how states vary in their approach to oversight of psychotropic drug use among foster children. For example, the Texas Department of Family and Protective Services (DFPS) and the University of Texas at Austin College of Pharmacy assembled an advisory committee that included child and adolescent psychiatrists, psychologists, pediatricians, and other mental health professionals to develop psychotropic drug use parameters for foster children. These parameters are used to help identify cases requiring additional review. Factors that trigger additional reviews include dosages exceeding usual recommended levels, prescriptions for children of very young age, concomitant use of five or more psychotropic drugs, and prescriptions by a primary care provider lacking specialized training.⁴² According to the Texas foster care agency's data analysis, after Texas released these guidelines in 2005, psychotropic drug use among Texas foster care children declined from almost 30 percent in fiscal year 2004 to less than 21 percent in fiscal year 2010. Texas also analyzes Medicaid claims data to monitor psychotropic drug prescriptions for foster children and to identify any unusual prescribing behaviors. Texas provides quarterly reports to child welfare officials on the use of psychotropic drugs among foster children and treating clinicians have access to a child's medical records on a 24-hour basis. However, the electronic health record system does not always capture the child's height, weight, and allergies, which is optional for prescribers to enter into the system. This information is helpful as a child's weight may be used to determine the recommended dose for some medications, while allergy information may be used to determine whether a child should take a particular medication. In addition, ongoing medical problems are not recorded in the electronic health record system and Texas does not measure the rate of adverse reactions at the macro level among youth in state custody.

Maryland fully applies only one of the six AACAP guidelines for oversight procedures and partially applies others. Maryland provides foster children in out-of-home placement with a "medical passport" that serves as a record of the child's previous and current medical file. Each topic included in AACAP's guidelines for maintaining ongoing medical records, including diagnoses, allergies, and medical history, is documented in the passport, and an additional copy of the passport is kept in the child's case record

⁴²Primary care provider prescriptions were not flagged when treating ADHD, uncomplicated depression, and uncomplicated anxiety disorders.

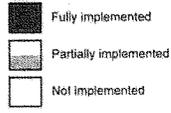
and maintained electronically. However, Maryland has not produced any specific guidelines for the use of all psychotropic prescriptions among foster children, thus limiting the state's ability to identify potentially risky prescribing practices for the foster child population.⁴³ Without guidelines for psychotropic drugs, there are no criteria to help agency officials monitor the appropriateness of prescriptions. Moreover, Maryland does not review Medicaid claims data statewide specifically for foster children, and therefore does not produce quarterly reports to identify the rate and types of drugs used in the foster care population that could help identify and monitor prescribing trends. In addition, as stated earlier, Maryland's 2008 foster care data were found unreliable. Maryland officials told us that transitioning to a new records system in 2007 resulted in incorrect and missing data for foster children.

Consultation program: According to interviews and documentation provided by state Medicaid and foster care officials, five of the six states have implemented some of AACAP's guidelines for consultation, but only one of the six selected states has implemented a consultation program that ensures all consent givers and prescribers are able to seek advice from child and adolescent psychiatrists before making consent decisions for foster children. States that do not have a consultation program to help link consent givers and prescribers with child and adolescent psychiatrists may reduce the extent to which prescribers and consent givers are informed about the expected benefits and risks of treatments, alternative treatments, and the risks associated with no treatment. Table 6 lists the AACAP guidelines relative to consultation programs and illustrates the extent to which selected states have implemented those guidelines.

⁴³Beginning October 2011, the Maryland Medicaid Pharmacy Program (MMPP) implemented a peer-review authorization process to ensure the safe and effective use of antipsychotic medications in children. Claims for antipsychotic medications that are for children younger than the FDA-approved age require a Prior Authorization (PA) based on the peer-review assessment. The MMPP's Board-Certified child psychiatrist oversees the peer-review project. According to a state agency official, a child and adolescent psychiatrist who is faculty at Johns Hopkins University School of Medicine monitors all psychotropic medication use for children entering foster care in Baltimore City. However, this practice is not statewide.

Table 6: State Consultation Programs Compared with AACAP's Best Principles Guidelines

Guideline	FL	MD	MA	MI	OR	TX
Recommended Design a consultation program administered by child and adolescent psychiatrists. This program provides consultation by child and adolescent psychiatrists to the persons or agency that is responsible for consenting for treatment with psychotropic medications	Fully implemented	Not implemented	Partially implemented	Not implemented	Partially implemented	Partially implemented
Recommended The consultation program provides consultations by child and adolescent psychiatrists to, and at the request of, physicians treating this difficult patient population	Fully implemented	Partially implemented	Fully implemented	Not implemented	Not implemented	Not implemented
Recommended The consultation program conducts face-to-face evaluations of youth by child and adolescent psychiatrists at the request of the child welfare agency, the juvenile court, or other state or county agencies empowered by law to consent for treatment with psychotropic medications when concerns have been raised about the pharmacological regimen	Not implemented	Not implemented	Fully implemented	Not implemented	Not implemented	Fully implemented



 FL Florida
 MD Maryland
 MA Massachusetts
 MI Michigan
 OR Oregon
 TX Texas

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states' Medicaid and Foster Care officials, and the AACAP's best principles guideline.

Massachusetts and Oregon provide examples of how states vary their approach in providing expert consultations to caregivers. For example, Massachusetts's foster care agency started an initiative to connect child welfare staff to Medicaid pharmacists who can provide information on medications and the foster child's drug history, including interactions between any current and proposed drugs. In addition, primary care physicians who treat children, including foster care children, also have access to the state-funded Massachusetts Child Psychiatry Access Project, a system of regional children's mental health consultation teams designed to help pediatricians find and consult with child psychiatrists. Massachusetts has six child psychiatrists who are available to provide consultations on a part-time basis to child welfare staff, but these

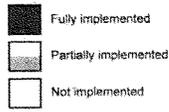
consultations are not available for other consent givers such as foster parents. The foster care agency's consultation program also provides face-to-face evaluations of foster children at the request of consent givers concerned about a child's treatment.

In early 2009, Oregon put a consultation program in place to help consent givers make informed decisions. In 2010, Oregon's foster care agency shifted the responsibility for all consent decisions where the agency has legal custody or is the legal guardian of the child from foster parents to child welfare agency officials, who now have access to a child and adolescent psychiatrist and can seek consultations before making consent decisions. However, the consultation program does not conduct face-to-face evaluations of children—by a child and adolescent psychiatrist—at the request of consent givers, nor does it enable prescribing physicians to consult with child and adolescent psychiatrists. Oregon has plans for the development of the Oregon Psychiatric Access Line for Kids, which would allow primary care physicians and nurse practitioners to consult with child psychiatrists, but agency officials told us the program is not operational due to a lack of funding.

Information sharing: Four of the six selected states have created websites with information on psychotropic drugs for clinicians, foster parents, and other caregivers. Access to comprehensive information can help ensure that clinicians, foster parents, and other interested parties are fully informed about the use and management of psychotropic drugs. Table 7 lists AACAP's guidelines relative to information sharing and illustrates the extent to which selected states have implemented those guidelines.

Table 7: State Information-sharing Laws and Policies Compared with AACAP's Best Principles Guidelines

Guideline	FL	MD	MA	MI	OR	TX
Ideal	Fully implemented	Not implemented	Partially implemented	Not implemented	Partially implemented	Partially implemented
Ideal	Fully implemented	Not implemented	Partially implemented	Not implemented	Partially implemented	Partially implemented
Ideal	Fully implemented	Not implemented	Not implemented	Not implemented	Partially implemented	Not implemented
Ideal	Not implemented	Not implemented	Not implemented	Not implemented	Not implemented	Not implemented
Ideal	Not implemented	Not implemented	Not implemented	Not implemented	Not implemented	Partially implemented
Ideal	Fully implemented	Not implemented	Not implemented	Not implemented	Not implemented	Partially implemented



 FL Florida

 MD Maryland

 MA Massachusetts

 MI Michigan

 OR Oregon

 TX Texas

Source: GAO analysis of information collected through interviews with, and various documentation provided by, the selected states' Medicaid and Foster Care officials, and the AACAP's best principles guideline.

For example, Florida's foster care agency has partnered with the University of South Florida to implement Florida's Center for the Advancement of Child Welfare Practice to provide needed information and support to Florida's professional child welfare stakeholders.⁴⁴ The

⁴⁴According to the Center's website, its mission is to support and facilitate the identification, expansion, and transfer of expert knowledge and best practices in child welfare case practice, direct services, management, finances, policy, and organizational development to child welfare and child protection stakeholders throughout Florida.

program's website is consistent with four of AACAP's six guidelines for information sharing. For example, the website includes policies and procedures governing psychotropic drug management, staff publications and educational materials about psychotropic drugs, consent forms, and links to other informative publications and news stories related to foster children and psychotropic drugs. However, the website does not provide reports on prescription patterns for psychotropic drugs or adverse effect rating forms.

In comparison, Oregon's foster care agency developed a website that includes information regarding psychotropic medication, but the website is not updated regularly to operate as an ongoing information resource. The website currently has information on state policies and procedures governing the use of psychotropic drugs and also contains web links to consent forms and a medication chart that can be used as a psychotropic medication reference tool. However, the website does not meet three of the six information-sharing guidelines, including those on posting adverse effect rating forms, reporting prescription patterns, and providing links to other informative websites. States with less accessibility to comprehensive information may limit the extent to which physicians, foster parents, and other interested parties are informed about the use and management of psychotropic drugs.

Conclusions

The higher rates of psychotropic drug prescriptions among foster children may be explained by their greater mental health needs and the challenges inherent to the foster care system. However, thousands of foster and nonfoster children in the five states we analyzed were found to have prescriptions that carry potential health risks. While doctors are permitted to prescribe these drugs under current laws, increasing the number of drugs used concurrently and exceeding the maximum recommended dosages for certain psychotropic drugs have been shown to increase the risk of adverse side effects in adults. Prescriptions for infants are also of concern, due to the potential for serious adverse effects even when these drugs are used for non-mental health purposes. Comprehensive oversight programs would help states identify these and other potential health risks and provide caregivers and prescribers with the information necessary to weigh drug risks and benefits. The recently enacted Child and Family Services Improvement and Innovation Act requires states to establish protocols for monitoring psychotropic drugs prescribed to foster children. Under the act, each state is authorized to develop its own monitoring protocols, but HHS-endorsed, nationwide guidelines for consent, oversight, consultation, and information sharing

could help states close the oversight gaps we identified and increase protections for this vulnerable population.

Recommendation for Executive Action

In our draft report, we recommended that the Secretary of HHS evaluate our findings and consider endorsing guidance to state Medicaid and child welfare agencies on best practices for monitoring psychotropic drug prescriptions for foster children, including guidance that addresses, at minimum, informed consent, oversight, consultation, and information sharing.

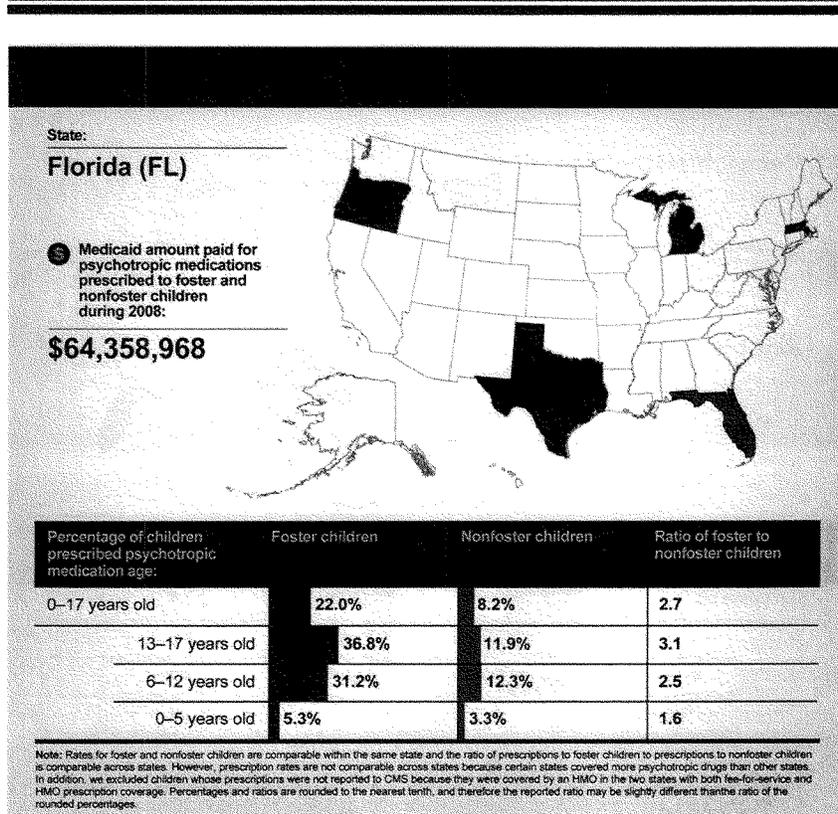
We have received written comments on our draft report from HHS and relevant agencies in 6 states. In written comments, HHS agreed with our recommendation and provided technical comments, which we incorporated as appropriate. In written comments and exit conferences, staff from state Medicaid and foster care agencies provided comments on key facts from the report. Agency comments will be incorporated and addressed in a written report that will be issued in December 2011.

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contacts

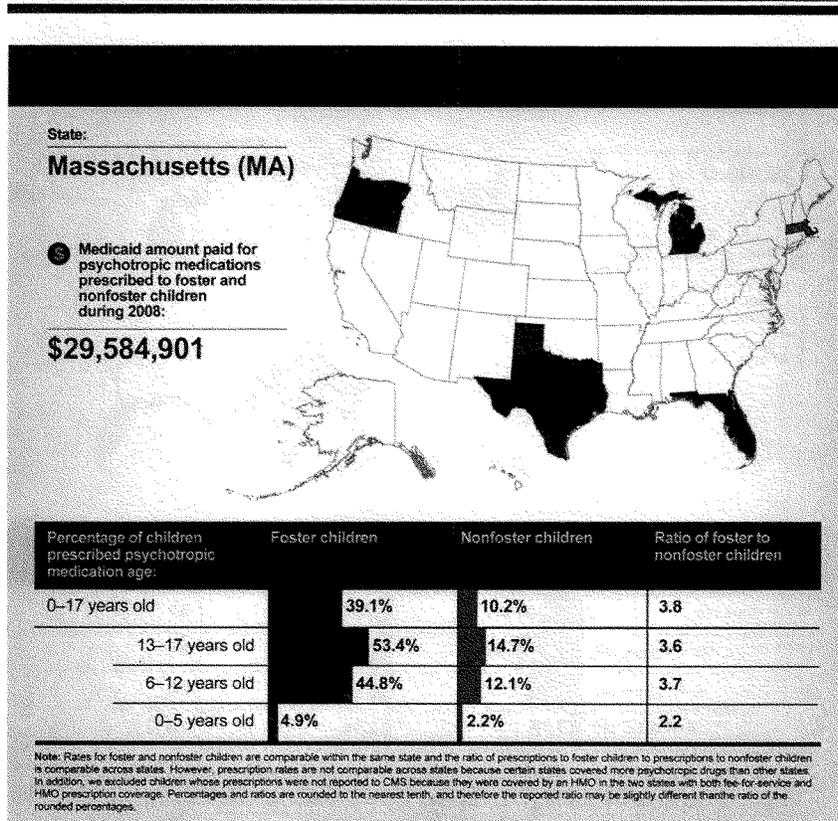
For additional information about this testimony, please contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

Appendix I: Print-friendly version of figure 1 and figure 2



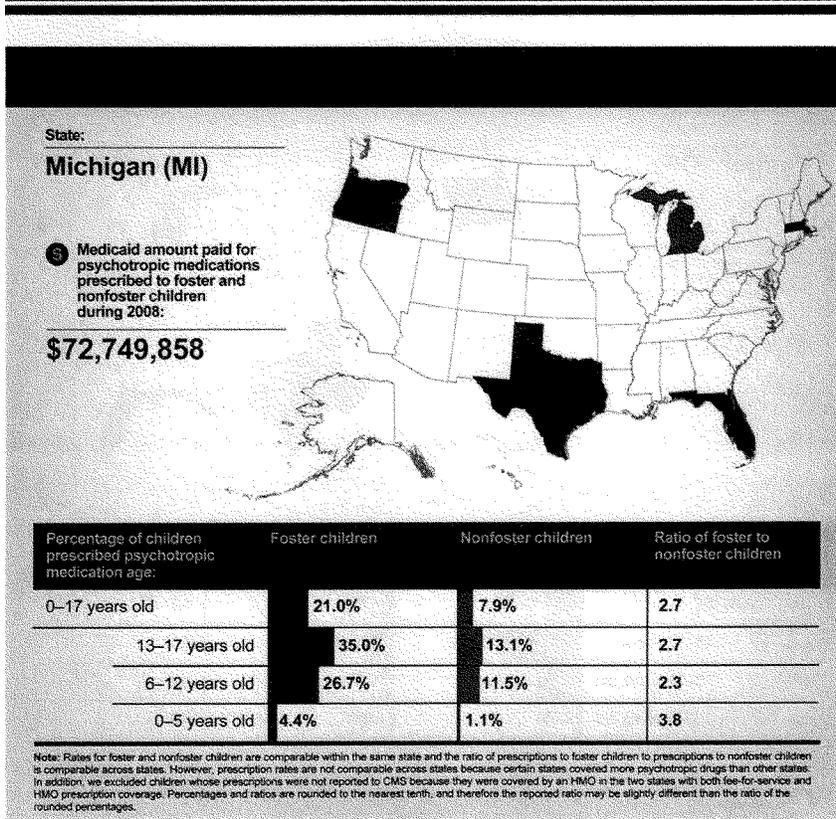
Source: GAO analysis of state Medicaid and foster care data

Appendix I: Print-friendly version of figure 1 and figure 2



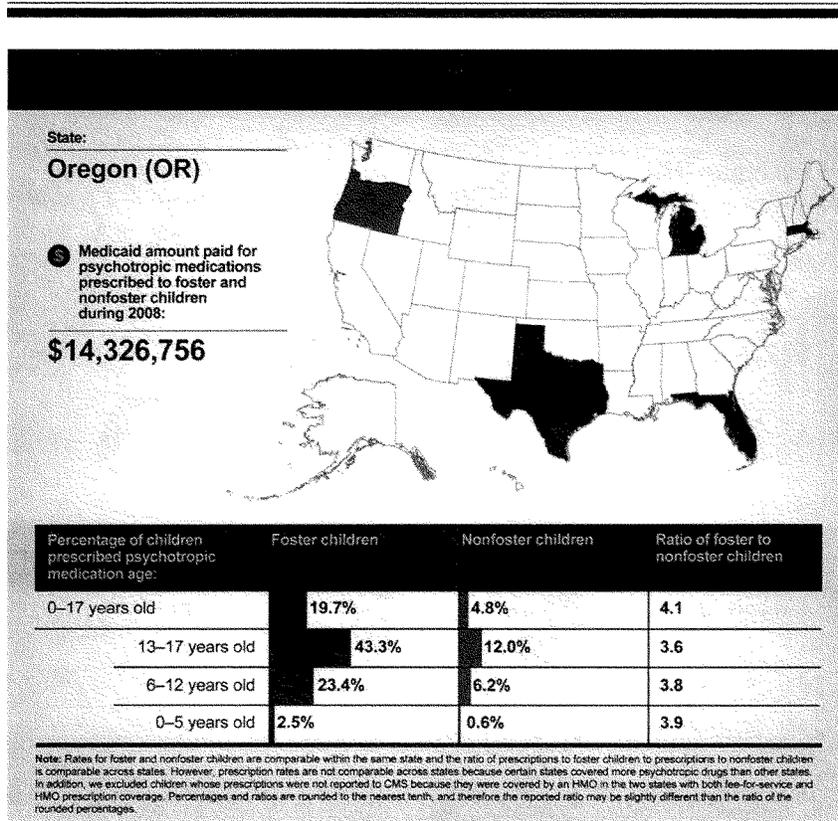
Source: GAO analysis of state Medicaid and foster care data

Appendix I: Print-friendly version of figure 1 and figure 2



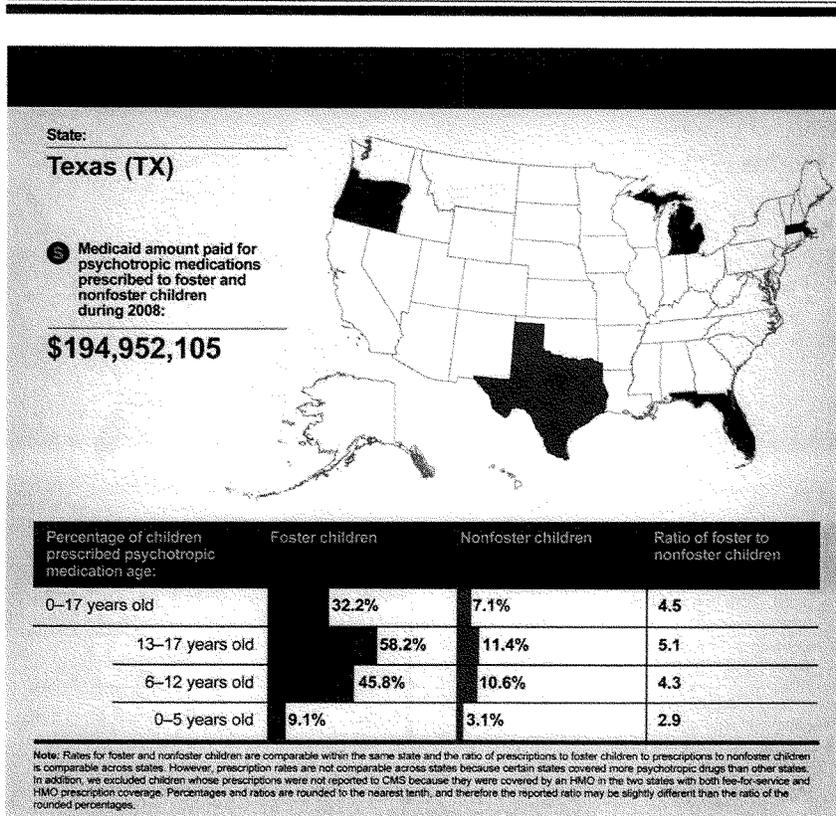
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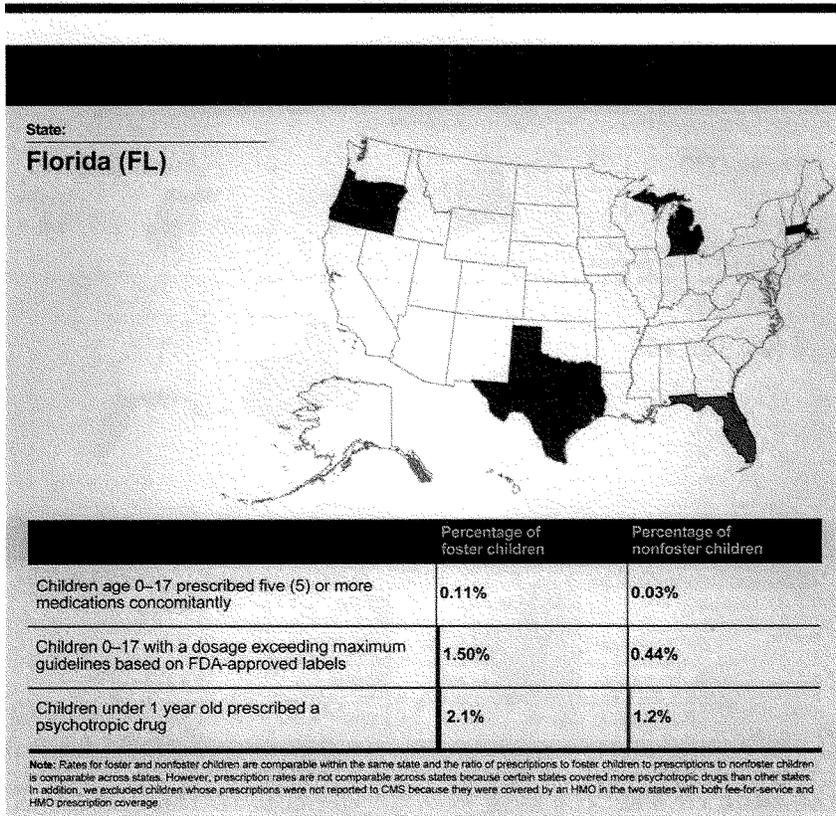
Source: GAO analysis of state Medicaid and foster care data

Appendix i: Print-friendly version of figure 1 and figure 2



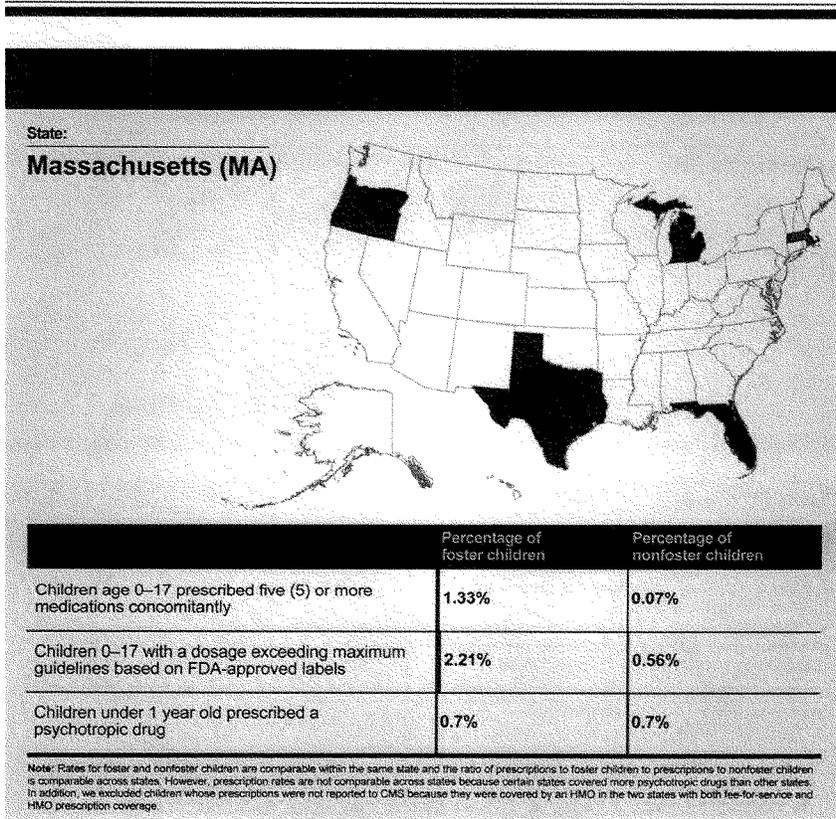
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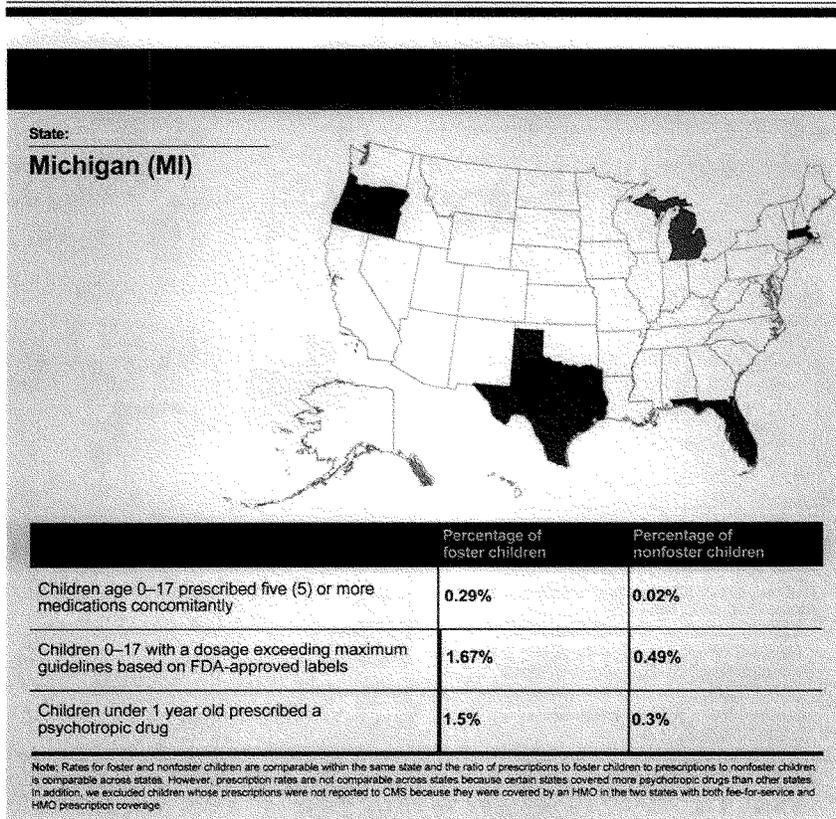
Source: GAO analysis of state Medicaid and foster care data.

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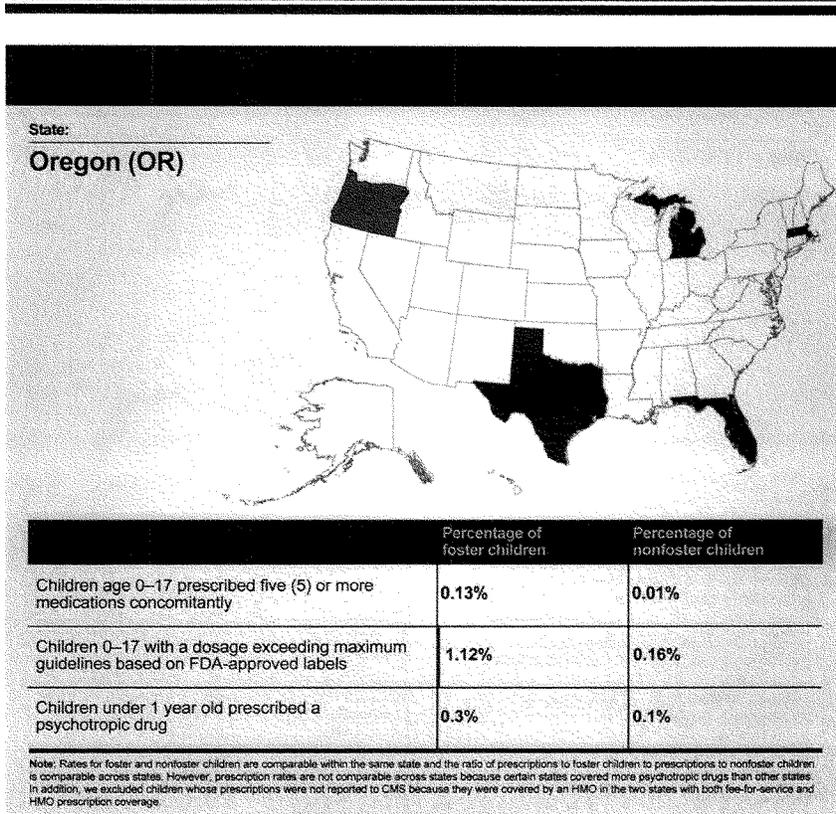
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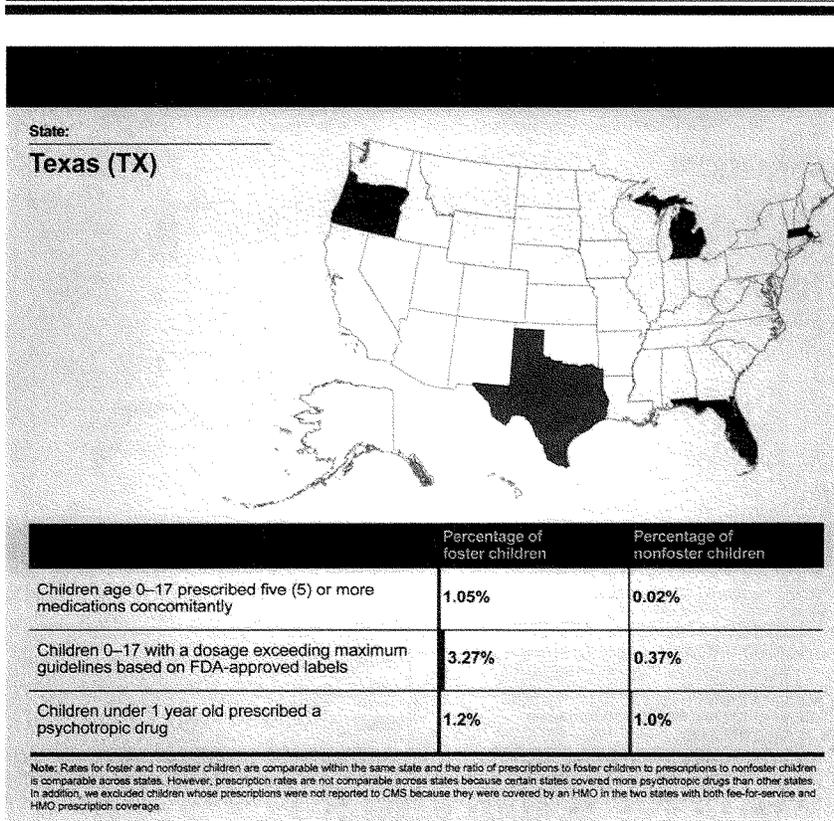
Source: GAO analysis of state Medicaid and foster care data.

Appendix I: Print-friendly version of figure 1 and figure 2



Source: GAO analysis of state Medicaid and foster care data

Appendix I: Print-friendly version of figure 1 and figure 2



Source: GAO analysis of state Medicaid and foster care data.



Testimony of

Bryan Samuels, Commissioner

Administration on Children, Youth and Families

Administration for Children and Families

U.S. Department of Health and Human Services

Before the

Subcommittee on Federal Financial Management, Government Information, Federal Services,

and International Security

Senate Committee on Homeland Security and Governmental Affairs

United States Senate

December 1, 2011

Chairman Carper, Ranking Member Brown, and members of the Subcommittee, thank you for the opportunity to testify before you this morning about the use of psychotropic medications among children in foster care. First, I would like to acknowledge the leadership demonstrated by Congress in this area already, most recently in the reauthorization of title IV-B of the Social Security Act. In September, Congress acted on an Administration proposal to provide HHS with additional authority in the Child and Family Services Improvement and Innovations Act of 2011 (Public Law 112-34) to require States to address the trauma needs of children and to develop protocols for monitoring the use of psychotropic drugs among children in foster care. Other notable Congressional work includes the passage of the Fostering Connections to Success and Increasing Adoptions Act, which requires the use of medical homes and oversight of prescription medications for children in foster care, and the recent work of the Senate Caucus on Foster Youth, led by Senators Landrieu and Grassley, to highlight the issue of psychotropics. In 2009, the Subcommittee on Income Security and Family Support of the House Committee on Ways and Means held a hearing on prescription psychotropic drug use among children in foster care. Additionally, I would like to thank this Committee for requesting that the Government Accountability Office review the use of psychotropics with children in foster care, as it has produced a comprehensive and useful report that can help guide ongoing action. As I have noted, much work has occurred already, and the hearing today furthers this critical conversation. Together, this work will advance the child welfare and mental health fields and truly benefit some of the most vulnerable children in our society.

During my testimony, I will address critical issues related to the use of psychotropic medication among children in foster care and outline the activities that the Department of Health and Human

Services (HHS) has undertaken to improve oversight and monitoring. It is impossible to discuss the use of psychotropics without addressing the impact of maltreatment on the overall social and emotional well-being of children who have experienced abuse or neglect. HHS is examining and responding to issues of psychotropic drug use within this context with the goal of building the capacity of child welfare systems to both identify the needs of children and youth who have been maltreated and deliver effective, evidence-based interventions to meet those needs. Certainly this includes strengthened protocols for the prescription and monitoring of psychotropic medications; more broadly, though, it requires that child welfare systems have increased ability to deliver effective psychosocial interventions, such as Trauma-Focused Cognitive-Behavioral Therapy, as treatment strategies alone or, when appropriate, in conjunction with pharmaceutical treatments to improve the well-being of the children and youth that they serve. Such a focus on social and emotional well-being increases the likelihood that children who enter foster care exit to reunification, guardianship, or adoption sooner and better equipped to become healthy, contributing adults.

When I became the Director of the Illinois Department of Child and Families Services (DCFS) in 2003, the State had seen a dramatic reduction in the number of children in the foster care system. However, our data indicated that the children who were in the State's custody exhibited significant emotional and behavioral problems. There was no question as to the need for intervention and treatment to address the complex needs resulting from the maltreatment these children had experienced. At the same time, biological, foster, and adoptive parents shared with me the concerns that they had with regard to the psychotropic medications with which their children were treated. Many felt that these drugs were being overprescribed and were causing adverse side-effects, such a sedation, weight gain, and attention problems. A common sentiment

among these parents was that they lacked the expertise to make decisions about psychotropic medications or monitor their use and side-effects in their children. Their concerns were representative of the lack of capacity in the child welfare system to understand and oversee pharmacological treatment of children's behavioral and psychological issues. During my tenure as Director, DCFS developed a comprehensive system of protocols and safeties to ensure that psychotropic medications are prescribed responsibly and monitored consistently. This included:

- requiring that all prescriptions be reviewed and approved at the State Deputy Director level;
- establishing time-limits for reviews to ensure that necessary treatment was not delayed;
- developing an electronic database for tracking all prescriptions for children in foster care;
- creating "red flags" in the database that elevated certain cases, such as those in which three or more medications were prescribed, for more thorough review; and
- establishing best practice guidelines and distributing them to prescribers. The electronic database was also designed to identify providers whose patterns of prescribing differed from the guidelines.

The net result of these activities was greater longitudinal oversight of the pharmacological treatment of young people in foster care. We collected better data on how psychotropic medications were being used among this population, and important safety checks were established to ensure that use was appropriate and responsible.

OVERVIEW

Over the last decade and a half, the child welfare system has become 27 percent smaller, declining from 559,000 children in 1998 to just over 400,000 in 2010.¹ Nearly all States have

been able to reduce the number of children in foster care significantly by providing necessary support services to families to prevent children from coming into care, and, when they do come into care, moving them more quickly to permanent placements, such as reunification, guardianship, or adoption. However, as the system continues to decrease in size, the children who have remained in foster care are more likely to have emotional and behavioral problems that hinder healthy functioning and make it difficult to achieve permanency. Children who experience the trauma of maltreatment have complex needs and require a comprehensive set of services to overcome the social and emotional impact of abuse and neglect to be successful in life. As the child welfare system continues to reduce in size, it must concurrently build the capacity to identify the repercussions of maltreatment and deliver effective interventions that facilitate healing and recovery.

Social-emotional, behavioral, and mental health needs of children in child welfare

Children who come to the attention of the child welfare system have disproportionately high rates of social-emotional, behavioral, and mental health challenges. When examining rates of mental health diagnoses or behavior problems requiring clinical intervention, it becomes clear that the impacts of abuse and neglect on child and adolescent functioning are profound. A key source of information about the social and emotional well-being of and use of psychotropic medications with children who have experienced maltreatment comes from the *National Survey of Child and Adolescent Well-Being* (NSCAW), a longitudinal study required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and overseen by the Administration on Children and Families. NSCAW has been the source of invaluable information about how children who have been maltreated are doing over time and across domains – in school, at home, as they receive services, and as they become adults. Although it provides high-quality data that

directly informs the work of child welfare and mental health providers, the continuation of this important survey is at risk. Without ongoing funding from Congress, we will lose our best window into the lives of children who experience maltreatment.

NSCAW and other sources of information about the well-being of children and youth known to child welfare demonstrate the impact of maltreatment on social-emotional, behavioral and mental health:

- 23 percent of children 17 and under who have experienced maltreatment have behavior problems requiring clinical intervention. Clinical-level behavior problems are almost three times as common among this population as among the general population.²
- 35 percent of children 17 and under who have experienced maltreatment demonstrate clinical-level problems with social skills – more than twice the rate of the general population.³
- Both internalizing problems (e.g., depression, anxiety, being withdrawn) and externalizing problems (e.g., aggression, delinquency) are common in children who have experienced maltreatment. Among children who enter foster care, approximately one third have clinical-level behavior problems.⁴
- Children in foster care are more likely to have a mental health diagnosis than other children. In a study of foster youth between the ages of 14 and 17, 63 percent met the criteria for at least one mental health diagnosis at some point in their life. The most common were Oppositional Defiant Disorder/Conduct Disorder, Major Depressive Disorder/Major Depressive Episode, Attention Deficit/Hyperactivity Disorder, and Posttraumatic Stress Disorder.⁵

- By the time they are 17, 62 percent of youth in foster care will exhibit both symptoms of mental health disorder and symptoms of trauma.⁶
- Although they make up only three percent of the Medicaid population under age 18, children in foster care account for 32 percent of the recipients of behavioral health services in this group.⁷

Psychotropic medication use among children in foster care

According to a 2010 study, children in 13 States who are in foster care and enrolled in Medicaid were prescribed antipsychotic medications at nearly nine times the rate of children enrolled in Medicaid who were not in foster care.⁸ Over three years, 22 percent of children in foster care will have taken a psychotropic drug at some point.⁹ Although numerous studies have demonstrated that rates of psychotropic medication prescription are high among this group, it is unclear to what extent these rates may be reflecting, at least in part, the increased distress among children who have experienced maltreatment, though other factors may also be playing a role.

Studies have shown the following, with regard to the prevalence of psychotropic drug use and factors influencing the likelihood of use among children in foster care:

- Age: Children in foster care are more likely to be prescribed psychotropics as they grow older, with 3.6 percent of 2-5 year-olds taking medication at a given time, 16.4 percent of 6-11 year-olds, and 21.6 percent of 12-16 year-olds. The likelihood that a child will be prescribed multiple psychotropic medications also increases with age.¹⁰
- Gender: Males in foster care are more likely to be receiving psychotropic medications (19.6 percent) than their female counterparts (7.7 percent).¹¹

- Behavioral Concerns: Children scoring in the clinical range on the Child Behavioral Checklist, a common tool for assessing both internalizing and externalizing behavioral issues among children and youth, are much more likely than those with subclinical scores to receive psychotropic medications.¹²

Additionally, researchers have identified some patterns of prescription of psychotropic medication to children in foster care that may be problematic:

- Documented geographic variation in psychotropic medication use among children coming into contact with child welfare indicates that factors other than clinical need impact prescription. One study found that children in Texas were five times as likely as children in California to be taking psychotropic drugs. The varying rates of use cannot be attributed to population differences, suggesting that factors other than clinical need, such as gender and age, may be influencing the practice of prescribing psychotropic medications.¹³
- To treat the multiple mental and behavioral health symptoms that a child may exhibit, more than one drug—and often more than one type of medication—are prescribed. Among children in foster care taking psychotropic medication, 21.3 percent are receiving monotherapy (one class of psychotropic medication), 41.3 percent are taking three or more classes of psychotropics, 15.4 percent are taking medication from four or more classes, and 2.1 percent taking five or more classes of drugs.¹⁴ Although children with histories of maltreatment often present with complex, co-morbid conditions, evidence of the effectiveness of concomitant psychotropic use is scant. There is no research to support the use of five or more psychotropic drugs, yet we know that a small number of

children in foster care are receiving medications at these levels. Further, taking multiple medications within and across classes increases the risk of adverse effects, including drug interactions.

It is clear that the current use of psychotropic medications among children, particularly children in foster care, goes beyond that which is supported by empirical research. In the absence of such research, it is not possible to know all of the short- and long-term effects, both positive and negative, of psychotropic medications on young minds.

DEPARTMENTAL ACTIVITIES

The Department of Health and Human Services (HHS) has undertaken an interagency effort to understand the unique needs of children who have experienced abuse or neglect and develop a coordinated strategy to build the capacity of child welfare systems to meet these needs. Research has demonstrated that maltreatment has long-lasting, adverse effects in all domains of development. As our understanding about the multidimensional impact of maltreatment has increased, our knowledge of effective, evidence-based treatments, both psychosocial and pharmacological, has grown as well. However, the child welfare system has lacked the capacity to incorporate this knowledge and consistently apply it to improve the lives of children who have been abused or neglected. Through ongoing, coordinated efforts across the Department to build knowledge and encourage best practices, HHS is working to build the capacity of child welfare, children's mental health, and State Medicaid systems to both recognize the social-emotional, mental, and behavioral health consequences of maltreatment and deliver a mix of services that effectively responds to the complex needs of the children they serve.

To this end, a joint letter from the Administration on Children and Families (ACF), Centers for Medicare & Medicaid Services (CMS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) was sent out on November 23, 2011 to raise awareness of these issues at the State level and to share expanded opportunities that will be offered to strengthen their systems of prescribing and monitoring psychotropic medication use among children in foster care. These opportunities draw on the existing authority and resources of HHS and are part of a collaborative, Department-wide strategy to address this issue.

Additionally, a workgroup with representatives from HHS agencies- ACF, CMS, SAMHSA, the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) convened in the summer of 2011 with an initial task of examining the monitoring and oversight of psychotropic medications among children in foster care.

As an initial task, the workgroup gathered information about the need for mental and behavioral health services among children in foster care, as well as the use of psychotropic medications in this population. Peer-reviewed journal articles, research reports, reviews of State practices, and conversations with expert researchers and clinicians informed this process. HHS is disseminating this information widely and continues to seek emerging knowledge about the impact of maltreatment and what works to meet the complex needs of children known to the child welfare system. Additionally, HHS is funding demonstration and research projects related to the use of psychotropic medications and/or behavioral interventions for children in foster care.

Much is known about how child welfare systems can deliver more effective services to treat children and youth who have experienced maltreatment. A number of professional organizations

have built upon a wealth of empirical and practice-based evidence to create guidelines for the treatment of children known to child welfare, including the prescription and monitoring of psychotropic medications. Several States and jurisdictions have taken steps to both improve controls on psychotropic medications for children in foster care and increase their ability to identify and respond to the consequences of maltreatment. HHS is encouraging child welfare systems to learn about what works and undertake changes to implement best practices based on the existing professional guidelines and state examples, both of which are grounded in rigorous research or prior successful application. This includes the development of guidance and provision of technical assistance to States, Territories, and Tribes to support the building of capacity to recognize and respond to the needs of children who have been abused or neglected.

Future Actions

HHS has identified concrete actions in the three areas outlined above: (1) increasing oversight and monitoring of psychotropic medications, (2) expanding the evidence base for effectively responding to the needs of maltreated children, and (3) expanding the use of evidence-based screening, diagnosis, and treatment of social-emotional, behavioral, and mental health issues among children who have experienced abuse or neglect.

Expanding oversight and monitoring of psychotropic medications. HHS is strongly committed to the appropriate prescription and use of psychotropic therapies for children. In the coming months, ACF will issue guidance to States on best practices for monitoring psychotropic drug prescriptions for foster children.

State practices regarding prescription and oversight of psychotropic medications vary widely, and experts agree that greater controls are needed to ensure safe and appropriate use. According

to the Child and Family Services Improvement and Innovation Act of 2011 (P.L. 112-34), States must develop their own psychotropic medication monitoring procedures and describe them in their Child and Family Services Plans (CFSP). In advance of their 2012 Annual Plan and Services Report (APSR) submission (annual plans update and amend CFSPs, which are completed every five years), HHS will provide technical assistance, including the dissemination of guidelines developed by professional associations and information about exemplary practices in place in some States.

Additional ongoing activities will enhance psychotropic medication oversight. CMS will work with States to enhance their Drug Utilization Review (DUR) programs, which allow States to monitor dispensing at the point-of-sale, the pharmacy counter, and to influence prescriber behavior. CMS also will encourage providers to adopt, implement, upgrade, and meaningfully use Electronic Health Records (EHRs) in order to access the Medicaid and Medicare EHR incentive payments. EHRs can improve the consistency and quality of health services for children, especially those whose residences changes frequently. The development of quality health homes, standards for behavioral health, and behavioral health coverage for children and adults are among the practices that CMS will promote.

Expanding the evidence base. Efforts to expand the evidence base regarding the needs of children who have been maltreated are twofold. First, HHS is actively disseminating existing information about effective treatment of children known to child welfare, including the prescription and monitoring of psychotropic medications. Among other resources, this includes a report funded by AHRQ summarizing the findings of a 16 State consortium of State Medicaid Medical Directors developing best practices to improve the use of antipsychotic medications in children in Medicaid. Mechanisms for disseminating this and additional information about

psychotropic medications and behavioral interventions for children in foster care include webinars; a joint letter to State child welfare, Medicaid, and mental health directors from ACF, CMS, and SAMHSA; an Information Memorandum and subsequent Program Instruction to child welfare directors; and a compilation of resources on the Child Welfare Information Gateway, an online clearinghouse of materials for child welfare and related professionals.

Second, HHS is growing the evidence base by funding research and demonstration projects that investigate both client-level interventions and system strategies to improve well-being outcomes for children and families. AHRQ has contracted for an evidence review of interventions that address child exposure to familial trauma in the form of maltreatment or family violence. Meanwhile, the Administration on Children, Youth and Families (ACYF) has organized its discretionary funding to promote the social and emotional well-being of children and youth who have experienced maltreatment. For example, in FY 2011, a cluster of five grantees received a total of \$3.2 million to implement evidence-based, trauma-focused practices and evaluate their impact on safety, permanency, and well-being outcomes. Findings from research and demonstration projects supported by HHS will also be widely disseminated to a variety of stakeholders.

Increasing the use of evidence-based screening, diagnosis, and treatment. Other HHS actions will serve to expand the use of evidence-based and best practices for the identification and treatment of social-emotional, behavioral, and mental health problems among children who have experienced maltreatment. HHS supports the use of evidence-based interventions by disseminating information about what works (for instance, via the National Registry of Evidence-Based Programs and Practices and the National Child Traumatic Stress Network) and providing funding for implementation of strategies grounded in rigorous research (e.g., Maternal,

Infant and Early Childhood Home Visiting Program). These practices serve to identify and assess the needs of children who are suffering from the negative effects of abuse and neglect, and to target and deliver the appropriate services to meet children's identified needs. As child welfare systems build the capacity to recognize the consequences of maltreatment with greater precision, their delivery of services will be more tailored, and therefore more effective and efficient.

Because children in foster care are involved with multiple systems, including education, health, mental health, Medicaid, and others, a coordinated, multi-system approach is necessary to meaningfully improve outcomes for this population. HHS is working to facilitate State-level collaborations for the purposes of fostering improved behavioral health diagnosis, treatment, and tracking of all children, including those in foster care. In addition to holding joint webinars and disseminating materials across systems, ACYF, CMS, and SAMHSA will, in July 2012, convene State child welfare, Medicaid, and mental health directors to develop action plans for enhancing oversight of psychotropic medications and improving well-being for children in foster care.

It should be noted that increasing the capacity of child welfare systems to conduct evidence-based screening, assessment, and treatment requires enhancing the clinical competencies of the workforce. As the research I have shared demonstrates, children who have experienced maltreatment have a complex behavioral profile requiring specialized services. In order to deliver these services, which we know can be effective, it is necessary to build the capacity of the child welfare workforce to recognize and respond to the impacts of abuse and neglect.

CONCLUSION

The research tells us that most of the children in foster care receiving psychotropic medications have legitimate needs that require careful, comprehensive intervention. There are effective treatments for the mental health disorders and trauma symptoms common among children known to child welfare, and efforts undertaken to ensure the appropriate use of psychotropics for these children must be accompanied by increased availability of evidence-based psychosocial treatments that meet the complex needs of children who have experienced maltreatment.

The experience of maltreatment can derail the development of a child and severely hinder his or her chances for success throughout life. However, we know that some children who have been abused or neglected do not develop the myriad problems listed above. That tells us that although children who have been maltreated face immense challenges, they are incredibly resilient. We also know that even among children who do develop social-emotional, behavioral, and mental health problems, healing and recovery are possible. With the right tools and capacity, child welfare systems can identify the complex needs of children who have experienced maltreatment and deliver targeted, evidence-based services that help young people overcome the social and emotional impact of abuse and neglect. By addressing these needs, we increase the likelihood that children in foster care will exit to positive, permanent settings, with the skills and resources they need to be successful in life. HHS is working to build the child welfare system's capacity to identify and treat the needs of maltreated children by expanding the evidence base around social-emotional well-being for children in foster care; improving oversight and monitoring of psychotropic medications among this group; and expanding the use of evidence-based screening, assessment, and treatment to promote healing, recovery, and well-being for these children.

Thank you. I look forward to working with you on these issues, and I am happy to take your questions.

¹ Administration for Children and Families (1998-2010). Adoption and Foster Care Analysis and Reporting System, Reports 11-18. Washington, DC: US Department of Health and Human Services.

² Data source: National Survey for Child and Adolescent Well-Being II

³ Ibid.

⁴ Ibid.

⁵ White, CR; Havalchak, A; Jackson, L; O'Brien, K; & Pecora, PJ. (2007). Mental Health, Ethnicity, Sexuality, and Spirituality among Youth in Foster Care: Findings from The Casey Field Office Mental Health Study. Casey Family Programs.

⁶ Griffin, G; McClelland, Holzberg, M; Stolbach, B; Maj, N; & Kisiel, C (In Press). Addressing the impact of trauma before diagnosing mental illness in child welfare. *Child Welfare*.

⁷ Center for Health Care Strategies, Inc. (Forthcoming). Analysis of Medicaid Claims Data for 2005.

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¹⁰ Raghavan, R; Zima, BT; Anderson, RM; Leibowitz, AA; Schuster, MA; & Landsverk, J. (2005). Psychotropic medication use in a national probability sample of children in the child welfare system. *Journal of child and adolescent psychopharmacology*. 15(1):97.

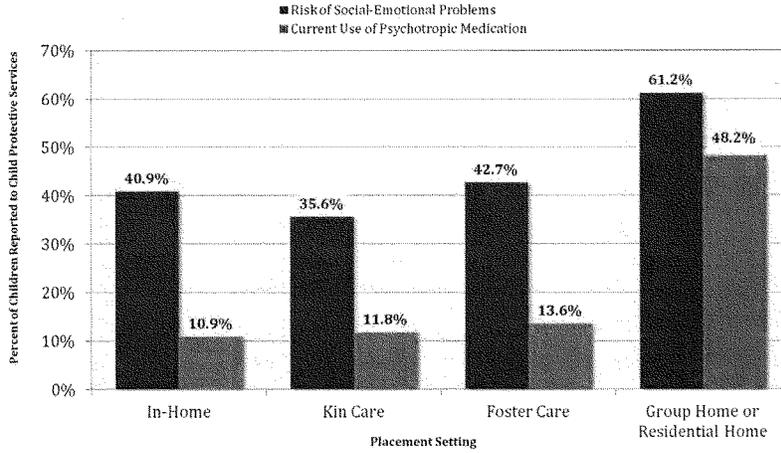
¹¹ Ibid.

¹² Ibid.

¹³ Raghavan, R; Gyanesh, L; Kohl, P; & Hamilton, B. (2010). Interstate variations in psychotropic medication use among a national sample of children in the child welfare system. *Child Maltreatment*. 15(2): 121-131.

¹⁴ Zito, JM; et al. (2008). Psychotropic medication patterns among youth in foster care. *Pediatrics*. 121(1): e157.

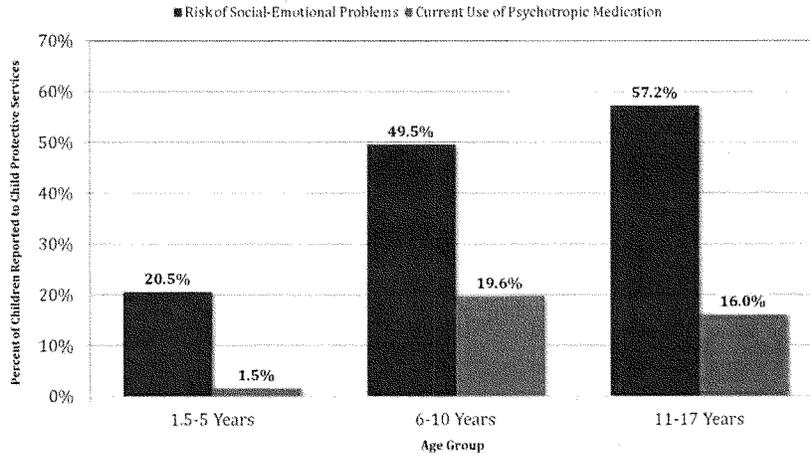
Risk of Social-Emotional Problems and Use of Psychotropic Medication, by Placement Setting



Data Source: National Survey of Child and Adolescent Well-Being II (NSCAW II). NSCAW II is a Congressionally required study sponsored by the Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (DHHS).

Risk of social-emotional problems as defined as scores in the clinical range on any of the following standardized measures: Internalizing, Externalizing or Total Problems scales of the Child Behavior Checklist (CBCL administered for children 1.5 to 18 years old), Youth Self Report (YSR, administered to children 11 years old and older), or the Teacher Report Form (TRF, administered for children 6 to 18 years old), the Child Depression Inventory (CDI, administered to children 7 years old and older), or the PTSD section Intrausive Experiences and Dissociation subscales of the Trauma Symptom Checklist (administered to children 8 years old and older).

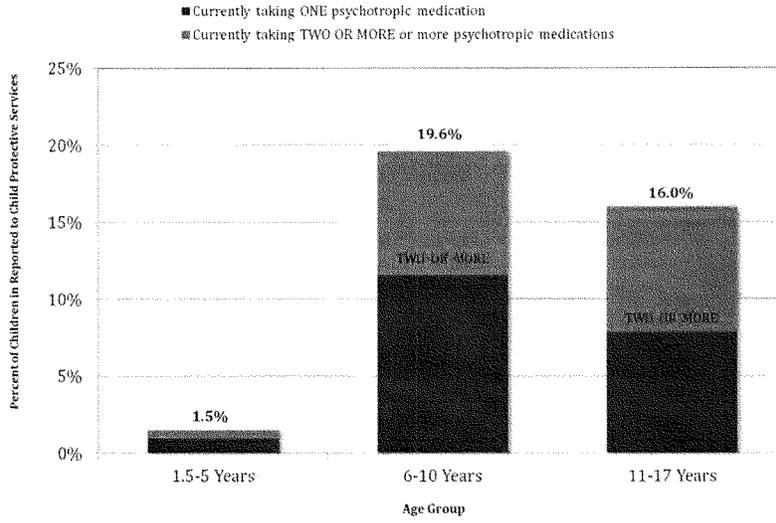
Risk of Social-Emotional Problems and Use of Psychotropic Medication, by Age Group



Data Source: National Survey of Child and Adolescent Well-Being II (NSCAW II). NSCAW II is a Congressionally required study sponsored by the Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (DHHS).

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Psychotropic Medication Use and Polypharmacy among Children Reported to Child Protective Services, by Age Group



Data Source: National Survey of Child and Adolescent Well Being II (NSCAW II). NSCAW II is a Congressionally required study sponsored by the Office of Planning, Research and Evaluation, Administration for Children and Families (ACEF), U.S. Department of Health and Human Services (DHHS).

The Financial and Societal Costs of Medicating America's Foster Children

Testimony of

Matt Salo

Executive Director

National Association of Medicaid Directors

Before the

Senate Homeland Security and Government Affairs Committee

**Subcommittee on Federal Financial Management, Government Information, Federal Services, and
International Security**

December 1, 2011

Good morning Chairman Carper, Ranking Member Brown, and distinguished members of the Committee. My name is Matt Salo, and I am the Executive Director of the National Association of Medicaid Directors (NAMD). We appreciate the opportunity to testify before you today on an issue of critical importance in our health care system.

Medicaid

Medicaid is the nation's health care safety net. Jointly financed by the states and the federal government, Medicaid will spend more than \$400 billion this year to provide health care to more than 60 million Americans. The program is administered by the states within a broad federal framework which leads to enormous variation across states in terms of who is covered, what services are provided, and how those services are delivered and paid for. Furthermore, within any given state, Medicaid's role is broad, varied, and complex. Medicaid funds more than 40 percent of all births, and the majority of all publicly financed long-term care in this country. It also provides most of the nation's funding for HIV/AIDS related treatments, mental health services, and others. It is therefore very difficult to talk simplistically about Medicaid (either nationally, or within a state), despite its incredible importance in the U.S. health care system.

NAMD is a newly formed organization created with the sole purpose of providing a home for the nation's Medicaid Directors and we represent all 56 of the state, territorial and DC agency heads. Our two broad objectives are to give the Medicaid Directors a strong, unified voice on national and federal matters as well as helping develop a robust body of technical assistance and best practices for them to improve their own programs. While no two programs look exactly alike, the Directors are unified in their heartfelt desire to improve the health and health care of the growing number of Americans who rely on the program.

Pharmaceutical coverage for children in foster care

Pharmaceutical coverage and expenditures have been a large and growing concern of the Medicaid Directors for a number of years. Psychotropics pose a unique concern primarily because the trends in costs and utilization are far outstripping every other baseline. Careful analysis of the data implies that this is a result of many factors, some legitimate, others less so. Concerns include both overutilization and inappropriate utilization, and this is true for adults, seniors, and, unfortunately, children as well.

As noted in the GAO report, this is also true, and especially concerning for one particularly vulnerable population, children in foster care. While psychotropic medications show enormous promise in treating a wide variety of serious conditions, there are clearly concerns about how current prescribing patterns can negatively impact the foster care population. The GAO report pointed out serious potential problems in three primary areas: the concomitant use of five or more psychotropics; prescribing doses higher than the maximum levels cited by FDA guidelines; and the prescribing of psychotropics to infants under 1 year old.

There is no question that subjecting our most vulnerable citizens to bad medicine is unacceptable and that we can and should and will do better by them.

But there is also no question that this problem is the result of a range of serious flaws in the US health care system: from the prescribing patterns of physicians to the lack of oversight of a variety of levels of government, the lack of effectively promulgated health information technology, and the fragmented nature of the relationship between acute care and behavioral health in this country. As such, solutions will require coordinated efforts from states, the federal government, mental health professionals, primary care practitioners, researchers, and others.

By definition, children in foster care are covered primarily by Medicaid, and, as noted in the report, "they tend to have more numerous and serious medical and mental health conditions than do other children." While this does not excuse the delivery of substandard care, it does help to explain why psychotropic prescribing patterns for this population are higher than for the general population. We also note a recent study in the medical journal *Pediatrics* that shows that psychotropic prescribing patterns for children in foster care are even higher than those in the SSI population, who are by definition facing much more serious disabilities than the general population. This is likely true because many of the children who qualify for SSI do so because of physical, as opposed to behavioral/mental disabilities. To that extent, the foster care population may legitimately require more significant behavioral intervention than the overall SSI population.

There are other reasons to make sure we are making valid comparisons before drawing conclusions. In conversations with the medical and behavioral health experts in the states surveyed for the report, questions that warrant exploration were raised about the survey. For example, multiple prescriptions might reflect a prescriber legitimately cycling through a variety of potential medications in order to find the one that works best for an individual. Similarly, there are instances where multiple psychotropics may well be in the best medical and behavioral needs of a given individual. Further analysis of prescribing patterns for infants show that many examples are for Benadryl. This is not to excuse unacceptable behavior, or rationalize away serious problems where they exist, simply that more analysis is needed to figure out the nature and scope of the real underlying problems.

Challenges

There are unfortunately a number of reasons why state oversight policy, or medical practice may have failed to keep up with the ever changing literature or other developments. These are not meant to be excuses for failure to act, but indicative of the breadth of the challenges that face systemic reform. Furthermore, it cannot be stressed enough how unique are the challenges faced by the children in the foster care system.

While government has an obligation to lead, doing so in violation of clear community opposition is fraught with risk, and pyrrhic victories are often short lived. As states grapple with finding solutions to the epidemic of over- and misuse of psychotropics in general, they often face opposition from the manufacturers of these products, from mental health advocates (who in many cases are funded in large part by these same manufacturers), and from the community at large, who tend to resist government intrusion into a doctor-patient relationship often viewed as sacrosanct.

In some states, this has resulted in state legislative action that has placed absolute prohibitions on prior authorization of psychotropics like atypical antipsychotics. These laws place significant barriers on state pharmacy managers in their efforts to ensure compliance with the latest practice guidelines. While state legislative barriers are not permanently set in stone, resolving them does require different strategies than in addressing state-level executive branch policy.

These challenges also play out in the complicated relationship between state foster care workers, the children in the system, and the prescribers themselves. A lot of behavioral problems in foster care kids are as a result of trauma which is under-diagnosed and requires specialized treatment approaches.

As a practical matter, in an emergency, most prescribers are more likely to add medications than discontinue them, and effectively minimizing medication use requires a stable ongoing treatment relationship with a prescriber – a relationship that is rare, especially among older children who can change placements frequently, seeing a different prescriber each time.

State agencies also face challenges in recruiting and retaining sufficiently trained staff who possess the clinical expertise necessary to challenge a prescriber's recommendation to treat with psychotropics. One state in particular had to abandon an attempt to strengthen the hand of foster care workers in these situations, when it became clear that BA/BS or MSW educated workers would face significant liability issues when disagreeing with prescribers.

Solutions

In the short term, I would note that in my conversations with the states that were a part of the GAO study, all were undertaking efforts to address the identified shortcomings. I know that your staff have had extensive conversations with many, if not all, of these states, but we would be happy to continue to work with you if there is any further outstanding follow up required.

But above and beyond these individual efforts, there is also a need for broader systemic reform. There are a number of solutions that can and should be implemented to help improve this situation. 1) The GAO report recommends promulgating additional federal guidance from HHS to the states; 2) More clinical research is needed on the effects and implications of treating children of any age and in any situation with psychotropics that have only been tested on adults; 3) More work needs to be done to break down the barriers to coordinating and integrating care for vulnerable populations in Medicaid, with an added focus on the varied, complex and challenging behavioral health conditions experienced by children in foster care; 4) While Medicaid coverage and payment policy can and should change, many of the challenges in this issue are medical policy issues, and as such, require the broader medical community to also adapt; and 5) NAMD, working collaboratively with key partners such as the Medicaid Medical Directors and the State Mental Health Program Directors can develop and disseminate best practices in this area and work with states to implement them;

More HHS Guidance

While HHS has provided some guidance thus far, states would clearly welcome additional information. On behalf of our members, NAMD is committed to working with HHS, across the various agencies that impact this population, including the Administration on Children and Families (ACF) the Substance Abuse and Mental Health Services Administration (SAMHSA), the Center for Medicaid and CHIP Services (CMCS), and others. This is especially true in instances where state Medicaid agency policymakers need additional tools or leverage to convince policymakers in the state legislative branch or even state medical association leadership about changes to current policy.

The American Academy of Child and Adolescent Psychiatry (AACAP) guidelines contain four broad categories: consent, oversight, consultation, and information sharing. The preliminary investigation into the six sample states demonstrates a wide range of compliance with the non-binding recommendations in these four categories. We know that HHS is developing comprehensive guidance, and combining those recommendations with the power of transparency on this poorly-studied issue should help states improve their practices and improve the lives of foster children entrusted to our care.

Research on Psychotropic Impacts on Children

There are three major holes in the body of medical research relevant to this situation. The broadest is that there is not enough evidence on the comparative effectiveness of the various generations of psychotropics. FDA's mandate is to approve new pharmaceuticals based on performance relative to placebos, not relative to existing products.

A second relevant issue is the lack of understanding of how psychotropic drugs affect children in general. Children generally do not participate in FDA clinical trials for a variety of reasons, but there must be ways to work around this barrier to better understand how these powerful substances affect developing minds.

Finally, as noted in the GAO report, in an unspecified state, "57 percent of foster children were diagnosed with a mental disorder – nearly 15 times that of nonfoster children receiving Medicaid assistance." However, the report goes on to say that "very little research has been done on the use of psychotropic drugs in foster children with severe symptoms. This limits the information available to providers on how best to treat their conditions." The challenges faced by children that result in their placement in foster care combined with the challenges they face once in the system are nothing like those faced by either children in the general population, or even non-foster care children diagnosed with several mental illness. More work is needed to evaluate these unique challenges and to prepare for them.

Integrated and Coordinated Care

Care coordination— the alignment of treatments, various health professionals and regular care givers around a care plan for individuals with mental and physical health problems—is essential to good health outcomes and too often lacking in our nation's health care system. Further complicating good care, is the fragmentation between the fields of mental and physical health care. Privacy concerns, divergent

professional training, and splintered payment and coverage systems are just a few of the reasons why behavioral and physical health needs are thought of and addressed separately.

As noted in the GAO report, "foster children who change placements often do not have a consistent caretaker to plan treatment, offer consent, and provide oversight...changes in placement pose significant challenges for agencies, foster parents, and providers with regard to providing continuity of health care services and maintaining uninterrupted information on children's medical needs and courses of treatment." For them, the fragmentation between mental health and primary care is exacerbated by the transitory nature of their care and treatment regimen.

Medicaid, Medicare and private payers are actively investing in care coordination efforts, including medical homes, health IT and evidence-based medicine. These efforts should benefit foster children, but they are likely insufficient to address the range of problems without focused initiatives.

Medical Policy Changes

As stated by the AACAP, "the ultimate judgment regarding the care of a particular patient must be made by the clinician in light of all of the circumstances presented by the patient and his or her family, the diagnostic and treatment options available, and available resources." Without disputing that assessment, it is clear that clinicians desperately need more information about not only the options available, but better data and analysis to determine their effectiveness and consequences. However, it is not enough to simply assume that more research will lead automatically and quickly to significant changes in practice. It is the medical professionals themselves, aided by their trade associations that must similarly commit to reforming how they practice medicine.

NAMD Best Practices

As I mentioned earlier, one of the two primary functions of our association is to help identify and disseminate best practices across all states. In this particular area, we have been and will continue to be strongly supportive of the efforts of groups like the Medicaid Medical Directors Learning Network (MMDLN) and the National Association of State Mental Health Program Directors (NASMHPD) to work with states to address these challenges. They have formed a consortium of 16 states representing about 12 million children and adolescents covered by Medicaid. Their work to date includes: analyses of each state's antipsychotic medical use rates and trends for children, adolescents and those in foster care; the development of a set of safety, quality, or appropriate-use indicators to monitor treatment patterns; identification of state-specific programs and policies that could improve the use of antipsychotic medications; providing a forum for discussion of policies and programs for optimizing antipsychotic medication; and the development of a compendium of state practices that could be shared with other states to address issues related to antipsychotic use in children and adolescents.

This work resides on a public website and is already changing statewide practices across the country. With these tools states have the ability to work with prescribers to provide safer and more effective medication management across Medicaid or any population that chooses to use the guidelines.

McClellan Testimony: Psychotropic Drugs in Children

Statement of Dr. Jon McClellan

Professor

University of Washington

Seattle, Wa

Senate hearing: December 1, 2011

“The Financial and Societal Costs of Medicating America’s Foster Children”

McClellan Testimony: Psychotropic Drugs in Children

Mr. Chairman and Members of the Subcommittee; thank you for inviting me to participate in this important discussion regarding the use of psychotropic medications in foster children.

I am a Child Psychiatrist at Seattle Children's Hospital, a Professor at the University of Washington, and the Medical Director of Child Study and Treatment Center, the State psychiatric hospital for youth in Washington State.

The high risk practices identified by the GAO study raise significant concerns regarding the treatment of severely mentally ill and vulnerable youth. Although the focus of this study is on foster care, the concerns raised are relevant to all children and adolescents prescribed psychotropic drugs.

Children in foster care often have emotional and behavioral difficulties. The high rate of medication use in this population is not a new discovery, nor does the use of these drugs always imply bad practice. Several psychiatric medications have been studied and approved for use in children and adolescents. When prescribed correctly, these treatments can help reduce suffering and enhance the functioning of young people.

McClellan Testimony: Psychotropic Drugs in Children

However, it is also well documented that many children in the child welfare system do not receive high quality psychiatric services. Treatment too often occurs during times of crisis, without adequate support or access to skilled clinicians and programs capable of providing effective social and behavioral interventions.

In these situations, medications become stopgaps, used to prevent the child from hurting themselves or others, or to help control disruptive behaviors that threaten the child's foster placement. The lack of effective long-term treatment exacerbates the risk for excessive and inappropriate medication use.

This problem is evident in the patterns of high-risk prescriptions identified by the GAO study. As a group, children in foster care were more likely than other children to be treated with multiple psychiatric drugs, and also were more likely to be treated with dosages that exceed recommended standards of care.

These practices impacted thousands of children. Some young people were prescribed as many as 10 different psychotropic drugs at the same time. Some children younger than 5 years of age were prescribed as many as 5 different medicines concurrently.

McClellan Testimony: Psychotropic Drugs in Children

Unfortunately, such practices are not uncommon. At my State hospital, kids are often admitted taking four or more medications. A few years ago, one young boy admitted to Seattle Children's Hospital was taking 13 different psychotropic drugs. There is no research that justifies these practices.

The most troubling finding of the GAO study is the use of psychotropic drugs in infants. Most of the prescriptions in babies were for antihistamines, some of which may have been used to treat other types of medical problems. Regardless, there is little research supporting the use of these medicines in very young children, and the prescriptions are concerning.

Furthermore, dozens of babies were prescribed antipsychotics, antidepressants, clonidine or lithium. Some infants were prescribed more than one drug. The use of psychotropic medications in babies defies both standard of care and common sense.

The findings of the GAO study strongly suggest the need for better oversight. The Best Practices outlined by the American Academy of Child and Adolescent Psychiatry provide a useful set of monitoring guidelines.

McClellan Testimony: Psychotropic Drugs in Children

Washington State has implemented a model system to oversee psychotropic drugs. Criteria were developed to identify prescriptions that exceed safety thresholds, based on dose, number of medications or age of the child. For prescriptions flagged by this process, a second opinion by a child psychiatrist is required before the medication is dispensed. This oversight system has reduced high-risk prescriptions, and over a two-year period, saved the State 1.2 million dollars.

The results of the GAO study also strongly call for more research. A hodgepodge of prescribing practices occurs in part because none of our current treatments work well enough. Genetics and neurobiological sciences have advanced substantially over the past decade, in large part due to the leadership of the National Institute of Mental Health. Nonetheless, given the marked complexity of brain functioning, the underlying causes of most psychiatric illnesses remain unknown. Without known causes, research on intervention inevitably struggles. We need continued investment, both fiscal and intellectual, in order to develop safer and more effective treatments, and to eventually find cures.

Thank you for listening.



January 23, 2012

The Honorable Thomas R. Carper
Chairman
The Honorable Scott P. Brown
Ranking Member
Subcommittee on Federal Financial Management, Government Information, Federal
Services, and International Security
Committee on Homeland Security and Governmental Affairs
United States Senate

*Subject: Post-hearing Responses on December 1st, 2011, Hearing on the Financial
and Societal Costs of Medicating America's Foster Children*

On December 1, 2011, we testified before your subcommittee at a hearing entitled *The Financial and Societal Costs of Medicating America's Foster Children*. This letter responds to your request that GAO provide answers to a number of post-hearing questions. The questions and our responses are provided in the enclosure. The responses are generally based on work associated with previously issued GAO products, which were conducted in accordance with generally accepted government auditing standards. We did not obtain comments on our responses to the post-hearing questions from the Department of Health and Human Services or the six states we reviewed.

If you have any further questions or would like to discuss these responses, please call me on (202) 512-6722.

Gregory D. Kutz
Director
Forensic Audits and Investigative Service

Enclosure-1

Post-Hearing Questions for the Record
Submitted to Gregory Kutz (GAO)
From Senator Thomas R. Carper

- 1. In your testimony, you said that the variation among the states' monitoring programs over psychotropic drugs is to be expected. This is apparently because each state sets its own guidelines and Department of Health and Human Services has not endorsed any specific measures for state oversight of psychotropic prescriptions. GAO recommended that they make such an endorsement. Did Department of Health and Human Services agree with your recommendation? What else, in your view, could Department of Health and Human Services do to assist the states in better overseeing psychotropic drugs?**

HHS agreed with our recommendation and stated that the Administration for Children and Families (ACF) will issue guidance to the states on best practices for monitoring psychotropic drug prescriptions for foster children. In addition, HHS stated that ACF will disseminate to states the current best practices for use in developing their approaches and protocols. In its comments to the draft report, HHS also stated that it has developed a plan to strengthen oversight; increase use of evidence-based screening, diagnosis and intervention; and expand the knowledge base about psychotropic drugs. It anticipates that these and other efforts will lead to enhanced data collection on diagnosis and medication use among foster children, a more thorough understanding of the effectiveness of pharmaceutical treatments, and more collaborative relationships between state foster care, Medicaid, and mental health agencies.

While we did not evaluate other actions that HHS could take to assist states as part of our review, we support the plans described in HHS' comments. More data on psychotropic prescriptions to foster children and the effectiveness of these drugs, many of which have not been approved as safe and effective for children of all ages, can help states better identify the risks and benefits of medications prescribed to children in state care. We agree that fostering collaboration among state agencies will also be beneficial, since a lack of collaboration among state agencies, professionals, and organizations responsible for the care of foster children was identified as a factor that may contribute to higher rates of prescribed psychotropic drug regimens to foster children.

- 2. In your testimony today you note that although prescription rates are higher among foster children, the total number of non-foster children taking psychotropic drugs is much, much higher than the number of foster children taking those drugs.**

a. Do you believe that separate controls should be in place to protect foster children in Medicaid?

Yes. Children placed in foster care are among our nation's most vulnerable populations. These children face unique challenges such as greater exposure to trauma before entering state care, frequent changes in foster placements, and varying state oversight policies affecting their care. Because of their unique needs and circumstances, we strongly support state efforts to implement consent, oversight, consultation, and information sharing processes specific to this population.

b. What do you believe should be done to help oversee the prescription of psychotropic drugs to the vast majority of children in Medicaid that are not foster children?

While we did not examine oversight of psychotropic drugs for nonfoster children in Medicaid, many of the controls recommended for psychotropic prescriptions for foster children could also improve oversight of prescriptions for nonfoster children. For example, best principles guidelines published by the American Academy of Child and Adolescent Psychiatry recommend facilitating the consent process with psycho-educational materials, monitoring rates and types of psychotropic prescriptions, providing consultations for consent-givers and physicians, and creating a website on policies and procedures governing psychotropic drugs, steps which could help states better understand and oversee psychotropic prescriptions to all children in Medicaid.

3. The GAO found hundreds of foster children and over a thousand non-foster children in Medicaid who were prescribed five or more psychotropic drugs at the same time. How did GAO select five psychotropic drugs as the threshold?

We developed indicators of potential health risks, including five or more concomitant medications, based on input from our child psychiatrists; a literature review; state guidelines; and interviews with officials from the Centers for Medicare & Medicaid Services, state Medicaid and foster care offices, the National Institute of Mental Health, and professional medical associations. According to our experts, the use of five or more drugs at once is a high-risk practice. Our experts also said that no evidence supports the use of five or more psychotropic drugs in adults or children, and only limited evidence supports the use of even two drugs concomitantly in children.

a. Did you find children receiving more than five psychotropic drugs at the same time?

We analyzed state Medicaid fee-for-service and foster care data from five selected states for 2008. In each of the five states, we identified foster children and nonfoster children who were prescribed more than five drugs

at a time, with nonfoster children in two states prescribed as many as ten drugs concomitantly.

b. How often did you identify children with 2, 3 or 4 psychotropic drugs prescribed at the same time?

The rate of children prescribed two psychotropic drugs concomitantly ranged from 3.0 to 7.3 percent among foster children compared to a lower 0.4 to 1.2 percent rate among nonfoster children, or a total of 4,859 foster children and 24,916 nonfoster children in five states. The rate of children prescribed three psychotropic drugs concomitantly ranged from 1.2 to 5.7 percent among foster children and 0.1 to 0.5 percent among nonfoster children, or a total of 3,016 foster children and 9,820 nonfoster children in five states. The rate of children prescribed four psychotropic drugs concomitantly ranged from 0.3 to 2.5 percent among foster children and 0.0 to 0.2 percent among nonfoster children, or a total of 1,346 foster children and 3,242 nonfoster children in the five states.

c. What are some of the risks these children face if given this number of drugs?

Increasing the number of drugs used concurrently increases the likelihood of adverse reactions and long-term side effects, such as high cholesterol or diabetes, and limits the ability to assess which of multiple drugs are related to a particular treatment goal.

Post-Hearing Questions for the Record
Submitted to Gregory Kutz (GAO)
From Senator Scott P. Brown

- 1) GAO reported that the 5 selected states spent at least \$375 million for psychotropic drugs prescribed to children in Medicaid. It has been discussed that some psychotropic drugs are prescribed to children for uses that are not FDA-approved and/or supported in one of three medical compendia.**

- a. Why did you raise the question of reimbursement for drugs not approved by FDA or supported in one of the three compendia?**

A state's individual Medicaid plan may choose not to include reimbursement for drugs used for a purpose not approved by FDA or supported in one of the three compendia. GAO has attempted to obtain HHS's legal position regarding whether federal financial participation is proper if a State does choose to include such uses of a drug in its plan, and we will be elevating this question to the Acting General Counsel of HHS.

- b. If HHS is not legally authorized to pay or reimburse states for certain psychotropic and other drugs not approved by FDA or supported in the three compendia, what is the implication for federal tax dollars?**

If HHS is not legally authorized to pay or reimburse states for these drugs, we would consider HHS payments for these drugs improper payments.

- c. Even if legally authorized, do you have any concerns about federal reimbursement for certain unsupported or high risk practices?**

According to our experts, the following three prescribing practices carry increased levels of risk for children; concomitant prescriptions of five or more medications, doses exceeding maximum levels in FDA-approved drug labels, and prescriptions for infants. Because of the risk of adverse reactions and long-term side effects, these practices raise concerns regardless of whether they are reimbursed or not.

- 2) GAO reported that Maryland did not have reliable data for its foster children in 2008. The data GAO received were materially different than the data Maryland reported to HHS. In GAO's statement, you said that Maryland was excluded from your analysis due to the unreliability of their foster care data. How did you determine that Maryland did not have reliable data, and what are the implications of this for the management of their programs?**

We determined through data tests, interviews, and reviews of state audit reports that data on children in Maryland foster care during 2008 were unreliable. State officials told us that Maryland's transition to a new records system in 2007 resulted in incorrect and missing data for foster children. A state audit in 2008 reported duplicate records with different identifying numbers for the same child, records showing children who had exited foster care as still enrolled in the program, and personal information for the mother recorded as that of the child. Our analysis of the data Maryland provided to us identified 8,869 children in foster care as of September 30, 2008—about 16 percent more than the 7,613 children that Maryland reported to ACF that year. Maryland's unreliable foster care data raises questions about its ability to adequately oversee the thousands of children in its care. However, it should be noted that subsequent audit reports for Maryland indicated that the state had taken some corrective actions as of March 2011.

3) In your written statement, you said that the six selected states' monitoring programs for psychotropic drugs provided to foster children fall short of best principle guidelines published by the American Academy of Child and Adolescent Psychiatry (AACAP).

a. Since your study covered several years from 2008 to 2011, did you see any states making progress on overseeing psychotropic drugs during that time?

Yes, during the course of our audit, we found that several states had implemented significant changes in the oversight of psychotropic drugs. For example, a couple of states reported beginning programs to review some or all psychotropic drugs prescribed to foster children. Oregon reported that since June 2010, annual reviews must be conducted for all children under 6 with a psychotropic prescription, or for any individual under 20 who remains in the care and custody of the state and who has more than two prescriptions for psychotropic drugs. Maryland reported that beginning in October 2011, the Maryland Medicaid Pharmacy Program implemented a peer-review authorization process to ensure the safe and effective use of antipsychotic medications in children. Claims for antipsychotic medications that are for children younger than the FDA-approved age require prior authorization based on the peer-review assessment. We did not test state-reported policies and procedures to ensure that they were implemented effectively.

b. What are some of the barriers for states to implementing the AACAP best principles or similar guidelines?

Although our audit did not specifically focus on the barriers states face in implementing controls over psychotropic drugs, we did find a couple of barriers for states to implement new oversight procedures. Both the Maryland Department of Human Resources and the Michigan Department of Community Health (DCH) noted in their agency comments to our draft report that additional resources would be necessary to implement new

oversight procedures. In addition, Michigan also reported challenges to coordinating data sharing among the state agencies to track rates and types of psychotropic prescriptions. Specifically, Michigan Department of Human Services completed an interagency agreement for data sharing with Michigan DCH to review foster children's prescription claims data on a quarterly basis, but was unable to build reliable reports with the first data set received in April 2011.

4) Your written statement notes that although prescription rates are higher among foster children, the total number of non-foster children taking psychotropic drugs vastly exceeds the number of foster children.

- a. Do you believe that separate controls should be in place to protect foster children?**
- b. What should be done to oversee the prescription of psychotropic drugs to the vast majority of children in Medicaid that are not foster children?**

See our answer to question 2 submitted by Chairman Thomas Carper.

5) In your analysis of psychotropic drug claims for foster children showing indicators of potential health risks, including drugs that can increase the risk of diabetes and high cholesterol. Did you evaluate any cases to see why these drugs were prescribed to kids and what kind of risks that they are exposed to? If not, what are your plans?

We did not evaluate any cases as part of this work. We plan to evaluate selected cases of foster children prescribed psychotropic drugs in our subsequent review.

6) According to a study done by Tufts last year, there is a noticeable "variation of rates of medication use for youth in foster care in different geographic communities." How do the differences in demographics and how state programs are run inform the data in Massachusetts specifically, and when analysis is attempted to find trends nationwide?

We did not evaluate the effect of differences in demographics or state programs on the psychotropic drug rate for each state.

**Senate HSGA Subcommittee on Federal Financial Management, Government Information,
Federal Services, and International Security
Post-Hearing Questions for the Record
Submitted to Bryan Samuels (HHS)
From Chairman Carper**

“The Financial and Societal Costs of Medicating America’s Foster Children”

December 1, 2011

Question: In your testimony you note that it’s clear many of the psychotropic prescriptions for foster children found by the GAO are not backed up by science. Prior to our hearing, the Department of Health and Human Services sent a letter to all 50 States regarding the monitoring and oversight of psychotropic prescriptions for foster care children. I’m told this was characterized by you – not as guidance – but as a “heads-up” to states that guidance is coming. Can you please provide a list of the steps Department of Health and Human Services is taking to address this issue and a firm timetable for completing them? Please include specific dates where you are able.

Answer: The below list identifies efforts across HHS agencies to address the use of psychotropic medication among children in foster care. The goal of these efforts is to improve the health, well-being, and future prospects of children who have been impacted by maltreatment.

ACF Activities

ACF is providing several opportunities for State child welfare staff to access information on the use of psychotropic medication among children in foster care, strategies to implement best practices, and recommendations for strengthening oversight. In their June 2012 Annual Progress and Services Report (APSR) submissions, States will be asked to submit comprehensive descriptions of procedures and protocols planned or in place to ensure the safe and appropriate use of psychotropic medications. The below activities are designed to support States as they develop and implement those plans.

- **Online Resources:** ACF’s Child Welfare Information Gateway has been updated to include an expanded array of resources pertaining to psychotropic medication use among children in foster care. These include guidelines for prescription and monitoring of psychotropic drugs for children in foster care developed by professional associations. Additionally, research articles examining the prevalence of and variation in use, and links to examples of States’ efforts to fortify prescription controls for this population are available. The Child Welfare Information Gateway is located at <http://www.childwelfare.gov>.
- **Webinars:** ACF is hosting three to four webinars in the coming months. The first webinar was held on January 9 and garnered over 430 attendees. Commissioner Bryan Samuels provided background information on the use of psychotropics among children in foster care and outlined the Administration’s current and future activities to address the

issue. Dr. David Rubin, Director of PolicyLab at the Children’s Hospital of Philadelphia, shared State based data on psychotropic medication usage in this population, and Dr. Eugene Griffin, Assistant Professor at the Northwestern University Feinberg School of Medicine, discussed trauma, mental health, and evidence-based interventions for these children and youth.

A second webinar is scheduled in February. Dr. Christopher Bellonci, Assistant Professor at Tufts University School of Medicine, will discuss the practice implications related to the existing and emerging evidence-base for psychotropic medication use among children in foster care, including a discussion of prescription practices that may be of concern with this population. Dr. Stephen Crystal, Associate Director for Health Services Research at the Institute for Health, Health Care Policy, and Aging Research at Rutgers University will provide a description of one way States have used Medicaid data to identify “red flag” prescription practices.

- A third webinar is scheduled in March and will feature State examples of practices and protocols for management of psychotropic medications among children in foster care.
- **Guidance:** In advance of June 2012, the Children’s Bureau will publish guidance documents providing information about the use of psychotropics with children in foster and detailing the information that will be requested of States in their Annual Progress and Services Review medical oversight submissions. Key considerations, exemplary practices from around the country, and technical assistance resources will be provided to guide State’s work and inform their responses to the enhanced APSR items.

CMS Activities

- **Share what is known:** CMS is working with partners to disseminate a report summarizing findings from a 16-State consortium of State Medicaid Medical Directors to develop best practices for the use of psychotropic medications among children in Medicaid. This report is available at: http://rci.rutgers.edu/~cseap/MMDLNAPKIDS/Antipsychotic_Use_in_Medicaid_Children_Report_and_Resource_Guide_Final.pdf.
- **Quality Measures:** CMS, through its Pediatric Quality Measures Program (PQMP), established in collaboration with the Agency for Healthcare Research and Quality (AHRQ), focuses on the refinement and development of children’s health care quality measures covering a range of health care issues, including behavioral health. The measurement development activities conducted through the PQMP build on the initial core set of children’s health care quality measures. This measurement set, released in 2010 for voluntary use by Medicaid and CHIP programs, includes three measures related to behavioral health (Follow-up Care for Children Prescribed Attention-Deficit Hyperactivity Disorder Medication; and Follow-up after Hospitalization for Mental Illness; and Developmental Screening in the First Three Years of Life). States choosing to collect the three measures can use these data in monitoring care and implementing initiatives to improve the quality of care for children with behavioral health conditions.

More information on the initial core set of children’s health care quality measures may be found at <http://www.cms.gov/smdl/downloads/SHO11001.pdf>.

- **Continuity of Eligibility and Care:** Children who move from one placement to another typically remain eligible for Medicaid but they may nonetheless see gaps in eligibility and disruptions in their care. Working with States, ACF, health care providers, and others, CMS will identify and communicate strategies to States for ensuring continuity of eligibility and care for children moving in and out of foster care, or between placements.
- **Working with States to Enhance Medicaid Drug Utilization Review (DUR):** States may use their Drug Utilization Review (DUR) programs to monitor dispensing at the point of service and influence prescriber behavior. For instance, at the point of service, the DUR programs can use system edits to limit inappropriate dosage and polypharmacy. In addition, States can use their retrospective DUR programs to reach out to providers whose prescribing habits vary significantly from recommended standards of care for children. CMS is developing a process for sharing with States best and innovative practices to enhance the functionality of their pharmacy programs. Additionally, CMS is considering new guidance to assist States in their efforts to monitor the utilization of psychotropic drugs dispensed by pharmacies and will be soliciting State input on what practices would be most helpful to address the special challenges of treating this population with psychotropic medications.
- **Health Homes:** Section 2703 of the Affordable Care Act, “State Option to Provide Health Homes for Enrollees with Chronic Conditions,” provides a new opportunity and an incentive for States, through temporary enhanced Federal reimbursement, to build a person-centered health care delivery system – caring not just for an individual’s physical condition, but providing linkages to long-term community care services and supports, social services, and family services, which are critical to children in foster care with chronic conditions. Through technical assistance pursuant to an already-published “State Medicaid Director/State Health Official Letter,”¹ CMS can support States’ interest in implementing this model, which integrates primary care and behavioral health services. States interested in receiving technical assistance may send an e-mail message to the Health Homes team at healthhomes@cms.hhs.gov or to the Integrated Care Resource Center mailbox, at IntegratedCareResourceCenter@cms.hhs.gov.
- **Health Information Technology:** Medicaid incentive payments are available at States’ option to certain providers who adopt, implement, upgrade or meaningfully use certified Electronic Health Records (EHR) technology. Electronic health records are used to capture clinical quality measures, such as those developed by CMS, AHRQ and SAMHSA for children and behavioral health. More information on health information technology may be found at <https://www.cms.gov/ehrincentiveprograms>.

¹ “State Medicaid Director/State Health Official Letter” available at <https://www.cms.gov/smdl/downloads/SMD10024.pdf>

SAMHSA Activities

- **Defining Best Practices:** SAMHSA and the American Academy of Child and Adolescent Psychiatry (AACAP) are finalizing guidelines for the use of psychotropic medications among children and adolescents being served in community-based agencies. These guidelines are for service providers and agency leaders to assist them in developing policy about the role of psychotropic medications in treatment planning for children and youth. These guidelines will be relevant to providers working with youth in foster care and will be disseminated to groups listed below.
- **Developing Resources:** SAMHSA is working with the AACAP to finalize a Tip Sheet for Child and Adolescent Psychiatrists on how to engage youth, how to give youth a voice in the treatment process, and how to improve communication between youth and their psychiatrists. This document will be disseminated to AACAP State and regional associations, the National Association of State Mental Health Program Directors (NASMHPD) Children's Directors, and through a number of other related listservs.
- **Infusing Clinical Expertise:** SAMHSA is sponsoring a Child and Adolescent Psychiatry Fellowship. Beginning in July of 2011, two child and adolescent psychiatrists were selected to spend 20 percent of a fellowship with SAMHSA working on policy issues and providing technical assistance to grantees and the field.
- **Health Homes:** Over the past year, SAMHSA and CMS have worked closely with States in the development and submission of their State Plan Amendments (SPAs) related to health homes. States that pursue the new health home optional benefit under section 2703 of the Affordable Care Act are required to consult and coordinate with SAMHSA to address the prevention and treatment of mental and substance use disorders among Medicaid eligible individuals with chronic conditions. Given the complex health problems faced by children and youth in the child welfare system, health homes are one vehicle for improving the care they receive.
- **Addressing Trauma:** As a part of its Strategic Initiative on Trauma and Justice, SAMHSA has identified child welfare as an area of focus for the prevention and treatment of the negative behavioral health consequences of traumatic events. In its portfolio of work on trauma, SAMHSA included a specific emphasis on serving children and youth in the child welfare system in the funding announcements released for the National Child Traumatic Stress Initiative. This work aims to support a balanced array of services for children who are experiencing trauma-related behavioral health problems. This effort includes a strong focus on empirically-validated psychosocial treatments in addition to the appropriate use of psychotropic medication.

Joint Activity

- **Facilitating Collaboration:** In summer 2012, ACF, CMS, and SAMHSA will convene State child welfare, Medicaid, and mental health authorities to address the use of psychotropic medications with children in foster care and the mental health needs of children who have experienced maltreatment. Peer learning and technical assistance to States will be made available.

Questions for Mr. Samuels and Mr. Salo: In their testimony, the GAO reported that the State of Maryland did not have reliable data for its foster children in 2008. I'm told this is why we only had five States examined and not six. I'm also told that the data GAO received from Maryland was "materially different" than the data Maryland reported to Health and Human Services. That's pretty troubling – the fact that officials in Maryland didn't have a good accounting for the children under their care.

Mr. Samuels, Were you aware that Maryland could not account for all of its foster children in its records in 2008?

Mr. Samuels and Mr. Salo, are either of you aware of any other States that have difficulty with maintaining accurate data for foster children under their care?

Finally, for both Mr. Samuels and Mr. Salo, what impact, if any, does this lack of accountability by a state have on its foster care and Medicaid federal grant funds?

Answer: The Administration for Children and Families (ACF) was aware of data quality issues with Maryland's foster care data, particularly in the time period used by GAO for this study. As noted in the GAO report, a major factor contributing to data quality problems at that time stemmed from implementation of Maryland's new statewide information system CHESSIE (Children's Electronic Social Services Information Exchange), which was implemented in all Maryland localities as of January 2007.

As part of ongoing oversight of State child welfare agencies, ACF conducted an Adoption and Foster Care Analysis and Reporting System (AFCARS) Assessment Review of Maryland's program in July 2008. A finding of that review was that, while the CHESSIE system was operational, the State had not completed data conversion and there was a significant amount of missing data in the records of children in foster care. The findings of the case file review indicated this information existed but was not entered into the official electronic file in CHESSIE. Following the AFCARS Assessment Review, the State entered into a Program Improvement Plan to address data quality and completeness and has undertaken significant efforts to improve the completeness and quality of its foster care data.

Maryland's experience with data conversion following implementation of a new statewide case management system is not atypical. States commonly experience issues involving less than comprehensive data for a period of time following such a system conversion. ACF monitors these issues and works with States to improve the quality and completeness of data on an ongoing basis. While work remains to be done, the overall quality of data on children in the foster care system has improved across the country in recent years.

ACF takes the need to hold States accountable for meeting Federal requirements and for improving outcomes for children and families very seriously. Clearly, accurate data are needed to assess State performance. All States operating a title IV-E Foster Care and Adoption Assistance program are required to submit AFCARS data every six months. After each submission, ACF reviews the files for substantial compliance with standards outlined in regulation. States found not to be in substantial compliance are notified in writing and strongly

encouraged to correct the data errors then resubmit the data files. In the past, penalties were assessed for data submissions that failed to meet compliance standards. However, several years ago, the Congress enacted legislation which superseded the previous penalty structure. Therefore, new penalty provisions, consistent with the revised law, need to be enacted through regulations amending the AFCARS requirements. Such regulations have not yet been published.

While AFCARS penalties are not currently being taken, ACF has continued to review State performance through the Child and Family Services Review (CFSR) process, which makes use of AFCARS data. Under CFSR protocol failure to address data concerns can still result in the application of financial penalties. Accordingly, these efforts are another way we prompt States to take steps as needed to improve data and ensure that progress in performance can be accurately measured.

Medicaid makes payments to States for medical assistance claims that comply with Federal law. In the instance of Medicaid reimbursement for covered outpatient drugs, Medicaid will reimburse States for covered outpatient drugs dispensed consistent with section 1927 of the Social Security Act. CMS is working with ACF and States to address the use of psychotropic medication among children in foster care.

Question for Mr. Samuels: I understand that language in the Child and Family Services Improvement Act of 2011, which President Obama signed into law in October of this year, gives the Department of Health and Human Services some new authority when it comes to psychotropic prescribing for foster children. One of my concerns is that, as I understand it, the new language requires that States have a plan to monitor the prescribing of psychotropic drugs for foster children – but it doesn't specify what should actually be in the plan. If not implemented well, it could become a compliance exercise instead of being a meaningful reform. First, can you talk about exactly what this new law changes and how Health and Human Services plans on meeting the new mandate?

Secondly, do you believe your Department needs further authority from Congress to make sure States are following the best guidelines possible for these prescriptions?

Answer: Your understanding is correct that the Child and Family Services Improvement and Innovation Act (Public Law 112-34) adds a specific requirement for States to adopt protocols relating to the monitoring of psychotropic medications for the first time. This amendment builds on a series of steps Congress has taken in recent years to strengthen oversight of the health care needs of children in foster care so some brief historical context is helpful to understand what exactly it changes.

The Federal requirement for child welfare agencies to provide oversight for the health care needs of children in foster care is a State plan requirement under title IV-B, subpart 1 of the Social Security Act, the Stephanie Tubbs Jones Child Welfare Services Program. Prior to the passage of the Fostering Connections to Success and Increasing Adoptions Act of 2008 the provision simply required a State agency to describe how it consulted with and involved physicians or other appropriate medical professionals in assessing the health and well-being of foster children and determining appropriate medical treatment.

The Fostering Connections to Success and Increasing Adoptions Act of 2008 expanded the provision, requiring States to develop a plan for ongoing oversight and coordination of health care services for children in foster care. This plan must be developed in coordination with the State Medicaid agency, and in consultation with pediatricians and other experts in health care, and experts in and recipients of child welfare services. It also must describe how the State will ensure a coordinated strategy to identify and respond to the health care needs of children in foster care placements, including both mental and dental health needs. As originally enacted, the law required States to address a number of specific points, including an outline of how the State oversees prescription medicines. In implementing the provision, ACF encouraged States to pay particular attention to oversight of the use of psychotropic medicines; however, there was still no specific statutory requirement for States to address this issue.

The Child and Family Services Improvement and Innovation Act strengthens the legal requirement by adding a specific provision requiring States to address protocols for the appropriate use and monitoring of psychotropic medications in their respective title IV-B Health Care Oversight and Coordination Plans. This statutory change formally allows for ACF oversight to work with States in strengthening their plans and ensuring they adopt appropriate protocols to monitor psychotropic medications.

We recognize that development of a plan does not, in and of itself, lead to improvements in practice. However, the new statutory requirement, coupled with technical assistance that provides to States best practice information on protocols and that addresses implementation issues, gives us the tools we need to ensure that States put in place strong oversight programs. Our response to your first question provides more details on what implementation will entail in the months ahead.

The Government Accountability Office identified and used guidelines developed by the American Academy of Child and Adolescent Psychiatrists (AACAP) as best practices for oversight and monitoring of the use of psychotropic medications with children in foster care in developing their report on the issue. These comprehensive guidelines provide important information to child welfare systems as they work to develop or enhance their processes for ensuring children in their care receive the best medical and psychiatric services available.

The Department will be issuing guidance in the coming months requiring States to develop protocols with recommendations of what should be included in those protocols.

Question for Mr. Samuels: GAO reported that the 5 selected States spent at least \$375 million for psychotropic drugs prescribed to children in Medicaid. I'm told that some psychotropic drugs are prescribed to children for uses that are not FDA approved or supported in one of three medical compendia. I understand Health and Human Services has yet to take legal position on whether these drugs can legally be covered by federal dollars. What is the Department's position as it relates to using federal dollars to pay drugs in these cases?

- a. Please clarify how Health and Human Services determines whether a use that is not FDA-approved is "supported" by one of the three compendia, as required by law. For example, is inclusion of the drug in the compendia for any use

sufficient, or are there criteria for the kind of studies that must be done on a drug before its inclusion in the compendia is considered to be supported?

Answer: Neither HHS nor CMS makes the determination on what studies must be done in order for a particular use of a drug to be considered “supported” by a citation in a compendium. It is up to each State Medicaid program to determine coverage policy within the parameters of section 1927 of the Social Security Act.

- b. Regardless of its legal position, does Health and Human Services review Medicaid prescription claims paid by the States and covered in part by Federal dollars to determine if the drugs can be legally reimbursed by CMS? If not, are there any restrictions on what drugs are reimbursed by CMS?

Answer: HHS does not review each claim. That is the responsibility of each State Medicaid agency. Per section 1927 of the Social Security Act, States are required to have a Drug Use Review (DUR) program for covered outpatient prescription drugs in order to assure that prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results. States are required to provide for a prospective drug review electronically, at the point of sale, by means of a predetermined set of edits which are approved by the Drug Utilization Review Board members, before each prescription is filled. A retrospective drug use review is performed by the State Medicaid agency to detect fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

Medicaid payment is available for covered outpatient drugs that have an associated drug manufacturer agreement and meet the definition of a covered outpatient drug in section 1927(k) of the Social Security Act. In addition, per section 1927(d) of the Social Security Act, States have the right to restrict access to certain drugs.

CMS is developing a process for sharing with States best and innovative practices to enhance the functionality of their pharmacy programs. Additionally, CMS is considering new guidance to assist States in their efforts to monitor the utilization of psychotropic drugs dispensed by pharmacies and will be soliciting State input on what practices would be most helpful to address the special challenges of treating this population with psychotropic medications.

- c. For what types of psychotropic or other prescriptions paid for by the States has HHS denied reimbursement with Federal dollars in the past?

Answer: In general, Federal Medicaid funds, also known as Federal financial participation (FFP), are available to States for payments to Medicaid providers. In general, with a few specified exceptions, States are required to cover every covered outpatient drug for every manufacturer that participates in the Medicaid drug rebate program.

CMS has denied FFP for drugs used to treat erectile dysfunction based on specific statutory authority enacted by Congress.²

² State Medicaid director letter 05-006, December 29, 2005, <http://www.cms.gov/smdl/downloads/SMD122905.pdf>

**Senate HSGA Subcommittee on Federal Financial Management, Government Information,
Federal Services, and International Security
Post-Hearing Questions for the Record
Submitted to Bryan Samuels (HHS)
From Senator Scott P. Brown**

“The Financial and Societal Costs of Medicating America’s Foster Children”

December 1, 2011

Question 1: For what types of psychotropic or other prescriptions paid for by the States has HHS denied reimbursement with Federal dollars in the past?

Answer: In general, Federal Medicaid funds, also known as Federal financial participation (FFP), are available to States for payments to Medicaid providers. In general, States that elect to cover prescription drugs in their Medicaid programs are required to cover every covered outpatient drug for every manufacturer that participates in the Medicaid drug rebate program.

CMS has denied FFP for drugs used to treat erectile dysfunction based on specific statutory authority enacted by Congress.¹

Question 2: What guidance has HHS provided to the States on what drugs will be covered by Federal dollars?

Answer: States are required to comply with section 1927 of the Social Security Act in order to obtain FFP for covered outpatient prescription drugs. CMS frequently communicates with States through State Medicaid Director letters and program releases on updates and changes to CMS policy related to the Medicaid prescription drug program. Generally, Medicaid payment is available for covered outpatient drugs that have an associated drug manufacturer agreement and meet the definition of a covered outpatient drug in section 1927(k) of the Social Security Act.

Question 3: Before GAO’s report (which used 2008 data), was HHS aware that Federal dollars are supporting potential high risk prescribing practices for concomitant use of multiple psychotropic drugs or the prescription of certain psychotropic drugs for infants? If yes, what has been done over the last three years to address this matter?

Answer: HHS is aware of concerns regarding possible inappropriate use of certain prescription drugs in State Medicaid programs. To help address these concerns, the President’s FY 2011 and FY 2012 Budget requests included a legislative proposal to require States to monitor high-risk billing activity in the Medicaid program to identify patterns that may show excessive or inappropriate use of certain prescription drugs. These activities would provide States with additional information to help identify and address possible inappropriate use.

¹ State Medicaid director letter 05-006, December 29, 2005, <http://www.cms.gov/smdl/downloads/SMD122905.pdf>

In addition, per section 1927 of the Social Security Act, all States are required to have a Drug Utilization Review (DUR) program for covered outpatient prescription drugs in order to assure that prescriptions are appropriate, are medically necessary and are not likely to result in adverse medical results. Using data from the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the DRUGDEX Information System compendia, States are required to provide for a prospective drug review before a prescription is filled and a retrospective drug use review to detect patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

Question 4: Since there is universal agreement on many of the potential high risk indicators, can HHS use edits through its reimbursement process as an additional check on high-risk prescriptions for foster children or children covered by Medicaid in general? What are the legal and statutory challenges to doing so?

Answer: It is the responsibility of each State to put in place edits that it deems appropriate for its Medicaid programs. States are required to have a DUR program for covered outpatient prescription drugs in order to assure that prescriptions are appropriate, medically necessary, and not likely to have an adverse medical result. In a letter sent to States on November 23, 2011 (<http://www.cms.gov/smdl/downloads/Tri-Agency%20Letter.pdf>), CMS reiterated the need for States to use their drug utilization review authority to monitor dispensing at the point of service. The retrospective drug review portion of the program provides oversight and education to positively influence prescriber behavior when deemed necessary. Additionally, as indicated in the letter, CMS is considering new guidance to assist States in their efforts to monitor the utilization of psychotropic drugs dispense by pharmacies and will be soliciting State input.

Questions 5: GAO reported that Maryland did not have reliable data for its foster children in 2008. The data GAO received were materially different than the data Maryland reported to HHS.

- a. Were you aware that Maryland could not account for all of its foster children in its records in 2008?
- b. Is HHS aware of any other States that now or in the past have had difficulty with maintaining accurate data for foster children under their care?
- c. What impact, if any, does this lack of accountability by a State have on its foster care and Medicaid Federal grant funds?

Answer: The Administration for Children and Families was aware of data quality issues with Maryland's foster care data, particularly in the time period used by GAO for this study. As noted in the GAO report, a major factor contributing to data quality problems at that time stemmed from implementation of Maryland's new statewide information system CHESSE (Children's Electronic Social Services Information Exchange), which was implemented in all Maryland localities as of January 2007.

As part of ongoing oversight of State child welfare agencies, ACF conducted an Adoption and Foster Care Analysis and Reporting System (AFCARS) Assessment Review of Maryland's program in July 2008. A finding of that review was that, while the CHESSIE system was operational, the State had not completed data conversion and there was a significant amount of missing data in the records of children in foster care. The findings of the case file review indicated this information existed but was not entered into the official electronic file in CHESSIE. Following the AFCARS Assessment Review, the State entered into a Program Improvement Plan to address data quality and completeness and has undertaken significant efforts to improve the completeness and quality of its foster care data, such as ...

Maryland's experience with data conversion following implementation of a new statewide case management system is not atypical. States commonly experience issues involving less than comprehensive data for a period of time following such a system conversion. ACF monitors these issues and works with States to improve the quality and completeness of data on an ongoing basis. While work remains to be done, the overall quality of data on children in the foster care system has improved across the country in recent years. Maryland continues to work on data improvement efforts.

ACF takes the need to hold States accountable for meeting Federal requirements and for improving outcomes for children and families very seriously. Clearly, accurate data are needed to assess State performance. All States operating a title IV-E Foster Care and Adoption Assistance program are required to submit AFCARS data every six months. After each submission, ACF reviews the files for substantial compliance with standards outlined in regulation. States found not to be in substantial compliance are notified in writing and strongly encouraged to correct the data errors then resubmit the data files. In the past, penalties were assessed for data submissions that failed to meet compliance standards. However, several years ago, the Congress enacted legislation which superseded the previous penalty structure. Therefore, new penalty provisions, consistent with the revised law, need to be enacted through regulations amending the AFCARS requirements. Such regulations have not yet been published.

While AFCARS penalties are not currently being taken, ACF has continued to review State performance through the Child and Family Services Review (CFSR) process, which makes use of AFCARS data. Under CFSR protocol failure to address data concerns can still result in the application of financial penalties. Accordingly, these efforts are another way we prompt States to take steps as needed to improve data and ensure that progress in performance can be accurately measured.

Medicaid makes payments to States for medical assistance claims that comply with Federal law. In the instance of Medicaid reimbursement for covered outpatient drugs, Medicaid will reimburse States for covered outpatient drugs dispensed consistent with section 1927 of the Social Security Act. CMS is working with ACF and States to address the use of psychotropic medication among children in foster care.

Question 6: How is HHS helping to facilitate data standards among a multitude of State systems and addressing interfacing with CMS databases?

Answer: In order to improve CMS and the States' data efforts, the Medicaid and Children's Health Insurance Program (CHIP) Business Information and Solutions Council (MACBIS), an internal CMS governance body, provides leadership and guidance for a more robust and comprehensive information management strategy for Medicaid, CHIP, and State health programs. The council's strategy includes:

- Promoting consistent leadership on key challenges facing State health programs;
- Improving the efficiency and effectiveness of the Federal-State partnership;
- Making data on Medicaid, CHIP, and State health programs more widely available to stakeholders; and
- Reducing duplicative efforts within CMS and minimizing the burden on States.

CMS' Center for Medicaid and CHIP Services (CMCS) leads this effort. The MACBIS projects will lead to the development and deployment of enterprise-wide improvements in data quality and availability for Medicaid program administration, oversight, and integrity.

CMS continues to improve access to better quality Medicaid data by leveraging the data available through the Medicare/Medicaid Data Match Expansion Project (Medi-Medi) and its participating States, as well as working directly with States to obtain Medicaid data for specific collaborative projects. CMS is also working closely with ten States to "test drive" a "Transformed Medicaid Statistical Information System (MSIS)" that will provide data on a more frequent basis with higher quality, an expanded set of measures, and reliable data on both fee for service and managed care beneficiaries.

Question 7: In his testimony, Mr. Salo suggested that one reasons states have not implemented more comprehensive oversight procedures is because they face opposition and resistance from drug manufacturers, mental health advocates, and the community at large.

- a. When developing a system of protocols in Illinois, what opposition did you face?
- b. How did it affect the final protocols that were put in place?

Answer: The work to develop enhanced oversight and specific protocols in Illinois was completed internally by the Department of Children and Family Services in conjunction with its private contractors. This included updating of the DCFS procedural manual and notifying all staff across the Department and within the contracted private agencies of the change then training them to implement the requirements.

No specific resistance to these changes was experienced prior to or after implementation.

Question 8: At the end of November, HHS issued a joint letter from the relevant agencies to state Medicaid directors to, according to your testimony, "raise awareness of these issues at the State level and to share expanded opportunities."

- a. When was the last time HHS sent a similar joint letter on this issue to the State Medicaid directors?

- b. Since this issue is not particularly new, why was this letter just now sent out?
- c. When will HHS issue its new guidance to the States?

Answer: This is the first time since 2001 that a joint letter to State child welfare and Medicaid directors has been issued and the Department is pleased to have had the opportunity to communicate with the directors on such a critical topic. In that letter, the Department outlined activities over the next nine to twelve months that will provide additional information and guidance to States. For example, a series of three to four webinars began on January 9th and garnered over 430 attendees. Commissioner Bryan Samuels provided background information on the use of psychotropics among children in foster care and outlined the Administration's current and future activities to address the issue. Dr. David Rubin, Director of PolicyLab at the Children's Hospital of Philadelphia shared State based data on psychotropic medication usage in this population, and Dr. Eugene Griffin, Assistant Professor at the Northwestern University Feinberg School of Medicine, discussed trauma, mental health, and evidence-based interventions for these children and youth.

A second webinar is scheduled in February. Dr. Christopher Bellonci, Assistant Professor at Tufts University School of Medicine, will discuss the practice implications related to the existing and emerging evidence-base for psychotropic medication use among children in foster care, including a discussion of prescription practices that may be of concern with this population. Dr. Stephen Crystal, Associate Director for Health Services Research at the Institute for Health, Health Care Policy, and Aging Research at Rutgers University will provide a description of one way States have used Medicaid data to identify "red flag" prescription practices.

A third webinar is scheduled in March and will feature State examples of practices and protocols for management of psychotropic medications among children in foster care.

The webinar series will lead up to the August summit. Teams comprised of the child welfare director (or designee with decision-making authority), Medicaid director (or designee with decision-making authority), and mental health/children's mental health director (or designee with decision-making authority) from each State will work together to review and refine their plans to strengthen oversight and monitoring of psychotropic medications and consider what appropriate service array is needed for children in foster care. A focus of the meeting will be addressing barriers to plan implementation.

In June, State plans for oversight and monitoring are due. Guidance documents will be provided to States before they are required to submit plans in June.

The letter's timing was due to the enactment of the Child and Family Services Improvement and Innovation Act (Public Law 112-34), which was just signed into law on September 30, 2011, which added a specific requirement for States to adopt protocols relating to the monitoring of psychotropic medications for the first time.

Question 9: As was pointed out in testimony during the hearing, there are several laws that already require States to improve their oversight over medical programs, including reporting on their monitoring program for psychotropic medications as part of requirements for receiving certain Federal aid.

- a. Some of the Federal laws that set the State requirements have been around for a number of years now, going back to the Fostering Connections to Success and Increasing Adoptions Act in 2008. Are all States meeting all requirements set in current law?
- b. How many are not in full compliance?
- c. Why are States having so much trouble meeting these requirements?
- d. Even if HHS issues comprehensive guidelines to the States, in current law, States will not be required to follow them. What actions are necessary to ensure that States adhere to the guidelines and put in place strong oversight programs?

Answer: The Federal requirement for child welfare agencies to provide oversight for the health care needs for children in foster care is a State plan requirement under title IV-B, subpart 1 of the Social Security Act, the Stephanie Tubbs Jones Child Welfare Services Program. This specific State plan requirement has been amended and significantly strengthened in recent years. Prior to the passage of the Fostering Connections to Success and Increasing Adoptions Act of 2008, the provision simply required a State agency to describe how it consulted with and involved physicians or other appropriate medical professionals in assessing the health and well-being of foster children and determining appropriate medical treatment.

The Fostering Connections to Success and Increasing Adoptions Act expanded the provision, requiring States to develop a plan for ongoing oversight and coordination of health care services for children in foster care. The plan is to be developed in coordination with the State Medicaid agency, and in consultation with pediatricians and other experts in health care, and experts in and recipients of child welfare services. It must describe how the State will ensure a coordinated strategy to identify and respond to the health care needs of children in foster care placements, including mental health and dental health needs. As originally enacted in 2008, the law required States to address a number of specific points, including an outline of how the State oversees prescription medicines.

In implementing the provision, the Administration for Children and Families (ACF) in HHS encouraged States to pay particular attention to oversight of the use of psychotropic medicines, as part of their plan for responding to the mental health needs of children and for providing oversight for prescription medicines. However, as you know, there was no specific requirement relating to oversight of psychotropic medications until the recently enacted Child and Family Services Improvement and Innovation Act, signed into law on September 30, 2011. This most recent amendment for the first time adds a specific provision requiring States to address in the title IV-B Health Care Oversight and Coordination Plan protocols for the appropriate use and monitoring of psychotropic medications.

All States have developed plans that meet the basic statutory requirement to develop a Health Care Oversight and Coordination Plan, as that requirement existed prior to passage of the Child and Family Services Improvement and Innovation Act. But clearly, as reflected in the GAO study, some State plans are more comprehensive than others. The most recent amendment requiring States to adopt specific protocols relating to the monitoring of psychotropic medications will allow ACF to work with States to strengthen their plans and ensure that they

adopt appropriate protocols to monitor psychotropic medications. We recognize that development of a plan does not, in and of itself, lead to improvements in practice. However, we believe the new statutory requirement, coupled with technical assistance that we are providing to States on this issue, give us the tools we need to ensure that States put in place strong oversight programs.

Official Responses of NAMD Executive Director Matt Salo

Questions from Senator Carper:

- 1) **Are you aware of any other states that have difficulty with maintaining accurate data for foster children under their care**

No. To the best of my knowledge, the situation in Maryland was fairly unique and resulted from efforts on behalf of the child welfare services agency to upgrade/modify their data reporting system. Unfortunately, this was being implemented in the same window as the requested data and therefore, there were significant problems in producing apples to apples data.

- 2) **What impact, if any, does this lack of accountability by a state have on its foster care and Medicaid federal grant funds?**

While unfortunate in its timing, the inability to produce appropriate and relevant data by the state of Maryland should not be equated with not having data or having accountability for either Medicaid or foster care funding. This appears to be largely an issue of an inability to produce data in the format that was being requested by the Committee.

However, there are legitimate reasons to proceed thoughtfully when examining state data (for example, Medicaid pharmacy claims data). In many instances, determining whether or not dosages are appropriate can be complicated by the fact that prescriptions may be written for more than 30 days. This can lead to confusion about the actual daily dose when physicians can write prescriptions for 30, 60 or 90 days. A 90 day prescription of a medication that turns out to be ineffective, so that a 2nd or sometimes 3rd prescription is needed can look like a patient is on 3 different medications, when in fact, over that 90 window, they have been cycled through 3 to find the right one.

Questions from Senator Brown:

- 1) **GAO reported that Maryland did not have reliable data for its foster children in 2008. The data GAO received were materially different from the data Maryland reported to HHS.**
- a. **From your perspective, would you say that most states have good accurate records?**

From my perspective, it appears that Maryland's situation is an anomaly and that all other states do in fact maintain accurate records. There are always differences in state by state reporting, but states generally do maintain accurate records in this area.

b. Would there be a problem trying to collect this data nationwide?

There generally should be no problem collecting this data nationwide, although as stated above, the ability to collect 50 state data is different than analyzing it, as states tend to collect different data sets, different quality/process/outcomes measures and other variables.

c. What are some of the challenges you hear from your members regarding access to reliable data both within their own state systems and interfacing with federal systems?

States have generally replied that they are able to access prescription drug claims internally within the state systems, and that, in theory, interfacing with a federal data systems should work, however, it is unclear what the question meant by "federal systems".

d. What effect is this having with states' ability to improve their child welfare and mental health programs overall?

Again, as the access to reliable data challenge is not one that is faced by many states, the fact is that there are far greater factors that challenge state's attempts to improve their child welfare programs and mental health programs overall.

e. How important are upgrades to Health IT for this purpose?

Very important. The adoption of electronic health records and interfaces that enable access to these children's comprehensive records will clearly provide better coordination of their care.

Texas reports that it maintains a Health Passport for its foster care population, which is an electronic health information system that includes:

- Medicaid claims encounter and pharmacy data
- The name and address of each of the child's physicians and health care providers
- A record of each visit to a physician or health care provider

- A record of immunizations
- Identification of the child's known health problems
- Information on all prescriptions

Forms may be uploaded to the passport, such as a child's health care service plan, the results of a psychotropic medication review, EPSDT forms, behavioral health summaries, and demographic and contact information.

Texas reports that while this Passport has been helpful in managing the care of patients as they move through the system, a comprehensive electronic medical record would be even more useful.

2) In GAO's written statement, they said that the six selected states' monitoring programs for psychotropic drugs provided to foster care children fall short of best principle guidelines published by the AACAP.

a. What prevents states from fully following the AACAP guidelines?

First, the guidelines are voluntary, not mandatory, so it should come as no surprise that there exist a multitude of approaches. As such, when decisions are left to the state level, they can be influenced by a variety of factors, including the attitudes and perspectives of prescribers and pharmacists at the state level.

Specifically, unlike most best practice parameters, which are typically widely known and circulated, the AACAP guidelines have not been broadly circulated. Texas reported difficulty in even finding out about them.

The state of Virginia replied that Medicaid does not require its mental health providers to follow AACAP guidelines for the prescribing of psychotropics. Medicaid's Drug Utilization Review (DUR) Board, however, has implemented clinical guidelines for the use of psychotropics for children under 6 in its fee for service population. Medicaid managed care organizations maintain their own formularies and guidelines for the use of psychotropics, although the state will be informing the managed care organizations as well as the DUR Board about the guidelines.

b. What can be done to encourage them to do so?

More explicit guidance from HHS could help, as could more education for prescribers about the appropriate use, side effects, and duration of treatment.

But it is important to keep in mind that any change to current practice, especially one that involves significant changes to information systems, involves significant time and resource investments. Most states face significant budget restraints and limited resources. In addition, states are already in the process of bidding out and procuring

other systems overhauls in preparation for the fundamental, transformational changes to Medicaid that will be required to comply with the Affordable Care Act. It may not be feasible to add these to the menu quickly and easily.

3) A major challenge in effectively minimizing medication use is the lack of a relationship with a stable ongoing treatment provider due to the tedious nature of foster care. What can states do to more effectively manage and stabilize the treatment of foster care children, even if they are frequently changing placements or providers?

Ensuring that comprehensive interoperable medical records accompany each child when a new placement or provider is engaged for their care would be enormously helpful. In addition, more robust oversight of prescribing patterns for these children would help to minimize the damage done.

Texas reported taking a number of steps to stabilize the treatment of foster care children, including:

- The implementation of the STAR Health program in 2008, which provides comprehensive, coordinated medical, behavioral, dental and vision care to children in foster care. These services are available to these children no matter where they are in the state, even when they move. It includes a medical home, ongoing Psychotropic Medication Utilization Reviews (PMURs) and an electronic health information system, the Health Passport.
- They are also in the process of "foster care redesign". The focus is on building incentives into the system that will keep children and youths closer to home, minimize placement changes, keep siblings together, and reward providers for quickly moving children to safe permanent homes. These incentives will help stabilize the treatment of children in foster care.
- The development of PMUR parameters for foster children in 2005, with subsequent updates in 2007 and 2010.
- The hiring of a child and adolescent psychiatrist in 2007 to serve as the Department of Family and Protective Services first medical director.

Virginia reported that it is in the process of placing its Medicaid-eligible foster care children, where feasible, in its managed care program, as opposed to leaving them in fee for service. Doing so will allow for their care (including pharmaceutical care) to be better managed. Frequent changes in foster care placements, however, will continue to pose challenges.

- 4) **According to a study done by Tufts last year, there is a noticeable “variation of rates of medication use for youth in foster care in different geographical communities.” What problems does this cause with trying to create and implement “national” guidance or a one-size fits all approach to state oversight of these programs?**

A key component of creating best practices standards is that they do not in fact become a one-size-fits-all model. Helpful national guidance would establish a clear standard of best practices and take into account legitimate differences. This flexibility is important because of the variation in coverage and benefits across the states, as well as the level of social and community support to impact practice standards.

There are variations between each state’s Medicaid program and its foster care system, including the population of children. Due to these differences, the health needs of children in foster care and the acuity of their needs may legitimately vary by region and by state. In addition, medication patterns for all populations vary significantly by geographic location (and other factors). This is also due to differences in prescriber/physician/pharmacist practice.

More restrictive guidance that allows for no avenues of exception would overcome this variation, but would come at a cost, including the political cost of rigidly mandating individual prescriber behavior.

- 5) **Where is the balance between the flexibility required for states to run their programs and the need to ensure some level of nationwide adoption of some important best practices?**

Guidelines should offer advice, but states should maintain the ability to adopt them and also have the flexibility to respond to exceptions when justification is provided. If true, accepted national guidance is widely publicized and best practices are robustly shared among states, this will a long way to helping states adopt best practices.

The state of California replied that the Quality Improvement Learning Collaborative would be a good model to apply. By avoiding punitive actions/consequences, and focusing on quality improvement which measures incremental improvements instead of absolute compliance rates, we can maintain flexibility while bringing much needed awareness to this problem.

Virginia reported that it places a high value on the autonomy of its mental health providers to provide services within existing regulatory and policy requirements. The Medicaid agency also believes that the mental health provider community should partner in any implementation of national guidelines specific to the use of psychotropics.

**Post-Hearing Questions for the Record
Submitted to Dr. Jon McClellan
From Senator Scott P. Brown**

“The Financial and Societal Costs of Medicating America’s Foster Children”

December 1, 2011

- 1) One of the AACAP principles was a rational consent procedure that included a “two-staged” process including informed consent by a person or agency acting on behalf of a child and assent of the child if appropriate and possible. According to GAO’s report, Massachusetts did not have a plan for the second stage – assent of the child. Why is this important? How difficult would putting procedures in place to address this gap in policy be?

Obtaining assent is part of standard treatment, and is important for several reasons. Requiring assent demonstrates respect for the child’s views and opinions. By obtaining assent, the child is more actively involved in the treatment planning process, which helps establish the expectation that the child take responsibility for their own treatment, and thus their own behavior. Educating the child in regards to the reasons for using medications, and also for possible side-effects, increases the likelihood that the child will comply with treatment.

Depending on the age of the child and relevant state law, the child may have the right to accept or decline treatment. In Washington State, children ages 13 years and older have the legal authority to consent for treatment. Without their consent, involuntary treatment procedures must be implemented in order to mandate care.

The challenge at a state-wide level is the task of developing monitoring procedures that are not overly burdensome in regards to administrative and clinical demands. Assent processes need to be clinically relevant, and meet the needs of different age and developmental groups. The assenting process for a 16 year old teenager with normal intelligence suffering from depression will not be the same as for a 6 year old child with autism, or for a 15 year old adolescent with psychosis and paranoia. Standardized assent forms for different classes of medications are useful, but need to be updated regularly as new information becomes available. For monitoring purposes, it is probably best for states to establish oversight procedures to insure that the assent is obtained, rather than narrowly dictating how the assent procedures are conducted with individual patients.

- 2) In several recent reports and testimony several issues related to systemic problems in prescribing psychotropic drugs have been raised. What issue concerns you the most and is in the most need of better oversight in foster care populations:

- Overly aggressive diagnosis
- Psychotropics being used as chemical restraints
- Psychotropics being prescribed “off-label”
- Psychotropics as a “stopgap” measure to control disruptive behaviors that threaten foster placement or in short-term times of crisis.
- The transient nature of the child welfare system for most children in general.

All of these issues raise potential concerns. In regards to diagnoses, perhaps the best example is the now common practice of characterizing youth as having “bipolar disorder”. The diagnosis of bipolar disorder in adults implies the need for aggressive medication therapy. Yet, in the pediatric population, “bipolar” is often used to describe angry and emotionally volatile children; symptoms that are commonly seen in kids who have lived through traumatic experiences and are placed in foster care. These problems clearly need treatment, but the available evidence does not suggest that bipolar disorder in children represents the same illness as classically described in adults (also known as manic depressive illness). Over the past decade, the shift in characterizing emotionally reactive and aggressive youth as “bipolar” has been associated with a marked increase in the use of psychotropic drugs in juveniles, particularly antipsychotic medications.

“Chemical restraint” refers to the use of medications to control acute behavioral outbursts. Psychotropic medications are often used in children to treat behavioral problems. Some psychiatric medications, including antipsychotic medications, have been shown to be helpful for treating aggression. However, clinicians need to be careful when using these medications to avoid simply making the child too sleepy to act out. Furthermore, although medications work in the short-term for aggression (i.e., “stopgaps”); long-term improvements depend upon the child learning better coping skills and anger management strategies. Similarly, parents and caretakers (including foster parents) benefit by learning more effective behavioral management strategies. Psychotherapeutic and behavioral treatments with proven effectiveness to accomplish these goals have been developed. However, skilled clinicians capable of providing such therapies are lacking in most communities.

The issue of “off-label” practices reflects the lack of research examining the safety and effectiveness of psychiatric treatments in youth. Most published medication research trials were conducted in adults. In the past 15 years, there have been a large number of well designed trials of different psychotropic medications for a variety of different psychiatric conditions in children and adolescents. Some of these studies have been funded by the National Institute of Mental Health; others have been sponsored by the pharmaceutical industry. At this time, there are FDA approved agents available for many psychiatric diagnoses in teenagers and for some psychiatric illnesses in children ages 6 years and older.

Clinicians do not always choose agents that are FDA approved for a specific diagnosis. Pharmaceutical industry marketing of new drugs influences physician behavior. Newer drugs

that are approved for use in adults are often prescribed in youth; even if there are no studies examining the safety and effectiveness of these medications in pediatric populations. The emphasis for pharmaceutical marketing is on newer drugs which cost substantially more than older generic versions.

Washington State has implemented a "generics first" policy requiring physicians to first prescribe a generic drug with FDA approval for the specific clinical situation, when available. However, there are limits on what states are allowed to do in regards to managing their Medicaid formulary. For example, Federal law (Social Security Act, section 1927 [42 U.S.C. 1396r-8] Payment for Covered Outpatient Drugs) mandates that all drugs with a Federal rebate agreement must be covered by Medicaid, even if there are cheaper alternatives. The rebates may save money in the short-term, but encourage the use of very expensive new drugs, thus costing the state millions of dollars with longer term use. To highlight the cost issues, paliperidone (Invega®) is a newer antipsychotic that is chemically related to an older drug risperidone, which is now available as a generic. There is no established benefit for using Invega versus risperidone. Thirty tablets of Invega costs ~ \$1000; the equivalent amount of risperidone costs ~ \$15.

In addition, pharmaceutical companies take advantage of the "off-label" issue to remarket old drugs as a new product. For example, guanfacine is a medication used to treat Attention-Deficit Hyperactivity Disorder (ADHD). The drug was originally FDA approved as a blood pressure treatment. Since the drug is available as a generic, the manufacturer had little incentive to obtain a new FDA approval for treating ADHD. However, Shire obtained FDA approval for a preparation of guanfacine that is long-acting (Intuniv®) to treat ADHD. There is no compelling clinical benefit to this preparation, but the longer-acting version of guanfacine is considered a new drug, and is still under patent. Therefore, Shire can sell the FDA approved Intuniv (~ \$5.50 per pill) at a substantially higher cost than the available generic guanfacine (less than ten cents per pill). There is no requirement that a new medicine works as well or better than an older version of the same drug or than other medications in the same class of drug. A company simply has to show that a new medication works better than placebo. Such strategies are fiscally innovative, but do not advance medical practice.

Finally, the transient nature of foster care systems definitely contributes to the risk of excessive medication use. Most importantly, the stress and trauma of being placed out of the home, and the abuse that often led to that placement, greatly increases the risk of children having emotional outbursts and anger problems. If these problems are severe, the child may be moved multiple times. Some children get caught in a spiraling cycle of emotional upheaval, acting-out behaviors and failed placements. Given a lack of adequate psychosocial interventions and stable placements with adequate support, medications are used to try and stabilize the crisis.

In addition, moving kids from home to home disrupts continuity of care. Important medical information may be lost when there are multiple changing caretakers. Furthermore, the child may end up being treatment by multiple different clinicians, each with different viewpoints and approaches to treatment.

- 3) In your testimony, you mention the oversight system in place in Washington state, explaining that criteria were developed to ID prescriptions that exceed safety thresholds, such as those pointed out in the GAO report, and that these cases are flagged for a second opinion review.
- a. Why isn't this system put in place everywhere?
 - b. What are the challenges in implementing such a review process?
 - c. Which state agency has responsibility to put such a system in place?

Federal law mandates the need to develop protocols for the appropriate use and monitoring of psychotropic medication use for children in the child welfare system (The Child and Family Services Improvement and Innovation Act, P.L. 112-34). To my knowledge, there are not a specified set of required strategies, so variable approaches have been adopted to address this mandate.

Challenges in the implementation of a review process include concerns raised by consumers, advocacy groups and providers regarding government regulated health care, as well as lobbying by the pharmaceutical industry to prevent any restrictions on prescribing practices. Some states have existing laws that prevent the regulation of prescription practices.

In Washington State, developing trust amongst all the interested parties was critical. There were a number of regulatory and statutory issues to address, including state laws related to mental health record confidentiality, competing rules on utilization controls, and the administrative and fiscal resources needed to create a system to provide second opinions. Established collaborations between the State's mental health administration and the University of Washington's Department of Psychiatry facilitated this process.

Depending on the state law(s), the Medicaid agency, the mental health department, or the State legislature is responsible for oversight systems. In Washington State, the Department of Health and Social Services (DSHS) is responsible for the monitoring program, under the leadership of Jeff Thompson MD Ph.D., chief medical officer for DSHS. Dr. Thompson is responsible within DSHS for managing publically administered Medicaid funds. In addition, for foster children, the State's Department of Child and Family Services (within DSHS) has the authority, as the guardian of these youth, to insure appropriateness of care.

- 4) If there is no evidence supporting the use of concomitant psychotropic drugs, why would doctors prescribe such a regimen-particularly they know a child is already on several medications?

In most situations, there is a crisis. The child's behavior is unsafe, there are not adequate psychotherapeutic resources, and the physician feels compelled to do something to try and improve the situation. It is also difficult to stop a medication that may not be working when everyone is scared of the child's behavior worsening. So medications may be added to try and stabilize the situation without stopping other drugs. In this situation, the goal should be to later

reduce the number of medications once the child is stable. However, for kids in chaotic situations (and multiple placements), such stability may be hard to achieve, and/or the kid may receive treatment from a series of changing clinicians. The lack of continuity of care means that each new prescriber may lack adequate information as to what drugs have been helpful or are necessary.

In addition, most children with serious mental health problems carry more than one psychiatric diagnosis. If the child is miserable, irritable, worried, acting-out and explosive (all of which are common for kids in stressful or traumatic situations), they may be diagnosed with several different illnesses (e.g., mood, anxiety and behavioral disorders). Medications may be prescribed for each of these conditions. Common sense would suggest finding the fewest number of medications to treat the overall problem, but some physicians add a medication to address each symptom. This is especially true when the child is not doing well.

Finally, some diagnoses suggest the need for multiple medications. Classic bipolar disorder in adults is a severe life-threatening illness that often requires treatment with more than one medication. By labeling children as having "bipolar", the implication is that the adult treatment guidelines should be followed. This is one reason why bipolar disorder in children is such a controversial diagnosis.

- 5) In your testimony, you mention a child admitted to Seattle Children's Hospital taking 13 different psychotropic medications. You said in your testimony yourself that there is NO research that justifies this practice.
- a. How did this happen with this child?
 - b. Were they in foster care?
 - c. Was this simply a case of "slipping through the cracks" or was there another cause?
 - d. What was done about it?

The child had developmental impairments, with a low IQ and symptoms of autism. He also had severe disruptive behaviors. The child's guardians were his grandparents; the biological parents were no longer involved with his care. The physician would add a new medication, or increase an existing medication, each time the grandparents reported that treatment was not working and the child was out-of-control. When medications were added, other drugs were not stopped. So the list kept growing. There were no external monitoring procedures in place at that time (the case occurred several years ago). There were not adequate psychosocial services available.

Given concerns over his behavior, and over his medications, he was admitted to Seattle Children's inpatient psychiatry service. Based on his initial presentation, it was unclear whether each medication was being given to the child at home as prescribed. The inpatient physician began to taper the medications, and eventually got the regimen down to three drugs. The child

was hospitalized for approximately two months (which would not be allowed now given current funding limits). By the end of his hospitalization, the child was much more alert, but still had significant behavioral outbursts. He was discharged with the plan to add psychosocial interventions in the community. We did not receive follow-up information about how he did after discharge.

- 6) In his testimony, Mr. Salo suggested that one reason states have not implemented more comprehensive oversight procedures is because they face opposition and resistance from drug manufacturers, mental health advocates, and the community at large.
 - a. What have been your experiences in Washington state? Has there been significant opposition or resistance from these stakeholders there?
 - b. How did it affect the final protocols that were put in place?

In Washington State, there was resistance from the pharmaceutical industry, patient advocacy groups, and medical associations. Lobbying was done directly, through State legislators and at times through the media. These groups were invited to the planning process, which helped make the decision-making transparent, but also slowed down implementation. Data demonstrating high risk practices (e.g., toddlers on antipsychotic medication) helped quell resistance. The pharmaceutical industry did not publically challenge concerns regarding "off label" practices, but were more vocal about any limitations on FDA approved drugs, regardless of dose or the use of multiple medications. Ultimately, the opposition from these stakeholders did not change the safety indicators adopted for the monitoring system.

- 7) In the testimony given in the hearing, it was stressed that more research is needed to better understand the impacts of psychotropic drugs on children, especially the challenges faced by foster care children.
 - a. How long does a drug need to be on the market for adequate research about long term affects to be done?
 - b. In reference to the list of psychotropic drugs included under GAO's review, how many of those has been adequate research done to test the long-term effects, (1) in general, and (2) in children?
 - c. Where should more effort and financial support be focused in your opinion?

In general, more information is needed regarding the long-term effects of psychotropic medications in both children and adults. With the exception of stimulants, more studies of psychotropic medicines have been conducted in adults as compared to children. The durations of treatment examined by these studies are similar in both age groups. Pharmaceutical industry sponsored trials are usually short-term (i.e., several weeks in duration). Long-term research studies are usually publically funded, including several well-designed trials sponsored by the National Institute of Mental Health (NIMH).

Stimulant medications (e.g., methylphenidate, dextroamphetamine) for attention-deficit hyperactivity disorder (ADHD) have the most available data regarding long-term use in children. Different forms of these medications have been used for decades, thus there also is substantial clinical experience. The NIMH funded study "The Multimodal Treatment of for Attention-Deficit Hyperactivity Disorder" studied stimulant medicines over an 18 month period, and has followed the youth participating in this study (some of whom continued to take the medicines) for up to 8 years.

The NIMH also has funded studies to examine the safety and effectiveness of antipsychotic medications for youth with schizophrenia, autism and bipolar disorder; antidepressants for juveniles with anxiety and depression; and mood stabilizers for bipolar disorder. These studies obtained information regarding drug effectiveness and safety for up to 1 year of treatment. Not all drugs within each class of medication have been studied long-term.

At this time, most of the demonstrated benefits for psychotropic drug treatments in children are for short-term use. The medications generally reduce symptoms, rather than cure disorders. Long-term evidence demonstrating substantial improvements in functional or clinical outcomes is lacking. It is also worth noting that many patients do not take psychiatric medications long-term, given the resolution of problems, lack of ongoing effectiveness, problems with side effects, and/or noncompliance to treatment.

Community treatment often does not reflect the existing research. Medication and diagnostic practices vary greatly across providers. In addition, although specific psychosocial interventions are known to be helpful, evidence-based psychotherapies are often not provided. We have a major work force problem. The lack of child psychiatrists is well documented. Many therapists working with children and families are not trained or proficient at evidence-based therapies. In my opinion, we spend an enormous amount of money and resources for treatment that does not work.

We need to develop and expand systems of care that promote the use of effective interventions; with a focus on community-based models of treatment that incorporate standard of care medication strategies with evidence-based psychotherapies. Systems interventions, such as reimbursement strategies, provider training, treatment adherence and fidelity, and models of leadership and organizational structure; should be developed and studied. Measures of success should include short-term improvements in symptoms and functioning, as well as long-term educational achievement, employment, and the avoidance of criminal justice or social welfare system involvement.

Such models can readily be applied to high risk populations, including youth in foster care. States could enroll all youth entering foster care into specialized treatment programs that provide basic pediatric and mental health services using clinicians specifically trained for this population.

There also needs to be substantial investment in basic science research. Genomic, molecular and neurobiological sciences have now advanced to the point where causal elements of mental illnesses can be identified. However, given the complexity of brain function, finding cures for the majority of affected individuals will require the strategic investment and organization of immense resources, both fiscal and intellectual. Advancements in genomic and neurobiological research will lead to the development of more effective treatments.



National Alliance on Mental Illness (NAMI)

Statement submitted to the

SENATE SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION,
FEDERAL SERVICES, AND INTERNATIONAL SECURITY OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS

FOR ITS HEARING ON

THE FINANCIAL AND SOCIETAL COSTS OF MEDICATING AMERICA'S FOSTER CHILDREN

DECEMBER 1, 2011 ~ WASHINGTON, D.C.

MONITORING IS NOT ENOUGH ...

INTRODUCTION

The National Alliance on Mental Illness (NAMI) applauds this committee for convening this hearing today. NAMI is the nation's largest grassroots family and consumer organization dedicated to improving the lives of children, adults and families affected by mental illness. Through NAMI's 1,100 chapters and affiliates in all 50 states NAMI supports education, outreach, advocacy and research on behalf of persons with mental health conditions.

Much has been learned through research supported by the National Institute of Mental Health (NIMH) about children with mental illness. Half of all lifetime cases of mental illness begin by age 14 and early identification and intervention helps to lessen the long-term severity of these illnesses.ⁱ

Children in foster care experience high rates of mental illness. Between half and three-fourths of the children entering foster care need mental health care.ⁱⁱ This is not surprising given that many of these children have had traumatic experiences in their young lives, including abuse and neglect, removal from their families and homes, multiple placements, *in utero* exposure to drugs and alcohol, for some a genetic predisposition to mental illness, poverty and related experiences.

The most prevalent mental health conditions in children in foster care are Post Traumatic Stress Disorder (PTSD) and abuse-related trauma, disruptive behavior disorders (including conduct disorder, oppositional defiant disorder and ADHD), depression and substance abuse.ⁱⁱⁱ

Medications, when prescribed appropriately for children with mental illness, can be lifesaving. They can enhance a child's ability to participate in school, to be safe with family, to avoid hospitalizations and out-of-home placements, to avoid harming oneself and to avoid engaging in life threatening activities. However, psychotropic medications can also pose serious risks for children because of the side effects associated with them. They should only be prescribed when the benefits of medication outweigh the risks and only as part of a comprehensive treatment plan that addresses the complex needs of vulnerable children in foster care.

NAMI greatly appreciates that this committee is examining issues related to the prescribing practices of psychotropic medications for children in foster care. It is also important that the U.S. Government Accountability Office (GAO) and federal agencies within the Department of Health and Human Services (HHS) are looking closely at these issues.^{iv} States have a duty to protect those children who come into their care and to ensure that they are receiving safe, appropriate and effective care, including mental health care. States also have a duty to ensure that these children are not prescribed medications that they do not need and that may be harmful to them.

However, it is not enough to call for the monitoring and oversight of prescribing practices. We need to ask why medications are being prescribed to children in foster care. It is essential to look at the multiple factors that are contributing to high rates of psychotropic medication use and how these factors are best addressed, including whether effective alternative interventions are readily available. If we want to get serious about ensuring that children in foster care receive safe and effective mental health care, then we must examine and address the broader issues outlined below.

Improving the Mental Health Care Delivered to Children in Foster Care

- **Require Oversight and Monitoring**

There is no question that expert prescribing guidelines for psychotropic medications should be developed and states should disseminate expert guidelines to the agencies and mental health professionals that serve children in foster care. Training, support and technical assistance are needed on an ongoing basis to help ensure that mental health professionals understand how to use the guidelines and are following them in developing treatment plans for children.

States also need to monitor the prescribing practices of those mental health professionals who are providing care to children in foster care. They need to identify those mental health providers who are outliers and are engaging in prescribing practices that fall well outside of the prescribing practice guidelines. These providers should be contacted and required to

undergo additional training and oversight to help ensure that their prescribing practices are appropriate.

In addition, children and youth in foster care who are prescribed psychotropic medications should be closely monitored for side effects and receive frequent evaluations by well-qualified professionals.

- **Demand Screening, Assessment and Evaluations**

Given the high prevalence of children in foster care with mental health care needs, every youth entering foster care should be screened for mental illness. Youth who screen positive should receive a comprehensive psychiatric evaluation by a qualified mental health professional. These children should also receive a comprehensive physical examination to rule out other physical health conditions that may be causing the child to exhibit signs and symptoms of mental illness.

A comprehensive psychiatric evaluation by a qualified mental health professional is essential to receiving an accurate diagnosis. And an accurate diagnosis is the critical first step in developing a treatment plan that includes the most appropriate and effective interventions, which may include psychosocial and/or medication interventions.

To help ensure that children are properly diagnosed, treated and monitored, states must provide adequate Medicaid reimbursement for comprehensive evaluations and assessments.

State child welfare agencies should ensure that caseworkers work closely with mental health providers to ensure that children coming into foster care are assessed and evaluated and receive timely and effective mental health services and supports. Unfortunately, in many communities, the mental health and child welfare systems operate in silos. This fragmentation must be addressed to help ensure that children in foster care receive effective mental health services and supports.

- **Increase Workforce Capacity and Training**

There is a critical shortage of child psychiatrists in our nation. Currently, there are about 7,000 child psychiatrists with a need at close to 30,000.^v With this shortage in mind, it is important to ask who is evaluating, diagnosing and treating children in foster care.

States should facilitate access to scarce child and adolescent psychiatric expertise through integrated care approaches such as co-location of child psychiatrists in primary care settings, implementing tele-psychiatry, and developing funding mechanisms that encourage telephonic and face-to-face collaboration and consultation between child psychiatrists and other treating professionals.^{vi}

Low Medicaid reimbursement rates must be adjusted to reduce the significant provider turnover rates that are negatively impacting the quality and continuity of care provided to children in foster care.

- **Effective and Evidence-based Psychosocial Interventions Must be Provided**

There are a number of psychosocial interventions that have been shown through research to be effective with PTSD and trauma, ADHD, oppositional defiant disorder, depression and substance abuse.^{vii} Among a large base of effective psychosocial interventions are Trauma-Focused Cognitive Behavior Therapy, the Incredible Years, Parent-Child Interaction Therapy and cognitive behavior therapy for depression.^{viii} Sadly, effective psychosocial interventions are often not available in communities to any children, including those in foster care. A lack of investment and commitment to making these effective interventions available has contributed to a greater reliance on medications, including for very young children.

We could significantly reduce the prescribing of psychotropic medications if effective and evidence-based psychosocial interventions were more widely available for children. When included as part of a comprehensive treatment plan, these interventions also produce positive results allowing children in foster care to function better in every domain of their life.

The Center for Medicare and Medicaid Services (CMS) should encourage states to add an array of effective and evidence-based interventions to their state plans and should provide technical assistance to help states understand the importance of these interventions. States should not only ensure that effective psychosocial interventions are billable under their state Medicaid plans, they must also make a commitment to work with the provider community and other stakeholders to provide the training, support and mentoring needed to make these interventions available to children in foster care. Although there is a cost associated with bringing effective psychosocial interventions to communities, there is a long-term savings when children's mental health conditions improve. They develop the skills they need to succeed in school and as productive members of society and they avoid costly hospitalizations and institutional care.

- **Increase Research on Psychotropic Medications and Therapeutic Interventions for Children**

Other than stimulant medications to treat ADHD, there is a dearth of research on the safety and effectiveness of psychotropic medications for very young children. This lack of research significantly raises the importance of providing effective psychosocial interventions to young children in foster care. At the same time, it is imperative that we increase our body of research.

We urge state and federal officials to join NAMI's call for new research approaches to provide opportunities to study the safety and effectiveness of psychotropic medications for

children, including long-term positive and negative effects, the development of better, more personalized medications and diagnostics, and additional research on effective alternative or supplemental therapeutic interventions.

- **Costs Should Not Dictate the Mental Health Care Provided to Children in Foster Care**

Costs and budget concerns should not result in denying children in foster care effective mental health services and supports. When appropriate mental health care is denied to children in need through cost containment and budget cuts, the consequences are costly. Children who require mental health services but do not get them often end up receiving costly services in institutional settings, including emergency rooms, hospitals, residential treatment centers, jails and juvenile detention centers. There is a high societal cost as youth drop-out of school, become entangled with law enforcement, use and abuse drugs and alcohol to self-medicate and ultimately end up homeless. We can do far better in improving the lives of children in foster care with mental health conditions. Their future depends on it.

ⁱ National Institute of Mental Health (2005). *Mental illness exacts heavy toll, beginning in youth*. Accessed at www.nimh.nih.gov.

ⁱⁱ Landsverk, J.A., Burns, B.J., Stamburgh, L.F., Reutz, J.A. *Mental Health Care for Children and Adolescents in Foster Care: Review of Research Literature*. February 2006. Prepared for Casey Family Programs. Accessed at <http://www.casey.org/Resources/Publications/pdf/MentalHealthCareChildren.pdf>.

ⁱⁱⁱ Ibid.

^{iv} Department of Health and Human Services letter dated November 23, 2011 to State Directors of Child Welfare, State Medicaid Directors and State Mental Health Authority Directors. This letter outlines steps that the Administration for Children and Families (ACF), the Center for Medicare and Medicaid Services (CMS) and the Substance Abuse Mental Health Services Administration (SAMHSA) are taking to address the use of psychotropic medications with children in foster care.

^v American Academy of Child and Adolescent Psychiatrists. *AACAP Workforce Fact Sheet*. Accessed at www.aacap.org.

^{vi} NAMI has developed a comprehensive family guide on integrated care. *A Family Guide: Integrated Mental Health and Pediatric Primary Care* can be accessed at www.nami.org/primarycare.

^{vii} Landsverk, J.A., Burns, B.J., Stamburgh, L.F., Reutz, J.A. *Mental Health Care for Children and Adolescents in Foster Care: Review of Research Literature*. February 2006. Prepared for Casey Family Programs. Accessed at <http://www.casey.org/Resources/Publications/pdf/MentalHealthCareChildren.pdf>.

^{viii} Ibid.

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Statement of

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DIRECTOR AND CEO
ON BEHALF OF
THE AMERICAN PSYCHIATRIC ASSOCIATION**

For the

**Senate Committee on Homeland Security and Government
Affairs
Subcommittee on Federal Financial Management,
Government Information, Federal Services, and
International Security**

December 1, 2011



The American Psychiatric Association (APA), the medical specialty society representing over 36,000 psychiatric physicians nationwide, appreciates the opportunity afforded by Chairman Carper and Senator Brown to submit the following statement regarding today's hearing: *The Financial and Societal Costs of Medicating America's Foster Children*.

Children in foster care systems experience high rates of mental illness, and require a broad spectrum of mental health services. According to the National Survey of Child and Adolescent Well-Being, upwards of three-fourths of all children entering foster care exhibit behavior or social competency problems that warrant mental health care.¹ While clinical factors contribute to mental illness suffered by foster children, studies show several non-clinical factors, such as age, racial or ethnic background, maltreatment, and types of placement, also make a significant contribution.² Post-Traumatic Stress Disorder (PTSD), abuse-related trauma, Attention Deficit Hyperactivity Disorder (ADHD) and other disruptive behavior disorders, depression, and substance use disorders constitute the most common conditions affecting foster children.³

APA endorses the comprehensive practice parameters promulgated by the American Academy of Child and Adolescent Psychiatry (AACAP) concerning the psychiatric assessment of children and adolescents.⁴ APA strongly believes psychotropic medications must be prescribed only when appropriately deemed necessary, and must form part of a larger customized treatment plan that includes both psychopharmacologic and psychosocial interventions. With that said, APA believes psychotropic medications play a vital role in treating certain children diagnosed with mental illness.

APA concurs with the preliminary findings of the Government Accountability Office (GAO) that the relatively high rate of psychotropic medications being prescribed to foster children in Medicaid is troubling. APA agrees with GAO's recommendation that the Department of Health and Human Services (HHS) should issue formal guidance to state Medicaid and child welfare agencies on best practices for monitoring prescriptions of psychotropic medications. APA believes appropriate and comprehensive guidance may be found in AACAP's *Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline*. APA also believes any guidance provided by HHS to states must be appropriately disseminated to physicians and other mental health professionals who provide care to foster children. Physicians and other qualified professionals who prescribe psychotropic medications should receive adequate training in prescribing practices and proper oversight by a psychiatric physician when necessary. Rigorous accountability standards should be implemented to ensure psychotropic medications are appropriately prescribed as part of a larger treatment regimen.

¹ John A. Landsverk, Ph.D., Barbara A. Burns, Ph.D., Leyla Faw Stambaugh, Ph.D., and Jennifer A. Rolls Reitz, M.P.H., *Mental Health for Children and Adolescents in Foster Care: Review of Research Literature*, (Casey Family Programs, 2006), 1.

² *Ibid.*, 3.

³ *Ibid.*, 4.

⁴ See the American Academy of Child and Adolescent Psychiatry (AACAP), *Practice Parameters for the Psychiatric Assessment of Children and Adults*, AACAP Publications, 1995.

Furthermore, APA believes more resources must be devoted to the expansion of the mental health workforce, particularly child and adolescent psychiatric physicians. Currently, 8,000 child and adolescent psychiatrists practice across the country. APA projects the estimated need is 30,000. Workforce shortages are especially acute in rural and socio-economically disadvantaged regions. Children and adolescents suffering from mental illness (both in and out of foster care systems) are routinely forced to see practitioners that may not be adequately trained or experienced in best practices for diagnosis and treatment. Investing in initiatives, such as the National Health Service Corps and Graduate Medical Education residency training, as well as the co-location of primary and mental health care, promises a return of greater numbers of accessible professionals fully qualified to meet the mental health needs of children and adolescents.

The preliminary findings of the GAO show that more can be done to ensure children in foster care systems receive the appropriate, life-saving care they are entitled to in a safe and comprehensive manner. APA looks forward to the release of GAO's report next year and the opportunity to work with members of Congress and other stakeholders in addressing this matter.

Once again, APA appreciates the opportunity afforded by Chairman Carper and Senator Brown to provide this statement on behalf of its members. Should you have any questions or need further information, please do not hesitate to contact my staff, Jeffrey P. Regan, at (703) 907-7800 or jregan@psych.org.



COMMENTS FOR THE RECORD

Submitted To:

Subcommittee on Federal Financial Management, Government Information, Federal
Services and International Security
Committee on Homeland Security and Governmental Affairs

By:

Shadi Houshyar, Vice President for Child Welfare Policy
First Focus

Hearing on:

The Financial and Societal Costs of Medicating America's Foster Children

December 1, 2011

www.FFCampaignforChildren.org

FIRST FOCUS CAMPAIGN FOR CHILDREN COMMENTS FOR THE RECORD



Chairman Carper, Ranking Member Brown and members of the Subcommittee, thank you for this opportunity to submit a statement for the record regarding the December 1 hearing on *"The Financial and Societal Costs of Medicating America's Foster Children."* We appreciate the attention that your Subcommittee is bringing to the issue of psychotropic medication prescription practices for children in foster care. Following on the heels of a number of recent media stories about what appears to be a disturbing trend in overprescribing medications and inadequate monitoring and prescription practices for this population, the Government Accountability Office (GAO) report requested by your Subcommittee and this hearing are each bringing much needed attention to this problem.

The First Focus Campaign for Children is a bipartisan organization advocating for legislative change in Congress to ensure children and families are a priority in federal policy and budget decisions. Our organization is dedicated to the long-term goal of substantially reducing the number of children entering foster care, and working to ensure that our existing system of care protects children and adequately meets the needs of families in the child welfare system. We are especially concerned with raising attention to the health concerns and policies impacting children in the foster care system, and identifying effective approaches to addressing the health and behavioral health needs of this vulnerable population. We believe that in order to truly improve the provision of health care for children in foster care, we must shift our federal efforts and investments toward developing a more comprehensive approach to addressing the needs of foster children.

Recommendations

As the GAO report highlights, states have made efforts to institute and implement consent, authorization and monitoring procedures in response to a call for measures to curb inappropriate prescribing and oversight of prescription practices. Such efforts were in part driven by recent Congressional action. Specifically, the Fostering Connections to Success and Increasing Adoptions Act (PL 110-351) includes a requirement for developing health care oversight and coordination plans, and as part of these, states are required to report on what will be done to ensure the oversight of prescription medications, including psychotropic drugs. More recently, the Child and Family Services Improvement and Innovation Act (PL 112-34) requires states to establish protocols for the appropriate use and monitoring of psychotropic medications prescribed to children in foster care. States studied as part of the GAO report, including Texas, have made notable progress in implementing policies and procedures to curb inappropriate prescribing practices but more remains to be done.



We echo the GAO's recommendation that the **Department of Health and Human Services (HHS) endorse guidance on specific measures for state oversight of psychotropic prescriptions for foster children.**

Additionally, we offer the following recommendations for future action:

- **Continuing to Monitor States' Progress.** States should develop and disseminate guidelines and institute protocols for the oversight, prescribing and monitoring of psychotropic medication usage for children in foster care. HHS and Congress should continue to closely monitor states' progress on this front.
- **Comprehensive Medical Evaluations and Diagnosis before Treatment.** It is critical that a child receives a comprehensive medical evaluation and a medical diagnosis before beginning treatment for a mental or behavioral disorder. To ensure that children are properly diagnosed, treated and monitored, states should provide adequate Medicaid reimbursement for comprehensive evaluations and assessments.
- **Psychosocial Interventions before Medications.** Gleason and colleagues (2007) recently reviewed available literature and developed recommendations regarding the psychopharmacologic treatment of preschool children. The researchers emphasized the importance of psychosocial interventions before medications are utilized.¹ We strongly support this practice, and believe that non-pharmacological interventions (e.g. psychotherapy) should be considered as an alternative to psychotropic medication, or if appropriate, in combination with pharmaceutical treatment. A number of effective psychosocial interventions exist; including Trauma-Focused Cognitive Behavioral Therapy, Multisystemic Therapy, Parent-Child Interaction Therapy and cognitive behavioral therapy for depression. Other effective home and community-based services such as Therapeutic foster care, including Multidimensional Treatment Foster Care should also be considered. The Center for Medicare and Medicaid (CMS) should encourage states to utilize such effective and evidence-based interventions, provide technical assistance to states on the utilization of such approaches, and offer states clarification on reimbursement for services such as Therapeutic Foster Care that may be covered as a package (with the exception of the cost of room and board, which is not reimbursable).
- **Routine Follow-Up Care.** Children on psychotropic medications should receive routine follow-up care and their prescription dosages should be regularly monitored and adjusted as appropriate. Any potential side effects of medications should be carefully monitored.
- **More Data Needed on Atypical Antipsychotic Use in Children.** We strongly support efforts to better understand the effects of atypical antipsychotic medications usage for children, especially younger age groups.



- Long-Term Drug Safety Investigations in Children Needed.** We must also invest in long-term drug safety investigations, provide ongoing clinical monitoring of psychotropic medication use in children, and develop the most appropriate and effective treatments possible for children. A number of prominent researchers have recommended expanding studies of the benefits and risks of pharmaceutical treatments beyond clinical trials and into sustained studies in community-based youth populations – especially high-risk populations on Medicaid (e.g., children in foster care), given the rather complicated and poorly evidenced, high-cost medication regimens these children typically receive.

A Growing Problem

Today, one in every five children and adolescents in the U.S. is diagnosed with a mental health disorder;² yet, as a 2001 Report of the Surgeon General on Children's Mental Health highlighted, a significant number of these kids do not receive the treatment and care they desperately need.³ In fact, fewer than 1 in 5 children actually receive treatment, and nearly 80 percent fail to receive specialty services.⁴ If left untreated, a mental health problem often has devastating long-term consequences, including contact with the juvenile justice system, job loss, homelessness, and even suicide. At the same time, prescriptions for psychotropic medications have increased dramatically for children with behavioral and emotional problems over the last 20 years, a trend evident for younger age groups- even preschoolers.^{5 6 7} In fact, prescription rates for atypical antipsychotics for children have increased more than fivefold over the past decade and a half. Today, atypical antipsychotics are being prescribed at a much higher rate today than ever, even though they have limited Food and Drug Administration (FDA) approval in older children and little is known of their impact on younger children.

For many children, Medicaid is a critical source of health and related support services, including both outpatient and inpatient mental health services. Medicaid supports the Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program and also funds long-term mental health care for children who need more intensive or restrictive services, including hospitalizations and residential treatments. In recent years, Federal spending on prescription medications has consumed a greater portion of Medicaid budgets. This can be partly attributed to growing Medicaid expenditures on new and more costly psychotropic medications for children – many of which have not been tested for use in children.

As Jeffrey Thompson, the Chief Medical Officer of Washington State's Medical program noted in an interview, "the number one drug class in expenditures is atypical antipsychotics in almost every state. And the fastest growing utilization is for both on and off-label use in children." Research has shown that children enrolled in Medicaid generally experience greater chronic health conditions and impairment,⁸ and have a higher prevalence of psychotropic medication use than those who are privately insured.^{9 10 11} In fact,

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in one study, the rate of psychotropic drug use was nearly double among Medicaid-insured children as compared to privately insured children; and, a greater proportion of Medicaid enrolled children were given prescriptions for multiple psychotropic medications, even though fewer received outpatient mental health services.¹² Similarly, in a 2004 report, Safer and colleagues found that psychotropic medication usage rates are significantly higher for SCHIP participants than privately insured children.¹³

Within the Medicaid program, certain populations are even more likely to utilize psychotropic medications. Specifically, children in foster care are much more likely to use psychotropic medications than children who qualify for Medicaid through other aid categories.¹⁴ As you know, children who have been abused or neglected often have a range of unique physical and mental health needs, physical disabilities and developmental delays, far greater than other high-risk populations. For instance, foster children are more likely than other children who receive their health care coverage through Medicaid to experience emotional and psychological disorders and have more chronic medical problems. In fact, studies suggest that nearly 60 percent of children in foster care experience a chronic medical condition, and one-quarter suffer from three or more chronic health conditions.¹⁶ ¹⁷ Roughly 35 percent have significant oral health problems.¹⁸ In addition, nearly 70 percent of children in foster care exhibit moderate to severe mental health problems,¹⁹ and 40 percent to 60 percent are diagnosed with at least one psychiatric disorder.²⁰

Studies have shown that kids in foster care are prescribed psychotropic medications at a much higher rate than other children - 2 to 3 times higher.²¹ For instance, a 2003 study found that in Connecticut, while children in state custody represented only 4.8 percent of the Medicaid population, they accounted for 17.8 percent of the psychotropic prescriptions filled—a 4.5 fold higher usage rate.²² Similarly, a study of children in the Los Angeles County foster care system found that these youth had a threefold higher rate of psychotropic drug use than the broader youth population, a pattern similar to a study of a mid-Atlantic state Medicaid program. Additionally, a 2007 GAO report identified over-prescribing of psychotropic medications to foster children as one of the leading issues facing child welfare systems in the coming years.²³ In addition, youth in foster care are often prescribed two or three medications, the effects of which are not well-known in combination.²⁴

In a 2008 study of Texas children with Medicaid coverage, Zito and colleagues found that youth in foster care received at least three times more psychotropic drugs than other children in poor families. Zito and colleagues report that from September 2003 to August 2004, of 32,135 Texas foster care children enrolled in Medicaid, 12,189 (38 percent) were prescribed one or more psychotropic medications. In addition, 41.3 percent of a random subgroup of 472 youths received three or more psychotropic drugs daily. Although the practice of prescribing psychotropic medications for children continues to grow, serious concerns about the safety and efficacy of use for this population have been raised. Many have expressed concerns about the

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safety, efficacy and long-term consequences of psychotropic medication use in children, especially younger age groups.^{25,26,27} Specifically, researchers have expressed concern about the effects of these medications on the developing brain, and the safety and effectiveness of medications tested in adults for alleviating behavioral and emotional symptoms in children.

For certain newer classes of drugs, medications have not been FDA-approved for use in children. In fact, between 50% to 75% of psychotropic drugs are not approved for use in children or adolescents.²⁸ As a result, providers are often prescribing drugs “off-label” (for use other than the intended). To date, we have no safety data and little understanding of the long-term effects of the use of atypical antipsychotics in younger children. In addition, available research suggests that use in younger children may contribute to weight gain and diabetes, can yield extrapyramidal side effects, and contribute to aggressive behaviors.²⁹

In 2007, State Medicaid Medical Directors and investigators from the Rutgers Center for Education and Research on Mental Health Therapeutics (CERTs) developed a plan for a collaborative project to examine the use of antipsychotic medications in children and adolescents in Medicaid. The product of the collaboration was a report on antipsychotic medication usage in Medicaid in 16 states. Among the report’s findings, children in foster care (12.4 percent) were prescribed antipsychotic medications at much higher rates than other children (1.4 percent). In addition, from 2004 to 2007, the pooled antipsychotic medication use rate for children and adolescents in the 16 participating Medicaid programs increased from 1.45 percent to 1.60 percent in 2007, about a 10 percent relative increase. For foster care children and adolescents, the antipsychotic medication use rate increased (on a relative basis) by 5.6 percent between 2004 and 2007 (from 11.7 percent to 12.4 percent).³⁰

A September 2010 Multi-State Study on Psychotropic Medication Oversight in Foster Care conducted by the TUFTS Clinical and Translational Science Institute found that the oversight of psychotropic medication use was a high concern for state child welfare agencies. Respondents reported an increase in the use of psychotropics for youth in foster care, including: antipsychotics, antidepressants and ADHD medications, increased medication use among young children, and an increased reliance on PRN medications (medications administered as needed), and “blanket authorizations” in residential facilities.³¹ In terms of state practices and policies, the report found that 26 states had a written policy/guideline on psychotropic medication use; 13 states were in the process of developing a policy/guideline; and 9 states had no policy/guideline on psychotropic medication use. States are moving in the direction of developing practices and policies to monitor and curb the overuse of psychotropic medications for children in foster care but clearly more work remains to be done.

**Federal Government Can and Must Act**

In closing, Mr. Chairman and members of the Subcommittee, the First Focus Campaign for Children stands prepared to work with you to ensure that the health care needs of foster children are adequately met. There is a significant role for federal government to play in delivering the progress children need. By providing guidance to states on appropriate oversight policies, HHS can increase awareness of best practices. States should develop and disseminate guidelines and institute protocols for the oversight, prescribing and monitoring of psychotropic medication usage for children in foster care. In practice, States should ensure that children receive medication only in response to a relevant diagnosis, only if a good-faith effort to address the condition in therapy has fallen short, and then only under close and frequent monitoring with careful attention to opportunities to adjust medications as a child's condition changes. HHS and Congress should continue to closely monitor states' progress on this front. And Congress should invest in research, so we can better understand how the new generation of antipsychotic drugs is affecting an entire generation of American kids in the real world, not just in clinical trials.

We thank you for your leadership in addressing this critical issue, and protecting the health and welfare of our most vulnerable children. We look forward to working with you to ensure better care for our nation's foster children. If you have any additional questions, please contact me at (202) 657-0678.



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Written Statement Submitted to the
Senate Subcommittee on Federal Financial Management, Government Information,
Federal Services and International Security of the Committee on Homeland Security and
Governmental Affairs

Regarding the December 1, 2011 hearing on
The Financial and Societal Costs of Medicating America's Foster Children

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Mr. Chairman and Members of the Committee:

Protecting America's 408,000 plus foster children is one of our nation's most important obligations. Studies have documented that upwards of 75% of children entering foster care exhibit behavior or social competency problems that warrant mental health care¹. These children often have biological, psychological and social risk factors that predispose them to emotional and behavioral disturbance. These risk factors can include abuse and neglect, removal from their families and homes, multiple foster home placements and *in utero* exposure to drugs and alcohol. Despite their disproportionate health needs many foster children do not receive psychiatric care until their situation reaches a crisis point and some not even then. The American Academy of Child and Adolescent Psychiatry (AACAP) applauds the committee for its oversight of this issue and for its hearing examining the Government Accountability Office's (GAO) report titled *Foster Children HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions*. The AACAP supports the GAO's recommendations to establish formal guidance to state welfare agencies on best practices for monitoring the use of psychotropic medication in children and adolescents in foster care agencies. The AACAP is pleased that the GAO selected our *Position Statement on oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline* (see appendix A) for their study on select state foster care agencies' oversight programs. However, the AACAP calls for further studies on other treatment options available to foster care children, and system-wide issues that may prevent optimal treatment for this vulnerable population with a focus on the following areas:

- Increased guidance to state welfare agencies on the use psychotropic medications;
- The use of comprehensive treatments plans including psychosocial therapy and the use of psychotropic medications when appropriate;
- Strengthening the child and adolescent mental health workforce; and
- Increased research on the effects of psychotropic medications on children and adolescents.

¹ John A. Landsverk, Ph.D., Barbara A. Burns, Ph.D., Leyla Faw Stambaugh, Ph.D., and Jennifer A. Rolls Reitz, M.P.H., *Mental Health for Children and Adolescents in Foster Care: Review Of Research Literature*, (Casey Family Programs, 2006),

AACAP is a medical membership association established by child and adolescent psychiatrist in 1953. Now over 8,500 members strong, AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7-12 million American youth under 18 years of age who are affected by emotional, behavioral, developmental and mental disorders.

Increasing Guidance to State Welfare Agencies

One of the areas that the AACAP recommends action on is section 101(b)(2) of the recently enacted Child and Family Service Improvement and Innovation Act (Public Law No: 112-34.) Under this law, states are required to establish protocols for monitoring psychotropic medications prescribed to foster children. AACAP strongly recommends that child and adolescent psychiatrists be involved in establishing these protocols. Child and adolescent psychiatrists have the unique training and understanding on how psychotropic medications affect a developing brain and when psychosocial intervention is called for in combination with psychotropic medications or in lieu of psychotropic medications.

The AACAP shares the committees' concern regarding the over use of psychotropic medications for children in the foster care system, especially those children who are on multiple psychotropic medications and any children under the age of one receiving psychotropic medications. In addition to the timely implementation of the Child and Family Services Improvement and Innovation Act the AACAP calls for the Department of Health and Human Services (HHS) to issue to state welfare agencies guidance on the best practices for monitoring the use of psychotropic medication in children and adolescents in foster care agencies. We recommend that HHS disseminate AACAP's *Position on the Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline* as an additional resource for the appropriate use of and monitoring of psychotropic drugs for children in state custody to all state child welfare agencies. While the AACAP agrees with the GAO's recommendations that formal guidance should be issued to state welfare agencies on the best practices for monitoring the use of psychotropic medications, policy makers must not interfere with accessing appropriate treatment and the patient provider relationship.

Comprehensive Treatment Plans

Medications, when prescribed appropriately for children and adolescents with mental illness can be lifesaving. Medications can enhance a child's ability to participate in school, to be safe with family, to avoid hospitalizations and out-of-home placements, to avoid harming oneself and to avoid engaging in life threatening activities. Psychotropic medications should be prescribed as only part of a comprehensive treatment plan that addresses the complex needs of foster children. A plan for treatment of the youth's identified needs should include non-medication interventions as well as medication, if appropriate, and must be developed with the youth and family based on the best available research evidence and the family's preferences. To be able to successfully address the underlying mental health issues of children in foster care we cannot solely rely on psychotropic medications. As demonstrated by the committees' witness, Ke'onte Cook, it was not till he received psychosocial therapy that he was able to control his emotions. To effectively address the myriad of psychological issues facing many children, in and out of the foster care system, states should ensure that effective psychosocial interventions are billable under their

state's Medicaid plans. By covering psychosocial therapy states could realize long term savings, as children's mental health improves they will develop the skills they need to succeed in school and become productive members of society and avoid costly hospitalizations and institutional care.

The Child and Adolescent Mental Health Workforce

The AACAP strongly agrees with Senator Colburn's statements that America needs to invest in the training of more child and adolescent psychiatrists. Senator Colburn spoke about his experiences as a physician in Oklahoma and the struggles that he had finding a child and adolescent psychiatrist to refer his patients to. Unfortunately, as noted by Senator Colburn, there is severe shortage of child and adolescent psychiatrists, not just for Medicaid patients but for all children and adolescent with mental illnesses. As stated earlier there is less than one-third of the needed child and adolescent psychiatrists in America. Dr. Colburn accurately described the struggles that many American families face when trying to find a child and adolescent psychiatrist. In 1990 the Council on Graduate Medical Education estimated that the United States would need 30,000 child and adolescent psychiatrists by 2000 to meet the mental health needs of America's children². Currently there are less than 10,000 child and adolescent psychiatrists. When children and adolescents are unable to get the mental health care they need they are more likely to drop out of school, and or become involved in the juvenile justice system. Both of the options are tremendously costly to not only the families and children themselves but to the nation as a whole. Each high school drop out over the course of their lifetime costs the nation approximately \$260,000³. It is estimated that at current dropout rates more than 12 million high school students will drop out during the course of the next decade. The result of this will be a loss of over \$3 trillion dollars to the nation. Children ending up in the juvenile justice system are even more costly, over 70% of youth in the juvenile justice system have been diagnosed with at least one mental health disorder.⁴ The average cost per child in the juvenile justice system is \$240 per day, per youth, this adds up to over \$5.5 billion dollars per year spent by the states on the juvenile correctional system.⁵ Many of these expenses can be avoided by children and adolescents receiving proper mental health care in a timely fashion. The AACAP requests that Congress take the first step to correct this problem by funding Section 5203, The Health Care Workforce Loan Repayment Programs, of the Patient Protection and Affordable Care Act. This section would establish a pediatric specialty loan repayment program, which would include loan repayments for child and adolescent psychiatrists and other child and adolescent mental and behavioral health professionals. The funding of this program would be a major step in addressing the shortage of child and adolescent psychiatrists and providing America's youth with the quality mental health care they need.

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<http://www.ncmhjj.com/pdfs/publications/prevalenceRPB>

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Increased Research on Psychotropic Medication and Children

Many psychotropic medications prescribed to children are not currently approved by the FDA for children due to a lack of research demonstrating the drug's safety and efficacy for children. When evaluating what medications to prescribe to children doctors are often forced to use data from studies in adults even though there are documented cases of medications that are safe in adults causing unanticipated side effects in children. The AACAP calls for increased research on the long term effects on the use of psychotropic medications in children and for additional research on the increased effectiveness of combining psychosocial therapy, with psychotropic medications versus psychotropic medications alone. We also call for more services and research on treating children in the foster care system.

Recommendations

The AACAP supports the GAO's recommendation to establish formal guidance to state welfare agencies on best practices for monitoring the use of psychotropic medications in children and adolescents in foster care agencies. This is a crucial first step but more needs to be done. In addition to increased guidance to state welfare agencies, AACAP calls for the development of comprehensive treatment plans including psychosocial therapy that is funded by Medicaid, additional research on the effects of psychotropic medication on children and adolescents, and loan forgiveness programs to strength the child and adolescent mental health workforce.

**Statement for the Record
Hearing on Financial and Societal Costs of
Medicating America's Foster Children**

**Senate Government Affairs Committee
Homeland Security Subcommittee**

Held December 1, 2011

Submitted by the Bazelon Center for Mental Health Law

The Bazelon Center for Mental Health Law is pleased to submit the following statement for the record of the hearing on the Financial and Societal Costs of Medicating America's Foster Children, before the Senate Government Affairs Homeland Security Subcommittee, held on December 1, 2011.

The Committee has heard from witnesses at the Hearing concerning the potential problems and dangers to children in the foster care system stemming from the use of psychotropic medications. We will not attempt to repeat these data here, but focus primarily in this statement on recommendations for federal and state action.

While the issues regarding psychiatric medications and children in the foster care system are the focus of this hearing, the committee should be aware that this is a broader problem. In the past few decades there has been an alarming increase in the use of psychotropic medication to treat children in the United States, including infants and toddlers. Furthermore, the number of off-label drugs prescribed for young children (<4 years) has increased dramatically. These practices appear to be particularly true for all Medicaid-eligible children, while being an especially serious problem for youth in the foster care system. Factors that reportedly influenced this increase include:¹

- Lack of access to psychosocial treatments, due in part to limitations in insurance coverage (including Medicaid coverage) for these services;
- Reductions in public funding for child mental health services;
- Marketing efforts of pharmaceutical companies to prescribers and consumers;^{2 3}
- More children identified with mental health disorders as a result of advocacy efforts and greater focus by pediatricians and other primary care providers (e.g. ADHD);
- Research showing the biological basis of some childhood psychiatric disorders;
- Shortage of child and adolescent psychiatrists, leading to more children treated in primary care settings;⁴
- Specifically with the use of psychotropic medications in very young children, the evidence of the efficacy of these medications in older children and adolescents.

While it is important to expand our knowledge through research, until more is known strong restrictions should be in place to protect children, especially those under the age of 3 years.

1

Public policy should ensure that public agencies are neither promoting nor funding inappropriate use of psychiatric medications for vulnerable children.

Recommendations

The most significant need, and the action most likely to have a system wide effect in improving these practices, is expansion of psychosocial services for children and youth. With access to evidence-based treatment, many children will not require medication and for those who do, combined medication/ psychosocial treatment is the most effective approach to achieve good outcomes.

CMS should review state coverage of evidence-based mental health services for children and youth and update federal guidance to state Medicaid agencies to encourage use of treatments that are evidence based and evidence informed so as to improve the quality of care and to eliminate coverage of services for which the evidence is weak at best. The Administration on Children, Youth and Families (ACYF) should likewise conduct a review of mental health services available to foster care youth and distribute guidance and educational materials that will help state agencies and family court judges presiding over neglect and abuse cases make better choices as to community based services for youth.

With respect to the specific issues brought out at the hearing regarding psychiatric medications, we recognize the important steps ACYF, CMS and SAMHSA are taking to provide opportunities for education and guidance on these issues through mailings, online resources and webinars. We urge HHS agencies to continue to issue guidance so state officials can be fully informed on best practice with respect to the use of psychiatric medications in children. This guidance should be based on the American Academy of Child and Adolescent Psychiatry (AACAP) and American Psychological Association (APA) guidelines, and the American Academy of Pediatrics' (AAP) recommendations.

However, guidelines and advice is insufficient in this instance. Children's wellbeing is clearly at stake and the federal government should require and expect that state agencies will adopt a minimum set of policies that address this critical issue. In addition to its guidance, HHS should therefore be required to issue a rule regarding quality of mental health care for children in the foster care system. This rule should include:

- A mandate that children diagnosed with mental disorders have a full assessment of their mental and emotional health and development, a comprehensive treatment plan and access to psychosocial interventions (especially if medication is to be prescribed).
- All children in foster care should be appointed a Court Appointed Special Advocate (CASA) who must be fully informed of the risks, benefits and side effects of any medication being considered, as well as the underlying research – or absence of such research – for children of that age and with that diagnosis.
- Procedures to allow youth to be actively involved in decisions about their care, including the use of medication.
- Development of oversight systems in every state, which should include: tracking of the use of psychiatric medications for infants/toddlers and older children separately;

retrospective review of practice patterns to identify potential problems; and prior authorization systems for, at a minimum, the use of 5 or more medications or 2 or more medications from the same class. Retrospective reviews should follow the ACCAP and AAP guidelines.

- A prohibition on using psychiatric medication as a form of chemical restraint for the purpose of discipline, convenience, coercion, retaliation or any other reason. Medication should only be used when medically indicated.

Additional protections should also be in place for younger children. The rule should require states to ensure:

- Off-label prescriptions of psychiatric medications for children age 3 and under require concurrence from a second physician who is trained in psychiatric medicine.
- Antipsychotic medication is only used with children under age 3 if approved by the FDA and only *after* behavioral interventions have been tried and found to be ineffective.

Child welfare agencies should be encouraged to use the data they collect from their oversight to help physicians improve prescribing practices. Physicians who are outliers in terms of their prescription of psychiatric medication to children should be identified and notified that they are not prescribing in accordance with best practice guidelines. This procedure has proven extremely beneficial in some states.

Child welfare agencies should release an annual report summarizing the data they collect from their oversight. The report should also be tailored and made available to family court judges, lawyers, social workers, CASAs, and foster parents.

State child welfare, Medicaid and state mental health authorities should collaborate around appropriate services for children with psychiatric conditions. The Substance Abuse and Mental Health Services Administration's Comprehensive Community Mental Health Services for Children and Their Families Program (also known as system of care program) should be expanded to provide funding for collaborations that are specific to this population of children. A state data base system for sharing of information should be part of such collaborations.

Given that this is a systemic problem, the committee should also consider measures that improve state Medicaid systems and the role of juvenile judges who encounter foster care youth in the courtroom. CMS should provide new and specific guidance to state Medicaid directors that recommends that states adopt the same policies as we recommend above for child welfare systems so that all low-income children on Medicaid are protected from inappropriate and substandard care, including such practices as the concomitant use of 5 or more medications, doses that exceed maximum recommended levels, and the use of medications in infants and toddlers, which have no research base and the potential for serious adverse effects and long term consequences.

Other ways in which CMS could be more active would be to review and improve state Drug Utilization Review (DUR) programs, assist providers to install electronic medical records that include red flags on childhood medication issues for psychiatric disorders and prioritize work to

encourage states to develop health homes for children that integrate physical and behavioral health care.

Given that the research in this area is so limited, the committee might also want to address the need to expand both research and surveillance regarding the use of psychiatric medications in children. For example the Best Pharmaceutical for Children Act (BPCA) of 2002 provides targeted funding for research on the safety and efficacy of medications used in pediatrics, including psychiatric medications, although only for a few drugs. Studies are examining long-term safety issues, effectiveness, and potential side effects, such as like metabolic derangements. Since research regarding off-label use of psychiatric drugs is still very limited at this time, we would recommend that:

- The BPCA research on use of off-label psychiatric drugs for children, especially use among very young children, be significantly expanded and considered a research priority.
- The FDA create a surveillance system that monitors the effects of all psychiatric medications approved for use in children as well as those commonly prescribed off-label to identify whether these medications (in the short- and the long-term) may adversely impact children's development, mental health and overall health condition.

Conclusion

The use of psychiatric medications in children is exploding. These medications are prescribed for extremely young children and for all age groups. They are frequently the first, rather than last, resort. There is a significant need for improved professional practice and stronger public policy. The goal of these recommendations is to reduce the exposure of children to medications that may be extremely harmful while maintaining access to those that are effective.

¹ Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents. *J. Am. Acad. Child Adolesc. Psychiatry*, 2009;48(9):961-973.

² Kravitz RL, Epstein RM, Feldman MD et al. Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. *JAMA*. 2005;293:1995Y2002.

³ Baird P. Getting it right: industry sponsorship and medical research. *CMAJ*. 2003;168:1267-1269.

⁴ Goodwin R, Gould MS, Blanco C, Olfson M. Prescription of psychotropic medications to youths in office-based practice. *Psychiatr Serv*. 2001;52:1081-1087.

