

**ATTENTION DEFICIT/HYPERACTIVITY DISORDER—  
ARE WE OVERMEDICATING OUR CHILDREN?**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON  
GOVERNMENT REFORM**  
**HOUSE OF REPRESENTATIVES**  
ONE HUNDRED SEVENTH CONGRESS  
SECOND SESSION

SEPTEMBER 26, 2002

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**ATTENTION DEFICIT/HYPERACTIVITY DIS-  
ORDER—ARE WE OVERMEDICATING OUR  
CHILDREN?**

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**THURSDAY, SEPTEMBER 26, 2002**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON GOVERNMENT REFORM,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:28 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Horn, Souder, LaTourette, JoAnn Davis of Virginia, Weldon, Putnam, Duncan, Cummings, and Watson.

Staff present: Kevin Binger, staff director; Chad Bungard, John Callendar, Jason Foster, Randall Kaplan, and Matt Rupp, counsels; S. Elizabeth Clay and Gil Macklin, professional staff members; Blain Rethmeier, communications director; Allyson Blandford, assistant to chief counsel; Robert A. Briggs, chief clerk; Robin Butler, office manager; Joshua E. Gillespie, deputy chief clerk; Michael Layman and Susie Schulte, legislative assistants; Nicholis Mutton, deputy communications director; Leneal Scott, computer systems manager; Mindi Walker, staff assistant; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. Good morning. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written and opening statements be included in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits, and extraneous or tabular material referred to be included in the record. Without objection, so ordered.

Today we're going to be discussing a very important issue that affects many, many children in the United States. As all of us know, our children are our future. I doubt there's a single Member of Congress that doesn't feel strongly that we need to do our dead level best to protect and improve the health and well-being of the children of this Nation.

Today we're going to talk about a group of symptoms known as "attention disorders." In the last two decades, we've heard more and more attention about deficit disorders, ADD, and attention deficit hyperactive disorder, ADHD.

The most common treatment for this disorder is a drug called Ritalin. This drug is being given to more and more children in this country. It has become very controversial. There have been a 500 percent increase in the use of Ritalin in the United States since 1990, a 500 percent increase. It is estimated that 4 to 6 million children in the United States take Ritalin every single day.

On one side of this issue we're going to hear from the associations of psychiatrists and a parents' organization known as "Children and Adults with Attention Deficit/Hyperactivity Disorder, or CHADD. They believe that 13 percent of the U.S. population, adults and children, suffer from an attention disorder, and that it should be treated with medication.

At the other end of the discussion is the Citizen's Commission for Human Rights. They challenge the legitimacy of calling ADHD a neurobiological disorder. They raise serious questions about giving strong medications to young children.

Also in the discussion are concerned parents.

Imagine being a parent of a young child and receiving a note from your school instructing you to take your child to their pediatrician for evaluation. In this note from the school there's a checklist for you to take to the doctor. The school officials have diagnosed your child as possibly having ADHD. These are the teachers and the school officials. They make this diagnosis because your child makes careless mistakes on homework, does not follow through on instructions, fails to finish school work, has difficulty organizing tasks, loses things, and is forgetful in daily activities. That sounds like me when I was in grade school. I did not take Ritalin and I became a Congressman. [Laughter and applause.]

When you take your child to your doctor, instead of blood tests and a thorough medical evaluation, you have a conversation with the doctor about the school's checklist, and you leave a few minutes later with a prescription for your young child for a psychotropic drug.

Did the doctor test your child for a thyroid disorder? Did your doctor test your child for a heavy metal toxicity? Did your doctor talk to you about your child's allergies? Did your doctor even mention nutrition or possible food sensitivities? Did your doctor ask if your child's IQ had been tested and if he was gifted? Probably not.

We all know that prescription drugs continue to command a greater percentage of the overall health care dollar. According to the Department of Health and Human Services, prescription drugs accounted for 9 percent of all U.S. health care expenditures in fiscal year 2001. This is a 14.7 percent increase in 1 year.

Ritalin, as you know, is classified as a Schedule II stimulant under the Federal Controlled Substances Act. In order for a drug to be classified as a Schedule II, it must meet three criteria:

One, it has to have a high potential for abuse; two, it has to have a currently accepted medical use in treatment in the United States; and, three, it has to show that abuse may lead to severe psychological or physical dependence.

This is a Schedule II drug, and this is the definition.

Some of the things we've heard about Ritalin cause me to have some concerns, and I'd like to hear from all of our witnesses today about those issues. The "experts" tell us that Ritalin is a "mild

stimulant.” However, research published in 2001 in the “Journal of the American Medical Association” showed that Ritalin was a more potent transport inhibitor than cocaine. This isn’t me saying this. This was in the “Journal of the American Medical Association.” It said that Ritalin was a more potent transport inhibitor than cocaine. The big difference appears to be the time it takes for the drug to reach the brain. Inhaled or injected cocaine hits the brain in seconds, while pills of Ritalin normally consumed take about an hour to reach the brain. Like cocaine, chronic use of Ritalin produces psychomotor stimulant toxicity, including aggression, agitation, disruption of food intake, weight loss, stereotypic movements, and death.

There have been only two large epidemiological studies on the long-term dopamine effects of taking Ritalin for years. One study found more drug addiction in children with ADHD who took Ritalin compared with children with ADHD who took no drug, while the other study shows the opposite result, so they are inconclusive at this moment.

The question that remains to be answered, according to the authors of this study, is whether the chronic use of Ritalin will make someone more vulnerable to decreased dopamine brain activity, as cocaine does, thus putting them at risk for drug addiction.

Even more disturbing than the prescribing of Ritalin to school-age children is a trend to prescribe this medication to preschoolers. A study published in the “Journal of the American Medical Association” in 2000 offered some key insights into this dangerous new trend. Of 233 Michigan Medicaid enrollees younger than 4 years of age with a diagnosis of ADHD, 57 percent received at least one psychotropic medication to treat the condition during a 15-month period in 1995 to 1996. Ritalin and Clonidine were prescribed most often.

Additionally, the authors found that in the midwestern States’ Medicaid population there was a threefold increase in total prescribing of stimulants between 1991 and 1995—a 300 percent increase. There was a threefold increase in prescribing Ritalin, a 28-fold increase in prescribing Clonidine, and a 2.2fold increase in prescribing of antidepressants. This is children between the ages of 2 and 4 years old.

These are trends that I think we ought to be concerned about. Is it safe to give these drugs to very young children? What will the long-term effects be? Are children being diagnosed correctly? I hope we can shed some light on all of these issues today.

In concluding, let me just say over the last 4 years this committee has looked at numerous health issues. We’ve looked at the role of dietary supplements, nutrition, and physical activity in improving health. We’ve looked at the role of complementary and alternative medicine in our health care system. We’ve looked at pharmaceutical influence on Advisory Committees at the Department of Health and Human Services. And we’ve looked at the possible relationship between childhood vaccines and the autism epidemic.

It is obvious to me that we can no longer ignore that our health care system is in need of a major overhaul and attitude change. We have a generation of doctors who have not been trained in nutrition. We have statistics that show that 85 percent of the illnesses

Americans face are related to lifestyle. We have camps of conventional doctors who are trained to suppress symptoms through drugs, and camps of complementary and alternative medical professionals, including doctors, who are trained to look at the whole person and their environment. It's time that we put the labels of conventional and alternative aside and think about an integral approach, a complete approach to care. We owe it to all of us, but especially our children.

I'm pleased that we have such a stellar list of witnesses today. Mr. Neil Bush, the brother of the President, was going to be here with us, but unfortunately he could not be, so what we have done is we have a tape of an interview that was conducted with Mr. Bush that we will show at the outset of our hearing before we hear from our witnesses. As everybody knows, he is not only the brother of the President, but he is the CEO of Ignite Learning and the son and brother of two Presidents and was supposed to be here, but unfortunately he couldn't. He did have a family experience with a misdiagnosis of ADHD.

Ms. Lisa Marie Presley—I'm sure everybody knows who Ms. Presley is. She's not only a very talented young lady and a very attractive young lady, she's the daughter of Elvis Presley and his lovely wife, and she's here today to testify, and we're looking forward to her testimony. She's a concerned mother and the international spokesperson for the Citizen's Commission on Human Rights.

Mrs. Patti Weathers, who is here with us—we're glad to have you—she will share her family's story about a school trying to force medication as a condition of school participation.

Dr. Mary Ann Block, the author of "No More ADHD" is here.

We appreciate your being here, as well.

And, of course, we have Mr. Wiseman, who has been active in this issue for a long time.

We appreciate your attendance, as well, Mr. Wiseman.

Mr. WISEMAN. Thank you.

Mr. BURTON. I want to thank all of our witnesses for being here to day. I look forward to your testimony. The hearing record will remain open until October 10th.

Mr. Waxman is not here at the present time, so I will now yield to the distinguished gentleman from New York, my colleague, Mr. Gilman.

[The prepared statement of Hon. Dan Burton follows:]

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Opening Statement  
Chairman Dan Burton  
Committee on Government Reform

September 26, 2002 Hearing

2154 Rayburn House Office Building  
Washington, D.C.  
10:00 a.m.

Good morning. Our children are our future. I doubt that there is a single member of Congress that does not feel strongly that we need to do our dead-level best to protect and improve the health and well-being of our nation's children.

Today we are going to talk about a group of symptoms known as attention disorders. In the last two decades, we have heard more and more about attention deficit disorder (ADD) and attention deficit hyperactive disorder (ADHD).

There are a Broad Range of Views on This Topic

The most common treatment for this disorder is a drug called Ritalin. This drug is being given to more and more people in this country. It has become very controversial. There has been a 500 percent increase in the use of Ritalin in the United States since 1990. It is estimated that four to six million children in the United States takes Ritalin daily.

On one side of this issue we're going to hear from the associations of psychiatrists, and a parent's organization known as

Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD). They believe that thirteen percent of the U.S. population – adults and children – suffer from an attention disorder, and that it should be treated with medications.

At the other end of the discussion is the Citizen's Commission for Human Rights. They challenge the legitimacy of calling ADHD a neurobiological disorder. They raise serious questions about giving strong medications to young children.

Also in the discussion are concerned parents.

#### How are Attention Disorders Diagnosed?

Imagine being a parent of a young child and receiving a note from your school instructing you to take your child to their pediatrician for evaluation. In this note from the school is a checklist for you to take to the doctor. The school officials have diagnosed your child as possibly having ADHD. They make this diagnosis because your child makes careless mistakes on homework, does not follow through on instructions, fails to finish

schoolwork, has difficulty organizing tasks, loses things, and is forgetful in daily activities.

When you take your child to your doctor, instead of blood tests and a thorough medical evaluation, you have a conversation about the school's checklist and leave a few minutes later with a prescription for your young child for a psychotropic drug.

Did the doctor test your child for a thyroid disorder? Did your doctor test for heavy metal toxicities? Did your doctor talk to you about your child's allergies? Did your doctor even mention nutrition or possible food sensitivities? Did your doctor ask you if your child's IQ had been tested and if he was gifted? Probably not.

#### Prescription Drug Use Is Rising

We all know that prescription drugs continue to command a greater percentage of the overall health care dollar. According to the Department of Health and Human Services, prescription drugs



accounted for nine percent of all U.S. health care expenditures in fiscal year 2001. This is up 14.7 percent in one year.<sup>1</sup>

Does the Use of Ritalin lead to Future Drug Abuse?

Ritalin as you know is classified as a Schedule II stimulant under the Federal Controlled Substances Act. In order for a drug to be classified as a Schedule II it must meet three criteria:

- (1) have a high potential for abuse,
- (2) have a currently accepted medical use in treatment in the United States, and
- (3) show that abuse may lead to severe psychological or physical dependence.

Some of the things we've heard about Ritalin cause me to have some concerns. I'd like to hear from all of our witnesses today on these issues. The "experts" tell us that Ritalin is a "mild" stimulant. However, research published in 2001 in the *Journal of the American Medical Association* showed that Ritalin was a more potent transport inhibitor than cocaine. The big difference appears to be the time it

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<sup>1</sup> Interim Report, President's Task Force to Improve Health Care Delivery for Our Nation's Veterans.

takes for the drug to reach the brain. Inhaled or injected cocaine hits the brain in seconds, while pills of Ritalin normally consumed take about an hour to reach the brain. Like cocaine, chronic use of Ritalin produces psychomotor stimulant toxicity, including aggression, agitation, disruption of food intake, weight loss, stereotypic movements and death.<sup>2</sup>

There have been only two large epidemiological studies on the long-term dopamine effects of taking Ritalin for years. One study found more drug addiction in children with ADHD who took Ritalin compared with children with ADHD who took no drug, while the other study shows the opposite result. The question that remains to be answered according to the authors of this study is whether the chronic use of Ritalin will make someone more vulnerable to decreased dopamine brain activity as cocaine does, thus putting them at risk for drug addiction.<sup>3</sup>

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<http://www.presidentshealthcare.org/pdffiles/InterimReport.pdf>

<sup>2</sup> Is Ritalin An Abused Drug?: Does it Meet the Criteria of a Scheduled II Substance? Cristine Samerud and Gretchen Fuessner (Provided by Drug Enforcement Administration).

<sup>3</sup> Vastag Brian, Pay Attention: Ritalin Acts Much Like Cocaine, JAMA, August 22/29, 2001, Vol 286, No. 8, pages 905-906.

Ritalin is Among the Drugs Increasingly Prescribed to Toddlers

Even more disturbing than the prescribing of Ritalin to school age children, is a trend to prescribe this medication to preschoolers. A study published in the *Journal of the American Medical Association* in 2000 offered some key insights into this dangerous new trend. Fifty-seven percent of 223 Michigan Medicaid enrollees younger than four years of age with a diagnosis of ADHD received at least one psychotropic medication to treat the condition during a 15-month period in 1995–1996. Ritalin and Clonidine were prescribed most often. Additionally the authors found that in the Midwestern States Medicaid population there was a three-fold increase in total prescribing of stimulants between 1991 and 1995. There was a 3-fold increase in prescribing Ritalin, a 28-fold increase in prescribing Clonidine, and a 2.2 fold increase in prescribing of antidepressants. This is children between the ages of two and four years.

These are trends that I think we ought to be concerned about. Is it safe to give these drugs to very young children? What will the

long-term effects be? Are children being diagnosed correctly? I hope we can shed some light on all these issues today.

### Conclusion

Over the last four years, this Committee has looked at numerous health issues. We have looked at the role of dietary supplements, nutrition, and physical activity in improving health. We have looked at the role of complementary and alternative medicine in our health care system: We have looked at pharmaceutical influence on Advisory Committees at the Department of Health and Human Services. We have looked at the possible relationship between childhood vaccines and the autism epidemic.

It is obvious to me that we can no longer ignore that our health care system is in need of a major overhaul and attitude change. We have a generation of doctors who were not trained in nutrition. We have statistics that show that 85 percent of the illnesses Americans face are related to lifestyle. We have camps of conventional doctors who are trained to suppress symptoms through drugs, and camps of

complementary and alternative medical professionals, including doctors, who are trained to look at the whole person and their environment. It is time that we put the labels of conventional and alternative aside and think about an integral approach – a complete approach to care. We owe it to our children.

I am pleased that we have such a stellar list of witnesses today. Mr. Neil Bush is the CEO of Ignite Learning and the son and brother to two Presidents was supposed to be here to share his family's experience with a misdiagnosis of ADHD. Unfortunately, he was unable to attend so we will be showing a brief interview he gave this week on Good Morning America.

Ms. Lisa-Marie Presley is here as a concerned mother and the international spokesperson for the Citizen's Commission on Human Rights. Mrs. Patti Weathers is also with us today and will share her family's story about a school trying to force medication as a condition of school participation. Dr. Mary Ann Block, the author of *No More ADHD* is here as well.

I want to thank all of our witnesses for being here today, and I look forward to your testimony. The hearing record will remain open until October 10.

I now yield to Mr. Waxman for his opening statement.

Mr. GILMAN. Thank you, Mr. Chairman. I want to thank Chairman Burton for holding this important hearing to examine the issue of medicating school children and the treatment of attention deficit hyperactive disorder.

As a congressional Member who has long been interested in the ongoing war on illicit drugs, I'm surprised by the extensiveness of the use of controlled substances such as Ritalin, with a high potential for abuse and the propensity for its dependence, to treat psychiatric disorders of children. This issue is surrounded by a substantial controversy, a debate that we fully expect to be highlighted by today's witnesses.

While we recognize the merits of the positions argued by each side, my concerns lie in another area. I don't doubt that there are many children with genuine illnesses and disorders that could benefit from a treatment regime involving Ritalin and similar drugs. I am concerned, however, with a number of other issues. The first of these is the trend toward treating younger and younger children with these dependent drugs. Ritalin is generally not recommended for children under age 6; yet, there was a threefold increase in its prescription for children aged 2 to 4 between 1991 and 1995.

Also of concern is that parents are being pressured into having their children take these drugs when a diagnosis is made by a teacher or other school official and not by any medical professional. As a result, the potential for abuse is enormous. Educators want conformity in the classroom, but the desire for order needs to be balanced against the health of the children.

The heavy advertising and the extensive lobbying on school districts by drug companies for these products is very distressing. The decisions involving treatment need to be made by medical personnel who know the individual patient and not by someone with some financial stake in the system.

Moreover, we've not seen any evidence that suggests the medical profession has any significant knowledge about the long-term effects of these drugs. Given that this is a relatively recent phenomenon, it is possible that long-term studies have not been undertaken. If that's the case, we could be setting ourselves up for a potential disaster down the road.

Once again, Mr. Chairman, thank you for holding this important hearing this morning. I look forward to the testimony of our witnesses.

Mr. BURTON. Thank you, Mr. Gilman.

Ms. Watson, do you have an opening statement?

Ms. WATSON. Yes, sir.

Mr. BURTON. Ms. Watson, you are recognized.

Ms. WATSON. I want to thank you, Mr. Chairman, and I have a few observations I'd like to share based on an experience while I was teaching and as a school psychologist.

Although fidgeting and not paying attention are normal and common childhood behaviors, a diagnosis of ADHD may be required for children in whom frequent behavior produces persistent dysfunctions. The challenge is to evaluate, inform the parents, and consider the alternatives before choosing an invasive and artificial drug treatment.

An adequate diagnostic evaluation requires histories to be taken from multiple sources—from the parents, from children, from teachers, and from others that are associated with the child; a medical evaluation of general and neurological health; a full cognitive assessment, including school history, use of parent and teacher rating scales, and all necessary adjunct evaluation, such as an assessment of speech and language patterns, etc. These evaluations take time and require multiple clinical skills. Regrettably, there's a lack of appropriate trained professionals and monetary resources in the current school systems.

As a school psychologist in Los Angeles, for every 10 students that I worked with, there were approximately 4 or maybe even 5 on Ritalin. It was very frustrating to see many of the medicated children completely numb to stimuli. In many cases they were almost like robots.

Drugs should not be overly prescribed or seen as the only solution to these problems. The American Academy of Pediatrics published a policy statement in 1996 on the use of medication for children with attentional disorders, concluding that the use of medication should not be considered the complete treatment program for a child with ADHD and should be prescribed only after a careful evaluation.

Because stimulants are also drugs of abuse, and because children with ADHD are at an increased risk of substance abuse disorder, I have concerns about the potential for the abuse of stimulants by children taking the medication or diversions of drugs to others. Just yesterday I read in the "Washington Post" sports Section that the Hall of Fame Pittsburgh Steeler, Mike Webster, pleaded no contest in September 1999, to forging prescriptions to obtain Ritalin.

I finally say that this point has to be made, and it goes to the fact that this great athlete is probably someone who early on showed hyperactivity and probably because he was bored in class, or whatever the circumstances might have been, but he now has an addiction that I think in some ways could be equated with the use of cocaine, which is so prevalent in my District and in the school district that I represent.

So I am very, very concerned that we are bringing our children up in a drug culture, and you can't turn on the television or the radio or read a newspaper that we're not pushing something to wake you up, put you to sleep, 1-2-3 take this, and so children are surrounded by this culture. We need not have this particular effect in our schools.

So, Mr. Chairman, thank you very much for holding this hearing. I look forward to hearing the presenters.

Mr. BURTON. Thank you very much, Doctor. We appreciate that. [The prepared statement of Hon. Diane E. Watson follows:]



**Statement of Diane E. Watson, M.C.  
Government Reform Hearing on September 26<sup>th</sup>, 2002  
“ADHD: Are Children Being Overmedicated?”**

Thank you Mr. Chairman.

I have a few observations that I would like to share, based on my teaching career. Although fidgeting and not paying attention are normal, and common, childhood behaviors, a diagnosis of ADHD may be required for children in whom frequent behavior produces persistent dysfunction. The challenge is to evaluate, inform (the parents) and consider the alternatives, before choosing an invasive and artificial drug treatment. An adequate diagnostic evaluation requires histories to be taken from multiple sources (parents, child, teachers), a medical evaluation of general and neurological health, a full cognitive assessment including school history, use of parent and teacher rating scales, and all necessary adjunct evaluation (such as assessment of speech, language). These evaluations take time and require multiple clinical skills. Regrettably, there is a lack of appropriately trained professionals and monetary resources in the current school system.

As a school psychologist in Los Angeles, for every 10 students that I worked with, there were approximately 4 on Ritalin. It was very frustrating to see many of the medicated children completely numb to stimuli. In many cases they reacted almost like robots.

Drugs should not be over prescribed or seen as the only solution. The American Academy of Pediatrics published a policy statement in 1996 on the use of medication for children with attentional disorders, concluding that use of medication should not be considered the complete treatment program for children with ADHD and should be prescribed only after a careful evaluation (American Academy of Pediatrics Committee on Children With Disabilities and Committee on Drugs, 1996).

Because stimulants are also drugs of abuse and because children with ADHD are at increased risk for a substance abuse disorder, I have concerns about the potential for abuse of stimulants by children taking the medication or diversion of the drug to others. Just yesterday I read in the Washington Post sport section, that the Hall of Fame Pittsburgh Steeler, Mike Webster pleaded no contest in September 1999 to forging prescriptions to obtain Ritalin. I say this not to point fingers at a great athlete, but to caution the use of a drug that has been equated in some effects to cocaine.

Thank You Mr. Chairman.

Mr. BURTON. Mr. Horn.

Mr. HORN. Mr. Chairman, I thank you for this further series of where there has been misuse of pharmaceuticals. I agree completely with my colleague, Mr. Gilman. We have been all over Europe and everywhere else to see that drugs, and when it's used for small children and they have no say about it and when it's wrong, we should make sure that doctors are properly put together, have what type of either adolescents or the others.

So I would commend you and would hope that we could get soon to the witnesses, since they are outstanding.

Mr. BURTON. Thank you, Mr. Horn.

Mr. BURTON. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank you for holding this hearing. I bring a very interesting perspective to this hearing in that, as a young African American boy in South Baltimore, I know that what happened to a lot of us, because we were actually pushed into special education, we were given all kinds of drugs, and they said that we were hyperactive, and told that, you know, our hyperactivity could not be controlled. But what they failed to understand in this poor neighborhood in South Baltimore was that we didn't have the playgrounds. We didn't have them. We played on glass, G-L-A-S-S. We didn't have the leagues, the baseball leagues. That's stuff that little boys would normally do to get that energy out of them.

And so what happened, as is happening today in my District, are little children are being drugged to keep them stable, so they say, so that they can learn.

I agree with Congresswoman Watkins that we've got a situation where we have to bring this whole situation under control.

Mr. Chairman, I applaud you for bringing attention to it, because it is a very serious thing.

Just today I was listening to one of our national stations and they were talking about how there are over 1 million African American men in prison, 1 million. There are more African American men in prison than there are in college. You have to wonder how many of them may have started off with folks saying that, you know, "There's something wrong with you."

We have to understand, when you tell a child that there's something wrong with them, it goes with them until they die, and it's not—I've often said it's not the deed, it's the memory that haunts folks.

And so I think that perhaps—I don't know what our witnesses will touch on this. I think that perhaps we categorize children at an early age and we misdiagnose them and then we put them on a train on a track that leads to nowhere, and so that's why, Mr. Chairman, I'm glad we're exploring this. I think that it took a lot of foresight on your part to even open up this door so that we could peek in, because I can tell you that I know of a lot of children right now who are sitting in classrooms and they have been drugged and they don't know—they're not sure what's going on with them. All they know is that they have been labeled.

And, last but not least, Mr. Chairman, let me say this. In our society today too often what we do is we look at a child's behavior and say to ourselves that that behavior is a deficit as opposed to

an asset. I can recall as a young boy, one of the reasons why they put me in special education and put me to the side is because they said I talked too much. They said, "You talk too much." I'm so glad that there were some people that saw it as an asset, did not drug me to quiet me, and said to use this asset that God has given you so that you can help to bring benefit to the rest of society.

And so for those reasons I take it very personal, what we're doing here today, because there are so many people that don't get off of that train leading to nowhere.

With that, Mr. Chairman, I yield back.

Mr. BURTON. Thank you, Mr. Cummings.

I'd just like to say that your testimony parallels some of the things I heard about me when I was in school. I guess I still talk too much sometimes.

Let's see. Mrs. Davis.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman. I appreciate your holding this hearing.

I want to bring an entirely different perspective to what has been said. I'm the Mom of an ADHD son who is now 21. I would have given anything back when he was 6 or 7 if someone from the school would have sent a note home and said, "Have your son tested or checked out." Instead, we went for several years thinking we were bad parents, something is wrong. We could not control our child. We didn't know what was wrong with him. And it was at the end of his second grade when his teacher said, "He's below grade level," and she passed him because she just didn't want to deal with him any more. It was a struggle at home. It was a strain on our marriage. This is our younger son. We just couldn't handle him. We couldn't control him.

During that summer, I happened to be talking to a lady who asked me had I ever had my son tested for attention deficit hyperactivity disorder, which I'd never heard of. I took him to my pediatrician, who sent me to a psychologist. We wrestled with putting our son on Ritalin. I did not want to medicate my child. My husband didn't want to medicate him. We wrestled with that a great deal.

The first day of school in third grade he was sent to the principal's office for acting up. That went on for a week. It wasn't acting up like bad behavior, it was he just couldn't control himself. And, to make a long story short, the second week we put him on Ritalin. We did not tell the school. Back then the teachers in our area were not trained on attention deficit hyperactivity disorder. They didn't know much about it.

At the end of the first 9 weeks when the report card came out—keep in mind, this is the young man they wanted to hold back in second grade, or said he was below grade level—we received a call to come to the school. I went to the school, met the principal, the reading specialist, and the third grade teacher, who said our son was a brilliant, gifted child and wanted to put him in the gifted learning class. He made straight A's.

We then told them we did not want him in the gifted class. We explained the Ritalin.

I will tell you that Ritalin was the savior to us for our son. We tried everything. We tried the diet. We tried the behavior changes. We tried everything before we succumbed to the Ritalin.

We didn't keep him on it during the holidays. We didn't keep him on it during the summer. He did great. The psychologist said it was all right not to have him on it during the summer and during the holidays. He did great.

When he was in high school he opted to go off the Ritalin. We've had no trouble with our son. He's not had a problem with drugs. In fact, just the opposite. We explained to him that with the Ritalin if he were to ever try drugs that it could totally harm him.

I believe that in this country we have a tendency to swing from one end to the other. I do believe we've swung to the other. We've gone from when people didn't know about Ritalin and attention deficit disorder to now any time you have a child who is active at all we put them on Ritalin.

I would not want to see the children going on Ritalin at age 2, 3, 4, 5. It was a hard decision for us at 8 to put our son on Ritalin. I do believe that in some cases Ritalin is what helps.

One thing we explained—and I don't mean to take up too much time, but one thing we explained to our son is that the Ritalin didn't make him smart. It didn't make him get the A's. It just helped him to concentrate to be able to use the abilities that he already had.

I do think there are children and parents who will need to put their children on Ritalin, but I don't think it is anywhere near the number of kids that I see on Ritalin today.

I appreciate your holding this hearing, and I hope and pray that before parents put their children on Ritalin they will have them tested in every respect, they will talk it out with everyone before they do it, and that they know it would just be the last resort. For us it was a lifesaver. He's 21. He's doing great. He's not on Ritalin, hasn't ben on it since 10th grade, but it was a lifesaver, Mr. Chairman. So I would hope we wouldn't outlaw it altogether, but that we would take a serious check on our conscience before we put our kids on the Ritalin.

I thank you, Mr. Chairman.

Mr. BURTON. Thank you very much, Mrs. Davis.

Dr. Weldon.

Dr. WELDON. Mr. Chairman, I want to commend you for holding this hearing and just mention that you are taking us into a very complicated but very, very important arena. I'm very, very appreciative of the lady from Virginia's testimony.

My perception is that Ritalin is, to a certain degree, a victim of its own success. It has helped a lot of children, but there are many children who are being placed on it unnecessarily.

I think there's a broader issue that I would like to see the committee address, though I expect we will not be able to in the confines of the amount of time remaining on the calendar, and that is: is there some other underlying process going on to account for the larger and larger number of kids that are being labeled with this behavioral and learning disorders? I'm specifically talking about something in the environment, something in the food that

could be playing a role. Vaccines is another thing worth considering.

Again, thank you very much for convening this hearing. I'm looking forward to hearing the testimony of our witnesses, so I yield back.

Mr. BURTON. If we don't get to those other issues you referred to, Dr. Weldon, we'll try to hopefully do that in the coming year.  
Judge Duncan.

Mr. DUNCAN. Mr. Chairman, first of all I want to thank you and the staff for calling this hearing. I don't believe there's any committee in the Congress that has held hearings on a wider variety of really important topics than this committee has under your chairmanship.

I listened very closely and intently, as all of us did, to Mrs. Davis' statement. I can tell you that I remember having lunch 1 day in the House dining room with a family that told me almost the exact same story. And I have no doubt that there are some children in this country, many children, perhaps, in this country that have benefited from Ritalin, but I also have spoken on the floor of the House twice about this subject because I believe that this drug—I have to believe that this drug is way over-prescribed in this country, and I believe it is all really about money.

I mentioned in one of my floor statements that I'd read an article in 1998 by the former second-ranking official of the Drug Enforcement Administration who had retired to Knoxville, and he wrote an article in the "Knoxville News Sentinel" and said that Ritalin was being prescribed in the United States six times more than in any other industrialized nation in the world. And he said in this article that Ritalin had the same properties basically as some of the most addictive drugs there are.

I read in 1999 in "Time Magazine" that production of Ritalin had increased seven-fold, seven times, in the past 8 years, and that 90 percent of it was being consumed in the United States. And "Time Magazine" said in that article, "The growing availability of the drug raises the fear of the abuse. More teenagers try Ritalin by grinding it up and snorting it for \$5 a pill than get it by prescription."

Then I read in "Insight Magazine," which has had several articles about this, that almost every one of the teenage shooters that we've read about in recent years have been boys who were at the time or had recently been taking Ritalin or other similar mind-altering drugs.

Late last year the same magazine, "Insight Magazine," had an article which said, "Thirty years ago the World Health Organization concluded that Ritalin was pharmacologically similar to cocaine in the pattern of abuse it fostered, and cited as a Schedule II drug, the most addictive in medical use." The Department of Justice also cited Ritalin as a controlled substance, as a Schedule II drug under the Controlled Substances Act. And the Drug Enforcement Administration warned that "Ritalin substitutes for cocaine and deamphetamines in a number of behavioral paradigms."

I also read one study that said that almost all Ritalin was being prescribed to young boys who were the children of very successful parents, both of whom were working full time outside of the house.

Now, I say again I know that there are people for whom Ritalin has been a lifesaving drug, but I also know that I think—and I have a family that has many teachers in it, but I know sometimes that there are some poor teachers who I think have recommended Ritalin just because they personally couldn't properly handle a young boy that was being what we used to say "he's all boy. He's very, very active."

I have known personally two or three of these young boys that have been put on Ritalin, and they've appeared to me to be in zombie-like states.

So I think we need to look very closely at this. I don't believe we need to outlaw Ritalin, but I believe it needs to be greatly, greatly reduced in its usage.

I'll say again I believe it is being over-prescribed in this country just because of the profit factor, the money that's out there that the drug companies want to make.

Thank you very much.

Mr. BURTON. What I'd like to do is take the committee to the 5-minute mark. We have almost 12 minutes left on the clock. Then we will have to recess for three votes. I would urge all Members to come back so we can hear our witnesses if it is at all possible.

With that, I'd like to have our witnesses stand and be sworn in. Would you please rise and raise your right hands.

Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses sworn.]

Mr. BURTON. Be seated.

I'd like to start off by showing a tape of Neil Bush, who could not be with us today, because he had some things he wanted to say and we'd like to show real quickly. So would we put our attention on the monitors.

[Videotape played.]

Mr. BURTON. I want to thank ABC for providing that tape to us. We are now at a point where we have to recess. Please forgive me, you on the panel and everybody in the audience. We'll get back here just as quickly as possible.

We have three votes. The first one will be through in about 10 minutes, and then we have two 5-minute votes, so we'll be back here in about 25 minutes. So get a cup of coffee or a glass of water and forgive us for having to recess. We'll be right back.

We stand in recess to the call of the gavel.

[Recess.]

Mr. BURTON. The meeting will once again come to order.

There will be other Members coming back besides me and Mrs. Davis, but we just had votes on the floor and we rushed back, so they will be wandering in. Those things happen.

Before we start with the panel—who are on our way out, as I understand it—I want to thank Sam Brunelli for helping me arrange this. For those of you who don't know who Sam Brunelli is, he was an All-Pro football player for some team out west called the Denver Broncos. Is that what it was, Sam? Yes. Well, Sam did a great job for them. He was All-Pro, but I think this year they're going to be whipped by the Indianapolis Colts in that division. And Sam's thinking over there, "Not in your lifetime." [Laughter.]

In any event, you've all been sworn and I want to thank you for being patient with us while we were gone.

I think what we'll do is we'll start right down the list there.

Ms. Weathers, why don't you start with your testimony? And if you can, keep your testimony to 5 minutes, but we won't kill you if you go just a few seconds over.

**STATEMENTS OF PATRICIA WEATHERS, PRESIDENT, PARENTS FOR LABEL AND DRUG FREE EDUCATION; MARY ANN BLOCK, D.O., AUTHOR AND MEDICAL DIRECTOR, THE BLOCK CENTER; LISA MARIE PRESLEY, NATIONAL SPOKESPERSON, CITIZENS' COMMISSION ON HUMAN RIGHTS; AND BRUCE WISEMAN, U.S. PRESIDENT, CITIZEN'S COMMISSION ON HUMAN RIGHTS**

Ms. WEATHERS. My name is Patricia Weathers. I am a mother from New York State. I have considerable concern regarding the outcome of this hearing because my son, Michael, was one of the children profiled for ADHD by our school district. When Michael was in kindergarten, I began getting reports that he was having behavioral problems. What was meant by this is that Michael was talking out of turn, clowning around in class, and apparently not sitting still.

The following year, while Michael was in first grade, his teacher told me that his learning development was not normal and that he would not be able to learn unless he was put on medication.

Near the end of first grade, the school principal took me into her office and said that, unless I agreed to put Michael on medication, she would find a way to transfer him to a special education center. I felt intimidated, scared, and unsure of what to do as a result of the school's coercive tactics. At no time was I offered any alternatives to my son's needs, such as tutoring or standard medical testing. The school's one and only solution was to have my child drugged.

At this point, his teacher filled out an actor's profile for boys, which is an ADHD checklist, and sent it to his pediatrician. This checklist, along with a 15-minute evaluation by the pediatrician, led to my son being diagnosed with ADHD and put on Ritalin. After a while, my son started to exhibit serious side effects from the drug. He was not socializing, became withdrawn, and began chewing on various objects. His eating and his sleeping were sporadic and of great concern to me.

Instead of recognizing the side effects of the drugs, the school psychologist claimed Michael now had either bipolar disorder or social anxiety disorder and needed to see a psychiatrist. She produced a name and a number of the psychiatrist I was to call. The psychiatrist talked to my son and I for a short period and, again, with the aid of school reports, diagnosed him with social anxiety disorder. She handed me a prescription for an antidepressant, telling me it was a "wonder drug for kids." Those were her exact words. There was no information about the serious side effects associated with this drug.

The drug cocktail that was to follow caused even more horrendous side effects, making his behavior more and more out of character. I could no longer recognize my own son.



Fearing what these drugs had done to him, I stopped them.

Through this whole ordeal, the school psychologist's favorite saying was that it was trial and error. If one drug didn't work, try another.

Realizing that I was no longer willing to fall in line and give my child drugs, the school threw him out. For a final blow, they proceeded to call child protective services on my husband and I, charging us with medical neglect for refusing to drug our child. This charge was later ruled unfounded.

On August 7th of this year the "New York Post" featured my son's story and the fact that I had decided to file a lawsuit against the school system on behalf of my son Michael's ordeal. On Friday, September 20th, this lawsuit was officially filed in Federal court. Within just a few days of the "New York Post" article being published, over 65 parents came forward to describe their own personal stories of coercion and intimidation used by school districts used to strong-arm them into drugging their children. Since then, many more have come forward.

Through my family's experience, I feel the issue of informed consent is crucial. As a parent, I was simply not provided with accurate and critical information regarding the issue of ADHD. I was never made aware of the controversy surrounding this disorder whereby many medical professionals do not validate it as a true medical condition. I was never provided with the information that there is no independent, valid test for ADHD. I was never given any warnings about the documented side effects that could occur with the drugs used to treat it. I was never informed that there are studies showing the correlations between stimulant use and later drug use. As a final point, I was at no time made aware that this drug use could bar my child from future military service. As a mother, I should have been given all of this information to make an informed decision on behalf of my child. After all, it is we who are ultimately responsible for the nurture, care, and protection of our children. We are unable to fulfill this obligation and make sound educated decisions without getting all the facts.

Accountability is what I am seeking. I would never have subjected my son to being labeled with a mental disorder if I had known that it was a subjective diagnosis. I would not have allowed my son to be administered drugs if I had been given full information about the documented side effects and the risks.

It is for this reason that I am asking this committee to fully investigate these matters as they relate to the issue of informed consent and to enact legal safeguards so that parents can fulfill their obligations to shield their children from any potential harm.

Thank you.

Mr. BURTON. Thank you very much, Ms. Weathers. I think that was a very, very important statement and we really appreciate your coming here to day.

[The prepared statement of Ms. Weathers follows:]

**Testimony of Patricia Weathers**  
**"Attention Deficit /Hyperactivity Disorders—Are We Over-Medicating Our Children?"**  
**Hearing September 26, 2002**

My name is Patricia Weathers. I am a mother from New York State. I have considerable concern regarding the outcome of this hearing because my son, Michael, was one of the children profiled for ADHD by our school district. When Michael was in kindergarten, I began getting reports that he was having "behavioral problems". What this meant is that Michael was talking out of turn, clowning around in class, and apparently not sitting still. The following year, while Michael was in first grade, his teacher told me that his "learning development" was not normal, and that he would not be able to learn unless he was put on "medication".

Near the end of first grade the school principal took me into her office and said that unless I agreed to put Michael on medication, she would find a way to transfer him to a Special Education Center. I felt intimidated, scared, and unsure of what to do as a result of the schools coercive tactics. At no time was I offered any alternatives to my son's needs such as tutoring, or standard medical testing. The schools one and only solution was to have my child drugged.

At this point, his teacher filled out an ACTERS Profile for Boys, which is an ADHD checklist, and sent it to his pediatrician. This checklist, along with a 15 minute evaluation by the pediatrician led to my son being diagnosed with ADHD and put on Ritalin. After a while my son started to exhibit serious side effects from the drug. He was not socializing, became withdrawn and began chewing on various objects. His eating and his sleeping were sporadic and of great concern to me. Instead of recognizing the side effects of the drug, the school psychologist claimed Michael now had either "bipolar disorder" or "social anxiety disorder" and needed to see a psychiatrist. She produced the name and number of the psychiatrist I was to call. The psychiatrist talked to my son and I for a short period, and again with the aid of school reports, diagnosed him with "Social Anxiety Disorder". She handed me a prescription for an antidepressant, telling me it was a wonder drug for kids. Those were her exact words. There was no information about the serious side effects associated with this drug.

The drug cocktail that was to follow caused even more horrendous side effects, making his behavior more and more out of character. I could no longer recognize my own son. Fearing what these drugs had done to him, I stopped them. Through this whole ordeal the school psychologist's favorite saying was that it was "trial and error"; if one drug didn't work then try another.

Realizing that I was no longer willing to "fall in line" and give my child drugs, the school threw him out. For a final blow, they proceeded to call child protective services on my husband and I, charging us with medical neglect (a charge that was later ruled unfounded) for refusing to drug our child. On August 7th of this year, *The New York Post* featured my son's story and the fact that I had decided to file a lawsuit against the school system on behalf of my son Michael's ordeal. On Friday September 20th this lawsuit was officially filed in Federal Court. Within just a few days of the *New York Post* article being published, over 65 parents came forward to describe their own personal stories of coercion and intimidation used by school districts to strong arm them into drugging their children. Since then, many more have come forward.

Through my family's experience I feel the issue of informed consent is crucial. As a parent, I was simply not provided with accurate and critical information regarding the issue of "ADHD." I was never made aware of the controversy surrounding this "disorder", whereby many medical professionals do not validate it as a true medical condition. I was never provided with the information that there is no independent, valid test for ADHD. I was never given any warnings about the documented side effects that could occur with the drugs used to "treat" it. I was never informed that there are studies showing the correlations between stimulant use and later drug use. As a final point, I was at no time made aware that this drug use could bar my child from future military service.

As a mother, I should have been given all of this information to make an informed decision on behalf of my child. After all, it is we who are ultimately responsible for the nurture, care and protection of our children. We are unable to fulfill that obligation and make sound educated decisions without all the facts. Accountability is what I am seeking. I would never have subjected my son to being "labeled" with a mental disorder, if I had known that it was a subjective diagnoses. I would not have allowed my son to be administered drugs if I had been given full information about the documented side effects and risks.

It is for this reason that I am asking this committee to fully investigate these matters as they relate to the issue of informed consent, and to enact legal safeguards so that parents can fulfill their obligations to shield their children from any potential harm.

Thank You.

Mr. BURTON. Dr. Block.

Dr. BLOCK. Thank you for inviting me to this hearing. I am Dr. Mary Ann Block, an osteopathic physician from Texas. For those of you who are unfamiliar with the osteopathic profession, let me tell you a little bit about us. We are fully licensed physicians with the ability to write prescriptions, perform surgery, and be residency trained in all the same specialties as M.D.s. The difference between M.D.s and D.O.s is two-fold: one, as a D.O. I had 150 more hours in medical school than M.D.s. Osteopathic physicians tend to be more holistic in their approach because of a philosophy that teaches us that the body and mind should be viewed as a unit.

Because of my medical training, my goal as a physician is to look for and treat the underlying cause of a patient's problem, rather than just covering the symptoms with drugs. I have seen and treated thousands of children from all over the United States who had previously been labeled ADHD and treated with amphetamine drugs. By taking a thorough history and giving these children a complete physical exam, as well as doing lab tests and allergy testing, I have consistently found that these children do not have ADHD but, instead, have allergies, dietary problems, nutritional deficiencies, thyroid problems, and learning difficulties that are causing their symptoms.

All of these medical and educational problems can be treated, allowing the child to be successful in school and in life without being drugged.

The American Osteopathic Association has published my program as the osteopathic approach to treating the symptoms called ADHD. This approach is supported in the medical literature, as well. The "Annals of Allergy" reported in 1993 that children with allergies perform less successfully in school across the board than children who do not have allergies, yet doctors prescribe amphetamines without ever checking the child for allergies.

A study in the "Journal of Pediatrics" in 1995 reported that children who ate sugar had an increase in adrenalin levels that caused difficulty concentrating, irritability, and anxiety.

A double blind cross-over study published in "Biological Psychiatry" found that Vitamin B-6 was actually more effective than Ritalin in a group of hyperactive children.

Another study found that children with magnesium deficiencies were characterized by excess fidgeting and learning difficulties.

There are many more studies in the medical literature that indicate an association between nutritional deficiencies and attention and behavioral problems, yet doctors prescribe amphetamines without checking a child's diet.

There is no valid test for ADHD. The diagnosis called ADHD is completely subjective. While some like to compare ADHD to diabetes, there really is no comparison. Diabetes is an insulin deficiency that can be objectively measured. Insulin is a hormone manufactured by the body and needed for life. ADHD cannot be objectively measured and amphetamines are not made by the body, nor are they needed for life.

The prescription drugs that are used to treat symptoms of attention and behavior come with a host of potential side effects. According to the manufacturers of the drugs, the following side effects can

and do occur: insomnia, anorexia, nervousness, seizures, headaches, heart palpitations, cardiac arrhythmias, psychosis, angina, abdominal pain, hepatic coma, anemia, depressed mood, hair loss, weight loss, tachycardia, increased blood pressure, cardiomyopathy, dizziness, and tremor, to just name a few.

These drugs are classified as Schedule II controlled substances with high abuse potential. According to reports in the "Journal of the American Medical Association," the drug Ritalin has been found to be very similar to and more potent than cocaine. Ritalin and cocaine are so similar that they are used interchangeably in scientific research.

There are no long-term studies on the safety and effectiveness of these amphetamine drugs, though millions of children are treated with them for years at a time.

When I was in school and when my children were in school, there was no need to drug millions of children. While there are children who have attention and behavioral problems, and these problems may have increased due to poor diets, an increase of sodas and candy in our schools, an increase in allergies due to changes in our environment, and an increase in learning problems, it does not mean these children have a psychiatric disorder called ADHD. It means they have medical and educational problems that can be fixed.

Most of the children I have seen who have been prescribed these drugs have never had a physical exam. No doctor listened to their heart, even though many of the side effects of the drugs are heart related. Since there is no valid test for ADHD, most doctors get the information for the diagnosis from the child's teacher in the form of a checklist. If the teacher wants the child to be taking these drugs, all she or he has to do is fill out the checklist indicating that the child has many problems in the classroom.

One child was diagnosed as ADHD and prescribed Ritalin, but I got to treat him, instead. Once his allergies and learning problems were corrected, he went on to become a National Merit finalist and accepted to an Ivy League university. Every child deserves that opportunity.

Many of the parents of these children have told me that the teachers and principals have pressured them to put their children on these drugs, threatening to report them to child protective services if they do not comply.

CPS actually removed a child from his home after the school reported the mother for not giving the child his drug. The ironic thing was she had been giving him the drug. The drug made him worse, not better.

I cannot imagine any reason to give a child an amphetamine to cover up symptoms when the problem can be fixed and no drug is required. Let's give our children the medical and educational evaluations they need to diagnose the real problems. Let's treat these real problems and give our children the future they deserve without drugs.

I will show a brief video which shows a child disruptive behavior caused from allergies. I'm also submitting as part of my written evidence my latest book, "No more ADHD: Ten Steps to Help your

Child's Attention and Behavior Without Drugs.”

Thank you.

[Videotape presentation.]

Mr. BURTON. Thank you very much.

[The prepared statement of Dr. Block follows:]

Testimony of Mary Ann Block, DO  
Committee of Government Reform  
Attention Deficit/Hyperactivity Disorders--Are We Over-Medicating Our Children?  
September 26, 2002

Thank you for inviting me to testify at this hearing. I am Dr. Mary Ann Block, an Osteopathic physician from Texas. For those of you who are unfamiliar with the Osteopathic profession, let me tell you about us. We are fully licensed physicians with the ability to write prescriptions, perform surgery and be residency trained in all of the same specialties as MD's. The difference between MD's and DO's is two-fold. As a DO, I had 150 more hours of education in medical school. Osteopathic physicians tend to be more holistic in their approach because of a philosophy that teaches us that the body and mind should be viewed as a unit.

Because of my medical training, my goal as a physician is to look for and treat the underlying conditions causing the patient's problem, rather than just covering up those symptoms with drugs. I have seen and treated thousands of children from all over the United States, who had previously been labeled ADHD and treated with amphetamine drugs. By taking a thorough history and giving these children a complete physical exam as well as doing lab tests and allergy testing, I have consistently found that these children do not have ADHD, but instead have allergies, dietary problems, nutritional deficiencies, thyroid problems and learning difficulties that are causing their symptoms. All of these medical and educational problems can be treated, allowing the child to be successful in school and life, without being drugged.

The American Osteopathic Association has published my program as the Osteopathic approach to treating the symptoms called ADHD. This approach is supported by the medical research as well. The Annals of Allergy, reported in 1993, that children with allergies perform less successfully in school, across the board, than children who do not have allergies.

A study in the Journal of Pediatrics, 1995, reported that children who ate sugar had an increase in adrenaline levels that caused difficulty concentrating, irritability and anxiety. A double blind, crossover study published in Biological Psychiatry, 1979, found that Vitamin B6 was more effective than Ritalin in a group of hyperactive children. Another study found that children with magnesium deficiencies were characterized by excessive fidgeting and learning difficulties. There are many more studies indicating an association between nutritional deficiencies and attention and behavior problems.

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Insulin is a hormone manufactured by the body and needed for life. ADHD cannot be objectively measured and amphetamines are not made by the body or needed for life.

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Most of the children I have seen who have been prescribed these drugs have never even had a physical exam. No doctor listened to their hearts even though many of the side effects are heart related. Since there is no valid test for ADHD, most doctors get the information for the diagnosis from the child's teacher in the form of a checklist. If the teacher wants the child to be taking these drugs, all she or he has to do is fill out the checklist indicating the child has many problems in the classroom. One child was diagnosed as ADHD and prescribed Ritalin. I treated him instead. Once his allergies and learning problems were corrected he went on to become a National Merit Finalist and accepted to an Ivy League University.

Every child deserves that opportunity. Many of the parents of these children have told me that the teachers and principals have pressured them to put the children on these drugs, threatening to report them to Child Protective Services if they do not comply. CPS actually removed a child from his home after the school reported the mother for not giving the child his drugs. The ironic thing was, she had given him the drug, but the drug made his symptoms worse, not better.



I cannot imagine any reason to give a child an amphetamine to cover up symptoms when the problem can be fixed and no drug is required. Let's give our children the medical and educational evaluations they need to diagnose the real problems. Let's treat those real problems and give our children the future they deserve, without drugs. Thank you.

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I will show a brief video showing a child's disruptive behavior resulting from an allergy. I am also submitting as part of my written evidence my latest book, *No More ADHD: 10 Steps To Help Your Child's Behavior Without Drugs*.

Mr. BURTON. Ms. Presley.

Ms. PRESLEY. Thank you very much, Congressman Burton and committee members, for the opportunity to address this hearing.

I'm here as a mother mostly, because I have to put my children in school, and I've also had direct contact with these children who are medicated, and I can tell by their behavior that they are. They're usually manic, very destructive, very interested in destruction. You know, we have already said it a hundred times, but between 6 and 8 million American children are being given Schedule II narcotics and/or mind-altering antidepressants. It's not just ADHD.

Some of the other drugs cause tics, cause this, which goes into a spiral of OCD, Turrette's, this, that, and the other thing, and all these, normal behaviors for children are now—everything is a disorder. I mean, I basically would have everything under the sun at this point. I'll stand up and testify to that, too.

But, anyway, I'm just saying I have personally seen the side effects of these drugs. Ritalin, for example, can cause nervousness, loss of appetite, weight loss, and manic behavior. Even the manufacturer warns that it can cause psychotic episodes. Suicide is a risk during withdrawal.

Some of these drugs are advertised as non-addictive, but I have known numerous people who have been to rehab centers to get off of them. Teenagers on powerful psychiatric drugs committed more than half of the recent teenage shooting sprees—that's very alarming—resulting in 19 deaths and 51 wounded. I don't think there has been a correlation made in the media with that, but it seems awfully coincidental—not coincidental.

Parents need to be informed of drug-free alternatives to the problems of attention behavior and learning. A child could be fidgeting in class or simply bored with what they are learning and then are diagnosed with a learning disorder and put on drugs. Some of these disorders, from what I understand, are also—you know, psychiatrists raise their hand and decide something is a disorder that's not factually, scientifically proven to be such. There is no blood test. There have been no autopsies to confirm brain chemical imbalance. A child could have allergies, lead poisoning, eyesight or hearing problems, be simply in need of tutoring, or something even more basic than that, which could be phonics.

I have not seen one happy and well-adjusted child as a result of these drugs. That's just my personal experience. What is basically happening is that we are relying on a chemical to change the mood of a child. At least one of these more drugs is more potent than cocaine, and we are turning children into drug addicts at a very young age.

My hope is that the committee will recommend legislation that prevents school personnel from coercing parents into placing their children onto mind-altering drugs. They become dependent on them and that leads to further drug addiction, which then leads to crime, which leads to all the other terrible things we always have to deal with in life, and ultimately that we don't allow these drugs into the schools, period. Our schools should only be there to educate our children and not to diagnose any—have the ability or the right to diagnose children with mental health problems. It is way over-pre-

scribed, way over done, and I think that at least—even with the people, from what I've seen here today, that want to go on the other side of the fence—still see that it is a situation and it is a problem.

That's all I have to say. It is a concern.

[The prepared statement of Ms. Presley follows:]

**Testimony Before House of Representatives Government Reform Hearing –  
Lisa Marie Presley, International Spokesperson for Children’s Rights, for  
Citizens Commission on Human Rights International**

Thank you Congressman Burton and Committee Members for the opportunity to address this Hearing.

I am speaking to you today as a mother of thirteen years, one who is intimately familiar with the unique and very special bond between a mother and her children.

However, I am also a mother who has repeatedly seen that bond seriously threatened as more and more parents have been convinced that their child’s creative endeavors, their enthusiastic energy, their misbehavior, or perhaps even their disillusionment with school, is a “mental disorder” which cries out for a “chemical fix.”

As a strong supporter of literacy for children, I am aware of the power of workable literacy training, even for children who have been convinced that they suffer from some supposed brain-based learning disorder or chemical imbalance which requires heavy drugging. Far too often, when sufficient time was spent teaching them true educational basics, including how to read, their so-called “learning disorder” disappeared.

I have spoken to children who have been forced to take a cocaine-like stimulant to control their behavior; I have shared their sense of sheer desperation. To see a child suffer a drug-induced psychotic break is not something one easily forgets.

I know of children who could have easily been labeled with “Attention Deficit Disorder” or ADHD sufferers, who were found to be suffering from nothing else than the toxic effects of chemicals in their environment.

I find it alarming that in my 13 years of motherhood, the use of Ritalin for ADHD has increased 700 percent. Today, it is estimated that between six and eight million American children take psychiatric drugs for ADHD and other so-called learning and behavioral disorders. I am not aware of any scientific evidence that validates these as diseases in the same way that medical diseases can be.

Today, more than 20 million prescriptions for stimulants are written each year. Prescriptions for one stimulant, Adderal, increased 1,017 percent since 1997.

The list of possible side effects of Ritalin alone includes nervousness, loss of appetite, weight loss, manic behavior and a potential for future drug dependence. Even the manufacturer of the drug warns that “frank psychotic episodes can occur” with abuse. Suicide is the major complication of withdrawal from Ritalin

and similar drugs.

Some 1.5 million children and teenagers are now prescribed antidepressants such as Prozac, Zoloft, and Paxil. The possible side effects of these drugs include anxiety, agitation, insomnia, bizarre dreams, suicidal thoughts, hostility and violent behavior.

Between 1988 and 1992, there were Food and Drug Administration drug adverse reaction reports of 90 children and adolescents who had suffered suicidal or violent self-destructive behavior while on one antidepressant.

In February 2000, a study published in the *Journal of the American Medical Association* revealed the number of American children between two and four years of age who had been prescribed psychiatric drugs, including antidepressants had soared 50% between 1991 and 1995.

Yet, now a peppermint flavored antidepressant is on the market as an added incentive for children.

And with ADHD increasingly under fire in the media and the community, parents are told that their child may not have ADHD after all, but so-called "bipolar disorder." The symptoms of this new affliction include "poor handwriting," "difficulty organizing tasks," "complains of being bored," "is very creative," "is willful," has "difficulty getting up in the morning," has trouble "concentrating in school," "argues with adults," and is "easily distracted."

These "symptoms" are no less subjective than those listed for ADHD. It seems that every childhood activity or protest in life is being redefined as a mental disease.

But there is much more to this alarming situation than just an expanding list of child mental illnesses and skyrocketing drug consumption.

Teenagers on powerful psychiatric drugs committed more than half of the recent teenage shooting sprees, resulting in 19 deaths and 51 wounded.

Government funds now permit parents, such as those testifying here today, to be coerced and threatened if they reject a questionable psychiatric diagnosis and refuse to put their child on mind-altering drugs.

Children have been wrenched from their family's care simply because their parents favored an alternative, drug-free approach to addressing educational and behavioral problems. The psychotropic drugging of millions of children has to stop.

It is a tragedy that some parents have been forced to resort to legal action to protect their children's and their own parental rights to be free of such coercion!

Meanwhile in our classrooms, our teachers have been co-opted into administering mental diagnostic tests to determine whether students are "hyperactive" or "bipolar." In fact, laws have had to be passed, for example in Connecticut, and one introduced in New York, to prevent teachers coercing parents into drugging their children.

These are just a few aspects of what I believe will one day be widely recognized as the totally needless and tragic drugging of innocent children.

I am not saying that children don't have problems, that they don't need special attention, or that parents cannot reach their wits end when all recommended solutions to their child's behavior have failed.

What I do want to emphasize here today though, is that only by looking for alternatives to drugs will parents discover for themselves the numerous simple, workable and drug-free answers to the problems of attention, behavior and learning.

The common denominator is correct diagnosis. A child could have allergies, lead toxicity, eyesight or hearing problems, be simply in need of tutoring, or something even more basic than that--phonics. The list of possible causes is very long and well-documented, but such child life-saving information has in effect been increasingly denied to, or hidden from the view of parents and others. This is a violation of their right to "informed consent."

Instead of supporting what is legal drug pushing, our governments, schools and doctors must ensure that all—not carefully selected—information is made available to parents in order for them to make an informed choice about their child's educational and medical needs.

In 1995 and 1997, the United Nations' International Narcotics Control Board said that governments needed to "...exercise vigilance" in order to prevent the over-diagnosing of Attention Deficit Disorder and its "medically unjustified treatment." I want to take this opportunity of thanking the Committee for its vigilance.

However, since 1997, the number of children put on psychotropic drugs has almost doubled. America now accounts for 90% of the world's Ritalin consumption.

Clearly, much more than vigilance is needed.

My hope is that this Committee will successfully and continually work to ensure that any legislation governing the mental health or education of our children,

provides parents with full information about the available diagnostic and treatment alternatives to child drugging in the true spirit of "informed consent."

We must love, educate and take proper care of the physical health of our children, and refuse to allow them to be falsely labeled as mentally ill and then be continuously drugged when there may very likely be a simple cause and solution for their problem. We will not achieve this without the broadly-informed support of our governments, our citizens and our parents.

Mr. BURTON. And you have been the head of this organization or one of the leading spokesmen for some time now?

Ms. PRESLEY. Actually, no, I'm just becoming one. I mean, I have done a lot of things with them before on this front, but I'm now taking on the title as the spokesperson for this committee.

Mr. BURTON. Very good.

Ms. PRESLEY. Yes.

Mr. BURTON. Mr. Wiseman.

Mr. WISEMAN. Thank you, Chairman Burton and members of the committee, for the opportunity to speak today. For over 30 years, CCHR's observations and conclusions have been drawn from speaking to hundreds of thousands of parents, doctors, teachers, and others.

For example, at 7, Matthew Smith was diagnosed through his school as having ADHD. His parents were told he needed a stimulant to help him focus and that noncompliance could bring criminal charges for neglecting their son's educational and emotional needs.

On March 21, 2000, while skateboarding, Matthew tragically died from a heart attack. The coroner determined that he had died from the long-term use of the prescribed stimulant.

We all know that there are children who are troubled who do need care, but what that care is or should be is the point of contention.

In 1999, in the wake of the Columbine school shooting, CCHR worked with Colorado State Board of Education member Mrs. Patty Johnson, who had a precedent-setting resolution passed that recommended academic rather than drug solutions for behavioral and learning problems in the classroom. Mrs. Johnson stated, "The diagnosing of children with mental disorders is not the role of school personnel, nor is recommending the use of psychiatric drugs."

The resolution told educators that their role was to teach and pursue academic and disciplinary solutions for problems of attention and learning.

In 2000, Jennifer L. Wood, chief legal counsel for the Rhode Island Department of Education, issued a letter to all schools that under the Individuals with Disabilities in Education Act, "it is not lawful for school personnel to require that a child continue or initiate a course of taking medication as a condition of attending school." School personnel cannot require, suggest, or imply that a student take medication as a condition of attending school, yet this is violated across the Nation.

Millions of children are being drugged with powerful stimulants and antidepressants, placing our Nation's children at risk. In 2001, the "Journal of the AMA" reported that Ritalin can act much like and is chemically similar to cocaine. It admits that, while psychiatrists have used this drug to treat ADHD for 40 years, they have never known how or why it worked.

As a result of over-medicating our children and the fact that so many parents were being forced to place their child on such drugs, currently more than half of our States have introduced and/or passed some type of legislation or regulation to restrict the use of psychiatric drugs for children. I'm submitting a selection of these for the committee's review. One of which cites the 1998 NIH Con-



ference on ADHD, which said, in part, "We don't have an independent, valid test for ADHD. There are not data to indicate that ADHD is due to a brain malfunction. And finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remain speculative." This is perhaps the crux of the problem. We're relying on a diagnosis that is subjective and open to abuse.

Evidence reviewed by the National Academy of Sciences this year indicates that toxic chemicals contribute to learning or behavioral problems, including lead, mercury, industrial chemicals, and certain pesticides. Furthermore, thousands of children put on psychiatric drugs are simply smart. The late Dr. Sydney Walker, psychiatrist and author, said, "These students are bored to tears, and people who are bored fidget, wiggle, scratch, stretch, and start looking for ways to get into trouble."

All of this information should be made available to parents when making an informed choice about the medical or educational needs of their child. This is in keeping with U.S. Public Law 96-88, which states, "Parents have the primary responsibility for the education of their children and States, locality, and private institutions have the primary responsibility for supporting that parental role."

As senior Government officials, you represent the lives of all citizens. Families are grieving for the loss of children because they are not provided with all the facts about mental health treatments, especially psychotropic drugs, and were denied access to alternative and workable solutions.

We respectfully request that the Government Reform Committee recommend Federal legislation that: A, makes it illegal for parents or guardians to be coerced into placing their child on psychotropic drugs as a requisite for his or her remaining in school; B, protects parents or guardians against their child being removed from their custody if they refuse to administer a psychotropic drug to their child; C, provides parents the right of informed consent, which includes all information about alternatives to behavioral programs and psychotropic drugs, including tutoring, vision testing, phonics, nutritional guidance, medical examinations, allergy testing, standard disciplinary procedures, and other remedies known to be effective and harmless; and, finally, that such informed consent procedure must include informing parents about the diverse medical opinion about the scientific validity of ADHD and other learning disorders.

Thank you.

Mr. BURTON. Thank you very much.

[The prepared statement of Mr. Wiseman follows:]



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**Bruce Wiseman, U.S. President**  
**of the Citizens Commission on Human Rights**  
**Evidence Presented to the U.S. Government Reform Committee Hearing into**  
**“Attention Deficit/Hyperactivity Disorders—Are We Over-Medicating Our**  
**Children?” – 26<sup>th</sup> September, 2002**

Thank you Congressman Burton and members of the Committee for the opportunity to speak today.

I am sure that each of us here feels a deep-felt concern for the well being of children. No one can disagree that the health and welfare of children and their families, are priorities for any country.

For over 30 years, CCHR's observations and conclusions have been drawn from speaking to hundreds of thousands of parents, doctors, teachers and others who have reported human rights abuse in the mental health system, especially against children.

For example, at seven, Matthew Smith was diagnosed through his school as having Attention Deficit Hyperactivity Disorder (ADHD). His parents were told that he needed to take a stimulant to help him focus. Initially resistant, Matthew's parents were told that non-compliance could bring criminal charges for neglecting their son's educational and emotional needs. "My wife and I were scared of the possibility of losing our children if we didn't comply," said Matthew's father, Lawrence Smith. They conceded to the pressure.

On March 21, 2000, while skateboarding, Matthew tragically died from a heart attack. The coroner determined that had died from the long-term use of the *prescribed* stimulant.

We all know that there *are* children who are troubled, who do need care. But what that "care" is or should be is the point of contention.

In 1999—in the wake of the Columbine school shootings—CCHR worked with Colorado State Board of Education member, Mrs. Patty Johnson, who orchestrated the passage of the precedent-setting school board resolution that recommended academic rather than drug solutions for behavioral and learning problems in the classroom. Teenage shooters, Eric Harris and Dylan Klebold had undergone psychological "anger management classes" and Harris was taking an antidepressant known to cause mania.

Mrs. Johnson stated, "The diagnosing of children with...mental disorders is not the role of school personnel, nor is recommending the use of psychiatric drugs...The [Colorado] resolution told educators that their role was to teach and to pursue academic and disciplinary solutions for problems of attention and learning."

Then in 2000, Jennifer L. Wood, Chief Legal Counsel for the Rhode Island Department of Education, issued a letter to all school superintendents stating that the federal *Individuals with Disabilities in Education Act* (IDEA) "prohibits school personnel from making a decision about a child's educational services without the consent of the child's parent(s). School personnel must refrain from making statements that may be construed as offering medical advice, or making a medical decision, such as 'Your child should be taking medication,' or 'I've seen many students like your child and based on that experience your child should be on medication'...It is not lawful for school personnel to require that a child continue or initiate a course of taking medication as a condition of attending school. School personnel cannot require, suggest or imply that a student take medication as a condition of attending school."<sup>1</sup>

Yet this is violated across the nation.

Millions of children are being drugged with powerful stimulants and antidepressants, placing our nation's children at risk. There are scores of studies that substantiate this. In testimony before a 1970 Congressional Hearing on whether or not to fund research into pharmacological treatment for school problems, Dr. John D. Griffith, Assistant Professor of Psychiatry, Vanderbilt University School of Medicine, stated: "I would like to point out that every drug, however innocuous, has some degree of toxicity. A drug, therefore, is a type of poison and its poisonous qualities must be carefully weighed against its therapeutic usefulness. A problem, now being considered in most of the capitols of the Free World, is whether the benefits derived from amphetamines outweigh their toxicity. It is the consensus of the World Scientific Literature that the amphetamines are of very little benefit to mankind. They are, however, quite toxic."<sup>2</sup>

In 2000, *The Journal of the American Academy of Child and Adolescent Psychiatry* reported, it is well known that psychostimulants have abuse potential. Very high doses of psychostimulants...may cause central nervous system damage, cardiovascular damage, and hypertension. In addition, high doses have been associated with compulsive behaviors, and in certain vulnerable individuals, movement disorders.<sup>3</sup>

In August 2001, the *Journal of the American Medical Association* reported that methylphenidate (Ritalin) acts much like cocaine. Injected as a liquid, it sends a jolt that "addicts like very much," said Nora Volkow, M.D., psychiatrist and imaging expert at Brookhaven National Laboratory, Upton, NY. The drug is chemically similar to cocaine, the study says. It also admits that although psychiatrists have used this drug to treat ADHD for 40 years, they and pharmacologists have never known how or why it worked.<sup>4</sup>

As a result of over-medicating our children and the fact that so many parents were being forced to place their child on such drugs through our schools, currently more than half of our states have introduced and/or passed some type of legislation or regulation to restrict the use of psychiatric drugs for children. Two years ago, the Texas State Board of Education passed a resolution indicating that Ritalin prescribed for ADHD resulted in "little improvement

in academic or social skills," and "psychiatric prescription drugs have been utilized for what are essentially problems of discipline which may be related to lack of academic success." Among a number of recommendations, it urged schools to "use proven academic and/or management solutions to resolve behavior, attention, and learning difficulties" and recommended that parents be informed of programs such as "tutoring, vision testing, phonics, nutritional guidance, medical examinations, allergy testing, standard disciplinary procedures, and other remedies known to be effective and harmless."

I am submitting a selection of state laws and resolutions for the Committee's consideration. In particular, I draw attention to the Model Legislation adopted by the National Foundation of Women Legislators Education Policy Committee, which quotes from a report by the 1998 NIH Conference on the Diagnosis and Treatment of ADHD. This, in part, concluded, "We don't have an independent, valid test for ADHD; there are no data to indicate that ADHD is due to a brain malfunction...and finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remains speculative."

Even the Surgeon General's 1999 report on mental health said that the exact etiology (cause) for ADHD is unknown. Indeed, the Surgeon General said, "The diagnosis of mental disorders is often believed to be more difficult than diagnosis of somatic or general medical disorders *since there is no definitive lesion, laboratory test or abnormality in brain tissue that can identify illness.*" [emphasis added]

In August, the Netherlands Advertising Code Commission ordered the country's Brain Foundation to cease advertising ADHD as a brain dysfunction, stating, "The information that the defendant presented gives no grounds for the definitive statement that ADHD is an inherent brain dysfunction....Under the circumstances, the defendant has not been careful enough and the advertisement is misleading."<sup>5</sup>

This is, perhaps, the crux of the problem—that we are relying on a diagnosis that is subjective and is open to arbitrary use and abuse. The symptoms of ADHD could be caused by anything from normal childhood antics to toxic or allergic reactions to too much sugar.

Dr. Arthur Teng of the Sydney Children's Hospital says that sleep apnoea "can have a very big impact on a child's behavior, learning ability and attention during the day."<sup>6</sup>

According to Dr. Mark Filidei from the Whitaker Wellness Center in California, the symptoms of lead poisoning are "strikingly similar to several psychiatric 'diseases' [and] can exhibit...learning disorders, hyperactivity, aggressive or disruptive behavior."

Evidence reviewed by the National Academy of Sciences this year indicates that toxic chemicals contribute to learning or behavioral problems, including lead, mercury, industrial chemicals, and certain pesticides. A University of Arizona study found that children exposed to a combination of pesticides before birth and through breast milk exhibited less stamina, and poorer memory and coordination, than other kids.<sup>7</sup>

In May, the Council of Europe, which investigated the misdiagnosing and drugging of children in response to concerns about American child drugging trends emerging in Europe, issued its findings, which included: "The Assembly also considers that more research should be conducted into the impact of proper tutoring and educational solutions for children exhibiting ADHD symptoms, into the behavioral effects of such medical problems as allergies or toxic reactions, and into alternative forms of treatment such as diet."<sup>8</sup>

Furthermore, thousands of children put on psychiatric drugs are simply "smart." The late Dr. Sydney Walker, psychiatrist, neurologist and author said, "They're hyper not because their brains don't work right, but because they spend most of the day waiting for slower students to catch up with them. These students are bored to tears, and people who are bored fidget, wiggle, scratch, stretch, and (especially if they are boys) start looking for ways to get into trouble."<sup>9</sup>

Also consider the similarities between the signs of giftedness and "learning" and "behavioral disorders."

Giftedness:

- Poor attention, boredom, daydreaming in specific situations
- Low tolerance for persistence on tasks that seem irrelevant
- Judgment lags behind development of intellect
- Intensity may lead to power struggles with authorities
- High activity level; may need less sleep
- Questions rules, customs and traditions

Compare to Behavior Associated with ADHD

- Poorly sustained attention in almost all situations
- Diminished persistence on tasks without immediate consequences
- Impulsivity, poor delay of gratification
- Impaired adherence to commands to regulate or inhibit behavior in social contexts
- More active, restless than other children
- Difficulty adhering to rules and regulations

There are so many potential causes for a child's learning or behavioral problems that to deny parents all the information about these is neglect in itself. I provide the Committee with a sample of cases of parents who fought to have their child properly diagnosed and found the correct, underlying problem.

No legislation should allow for the drugging of children, especially the enforced drugging of children, to be based on the arbitrariness of today's "Learning Disorders" diagnostic criteria.

For example, the President's Commission on Excellence in Education revealed this year that 40 percent of kids are being labeled with "learning disorders" simply because they have not been taught to read. State and federal governments spend \$28 billion per year for educating children categorized under the label, "Non Specific Learning Disorder."

According to pediatric neurologist, Dr. Fred Baughman, Jr., "The most fundamental aspect of reforming the IDEA is to provide a definitive physically based definition of disability. This must include the necessity to establish a tangible, objective physical abnormality which can be determined by a test such as, but not limited to, blood or urine test, x-ray, brain scan or biopsy. If none of these learning 'disorders' can meet this test, then clearly there is no physical abnormality and we are labeling entirely normal children as abnormal."

All this information should be made available to parents when making an informed choice about the medical or educational needs of their child. This is in keeping with U.S. Public Law 96-88, which states, "parents have the primary responsibility for the education of their children, and States, localities, and private institutions have the primary responsibility for supporting that parental role."

And it would align with the American Medical Association's standard for Informed Consent which calls for communicating the "nature and purpose of a proposed treatment or procedure; the risks and benefits" of such treatments and the *alternatives....*" In relation to parental permission and assent in pediatric practice, The American Academy of Pediatrics also notes that "...the patient has the freedom to choose among the medical alternatives without coercion or manipulation."

Millions of children are being told there is something 'wrong' with their brain, although no one can prove it. They are labeled "mentally disordered" with diagnoses that are subjective and then subjected to potentially dangerous and addicting drugs in order to control or change their behavior, a stigmatizing process to say the least.

As senior government officials, you represent the lives of all citizens. Families are grieving for their lost children because they were not provided with all the facts about mental health treatments, especially psychotropic drugs, and were denied access to alternative and workable solutions.

We respectfully request that the Government Reform Committee recommend federal legislation that:

- 1). Makes it illegal for parents or guardians to be coerced into placing their child on psychotropic drugs as a requisite for his or her remaining in school;
- 2) Protects parents or guardians against their child being removed from their custody if they refuse to administer a psychotropic drug to their child;

- 3) Provides parents the right to "informed consent" in relation to solutions to resolve behavior, attention, and learning difficulties which includes *all* information about alternatives to behavioral programs and psychotropic drugs, including tutoring, vision testing, phonics, nutritional guidance, medical examinations, allergy testing, standard disciplinary procedures, and other remedies known to be effective and harmless.
- 4) Ensures the "informed consent" procedure includes informing parents about the diverse medical opinion about the scientific validity of ADHD and other "learning disorders."

Thank you again, for the opportunity to present this information.

**Attachments: 7**

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<sup>1</sup> Jennifer L. Wood, Chief Legal Counsel, "Re: Students with Disabilities and Prescription Medication," Letter to the Superintendents of Schools, Principals, Special Education Directors, Guidance Counselors, School Social Workers and School Psychologists," Rhode Island, May 15, 2000.

<sup>2</sup> Dr. Fred Baughman testimony to the Parliamentary Assembly, Council of Europe, Nov. 23, 2001, citing, Griffith JD, Assistant Professor of Psychiatry, Vanderbilt University School of Medicine, Testimony to: Federal Involvement in the Use of Behavior Modification Drugs on Grammar School Children of The Right to Privacy Inquiry Hearing Before Subcommittee on The Committee on Government Operations House of Representatives 91st Congress, Second Session, Sept. 29, 1970.

<sup>3</sup> National Institutes of Health Consensus Development Conference Statement, *Journal of the American Academy of Child and Adolescent Psychiatry*, p. 5.

<sup>4</sup> Brian Vastig, "Pay Attention: Ritalin Acts Much Like Cocaine," *JAMA*, August 22/29, 2001, Vol. 286, No. 8, p. 905.

<sup>5</sup> Netherlands Advertising Code Commission, document 02.0249, 6 August, 2002.

<sup>6</sup> "Sleep link offers hope to ADD sufferers," *Sydney Morning Herald*, 6 March, 2001.

<sup>7</sup> "Toxic chemicals can cause learning disabilities," *Colombia Journalism Review*, September/October, 2002.

<sup>8</sup> Council of Europe Parliamentary Assembly report, "Controlling the diagnosis and treatment of hyperactive children," May, 2002

<sup>9</sup> Sydney Walker III, M.D., *The Hyperactivity Hoax*, (St. Martin's Paperbacks, New York, 1998), p.165.

Mr. BURTON. Let me just start with you, Mr. Wiseman. You indicated that—are there some States that don't allow the dismissal of a child because of the parents' refusal to use these mind-altering substances?

Mr. WISEMAN. That don't allow the dismissal of a child?

Mr. BURTON. No. Are there some States that have some kind of a last right of refusal for parents to keep the child in school if they refuse to take these mind-altering substances?

Mr. WISEMAN. Well, there are States, if I am understanding the question correctly, States have started in 1999 to actually pass legislation and regulations prohibiting schools from doing that, but it has been a problem—so much of a problem that there are now 27 States that have passed or have legislation or resolutions in progress that address this issue. So it was enough of a problem that, as I say, more than half the States in the country have actually had to address the problem with legislation because it was being abused. Parents were being coerced.

Mr. BURTON. Well, the reason I ask that question is many school districts and many States around the country, they require children to get inoculations for as many as 26 different childhood diseases. My grandson received 9 shots in 1 day, and I think in total number of shots that he will receive prior to going to first grade would be around 26.

Mr. WISEMAN. My word.

Mr. BURTON. He received 47 times the amount of mercury that is tolerable in an adult in 1 day, and 2 days later he became autistic. While we're hoping he is going to recover, he may be permanently damaged.

I guess the point I'm trying to make is these requirements are at the school board level or at the county level or at the State level, they're not requirements that the Federal Government imposes. And so I'm wondering, you're asking for legislation at the Federal level that would give parents the right to refuse these mind-altering substances, and one of the problems that we will have with some of our colleagues is that that will be looked upon as an infringement of the local school boards' or States' rights. I just wondered if you had given that any thought.

It's not that I'm opposed, you understand, to trying to do what we can here at the Federal level to deal with the problem after we hear all the testimony, but each individual State has, up to this point, been dealing with childhood problems like this.

Mr. WISEMAN. Yes. Unfortunately—and not to be repetitious, but, unfortunately, we hear in our organization mothers calling in that are being coerced, and the abuse is tragic. Parents are being threatened with either criminal charges, as I mentioned in my testimony, or in some cases the loss of their children because they're not put on mind-altering drugs. I mean, we're at the dawn here of the 21st century, and there are some children who aren't permitted to go into school unless they're on a mind-altering drug.

The Federal legislation that bears on this is the Individuals with Disabilities in Education Act. The problem is that the definitions in that law and the definitions that filter down to the school districts under that law are so subjective that the disorder is in the eye of the beholder. There are no objective tests for this, as has



been testified here this morning and from folks on the panel. There is no scientifically based studies that enable somebody to make such a diagnosis. So, because they are so subjective, it is open to abuse.

Mr. BURTON. What I'd like to have from you, Mr. Wiseman, is some proposed language that we can take a look at that might be appropriate at the Federal level. We approach stepping into States' rights with great trepidation, at least on this side of the aisle, so this is something we'd have to take a hard look at. But I will look at it and see if we can fashion something that will maybe encourage the States to be more concerned about parental rights and how the children are handled and whether or not they're completely, properly tested before they start putting these drugs into them.

Mr. WISEMAN. As a former teacher of American history, I share, one, your love of the Constitution, and your concern for States' rights very, very much. But with somewhere on the order of 6 million children in this country being placed on the Schedule II narcotics, I do think it is something the Federal Government should look for, and we'll be happy to provide you with some suggested wording.

Mr. BURTON. Very good.

I'll get to you, Mrs. Davis, in just a minute, as soon as we finish these first questions. We'll be with you in just a second.

Ms. Weathers, you stated that your son's school pressured you to medicate your son, and that at the time you trusted them because they were "the experts." At any time did the school or your son's doctor talk to you about the potential side effects of those drugs?

Ms. WEATHERS. Absolutely not. The most the pediatrician had told me was that there was possible appetite suppression and possible insomnia. She never at any time advised me that there are deaths related to this, there's cardiac problems, heart problems related to these drugs, that his growth would be seriously impaired.

When I took Michael off these drugs, within 3 weeks he grew three sizes, so nobody can tell me that those drugs didn't have a great, a tremendous, a horrendous effect on him.

Mr. BURTON. Did your doctor also recommend any behavioral modification training or counseling for your son?

Ms. WEATHERS. Absolutely not. She did not. Basically, I had to go in, I believe every 3 to 4 months, for a prescription refill.

Mr. BURTON. So they just didn't check any of that out? They just said, "These are the things that you have to do," and prescribed the drugs?

Ms. WEATHERS. They basically—all she did was ask me how he was doing.

Mr. BURTON. Did the doctor ever do any blood tests or objective medical evaluation to look at any possible biological basis for his behavior?

Ms. WEATHERS. I don't believe there was. I think early on there was a blood test taken, but, once again, you don't have a blood test to determine ADHD. You can only have a blood test to rule out underlying causes. I believe the only thing they did rule out was lead toxicity.

Mr. BURTON. Dr. Block, what have you found that the schools do specifically to encourage the use of medications for attention behavior?

Dr. BLOCK. The parents that come to me report consistently that the teachers and the principals and even the school nurses pressure them to go to a physician and get their child labeled and drugged. In addition, even though the State of Texas Board of Education has passed one of these State resolutions being concerned about the drugging of children, it appears to me that the teachers are not yet aware of it, because nothing seems to have changed since that resolution has passed.

Some schools are giving lectures to parents, inviting parents to come hear talks about diagnosing and drugging their children for ADHD.

Another thing that has recently occurred, it's not unusual for me to make recommendations for certain nutrients or other things that the child may need to naturally help their body and mind work better, and I will write a prescription for that child to receive that nutrient at school. What is happening now, though, is that the schools are denying my medical prescription and saying that they will not give a child anything at school except a drug. That, to me, is practicing medicine without a license.

And, unfortunately, physicians, themselves, according to the FDA, less than 1 percent of doctors actually know the side effects of the drugs that they are prescribing. Pharmaceutical reps that come to my office have told me more than once that I'm the only doctor they've called on that asked what the side effects of the drug was that they were repping to me.

Mr. BURTON. Let me—I see I'm running out of time here and I want to get to Mrs. Davis, but do you have any idea how physicians are influenced by the pharmaceutical companies to prescribe these medications for kids?

Dr. BLOCK. Yes. As a physician I see this influence all the time. For one thing, I don't think any of us can turn on the television, radio, open up a newspaper or magazine without seeing multiple advertisements for prescription drugs. They go so far as to say, "Ask your doctor if this drug is right for you," encouraging the public to go to the doctor to get a drug.

But, in addition, I don't believe the public is aware of the strong influence the pharmaceutical industry has on physicians. From the time we start medical school until the day we stop our practice, we are strongly influenced or attempted to be strongly influenced by the pharmaceutical industry. Our medical journals, which are purported to be unbiased, usually have about 60 percent of their pages as full-page ads from the pharmaceutical industry.

If I go to a continuing medical education meeting, which is required by law that I attend so many hours each year, the doctors who are talking to us are being paid by the pharmaceutical industry to give those lectures. Many doctors are being paid in their offices to do research for the pharmaceutical industries, as well. They also give money to different groups who go out and promote the use of these drugs for our children.

So the pharmaceutical companies have a tremendous influence on our society, and especially on physicians. It is concerning when

doctors don't even know the side effects. There's no way that they can tell a patient if they don't know them themselves.

Mr. BURTON. I will yield to Mrs. Davis, but let me just say my son-in-law is a doctor and I've gone to a number of these lectures that are put on by pharmaceutical companies, and I can tell you, as one who goes—and they're very nice dinners they put on, and very expensive in many cases, have great wines and all those sorts of things—they do have doctors that come in and talk about the attributes and the positives about these drugs so that they are very effective in selling their products to the doctors and the doctors writing those prescriptions.

Incidentally, we will have a second round of questions, because I have some more questions for the panel.

Mrs. Davis.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman. I don't have too many.

I tried to say at the beginning that we just have this tendency in our country to go from one end to the other and we never seem to find the right balance, and I think that's where we are right now with the ADHD and the Ritalin. Like I said, when my son was put on it the teachers didn't even know about ADHD, and I understand now they're even training the teachers in school or something. In fact, my son's pediatrician wasn't even that familiar with it. He sent me to a psychologist, and we did a lot of testing.

It was explained to me—and, Dr. Block, this is for you—it was explained to me that, with the ADHD, the child has the blood in the frontal lobe of his brain, I guess, just goes so slow that that's why he can't concentrate—he's seeing, like, three different pictures, or what have you, and that's why they can sit in front of a TV for hours, because so much is going on—and that the Ritalin would speed up the blood flow and then cause them to be able to concentrate. Have you ever heard that?

Dr. BLOCK. I certainly have heard that and it is an interesting theory, but it has never been proven. In fact, drugs like Ritalin and other amphetamine-type substances, one of the basic things they do is make you focus. They can make you over-focus, but they—it has been found that anyone who takes this type of drug will have a similar effect, because that's what it is. It doesn't prove that someone needs the drug because they have that effect.

But there is many theories going around, and there's many people who are looking at all kinds of brain scans and everything else, but when you look at the child in my video who was reacting to an allergy, I assure you if you did a brain scan of him at the time when he's reacting you would see reactions.

And so my focus is really on information, informed consent, that parents be told what all their options are, that they be told all the possible side effects to any treatment.

You know, I think parents always care so much for their children, they're going to do what is right for their child if they are given all the information.

Mrs. JOANN DAVIS OF VIRGINIA. I agree with you, and we were told the side effects of Ritalin when we gave it to our son. That's why it took us so long to give it to him, because you just—we didn't

want to do it. We did not. And it was actually a last resort for us to do that. It did work for him.

Ms. Weathers, I had a question for you, and if you will give me a second it will come back to me.

You said that the teachers all said your son had a problem. Did you ever find out what the problem is or was? Or is this just recent?

Ms. WEATHERS. No, this isn't recent. You know, in my opinion Michael is extremely bright. He was not reading at grade level. There was a lot of factors that were playing a role in his behavior that were not even addressed by the teachers. When he was going into fifth grade he was reading at a second grade 8 month level. OK? That isn't normal. They were putting him in a special ed room and not teaching him phonics. I think that's horrendous. I really do.

Mrs. JOANN DAVIS OF VIRGINIA. Did you have problems with him at home?

Ms. WEATHERS. No. I would never, ever—and I want to make this perfectly clear for everybody in this room—I would never have contemplated drugging my child ever. He never had behavior problems at home. The minute he entered school, that's when the trouble started. That is when I was coerced. I felt under pressure. I felt like everyone was telling me that this was the best thing. I was a single mom. I was scared. I was unsure. You know, I felt, "These are the experts. They know children." And I know, I get hundreds of phone calls throughout the country, hundreds from other parents having the same experience that I have endured and my family and my son has endured, as far as Hawaii. I have a woman in the State of Hawaii who had to leave the State of Washington because she was so pressured. She wanted to pick the State with the lowest consumption of Ritalin abuse, and she flew her entire family to Hawaii. Her name is Susan Perry, and I am in contact with her now, and we are fighters, and I'm going to fight this issue until the very end, because parents are not informed nowadays. We're not told the side effects. We are just not. And it is just tragic because our children are suffering and our children are what counts.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Ms. Weathers. I totally agree with you. As a Mom, there's nothing more important to me than our kids, and I know how you feel.

Thank you, Mr. Chairman.

Mr. BURTON. We'll have a second round of questions.

Let me just tell you something that is of interest that you might find interesting, Ms. Weathers. Mercury is in a lot of our vaccines. Mercury is a toxic substance. I've talked to a number of doctors, including doctors here on the Hill that treat Congressmen, and I told them, I said, "Do you know that in our flu shots that we get there's mercury?" And some of the doctors said, "No, no. There's no mercury in there." And I took the insert out and I showed it to them, and it says, "thimerosal." And they said, "See, there's no mercury in there." And I say, "Thimerosal contains mercury." It has never been properly tested since 1929. It was tested on 27 people who all were dying from meningitis. All of them died, and so they said that the mercury didn't cause it. But they've never tested it ever since, and it has been given to our children. My grandson got nine shots,

many containing mercury, in 1 day, and 2 days later he was autistic and may be maimed for life. He's not responding as we would like.

And so you are absolutely correct. Parents need to be informed about the substances in the vaccines and in the pills and all the other treatments they're getting, and if they don't get that then shame on us. And doctors need to be given the proper information from the Food and Drug Administration, and the Food and Drug Administration has been derelict in their responsibilities in doing that.

I'm very sorry we don't have the FDA here today, because the FDA's responsibility is not only to test these things, to do double blind studies and everything else before we start administering these things to the population and our children, but they're also supposed to inform people, and they haven't been doing that, as well, and that's one of the reasons why we've had so many problems with them over the years. But we will be contacting the FDA about that.

Let me ask you, Dr. Block, one more question. And I will have other questions I'd like to submit to you for the record that you can answer later.

As you know, we've learned that a Government-funded study found a correlation between the use of thimerosal, mercury-containing vaccines, and a diagnosis of ADD. Do you think that every child that is referred to a doctor for ADD evaluation should be tested for heavy metals?

Dr. BLOCK. Yes, I do think every child should be. In addition to seeing a lot of children with attention and behavioral problems in my practice, I see a lot of children who have been diagnosed as autistic, and through testing these children for heavy metals and often finding mercury and lead and other heavy metals, begin testing the children who have attention and behavior problems, and often find the same thing with them, as well.

I think that these problems are on a continuum where one child has severe symptoms and gets the autistic label, while another child gets an ADHD label, but I'm finding the same underlying problems in all of these children.

Mr. BURTON. Heavy metals being one of them?

Dr. BLOCK. Heavy metals being a major one, yes.

Mr. BURTON. And so it would be your opinion that these preservatives they're putting in that contain aluminum and mercury, in particular, should be taken off the market? They should take those things out of there?

Dr. BLOCK. They should be taken off the market. They were supposed to be taken off the market was my understanding, but they have not been taken off the market. Many pediatricians actually believe they have been taken off the market, so they've not looked to see if the thimerosal is in the vaccine. But they are still in the vaccines. Children are still getting as many as eight or nine different diseases immunized against in a single visit to the doctor's office, and many of those vaccines do contain the mercury and aluminum, which work together to make the problem even worse.

Mr. BURTON. Let me just say that we suspect—in fact, I'm pretty sure—that, while they're starting to get mercury out of children's

vaccines here in the United States, we send vaccines all over the world to Third World countries, and we send them with multiple vaccines in one vial, and they are still using the mercury, the thimerosal in those almost entirely around the world. And so, while we're starting to get them out of our vaccines, we're continuing to inject mercury into children all over the world in Third World countries, which I think is almost criminal.

Let me ask Ms. Presley a question here.

Ms. PRESLEY. Yes, sir?

Mr. BURTON. Why did you choose to get involved in this discussion of ADHD? Have you had a family that was misdiagnosed?

Ms. PRESLEY. Yes, I have. I have also had experience with mercury. I had nine fillings at one point, and I went 2 years almost going crazy getting asthma, hypoglycemia, candida, all these troubles. I've baffled every doctor from one coast to the next. And then, when I finally got the diagnosis you're supposed to have between zero and three normal in a human body and I had 1,000-plus. The doctor called me and said the term "Mad as a Hatter" is from people who used to work in felt factories where they would be exposed to mercury and they would go crazy.

I had experience with that, and the moment I started taking things either naturally or a chelation agent to get it out, all the symptoms stopped. So I have had personal experience with that and I do know that mercury is not only in vaccines, they are in fillings of children. They still use it in the mouth.

Mr. BURTON. Amalgams.

Ms. PRESLEY. Yes, amalgams.

Mr. BURTON. Most people don't know that 50 percent of the silver fillings in your mouth, 50 percent of those are mercury.

Ms. PRESLEY. Yes, sir.

Mr. BURTON. A lot of people don't know that.

Ms. PRESLEY. Other than that—I'm sorry—the reason I got involved was because I've had personal experience around children who are medicated and I see their behavior and I see that it is usually something very obvious, they do have allergies. I've seen them. I've seen them manic, crazy, and then they come off of it and there's a whole other story. They actually find the reason. You know, there's always a simple explanation for it. I just don't want to see our future generation being drugged, and I also don't like to see it being promoted as something non-addictive when it absolutely is.

Mr. BURTON. One last question of Mr. Wiseman, and I may ask a few more after we get through with my colleagues here.

Are teachers qualified to diagnose medical conditions?

Mr. WISEMAN. Absolutely not, Congressman. We have talked to people in the Department of Education who say that that's a DOE policy, and virtually every State has that as a policy, yet it is happening across the country.

Mr. BURTON. We actually have teachers in schools using a checklist that go to a doctor and they are making a direct or indirect recommendation to the doctor that this child be put on Ritalin.

Mr. WISEMAN. Yes. They have checklists that come out of the "Diagnostic and Statistical Manual" for ADHD. I've seen them.

Mr. BURTON. And the doctors many times have followed the recommendations of the teachers?

Mr. WISEMAN. Of course.

Mr. BURTON. Yes.

Mrs. Morella, do you have questions?

Mrs. MORELLA. Yes, sir.

Mr. BURTON. Mrs. Morella.

Mrs. MORELLA. Thank you. Thank you, Mr. Chairman, and thank you for calling this hearing. I want to thank the witnesses also for coming together to offer their comments on it.

You know, what I particularly like is that you brought in witnesses that have various perspectives from all sides of the debate, and I think it is important that we listen to arguments from those who believe attention deficit disorder is not a brain disorder and those who believe it is and warrants medication along the lines of Ritalin.

Considering there has been a 500 percent increase in the use of Ritalin in the United States since 1990, and roughly 4 to 6 million children may be using it daily, I think it is important that we ascertain the root causes of ADHD and how to best alleviate its effects.

I wanted to ask a couple of questions, if I may. One, I might ask it of Ms. Presley. It is a pleasure to see you in person.

Ms. PRESLEY. Thank you.

Mrs. MORELLA. Thank you for being here, and also to Mr. Wiseman, because I have before me a statement that has been made by the International Citizens Commission on Human Rights president, Jan Eastgate. This is a quote. "Society has been under a concerted attack for decades. Designed and implemented by psychiatrists, this attack claims countless lives each day. Like some malignant disease running rampant, it threatens the future of society and ultimately mankind."

Now, what I'm wondering is: do you believe in this expression that I have just read to you? If both of you would comment on that, I'd appreciate it.

Mr. WISEMAN. I can comment, Congressman. We are a psychiatric watchdog group. We investigate and expose psychiatric abuse. And what we see going on in psychiatric hospitals, not only in the United States but around the world, would make you weep. I have personally investigated the abuses that go on in these hospitals, the physical abuse, the sexual abuse, the drugging people into stupors, the electroshock treatments, what psychiatry has done to our educational system, psychiatric testimony in the courtroom where murderers and rapists are let go because they're not guilty because they had an irresistible impulse based on psychiatric testimony. So I would certainly agree with Ms. Eastgate's comments.

Ms. PRESLEY. I personally have not seen psychiatry do any good for anyone I've ever known, personally. That's just my own experience, whether it be drugging, electric shock therapy, which does still exist, which is very barbaric. I don't think it goes—I mean, I have my own personal issue with the subject, but that's not why I'm here right this moment. This is more related to the drugs, again, upon which psychiatry is based, of course.

Mrs. MORELLA. So you put them all into that one category?

Ms. PRESLEY. I think they're all correlated.

Mrs. MORELLA. All right. If I could ask one other question, several medical organizations like the AMA, the Centers for Disease Control and Prevention, and the National Institutes of Health believe that attention deficit hyperactivity disorder is a brain disorder that may require psychiatry or psychiatric drugs for treatment. I wonder how could you explain the considerably different viewpoint that they hold as opposed to the viewpoint of CCHR?

Mr. WISEMAN. Well, I don't know if you are asking me or Ms. Presley, but I'll address it and she can, as well.

Mrs. MORELLA. If she would like to add something.

Ms. PRESLEY. I'll address it, as well.

Mrs. MORELLA. Thank you.

Mr. WISEMAN. I think the operative word in your question, Congresswoman, is the word "believe." It is a matter of belief. Our concern is that there is no biologic, organic, scientific basis for ADHD. These are subjective symptoms. These are behavioral symptoms. The child fidgets, he looks out the window, he butts into line. The psychiatrist wraps these attributes up and throws a label on it, and the children are subsequently drugged.

That various medical organizations believe that it is a brain disease is just that. It is a belief without true scientific validity.

Our point here really is parents should have an opportunity to get the other side. They need to have informed consent. They need to know, at the very least, that the diagnosis is controversial.

Mrs. MORELLA. Ms. Presley, did you want to comment on that?

Ms. PRESLEY. Yes. I haven't seen any evidence. I'm not a scientist. I can't back it up scientifically, but I just have not seen, whether it be a blood test to diagnose or any other thing to diagnose, it is not confirmed, there is no way to do it. And there are too many people, if you spend—I would like to do a documentary on it, actually, 1 day, just to show how long it takes, if you take a child to a psychiatrist, before they whip the thing out and start writing a prescription. It's usually 10 minutes, 15 maybe, and it is usually just basically, you know, based on—sorry.

Mrs. MORELLA. Well, I could go on, and I'm not a scientist, but I have always had a great belief in CDC and NIH and AMA, and you just said forget it.

Ms. PRESLEY. I would like to just also point out that there is an inter-mingling of those three, of course. You know, the drug companies, pharmaceutical companies go along very much with the APA. They all make money. It's a big industry, you know, to push drugs—diagnose disorders and give drugs for it. It is an industry. They're making money, a lot of money, a lot of money.

Mrs. MORELLA. Dr. Block, did you want to comment?

Dr. BLOCK. Yes. The National Institutes of Health has stated that there is no valid test for it and that it is not a brain disorder. And also, the medical profession is based on coding, and it is coding based on getting paid by the insurance company, so a diagnosis that can be objectively defined such as diabetes, hypertension, things like that, there are codes for those things. The psychiatric community has made codes for their psychiatric disorders. But just because there is a code for it and doctors can diagnose it and get



paid for it doesn't mean that there is an objective brain disorder going on.

Mrs. MORELLA. Mr. Chairman, I would yield back, but I would guess, Dr. Block, you probably would gain a little bit, too, if we—if people were scared away from psychiatric drugs, right?

Dr. BLOCK. Do I gain?

Mrs. MORELLA. You probably would gain financially.

Dr. BLOCK. I have a medical practice working with these children, but for me if I get them well and out of my office they don't have to keep coming back, whereas if they're being drugged they do keep coming back.

Mrs. MORELLA. Fine. Thank you very much, Mr. Chairman.

Mr. BURTON. Mrs. Davis.

Mrs. JOANN DAVIS OF VIRGINIA. I have one more question for Ms. Weathers. When you took your son back to the pediatrician to get the prescription refilled, did you say he did not do a physical—her or she?

Ms. WEATHERS. No, she didn't. She did not do a physical exam to refill the prescription for Ritalin. He would have once-a-year physical before he started school. That was the only physical he had during the course of the year.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

Mr. BURTON. Judge Duncan.

Mr. DUNCAN. Mr. Chairman, I apologize. I have another meeting I had to go to, so I'm not going to ask any questions at this time. I'll ask them of the next witnesses.

Mr. BURTON. OK.

Let me just ask a few more questions. In particular, since Mrs. Morella is still here, I'd like for her to hear just a couple things that were said in her absence.

According to the AMA, the properties of Ritalin very closely parallel cocaine; is that correct?

Mr. WISEMAN. Yes.

Dr. BLOCK. Yes.

Mr. BURTON. And, according to the AMA—or not the AMA in this particular case, according to some testimony that was given today, if you grind up Ritalin and make it into a powder, the effect of the Ritalin is very, very similar to the effect of cocaine, and it is habit forming?

Dr. BLOCK. Not just the same, it is. I mean, it is the same, not just similar.

Mr. BURTON. So cocaine and Ritalin, when put into powder form, are the same?

Dr. BLOCK. They go to the same receptor site in the brain and they provide the same high when taken in the same manner and are used interchangeably in scientific research.

Mr. BURTON. They're used interchangeably in scientific research?

Dr. BLOCK. Correct.

Mr. BURTON. OK. So when you put a child on Ritalin for a long period of time, there is a fairly good chance that that child will be addicted, just like a person who uses cocaine?

Mr. WISEMAN. Congressman, I know you asked that of Dr. Block, but if I might point out, there's a study by a Dr. Nadine Lambert at the University of California Berkeley that followed 492 children

for 26 years and found that those who were labeled with ADHD and given stimulants were 200 to 300 times more likely to abuse tobacco and cocaine in adulthood.

Mr. BURTON. They were 300 times more——

Mr. WISEMAN. Two to three times more.

Mr. BURTON. Two to three times more likely to use——

Mr. WISEMAN. Tobacco and cocaine.

Mr. BURTON. OK.

Mr. WISEMAN. In adulthood.

Mr. BURTON. Now let me ask you a question that I think we will ask of the doctors that are going to come up here, so they'll have a preview of some of the questions we're going to ask. Has there been any autopsies on children who allegedly have ADHD to see if there was any difference between their brain and the brain of a child that had ADHD and were given these substances like Ritalin?

Dr. BLOCK. I don't know of any autopsies. I know that there are studies that have shown changes in the brain of children, but these children were taking drugs like Ritalin. And there have been studies that showed children who took cocaine had brain changes that looked like holes in their brain, just spots on the X-rays. And so the Ritalin may be doing the damage that shows up in these children's brains.

Mr. BURTON. Is there any evidence through autopsies of brains that would show that children who have ADHD have any abnormality?

Dr. BLOCK. I know of no such studies.

Mr. WISEMAN. I know of no such, sir.

Mr. BURTON. Any other questions?

Mr. Wiseman, let me just ask you a couple more questions. We've seen reports that Ritalin and antidepressants are being prescribed for 2-year-olds in the Medicaid population. Are you aware of any clinical trials that have evaluated the safety of these drugs in children age 2 years old?

Mr. WISEMAN. No, sir.

Mr. BURTON. OK.

Mr. WISEMAN. In a word. And, if I can say, I think it is a travesty that children in some cases still in diapers are labeled with ADHD and put on, in some cases, several mind-altering drugs. I think it is barbaric.

Mr. BURTON. So there have been no clinical trials, to your knowledge?

Mr. WISEMAN. Not that I'm aware of, sir.

Mr. BURTON. You are aware that the NIH conducted a consensus conference on ADHD several years ago. Did they look at the entire scope of treatment options, or did they just focus on Ritalin?

Mr. WISEMAN. No. They primarily focused on Ritalin. I testified at those hearings in November 1998, and they had 3 days of slides and presentations and so forth, and I read the final conclusion. We do not have a valid, independent test for ADHD. There are no data to indicate that ADHD is due to a brain malfunction. And finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remain speculative. That was after 3 days of speculations.

Mr. BURTON. But did they look at the entire scope of treatment options—

Mr. WISEMAN. No, sir.

Mr. BURTON [continuing]. Besides Ritalin? It was just Ritalin, only? OK.

And, finally, what biologic conditions can lead to an inability to concentrate in class in a schoolroom?

Mr. WISEMAN. Well, as I mentioned in my testimony, and as Dr. Block has said, there's a number of underlying physical problems such as mercury poisoning, lead toxicity, and those kinds of things that actually can affect the nervous system and can make children act hyperactively.

Mr. BURTON. And just being kids.

Mr. WISEMAN. Yes.

Mr. BURTON. I will tell you, if they had had Ritalin when I was a boy I have no question in my mind, as many times as I was sent to the principal's office for being out of control, that I would have been on Ritalin. I really believe that, because I was a real pain in the foot. [Laughter.]

Did you have any questions?

Mrs. JOANN DAVIS OF VIRGINIA. Yes, if you will indulge me for a minute.

You're saying that there's no proof that it's not a biological disorder, but there's no proof that it isn't—there's no proof that it's not a biological disorder, as well, right?

Mr. WISEMAN. It's kind of trying to prove a negative, but that's correct.

Mrs. JOANN DAVIS OF VIRGINIA. What do you say to a parent who has had their child tested, there's no physical disorder, there's no mercury because there has been no fillings, there's no allergies, there's no nothing, and you have more than, Mr. Chairman—I believe the children who are ADHD, it is a lot more than just out of control. There's many more symptoms other than out of control. They're not just a hyper child. What do you say to that parent who has had the child tested for everything and there's no other explanation, and then they take the Ritalin and it totally changes things?

Dr. BLOCK. I think that every parent has the right to choose what's best for their child. The problem is they're not being made aware of the options and the possible side effects, that they are being pressured to put the child on the drug, even when they choose not to, and we are learning new things all the time, because mercury doesn't just come from fillings. Mercury comes from vaccines, and all children—almost all children have had vaccines.

So there are many different reasons why children have these problems, and learning problems are a big one that schools often overlook. Nowadays, I'm finding out that even some of the places that used to test children for learning disabilities are now saying, "Well, go see if they have attention deficit first, and then we'll look at that." But it is the tail wagging the dog—the learning problems causing attention and behavior problems. We need to fix those first.

Mrs. JOANN DAVIS OF VIRGINIA. I don't disagree with you.

And, just to set the record straight, Mr. Chairman, I fully believe in my heart that children are being over-medicated and everybody is being diagnosed if they are just being children. Thank you.

Mr. BURTON. Thank you, Mrs. Davis.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman.

Mr. BURTON. My great friend from Maryland.

Mrs. MORELLA. Thank you.

It's simply that I was looking over the credentials, and I noted that the Citizens Commission on Human Rights was established by the Church of Scientology; therefore, I wondered how is the organization now related to Scientology, and what is the church's stance on psychiatry and psychiatric drugs?

Mr. WISEMAN. Well, Congresswoman, we're proud to have been founded by the Church of Scientology some 32 years ago. We are, however, an independent, IRS-recognized, public benefit corporation, and our role is a social reform activity to clean up the field of mental health, so we investigate and expose psychiatric abuse and psychiatric violations of human rights.

Mrs. MORELLA. Does the church have a stance on it, or—

Ms. PRESLEY. Can I just say "no" on that one? No. I'm not—I mean, I personally am not here for that reason at all. I'm here because I'm a mother and I care about children and that's it. And I knew that that was going to come up as a question in here and I knew that it was going to be speculated that it is because you're a Scientologist, blah, blah, blah. The bottom line is that I just think it is inhumane and it's not right and it is abusive and an epidemic and it needs to be looked into. It has nothing to do with religious beliefs and/or anything else, as far as I am concerned.

Mrs. MORELLA. No. I believe that you are motivated, obviously, because you care deeply about it, but I just wondered does the church have a stand on it?

Ms. WEATHERS. Can I say something as a parent, and just as a parent?

Mrs. MORELLA. OK.

Ms. WEATHERS. I feel that this issue transcends all social and political and religious backgrounds. I think this is our children, and we need to really address the issue that this is our children, and this is our future generation here. This doesn't have to deal with anything other than our children.

Mrs. MORELLA. I believe your motivation, I truly do. I'm a mother, myself. But I am curious still about whether or not Scientology—

Mr. WISEMAN. Sure. I'm delighted to answer your question. I have been a Scientologist for 32 years. Every Scientologist I know is very concerned about human rights abuse, but that's not really the issue from our point of view and why we're here. Our concern is that parents aren't being given all the information and the choices. They're not given informed consent on the issue. That's really the concern, Congresswoman.

Mrs. MORELLA. Thank you.

Thank you, Mr. Chairman.

Mr. BURTON. Before I yield to Mr. Gilman, let me just say—because we're going to have some votes on the floor—we had 1 in

10,000 children, according to CDC, that were autistic a decade or so ago. We now have 1 in 250 children or more that are autistic today. We've had a 40-fold increase, 40 times increase in the number of children that are autistic in America. And there are a great many scientists and doctors who believe that some of the contents, including mercury, in vaccines are a major contributing factor. We have an epidemic.

The young lady, Ms. Weathers, talks about our kids and our future and what it is going to do to our society. Put a pencil to the amount of money it is going to take to take care of children today who are going to be adults in 15 years who are autistic, who can't get a job, who can't function properly in society. You're talking about billions, maybe trillions, of dollars, and we need to find the answers and get it straightened out. And if mercury, as I suspect, is a major cause, then we damn well better get it out of our vaccines.

Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman.

I'm curious, Dr. Block—and I regret I had to go to another meeting and couldn't be here for your testimony—has there been any long-term study of the long-term effects of utilizing Ritalin?

Dr. BLOCK. No, there has not. The drug manufacturers, themselves, say there are no long-term studies. The National Institutes of Health, when they had their conference, stated that most drug trials were very short, up to 3 months, yet children are placed on these drugs for years and years without the knowledge that we need to know if they are safe.

Mr. GILMAN. Sounds like we have to undertake that study.

Background material provided to our committee cites American Academy of Pediatrics data that estimates 4 to 12 percent of the children in the United States have some form of ADHD. Is this estimate applicable to other countries like Japan, or is this uniquely an American problem?

Dr. BLOCK. This is uniquely an American problem. Of all Ritalin in the world, 90 percent is sold in the United States. I have seen families from all over the world at my medical clinic, and those who have come from other countries always have an American connection—they were in an American school and told their child needed to be drugged. If they moved them to a British school, they were told their child was fine. I've seen this story occur over and over again.

Mr. GILMAN. When educators observe potential ADMD [sic] cases, how much weight is given to non-ADMD [sic] factors such as level of physical activity, diet, environment, and other possible disorders?

Dr. BLOCK. Usually there's not anything given to that. What is usually done is the teacher fills out a checklist describing behaviors that the child has at school, and parents may be asked to fill out this check list. The parents that bring their children to my office have told me that their doctor, in most cases, never did a physical exam, never listened to their child's heart, even though many of the side effects of the drugs can affect the heart. They're not looking for other problems, not looking for allergies, learning problems,

thyroid problems, anything physical or educational that might be wrong with the children before labeling and drugging them.

Mr. GILMAN. In previous, unrelated hearings covering the war on drugs, the Drug Enforcement Administration, DEA, has testified that many adolescent takers of Ritalin often poured more supply and sell it to customers through an illegal secondary market. Is this a significant problem? I address that to any of our panelists?

Dr. BLOCK. This is a significant problem, and there have been reports that indicate that Ritalin is the most abused drug in high school and colleges. And there are other drugs like Adderol. I don't want to just focus on Ritalin. There are many other amphetamine or amphetamine-type drugs that are abused on the street in the same way.

Mr. GILMAN. And, in general, the percentage of the student body taking Ritalin or similar drugs is smaller in parochial schools than the same percentage in public schools. Why do you think that's the case?

Dr. BLOCK. Well, I can't speak to exactly why, but from what I've heard there is a great deal of discipline in many parochial schools, but I'm also seeing a change there where the drugging of children is increasing in private and religious schools to a great extent, as well.

Mr. GILMAN. Do any of our panelists want to add any comments to the questions I've just asked?

Mr. WISEMAN. Only, Congressman, that last year, or perhaps the year before, there was legislation proposed, and I believe passed, by Congressman Henry Hyde's committee that dealt with this issue of the abuse of Ritalin in schools. The DEA was very concerned about it. I don't recall the number of that legislation or its name, but I think that was in the year 2000. Legislation was actually proposed and passed, I believe in this Body, that dealt with that issue.

Mr. GILMAN. Ms. Presley, did you want to comment?

Ms. PRESLEY. I don't know the statistics and the formalities of what exactly—this is more for you two, I think.

Mr. GILMAN. And Ms. Weathers, did you want to comment?

Ms. WEATHERS. No, not at this time. I don't know the statistics.

Mr. GILMAN. All right. And, Dr. Block, do you have any final statement you'd like to make?

Dr. BLOCK. Well, as I think all of us have consistently stated, we're very concerned about the abuse of these drugs in our children and the fact that parents are not given informed consent and not given all the options to look at all the possible problems that their children might have to correct those problems and not drug them. I think that's what we'd like to see changed.

Mr. GILMAN. I want to thank our panelists for being here today and giving us your testimony.

Thank you, Mr. Chairman.

Mr. BURTON. We have 8 minutes and 33 seconds on the clock. I have a couple more questions for this panel, and then we'll dismiss them, unless the other panelists have some questions. We have one vote on the floor, and then if you could come back we'd appreciate it.

Let me just say that I really appreciate your being here. One thing I would like to clear up is, although there are people here

who are members of the Church of Scientology, there are a lot of other people that you work with that are not members that share the same views; am I correct on that?

Ms. PRESLEY. Yes, sir.

Mr. WISEMAN. We work with allied groups across the country.

Mr. BURTON. Dr. Block, you're not a Scientologist are you?

Dr. BLOCK. No, sir, I'm not.

Mr. BURTON. Ms. Weathers, you're not a Scientologist, are you?

Ms. WEATHERS. No. Absolutely not.

Mr. BURTON. Well, I just hope that there's no stigma attached to the people at this hearing because of their religious beliefs. We're here today to find out if—find evidence to find out if there is an abuse of Ritalin and other drugs of that type and whether or not they are habit forming and whether or not they are absolutely necessary and whether or not parents are getting adequate information so they can make an informed decision. Those are the major issues that we're looking at here today, and I appreciate it very much.

I will have additional questions for this panel that I'd like for you to submit in writing, and any legislative proposals that you think need to be made, we'd like to have that in writing. We can't guarantee that all of them are going to be enacted. You know, the legislative process is like watching sausage being made. You don't want to watch it. But we will take a look at all of that.

Anything else from the committee before we recess?

[No response.]

Mr. BURTON. OK. We stand in recess until the call of the gavel, and we'll go to the next panel when we come back.

Ms. PRESLEY. Thank you very much.

[Recess.]

Mr. BURTON. The committee will reconvene.

We'll now hear testimony from the second witness panel, Dr. Richard K. Nakamura. He is the acting director of the National Institute of Mental Health, National Institutes of Health, U.S. Department of Health and Human Services.

Unfortunately, the Department of Education's witness was unable to be here today.

Would you please stand so you can be sworn, sir? Do you swear to tell the whole truth and nothing but the truth so help you God?

Dr. NAKAMURA. I do.

Mr. BURTON. Thank you.

I presume, after hearing the testimony of the other witnesses and the questions, you have an opening statement? Would you proceed?

**STATEMENT OF RICHARD K. NAKAMURA, ACTING DIRECTOR,  
NATIONAL INSTITUTE OF MENTAL HEALTH**

Dr. NAKAMURA. Thank you, Mr. Chairman and members of the Committee on Government Reform, for the opportunity to discuss an important medical condition here today. I am Richard Nakamura, the acting director of the National Institute of Mental Health. Professionally, I am a brain scientist, also called a neuroscientist.

The National Institute of Mental Health is one of the National Institutes of Health. We are the Federal health institute responsible for research to reduce the burden of mental illness and other behavioral disorders. We take that responsibility seriously.

Ultimately, this hearing is about our children and helping them live full, productive lives.

I come here before you both as a scientist and as a parent of children, some of whom have received services themselves.

Permit me to provide some background information from the neurosciences. We used to think that the brain simply unfolded according to strict genetic instructions, and those instructions, like body growth, ended in late adolescence and the brain was done. From there it was thought that it was all downhill and one could only lose neurons. But now we know that the brain is actively constructed from birth, and even before birth, by an interaction of genes with behavior and the environment.

On the way, the brain goes through periods of massive growth and significant pruning or cell loss. This is normal. We know that that pruning occurs in neurons that do not get incorporated into behavioral programs of the brain; thus, we lose neurons that are not used.

Genes provide the scaffold for this growth, but the actual survival of neurons and their connections are determined by our environment and our behavior. This has important implications for disorders such as ADHD. Parenthetically, we also know that there are some new neurons that develop in the brain every day of life through to at least the age of 72 to help us older dogs learn new tricks.

What is ADHD, or attention deficit hyperactivity disorder? There are two major components. First, there is an inattention or distractibility component, and this is the primary feature in ADD. Then there is a hyperactivity or impulsivity component. For a diagnosis of ADHD, the condition must be of long duration, it must be developmentally inappropriate, it must cause significant impairment, and it must be present in two or more settings of a child's life—for instance, at least school and home.

When diagnosing ADHD, a clinician must be very careful to distinguish between that disorder and several other conditions that may look similar, such as sensory or learning disorders, anxiety or bipolar disorders, and many others that have already been mentioned here.

An adequate workup cannot be done in 15 minutes. In this regard, I have the statement from the American Academy of Pediatrics, which has a very good guideline for how to do an adequate workup of ADHD, and I would like to submit this and some other documents for the record.

Mr. BURTON. Sure, without objection.

Dr. NAKAMURA. Of children, 3 to 5 percent are diagnosed with ADHD, with boys being much more affected than girls. While some have questioned the reality of ADHD because we do not have a biological marker for the condition, the reality of individuals that cannot focus on a task for developmentally appropriate periods of time and show significant learning and job performance deficits as a result have convinced most physicians and scientists, just as most



are convinced that other behavioral disorders without clear biomarkers, such as autism and schizophrenia and pain, are real.

In these cases, it is the clarity and consistency of the behavioral syndrome or the effectiveness of interventions that is convincing. Many large professional and scientific bodies have looked into the topic of ADHD and have concluded that it is real. Some of these groups, for the record, are: U.S. Surgeon General, the American Medical Association, the American Psychiatry Association, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, and the American Academy of Pediatrics. Also, in 2002 an international consensus statement on ADHD was published by a large group of scientists who indicated their belief that the evidence for ADHD was very well justified and scientific.

What about the outcomes of untreated ADHD? There is an initiation of a trajectory because children who cannot attend or are hyperactive have great trouble learning. Since learning is progressive and since our brain structures are determined by our behavior and learning, we need an active intervention to keep healthy outcomes on track. Untreated, ADHD leads to increased medical utilization, school failure, poor social relationships, antisocial activities, use of harmful substances, brushes with the law, and serious accidents.

So how is ADHD treated? Because ADHD is a chronic problem and treatments need to work for long periods, we recommend early detection and beginning with behavioral approaches, including parent and child training. Now, remember this is after a diagnosis has been reached and all other possibilities have been eliminated through the appropriate differential diagnosis.

Obviously, if behavioral approaches work, they should be employed with occasional booster training sessions; however, in many cases this will not result in improvement, so then we recommend a trial of stimulant medication. In our experience, stimulant medications are highly safe and effective for properly diagnosed children and adults.

No choice of a stimulant medication should be made without careful consultation between parents, the children, and clinicians. We do not believe that teachers—other than potentially making a suggestion that the child has a problem and it might be ADHD. Teachers should not be diagnosing nor recommending treatment for the condition.

When stimulant medications are used, there should be a long-term followup to ensure the continuing efficacy of treatment, proper dosing, and proper adherence. What this means for children is that a trajectory that can lead to school failure—I'm sorry, there's one other important point to make.

We have estimated and our data suggests that behavioral and/or medication treatment therapies will help 90 percent of children with ADHD. What this means for children is that a trajectory that can lead to school failure and social difficulties can be interrupted and replaced by a trajectory that can lead to more normal behavior and therefore more normal brain and behavioral development.

Mr. BURTON. Excuse me, Dr. Nakamura. Would it be possible for you to summarize the rest of your statement so we can get to the questions, because—

Dr. NAKAMURA. Sure.

Mr. BURTON. I want to get all of the substance of everything you have to say, and we will be—all the Members will be reading your statement.

Dr. NAKAMURA. I have one more paragraph, if I can do that.

Mr. BURTON. OK.

Dr. NAKAMURA. By intervening to keep a child's development on track, many ADHD children can be helped to normal, productive lives. That is the point of our efforts.

I would like to say a final word about science. Science is a procedure that helps us learn the truth about interventions and outcomes by systematically testing ideas about the world and about human beings. This is the best way we know to learn whose ideas are right and how to keep us from continuing therapies that do not work or actually cause harm. Ultimately, we need to move away from anecdotes to scientific tests of ideas if we are to have the best and most helpful lives.

Thank you.

Mr. BURTON. Thank you, Doctor.

[The prepared statement of Mr. Nakamura follows:]



**Testimony**  
**Before the Committee on Government Reform**  
**United States House of Representatives**

**Attention Deficit/Hyperactivity  
Disorders: Are Children Being  
Overmedicated**

*Statement of*

**Richard K. Nakamura, Ph.D.**

*Acting Director*

*National Institute of Mental Health*

*National Institutes of Health,*

*U.S. Department of Health and Human Services*



For Release on Delivery  
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Good morning, Mr. Chairman and members of the Committee. My name is Richard Nakamura; I am Acting Director of the National Institute of Mental Health (NIMH), part of the National Institutes of Health (NIH). I have been Acting Director for approximately 10 months, and before that I served as NIMH's Deputy Director for almost 6 years. Before that, I was a program scientist dealing with basic research grants—in total; I have been at NIMH for 26 years. First, let me tell you that I am not a clinician, nor am I a psychiatrist. I am trained in neuroscience—I am a PhD scientist who studies the brain. But I am very well aware of the issue that has brought us here today. Let me begin in the way that scientists do—with a careful examination of the problem and its effects. Much of the information I will discuss is available through the NIMH web site, and I heartily recommend that you take the time to review it.

The NIMH supports research throughout the country to reduce the burden of mental illness and other behavioral disorders. We are well aware that all childhood disorders need urgent and effective attention and this position is underscored by the testimony presented in this hearing. There are many questions that need to be answered and there is no time to be lost. Parents are searching for answers because they know that childhood is all too short and the opportunity for quality development is easily lost. They know that the early years can set the path for a child's entire future. Attention Deficit Hyperactivity Disorder (ADHD) has been the focus of much public concern and NIMH is very aware of, and sensitive to, concerns about the need for accurate treatment and diagnosis.

**What Is ADHD?**

ADHD is the most extensively studied mental disorder of children, with several thousands of peer-reviewed papers in the scientific literature devoted to this topic. ADHD-- which affects an estimated 3-5 % or 2 million young school-age children and an unknown

number of teenagers and adults--refers to a family of related chronic neurobiological disorders that interfere with an individual's capacity to regulate activity level, inhibit behavior, and attend to tasks in developmentally appropriate ways. The exact etiology of ADHD is unknown, although neurotransmitter deficits, genetics, and perinatal complications have been implicated. ADHD tends to run in families. Between 10 and 35 percent of children with ADHD have a first-degree relative with past or present ADHD. Approximately one-half of parents who had ADHD have a child with the disorder.

As its name implies, ADHD is characterized by two distinct sets of symptoms: inattention and hyperactivity-impulsivity. Although these problems usually occur together, one may be present without the other to qualify for a diagnosis. Inattention or attention deficit may not become apparent until a child enters the challenging environment of elementary school.

The symptoms of hyperactivity may be seen in very young preschoolers and are nearly always present before the age of 7. They include excessive restlessness, squirming around when seated, and the frequent need to walk or run around. Hyperactive children have difficulty playing quietly, and they may talk excessively, often behaving inappropriately and impulsively, not waiting their turn, and interrupting. Many of these symptoms may occur in normal children. However, in children with ADHD they occur very frequently and across several domains, at home and at school, or when playing, interfering with the child's normal functioning. These children are often poor students and unpopular among the other children and their behavior can present significant challenges for parents.

Inattention tends to persist into adulthood, while hyperactivity and impulsivity tend to diminish with age. Hyperactive behavior is often associated with the development of other disruptive disorders. The reason for the relationship is not known. Even though a great many

children with this disorder ultimately adjust, some—especially those with disruptive disorders—are more likely to drop out of school and fare more poorly in their later careers than children without ADHD. As they grow older, some teens who have had severe ADHD since middle childhood experience periods of anxiety or depression.

A large consortium of international scientists, deeply concerned about the portrayal of ADHD as a "myth, fraud or a benign condition", signed a letter in which they expressed concern over the inaccurate notion that somehow ADHD is not real. Here is how they put it. (I will be happy to insert the entire statement in the Record):

We cannot overemphasize the point that, as a matter of science, the notion that ADHD does not exist is simply wrong. All of the major medical associations and governmental agencies recognize ADHD as a genuine disorder because the scientific evidence indicating it is so is overwhelming....The central psychological deficits in those with ADHD have now been linked through numerous studies using various scientific methods to several specific brain regions (the frontal lobe, its connections to the basal ganglia, and their relationship to the central aspects of the cerebellum). Most neurological studies find that as a group those with ADHD have less brain electrical activity and show less reactivity to stimulation in one or more of these regions. And neuro-imaging studies of groups of those with ADHD also demonstrate relatively smaller areas of brain matter and less metabolic activity of this brain matter than is the case in control groups used in these studies.<sup>1</sup>

#### **How is ADHD Diagnosed?**

A most essential step is accurate diagnosis, not to solve the problems of overcrowded or chaotic classrooms, but to find the children who need and can benefit from proper treatment. So, good treatment begins with accurate diagnosis, which can best be achieved through implementation of state-of-the-art diagnostic approaches in practice settings. We know through

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<sup>1</sup> Barkley, R.A. International Consensus Statement on ADHD, January 2002, signed by over 70 leading scientists. *Clinical Child Family Psychology Review*, 2002, Jun 5(2): 89-111.

research that a clinically valid diagnosis of ADHD can be reached through a comprehensive and thorough evaluation done by specially trained professionals using well-tested diagnostic interview methods. The key elements include a thorough history covering the presenting symptoms, including ruling out other physical or mental conditions that may have the same symptoms, possible comorbid conditions, as well as medical, developmental, school, psychosocial and family history. The criteria for diagnosis with ADHD specify that symptoms of inattention must have persisted for at least 6 months to a degree that is maladaptive and inconsistent with the child's developmental level. Proper diagnosis also avoids the possibility that these symptoms are occurring exclusively during the course of a pervasive developmental disorder, schizophrenia, or other psychotic disorder and are not better accounted for by another mental disorder (e.g., mood disorder, anxiety disorder, dissociative disorder, or a personality disorder.) The problems involved with accurate diagnosis of these illnesses are particularly acute in pediatric primary care settings, where many of these children are seen, because these evaluations take time and require multiple clinical skills, for which we have few appropriately trained professionals.

There is no doubt that the ability to diagnose childhood mental disorders is not as advanced as our capacities for diagnosing adult disorders. The NIMH is actively working to increase what we know about child mental disorders to make diagnosis more accurate. It is very difficult to distinguish the early symptoms of disorders that portend life-long difficulties from still serious, but transient dysfunction—this is a skill that takes years of highly specialized training. The paucity of normative information on the developmental progression of ADHD leads to a wide variation in clinical and research approaches for identifying and diagnosing the disorder. In response to these observations, NIMH is now supporting interdisciplinary research

networks on ADHD, to translate what is already known in the basic sciences (particularly cognitive neuroscience, molecular genetics and biology) into clinical preventive, interventive and treatment strategies.

### **ADHD Treatment**

Mental Health: A Report of the Surgeon General<sup>2</sup> contains an informative, thoroughly researched chapter on ADHD and includes recommendations for treatment. " The practice parameters state, 'the cornerstones of treatment are support and education of parents, appropriate school placement, and pharmacology.' These practice parameters evolved out of research relating to two major types of treatment: pharmacological treatment and psychosocial treatment, particularly behavioral modification, as well as multimodal treatment, the combination of psychosocial and pharmacological treatments."

Most often, the first treatment used should be psychosocial, including behavioral therapy, social skills training, support groups and parent and educator skills training. Psychostimulant medications, including methylphenidate are the most widely researched and commonly prescribed treatments for ADHD. Numerous studies have established the safety and efficacy of stimulants and psychosocial treatments for alleviating the symptoms of ADHD. NIMH research has indicated that the two most effective treatment modalities for elementary schoolchildren with ADHD are a closely monitored medication treatment and a treatment that combines medication with intensive behavioral interventions. In the NIMH Multimodal Treatment Study for Children with ADHD (MTA), which included nearly 600 elementary

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<sup>2</sup> U.S. Department of Health and Human Services. *Mental Health: A Report of the Surgeon General*. Rockville, M.D.: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health, 1999, Chapter 3, page 146.



school children across multiple sites, nine out of ten children improved substantially on one of these treatments.

Failure to provide appropriate treatment for certain disorders—including ADHD—also poses a risk to brain integrity and function. The brain is a very flexible—or "plastic"—organ that needs certain stimulation in order to mature properly—to make the correct connections. In the same way that covering one eye [and eliminating visual stimulation] during a critical phase of development leads to life-long visual impairment, failure to receive and properly process cognitive and emotional stimuli during critical periods when the brain is undergoing rapid growth and maturation may result in damage with lifelong consequences. Therefore, a child who cannot pay attention and who cannot learn is at risk of having his or her brain and development adversely affected and many children with ADHD develop learning delays and academic failures that lead to early school drop out. Children with ADHD who are untreated may be at increased risk for some medical and social problems such as reckless driving, drug and alcohol abuse, smoking, academic failure, difficulty in making relationships and trouble with the law.

I would like to be sure that we focus carefully on two questions that deserve answers: 1) Are diagnoses being made effectively and are appropriately diagnosed children receiving properly selected treatments that will help them gain an upward trajectory in life? Too many children with ADHD are being ignored and remain at high risk for other lifelong problems, including depression and substance abuse. 2) While it is also well known that many children are being given medications for a variety of disorders, it is clear that not all of those children ought to be taking medications. Are some of our children, particularly active boys, being overdiagnosed with ADHD and thus are receiving psychostimulants unnecessarily? Little

evidence of overdiagnosis of ADHD or overprescription of stimulant medications has been verified in research. Indeed, fewer children (2 to 3 percent of school-aged children) are being treated for ADHD than suffer from it. Treatment rates are much lower for girls, minorities, and children receiving care through public service systems. Medical and public awareness of the problem of ADHD has grown considerably so that people, who were underdiagnosed in the past, are being identified and treated. Most researchers believe that much of the increased use of stimulants reflects this better diagnosis and more effective treatment of a prevalent disorder.

These are very difficult and serious problems that we must address through better access to treatment and further research. The enormous advances occurring in the brain sciences will contribute to an increased understanding of the etiology and pathogenesis of ADHD and other brain disorders. As a neuroscientist, I am in awe of the leaps in knowledge we have taken in this arena, and I am most anxious to see these advances used to increase our understanding of the biological basis of ADHD, including finding biological markers that can lead to definitive, objective methods of diagnosis.

Accurate diagnosis and evaluation, however, is possible with our current state of knowledge. NIMH supports the largest and most long-term study to date of children with ADHD. Children received 14 months of treatment, and an extended follow-up for 6 more years is currently underway. Results have demonstrated that methylphenidate with careful medication management was safe and effective for the length of the trial, and was more effective than intensive behavioral treatments in relieving symptoms. The combination of medication management and intensive behavioral treatments was particularly advantageous when children with ADHD had symptoms of other disorders as well.

We can successfully treat ADHD, which is real and can be crippling if left alone. But I cannot emphasize too much the critical importance of careful, expert evaluation for each and every child, and for those diagnosed with ADHD, a very carefully structured treatment regimen trying behavioral interventions as a first line of defense, with the addition of carefully managed medication if necessary. Children who need, but do not receive, these services are being placed at serious risk during a critical period in their brains' development. Failing to enable them to respond to their fullest potential to both external and internal psychological stimulation will deprive their brains from the opportunity of reaching their optimal growth and maturation potential, thereby hampering mental development. For many, this will have obvious life-long, negative, preventable consequences.

I would be happy to answer your questions.

Mr. BURTON. There are about 6 million children in America that are using Ritalin or substances very similar to that. Do you think they all need that?

Dr. NAKAMURA. We have heard different numbers. We don't know exactly how many children are being prescribed, but we have heard the number in the range of 3 million as opposed to 6; 6 might include all the adults.

Mr. BURTON. Well, Pat—

Dr. NAKAMURA. But I won't dispute it.

Mr. BURTON. Pat Weathers, who testified, she said that her child was fine at home but at school didn't pay much attention and was looking out the window and that sort of thing, like I did when I was a child, because I wanted to play baseball or, as I got older, chase the girl down the street. And she said that the teacher had a checklist and went through the checklist and called her in with the principal and said, "Your child has attention deficit problems, and we think that he ought to be treated."

They went to the doctor, and she said the doctor looked at that, spent less than 15 minutes with them, and prescribed Ritalin.

Now, according to your testimony, that's not the way it should be done; is that correct?

Dr. NAKAMURA. Given the description, because I don't know the particulars of this case, but, given the description, no, that is not the way it should be done.

Mr. BURTON. I mean, I listened to your testimony very closely, and you said that you ought to look at school, you ought to look at home, there ought to be consultation, there ought to be a whole lot of things that take place before you start using Ritalin. Isn't that what you said?

Dr. NAKAMURA. Yes.

Mr. BURTON. Yes. We have heard a lot of stories about teachers saying this child has an attention deficit problem, and they do this checklist, and they send them to doctors, and the Ritalin is just a fait accompli. They're going to give it to them when they go there. You don't think that's right, do you?

Dr. NAKAMURA. The guidelines of the American Academy of Pediatrics and Institute's position are that you cannot make the diagnosis and you should not be writing a prescription with that little information.

Mr. BURTON. Well, has our health agencies informed our educational system around the country or State superintendents of public instruction or local school boards that there are certain things that should be followed to give them a diagram on what they should do before they start giving children Ritalin and sending them to the doctor?

Dr. NAKAMURA. The information is certainly available on Web sites. We have not, as an institute, sent information directly to all the schools in the country.

Mr. BURTON. Well, let me just tell you a story. One of the doctors, one of the most important doctors here on Capitol Hill, I said, "Did you know there's mercury in the vaccines you're giving us for flu?" And he said, "No, there's not." And so I took the insert out and I gave it to him and he looked at it and said, "Well?" And I

said, "Well, thimerosal has mercury in it." Well, he didn't know that. The doctor didn't know that.

Now, if we're spending all this money on our health agencies and you have a criteria that's supposed to be used for children before they go on these mind-altering drugs, then why in the heck doesn't the schools know about it, because they don't. Many of the doctors don't even know that.

I want to talk to you about neurons. And I would submit to you that our health agencies for a very low cost could put it on their e-mail site and they could send a notification out to all State boards of education and local school boards and say, "On our e-mail site we have the criteria that should be followed before a child starts taking Ritalin or other drugs of this type." I don't know why you don't do it. It makes sense to me, and it would save the legislative branch a lot of time and trouble.

Now I want to talk to you a little bit about the neurons you were talking about. You talked about the neurons growing and being replaced and replicated on a very regular basis. Do you think mercury has an adverse effect on neurons?

Dr. NAKAMURA. I honestly don't know. I believe that mercury is clearly a substance you don't want in the body.

Mr. BURTON. Let me ask you this. Thimerosal—most of the vaccines we're sending overseas to all these kids in Third World country still has it in there, and they're getting it out gradually here in the United States, but not as quickly as they ought to because we've had this absolute epidemic of children that are autistic, from 1 in 10,000 now to 1 to 250, and a lot of people say, "Well, that figure, 1 in 10,000 might be way off," but everybody acknowledges we've got a big, big problem, even if that figure is incorrect. I don't think it is.

But we had some scientists from Canada send us a video—which I want you to give a copy to the doctor. Have you seen that video?

Dr. NAKAMURA. I don't believe so.

Mr. BURTON. It shows the neurons—there's a sleeve on the neurons, is there not? Isn't there a sleeve?

Dr. NAKAMURA. Right.

Mr. BURTON. It shows what happens—

Dr. NAKAMURA. Myelin.

Mr. BURTON [continuing]. To the sleeve on the neurons when a very minute amount of mercury is introduced into the close proximity to it. It just destroys it. It just destroys it, and ultimately it destroys or damages severely the neurons. Would you say that would have an impact on the brain of that child?

Dr. NAKAMURA. Yes. It certainly depends on the form of the mercury, but—

Mr. BURTON. Wait. You say the form of the mercury.

Dr. NAKAMURA. There are some forms of mercury—

Mr. BURTON. I know. There's two different kinds that we're talking about.

Dr. NAKAMURA. Correct.

Mr. BURTON. Has there been testing done to show that one has an impact that the other one doesn't on neurons?

Dr. NAKAMURA. I could not tell you about that result. I do know that one form is much more destructive than the other form, and

that thimerosal contains the less-destructive form; however, I would agree that I would not like to see mercury—

Mr. BURTON. Well, the hearings we've had—and I've had scientists and doctors of your caliber from all over the world, and the thimerosal and the mercury in these vaccines is very damaging and they believe it contributes to neurological problems in these kids. And you said yourself no mercury should be introduced into the human body, and yet they're doing it every day, and they did it to me, and they did it to every Member of Congress that wanted to get a shot for flu.

Dr. NAKAMURA. Yes.

Mr. BURTON. Why is that?

Dr. NAKAMURA. I can't offer you an explanation.

Mr. BURTON. You're with the Department of Health here.

Dr. NAKAMURA. I am with the Department of Health and Human Services, but the Centers for Disease Control and the FDA are the controlling organizations.

Mr. BURTON. Are they part of the Department of Health?

Dr. NAKAMURA. Yes.

Mr. BURTON. Do you guys have any—do you ever talk?

Dr. NAKAMURA. They don't ask my advice on the issue of vaccines.

Mr. BURTON. So how do we get—I mean, how do we get the message down to them besides going down there with a ball bat and hitting them in the head?

Dr. NAKAMURA. I will be happy to pass this information on through the Department, through the appropriate—

Mr. BURTON. I think they already know this.

Dr. NAKAMURA. I believe they do, too, sir.

Mr. BURTON. Yes, they've been to my committee before, and they're going to be back here again, and they think they're going to get rid of me when I—

Dr. NAKAMURA. You are very, very clear.

Mr. BURTON [continuing]. When I'm not chairman any more, but I'm going to be here and I'm going to probably be a subcommittee chairman, and I can guarantee you, if I am, I'm going to be on the Health Subcommittee, so I'm going to have you guys back again and again.

Now let's talk about the cocaine. Is there any relationship between—and I'm going to go to my colleagues as soon as this question is over. I've run way over, so excuse me.

Is there any connection or is there any relationship between cocaine and Ritalin? Do they have any of the same properties?

Dr. NAKAMURA. Yes. The stimulant properties of both derive from similar chemical properties, and—

Mr. BURTON. If a person who has wanted to snort cocaine, if they ground up Ritalin and made it into a powder form would it have a similar effect on their brain?

Dr. NAKAMURA. It would probably not do as much for them; however, yes, they would get a high from ground up methylphenidate.

Mr. BURTON. So they're similar?

Dr. NAKAMURA. They're similar in that sense, yes.

Mr. BURTON. Could you become addicted to Ritalin ground up and snorted like cocaine?

Dr. NAKAMURA. That would increase the addiction potential of the methylphenidate, yes.

Mr. BURTON. OK. So why is it that children taking Ritalin might not become addicted and become a more likely prospect for long-term addiction to more strong—

Dr. NAKAMURA. There are a couple of things going on. One is that our experience has been that this is not happening; that most children are using this appropriately; that pharmacies and physicians are being fairly careful about their prescribing practices, so they don't allow automatic renewals of prescriptions; and that the number of pills are counted to make sure of the number of pills being taken by the child—

Mr. BURTON. I understand, but a lot of children get this in early years and they spread it out, maybe all the way through high school. Is there a possibility of addiction?

Dr. NAKAMURA. So far, when we have looked, there is either no increase in addiction or slightly reduced level of addiction for kids who are on medications compared to kids who are not on medications.

Mr. BURTON. You've done long-term studies on this?

Dr. NAKAMURA. We have done studies that have varied in the amount of time from 14 months to 20-something years.

Mr. BURTON. Is that right? And yet you say the properties are very similar to cocaine?

Dr. NAKAMURA. Yes.

Mr. BURTON. I don't understand that disparity there. Maybe you can explain that in the second round.

Let me yield to my colleague, Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman.

Dr. Nakamura, welcome to our panel.

Dr. NAKAMURA. Thank you.

Mr. GILMAN. In your testimony you stated that, "Good treatment begins with accurate diagnosis, which can best be achieved through implementation of state-of-the-art diagnostic approaches in practice settings. We know through research that a clinically valid diagnosis of ADHD can be reached through a comprehensive and thorough evaluation done by specially trained professionals using well-tested diagnostic interview methods." That's your testimony, is it not?

Dr. NAKAMURA. Yes.

Mr. GILMAN. Basically, your testimony implies that doctors don't need to do any evaluation of possible biological issues such as thyroid or heavy metal toxicities, things for which there are objective clinical tests, rather than the subjective interview method. Doesn't it worry you that by not doing good medicine—in other words, biomedical evaluation—children with biological issues are simply having the symptoms suppressed rather than resolved? Does that concern you at all?

Dr. NAKAMURA. By stating that a proper workup be done, we meant that proper differential diagnoses also be done, and we recommend the American Academy of Pediatrics clinical practice guidelines, which make it very clear that you need to do an adequate differential diagnosis, so you eliminate other possibilities.

Now, there are, I think, reasonable questions about whether or not some other factors may produce these kinds of symptoms, so I believe between ourselves and the earlier panel there may be disagreements about how much allergies can participate in this, but we do recommend that those be checked before making a recommendation and a diagnosis of ADHD.

Mr. GILMAN. So there should be a good biomedical evaluation? Is that what you're saying?

Dr. NAKAMURA. Yes.

Mr. GILMAN. You state that ADHD is one of the most-researched conditions in children's mental health. Just how much is being spent on that kind of research at NIMH and NIH?

Dr. NAKAMURA. Well, while more than just NIMH is spending money, I can tell you that last year NIMH spent \$53 million studying ADHD.

Mr. GILMAN. Is any of this research evaluating biological issues such as mercury or lead toxicity that our chairman has indicated?

Dr. NAKAMURA. None of this at the moment is looking at lead toxicity and mercury.

Mr. GILMAN. Is there any reason why you're not looking at it?

Dr. NAKAMURA. We have, as our process, a peer-reviewed competition for grants. We would be quite interested in getting an application which tried to look at the contributions of both lead and mercury to ADHD.

Mr. GILMAN. Do you need an application to undertake that kind of a study?

Dr. NAKAMURA. Well, we've found that, in order to get studies done well and assume excellence in science, getting them in through a peer review process is very important. If you have—if any of you have investigators who have indicated that they are interested in pursuing this study—

Mr. GILMAN. Well, we're interested in this committee. Do you need an application to dig into that kind of an approach?

Dr. NAKAMURA. We need an application to make sure that the research that is proposed will answer the question.

Mr. GILMAN. Don't you initiate any studies on your own? Do you have to wait for applications if there is some problem out there?

Dr. NAKAMURA. We can initiate studies on our own.

Mr. GILMAN. Well, I suggest that maybe you ought to take a look at the mercury or lead toxicity on your own rather than waiting for an application.

Is any of the research evaluating alternative therapies such as acupuncture, neurofeedback, massage, cranial sacraltherapy, and special dietary approaches—is there any research now looking at any of those?

Dr. NAKAMURA. I understand that the National Center for Complementary and Alternative Medicine is pursuing all of those.

Mr. GILMAN. They are—

Dr. NAKAMURA. Yes.

Mr. GILMAN [continuing]. Undertaking that?

I just have one or two other questions, Doctor. In a 1995 background paper from the Drug Administration, DEA, the following statement was made. "It has recently come to the attention of the DEA that CIBA/Geigy, the manufacturer of Ritalin marketing



under the brand name Ritalin contributed \$748,000 to CHADD from 1991 to 1994. The DEA has concerns that the depth of the financial relationship with the manufacturer was not well known to the public, including CHADD members that have relied upon CHADD for guidance as it pertains to the diagnosis and treatment of their children.”

In a recent communication from United Nations International Narcotics Board, INCB, expressed concern about non-governmental organizations and parental associations in the United States that are actively lobbying for the medical use of Ritalin for children with ADHD. The U.N. organization further stated that financial transfer from a pharmaceutical company with the purpose to promote sales of an internationally controlled substance would be identified as hidden advertisement and in contradiction with the provisions of the 1971 convention.

In fact, a spokesman for CIBA/Geigy stated that “CHADD is essentially a conduit for providing information to the patient population.” That’s a direct quote from them. The relationship between CIBA/Geigy, which is now Novartis, and CHADD raises serious questions about CHADD’s motive in proselytizing the use of Ritalin.

This is what DEA had to say. This same DEA paper states that CHADD, in conjunction with the American Academy of Neurology, submitted a petition to reschedule Ritalin from Schedule II to Schedule III under the Controlled Substances Act because controls are unduly burdensome for the manufacturer and for physicians who prescribed it and patients who needed it. CHADD denied that the financial contributions received from CIBA/Geigy have any relationship to their action.

And the DEA went on to note that of particular concern to them was that most of ADHD material prepared for public consumption by CHADD and other groups and made available to parents does not address the above potential or actual abuse of Ritalin. Instead, it is portrayed as a benign, mild substance that’s not associated with abuse or any serious side effects.

The DEA went on to note in their report, “In reality, however, there is an abundance of scientific literature which indicates that Ritalin shares the same abuse potential as other Schedule II stimulants. Case reports document that Ritalin abuse, like any other Schedule II stimulant, can lead to tolerance and severe psychological dependence. A review of the literature and examination of current abuse and trafficking indicators reveals a significant number of cases where children are abusing Ritalin.”

So what is your comment with regard to DEA’s report?

Dr. NAKAMURA. The key comment is it’s very important to realize that when ADHD is properly diagnosed there seems to be very little problem with substance abuse and even diversion. The GAO recently put out a report on attention disorder drugs and reported that there were few incidents of diversion or abuse identified by schools.

And it is the experience that we have so far which indicates that there is not an increase in abuse by those with ADHD who are taking Ritalin; rather, there is either a normal amount or a reduced amount of abuse by those kids.

We do know that untreated ADHD kids go on to abuse drugs at high proportions.

Mr. BURTON. The gentleman's time has expired.

Mr. GILMAN. I just have one more.

Mr. BURTON. Sure. OK. Go ahead. Yield to me for just 1 second?

Mr. GILMAN. Sure.

Mr. BURTON. Was that the only study that was done on that, that said that there was no increased abuse?

Dr. NAKAMURA. No. There were three studies.

Mr. BURTON. OK. Tell me about the other two studies real quick. Weren't there other studies that showed that there was increased use?

Dr. NAKAMURA. There was one study—

Mr. BURTON. And did the—there was one study. You didn't mention that. It's interesting that you mention the one that says what you want but you don't mention the one that says what you don't want. This Congress up here doesn't want you to come up here and shade things the way that the health agencies want. We want you to tell the truth for the American people. It really bothers me that you guys do this all the time. You do it all the time. Tell the whole truth, not just the part that you want told.

And the pharmaceutical companies—Congressman Gilman just made a strong point. The pharmaceutical companies fund an awful lot of this stuff, these studies and other things that you're talking about. You said the GAO said that there was no problem with this. You didn't quote the DEA. The DEA is the agency that we charge to go after the drug dealers and the drug abusers and the drug problems in this country. Why is it you didn't quote the DEA instead of just the GAO study that you asked for?

Dr. NAKAMURA. I had just been given the information about DEA, and—

Mr. BURTON. You mean to tell me you guys don't have access to that over there?

Dr. NAKAMURA. No. I just pointed out that there was other information, as well.

Mr. GILMAN. Thank you. I'll yield in just a moment. But, Doctor, are you concerned about the relationship between CHADD and the pharmaceutical company? Is there any concern by NIH with regard to that?

Dr. NAKAMURA. That is not an area of—I don't believe that the NIMH has a right to interfere with that transaction. What we try and do at NIMH, is very carefully make certain that there is no interaction with drug companies that could influence our decisions.

Mr. GILMAN. But here we have a drug company that is influencing a parental group, and that drug company has some financial motivation. Isn't there any oversight by NIH of that kind of a relationship?

Dr. NAKAMURA. No, there's no oversight that I'm aware of, by NIH. NIH's job is to do good research, and that's what we try and do.

Mr. GILMAN. Well, I hope that NIH would do more than just do research, and make certain that the information given to the public is factual and not motivated by any financial interests.

I'll be please, Mr. Chairman, to yield the balance of my time.

Mr. BURTON. Mr. Horn.

Mr. HORN. Dr. Nakamura, a study conducted at Georgetown found that children with ADHD are seven times more likely to have food allergies than other children. Isn't it true that children in an allergic state would be adversely affected in their ability to focus and concentrate? What has NIMH and NIH done to evaluate the correlation between food allergies and attention disorders?

Dr. NAKAMURA. My understanding is that we have had some earlier studies in which we looked for allergies as related to ADHD and other kinds of externalizing or disruptive behavior disorders and found that a small proportion, about 5 percent, could be accounted for by those allergies. And certainly we believe that, where they exist, you take care of those before you develop a diagnosis.

Mr. HORN. Are you concerned that children may be misdiagnosed with ADHD?

Dr. NAKAMURA. Absolutely.

Mr. HORN. Well, that's good to know.

Dr. NAKAMURA. We would very much like to see children properly diagnosed. In our current system, physicians are compensated inadequately for doing a full work-up. It is hard for physicians, as we understand it, to get more than a certain amount of time and money per patient. This might have a tendency to cause them to move a little too fast and maybe not have enough time to come up with alternative conclusions about a disease process.

Mr. HORN. Dr. Nakamura, in the Novartis PDR in Ritalin there's a warning that Ritalin should not be used in children under the age of 6 years because the safety and efficacy had not been established. I'm troubled that the National Institutes of Health would offer to pay parents of 3-year-olds over \$600 to test Ritalin on their children, and there's apparently a—let's see here—it was the APA meeting quote, and is the Federal Government testing psychotropic drugs in children under the age of 6?

Dr. NAKAMURA. Let me tell you how this study is being conducted.

Mr. HORN. Go ahead.

Dr. NAKAMURA. Because of the reports that so many children are being provided with Ritalin at younger ages, the National Institute of Mental Health decided that it needed to do a study on the safety of such drugs at those lower ages. Our review board, or IRB looked at this issue very carefully, and we did the following. We have run the most rigorous study possible to exclude children from this study in the sense that we do a very vigorous examination of whether or not there are alternative possibilities for explaining the behavior of the children.

We require that the children go through a full behavioral therapy session that is really a set of sessions before they are accepted for the trial, and only then is there a final getting the parents' permission to go ahead with a trial of Ritalin.

Mr. HORN. How many children are under 6 years of age?

Dr. NAKAMURA. I believe that the design is to get 100 children.

Mr. HORN. In your testimony you talk about the studies that have been conducted on individuals with ADHD have "less brain electrical activity and show less reactivity to stimulation in one or more of these regions." Are you still standing by that? Can you

please tell us if any of these tests were conducted on individuals diagnosed with ADHD who had never been treated with psychotropic drugs?

Dr. NAKAMURA. In those studies, no. We are about to see a study come out in which that specific comparison has been made.

Mr. HORN. Please explain how the drugs can affect these same activities in the brain.

Dr. NAKAMURA. Pardon me. I don't understand.

Mr. HORN. Please explain how the drugs can affect these same activities in the brain.

Dr. NAKAMURA. I'm sorry. It's—which same activities in the brain?

Mr. HORN. We'll submit it to you and put it at this point in the hearing record.

Dr. NAKAMURA. I apologize for not understanding.

Mr. BURTON. He's talking about the brain activity, less brain electrical activity.

Dr. NAKAMURA. And the drug stimulating it?

Mr. BURTON. Yes. He's talking about how would it affect it.

Go ahead.

Dr. NAKAMURA. OK. So let me explain what we believe is going on with stimulant medications. That is, that certain portions of the brain show reduced activity compared to normal children, and this is in the area of executive function, particularly in the frontal lobes.

Unlike an earlier statement, it isn't because blood is going slower. Blood is going at the normal rate. It is the activity and the oxygen pickup of those neurons which is different, which means that the frontal lobes aren't using as much energy as those in normal. And, a small amount of Ritalin, selectively increases the amount of energy and the activity of neurons in the frontal lobes, which provides the executive function these kids need in order to control their behavior better.

Mr. HORN. I yield back my time to the chairman.

Mr. BURTON. Thank you, Mr. Horn. We are not through questioning Dr. Nakamura, so you'll have another chance.

Mrs. Davis.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

If I just heard you correctly, you said the Ritalin speeds up the activity in the frontal lobe. Did you hear me give the explanation earlier to the first panel about the blood flow in the frontal lobe of the brain?

Dr. NAKAMURA. Yes.

Mrs. JOANN DAVIS OF VIRGINIA. Can you comment on that?

Dr. NAKAMURA. Yes. When you do certain studies in order to look at the activity of the brain, what it actually does is looks at the flow of oxygen through the brain, or sometimes called "blood flow." What you're really concerned about is the activity of the neurons in the brain, and so it isn't so much a problem of slow blood, it's a problem of neural activity, for which the blood is a surrogate measure.

What we have been finding is that frontal lobe activity in those with ADHD is reduced and that the Ritalin helps increase it. Because frontal lobes are responsible for executive function, that

makes it easier for self control and for self-directed activity to go on.

Mrs. JOANN DAVIS OF VIRGINIA. Based on that, and to go back to—I forget who asked the question about the possible addiction of Ritalin because it has similar characteristics of cocaine. It was my understanding that if you put a child—and I'd like you to comment on it—put a child on Ritalin who is not ADHD, it has a different effect on that child than the child who has ADHD. For instance, our son, when we put him on Ritalin, became normal, had normal behavior, not, you know, slowed down, dead, lethargic, or a zombie, or what have you, but actually became what you would call normal. But if you put a child who was not ADHD on Ritalin it was like giving them speed and they actually become the opposite and become hyper. Can you comment on that?

Dr. NAKAMURA. In general, if children, normal children, use Ritalin at normal doses through normal pathways—that is, ingestion—they might have side effects of losing sleep and losing weight, but at those levels it shouldn't become addictive. And cocaine has much less addictive properties when ingested in a slow way. If you change the way it is delivered to the body, for example if you figure out a way of injecting it, a way of snorting it or sniffing it, that speed can increase the addictive properties.

I understand that one of the things the drug companies are trying to do is create a form of methylphenidate which is less able to be ground up and used in any form other than the appropriate ingested form. So I believe the drug companies are trying to solve the problem, and the potential addictive properties if you misuse these chemicals.

Mrs. JOANN DAVIS OF VIRGINIA. Is there any validity to giving Ritalin to a child who is not ADHD and giving it to one who is, that there's difference in the behavior?

Dr. NAKAMURA. I'd like to liken it to a bell-shaped curve in the sense that if performance is optimal at the peak of the curve for a normal child who is at the peak of the curve, you're going to push them past optimal performance. There may be some gains in terms of being able to stay up late or to do a short-term sports event, but there are more penalties to be had for those children. For those with ADHD, it appears that they are to the left of the curve and can be pushed up to normal performance by these drugs.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you, Mr. Chairman. Thank you, Doctor.

Mr. BURTON. Judge Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman.

Dr. Nakamura, you may have heard me this morning when I stated this morning or quoted one article in which the just-retired Deputy Director of the Drug Enforcement Administration said that Ritalin is prescribed six times as much in the United States as in any other industrialized nation, six times as much as in Canada and Great Britain, other countries like that. Does that concern you?

Dr. NAKAMURA. I certainly—

Mr. DUNCAN. Do you know of any reason why that would make any sense at all? And also "Time Magazine" said that production

of Ritalin has increased sevenfold in the past 8 years, and that 90 percent of it is consumed in the United States—90 percent?

Dr. NAKAMURA. Yes, this is of concern; however, the United States is often at the leading edge of a number of things, and so it is not completely surprising that it should be happening more in the United States. I do know that the use of Ritalin is up strongly in Europe and that it is perceived as being safe and effective, and the experience of the United States is being taken into consideration there.

Mr. DUNCAN. I have an article here that says—an article last year in the “Journal of the American Medical Association” said that “psychotropic medications have tripled in preschoolers ages 2 to 4 during the previous 5 years, the past 5 years. More disturbing is that during the last 15 years the use of Ritalin increased by 311 percent for those ages 15 to 19, and 170 percent for those ages 5 to 14.” That’s from the “Journal of the American Medical Association.” And this “Insight Magazine” that I quoted earlier this morning says that, “Of approximately 46 million children in kindergarten through grade 12, 20 percent have been placed on Ritalin at some point.”

Your figures are much, much lower than that.

Dr. NAKAMURA. Yes. All the figures that we have on national prevalence of the use would make us very surprised if the figure surpassed 5 percent.

Mr. DUNCAN. But you don’t question these figures from the “Journal of the American Medical Association” that say that psychotropic medications have tripled in preschoolers during the previous 5 years?

Dr. NAKAMURA. We accept that and we are very concerned about what that means and how practice is being changed. Our previous director, Steve Hyman, was not convinced that we knew enough about diagnosis of some of our disorders at those ages to be prescribing medications. One of the—

Mr. DUNCAN. It says in this article here, it says, “This can be good news only for investors in the Swiss-based pharmaceutical company Novartis, which makes Ritalin. For instance, if the number of children taking the drug increased five-fold, so did the drug company’s resultant profits and presumably stock value.”

In a June 28, 1999, article, “Dope and Kids,” it was estimated that Novartis generated an increase in the stock market value of \$1,236 per child prescribed Ritalin. Based on these evaluations, the drug company would have enjoyed an increased stock market value of approximately \$10 billion or more since 1991.

Dr. NAKAMURA. I can assure you that I haven’t shared in any of that. It’s—

Mr. DUNCAN. You know, I know you meant that to be humorous, but I think this is very sad that we may be drugging or doping children and that it is all about helping a big drug giant make whopping profits.

Let me ask you this. Getting more directly into your field—and I’m just curious about this. I know nothing about it—is there a real difference or are there significant differences between the brains of small boys and small girls?

Dr. NAKAMURA. There are some differences.

Mr. DUNCAN. The way they operate?

Dr. NAKAMURA. Yes.

Mr. DUNCAN. That might cause this? Because everybody said that there are many more small boys that are being prescribed this medication than small girls. Is there anything in your research on the brain that would help explain that?

Dr. NAKAMURA. There's no question that the hormone differences between boys and girls, which increases at early adolescence, creates differences in behavior.

Mr. DUNCAN. Early adolescence, though. Most of these kids are being prescribed this before early adolescence.

Dr. NAKAMURA. Yes. There are hormone differences that start from birth, and one important point is that there are some who feel that attention deficit is much more prevalent in girls than we have measured, and that girls have simply not been identified because they are not seen as a problem. They simply sit in a classroom and fail quietly, whereas boys tend to act out at the same time, so they come to the attention of teachers and the girls are ignored.

Mr. DUNCAN. My time is up, but let me just ask one more quick question. I spent 7½ years before coming to Congress as a State trial judge trying the felony criminal cases, the most serious criminal cases, and the first day I was judge they told me that 98 percent of the defendants in felony cases came from broken homes. And I went through, because 96 or 97 percent of the people plead guilty and apply for probation, I went through about 10,000 cases, and I can't tell you how many thousands of times I read, "Defendant's father left home when defendant was two and never returned. Defendant's father left home to get a pack of cigarettes and never came back." And I can tell you this—crime goes back, it's caused by drugs and alcohol and running with the wrong crowd and all that, but you can trace all the felony crimes, with very few exceptions, back to this broken home situation.

I remember reading one article that said that I think 90 percent of these children that were being prescribed Ritalin were in homes from very successful two-parent families, but where both parents were working.

I'm wondering—and I don't have any doubt that some children really benefit from Ritalin and really need it, but I'm also wondering is somebody studying where there may be some sort of a social cause of this, that maybe this is in some way a voice crying out for attention that they're not getting?

Dr. NAKAMURA. There is—

Mr. DUNCAN. Because there sure is a cause of the serious crime in this country, I can tell you that.

Dr. NAKAMURA. There are a lot of social changes that are going on in our country and—

Mr. DUNCAN. Wouldn't that also help explain why possibly that some of these other industrialized nations are not seeing nearly as much of this as we are, because they don't have as much of the breakdown of the family as we do?

Dr. NAKAMURA. We don't know the answer to that. There are social changes that are going on with great rapidity in our country, and we are trying to figure out ways with which we might measure what effect these might have on subsequent behaviors. There is a

proposal for a large-scale study of a birth cohort by the National Child Health Institute in which they would propose to look at 100,000 births following these children, understanding everything that they are consuming, their vaccinations, how the family is structured, etc., to see how those might relate ultimately to disease and other behavioral problems, as well as medical problems. So there are proposals to do that. This would be extremely expensive.

Mr. DUNCAN. Thank you.

Mr. BURTON. Let me just followup. You said that you thought 3 million children or thereabouts was on Ritalin or similar products?

Dr. NAKAMURA. Yes.

Mr. BURTON. We've been told it's 6 million. Why is it you don't have some idea? Can't you find out from the drug company how many prescriptions are being written for that?

Dr. NAKAMURA. Yes. We do—we are aware of how many prescriptions. Relating that to the number of individuals is a little trickier. I'm sure I could get you the information that we have for the record on what is the number that we are able to document.

Mr. BURTON. OK. Now, Novartis gave \$748,000 plus \$100,000 last year to this organization called CHADD. You don't see anything wrong with that?

Dr. NAKAMURA. Organizations which—many organizations receive money from companies, and I guess my feeling is that with much of it, as long as that's revealed, it is—

Mr. BURTON. It's OK, even though they're touting their own product? What about the \$750,000 that the FDA gave to them for the same reason?

You know, I hope, if one thing comes out of this, that you'll get information to all of the school boards in the country and the State school superintendents saying that there is a prescribed policy that should be followed before you put children on these drugs, not just some checklist that a teacher comes up with. That's very important.

You think that needs to be done, but most people out there in the hinterlands don't know that.

Now, my grandson—and we all talk about our personal experiences—he got nine shots in 1 day and got 47 times the amount of mercury that was tolerable in an adult, and 2 days later he became autistic. Like I told you earlier, we've gone from 1 in 10,000 to 1 in 250 kids, according to our health agencies, your health agencies, that have autism, they're autistic, so it is an absolute epidemic.

I wanted to show you, since you weren't familiar with this, a tape we got from Canada on what happens when mercury is introduced into the neurons of the brain.

Can you roll that tape real quick.

[Videotape presentation.]

Male VOICE. How mercury causes brain neuron degeneration: mercury has long been known to be a potent neurotoxic substance, whether it is inhaled or consumed in the diet as a food contaminant. Over the past 15 years, medical research laboratories have established that dental amalgam tooth fillings are a major contributor to mercury body burden.

In 1997, a team of research scientists demonstrated that mercury vapor inhalation by animals produced a molecular lesion in brain protein metabolism which was similar to a lesion seen in 80 percent of Alzheimer-diseased brains.

Recently completed experiments by scientists at the University of Calgary's faculty of medicine now reveal, with direct visual evidence from brain neuron tissue



cultures, how mercury ions actually alter the cell membrane structure of developing neurons.

To better understand mercury's effect on the brain, let us first illustrate what brain neurons look like and how they grow. In this animation, we see three brain neurons growing in a tissue culture, each with a central cell body and numerous neurite processes. At the end of each neurite is a growth cone where structural proteins are assembled to form a cell membrane. Two principal proteins involved in growth cone function are actin, which is responsible for the pulsating motion seen here, and tubulin, a major structural component of the neurite membrane.

During normal cell growth, tubulin molecules link together end to end to form micro-tubules, which surround neurofibros, another structural protein component of the neuronal axon.

Shown here is the neurite of a live neuron isolated from snail brain tissue displaying linear growth due to growth cone activity. It is important to note that growth cones in all animal species, ranging from snails to humans, have identical structural and behavioral characteristics and use proteins of virtually identical composition.

In this experiment, neurons also isolated from snail brain tissue were grown in culture for several days, after which very low concentrations of mercury were added to the culture medium for 20 minutes. Over the next 30 minutes the neurite membrane underwent rapid degeneration, leaving behind the denuded neurofibrils seen here.

In contrast, other heavy metals added to this same concentration, such as aluminum, lead, cadmium, and manganese, did not produce this effect.

To understand how mercury causes this degeneration, let us return to our illustration. As mentioned before, tubulin proteins link together during normal cell growth to form the micro-tubules which support the neurite structure. When mercury ions are introduced into the culture medium, they infiltrate the cell and bind themselves to newly synthesized tubulin molecules.

More specifically, the mercury ions attach themselves to the binding site reserved for guanine triphosphate, or GTP, on the beta sub-unit of the affected tubulin molecules. Since bound GTP normally provides the energy which allows tubulin molecules to attach to one another, mercury ions bound to these sites prevent tubulin proteins from linking together. Consequently, the neurite's micro-tubules begin to disassemble into free-tubulin molecules, leaving the neurite stripped of its supporting structure.

Ultimately, both the developing neurite and its growth cone collapse and some denuded neurofibrils form aggregates or tangles, as depicted here.

Shown here is a neurite growth cone stained specifically for tubulin and actin before and after mercury exposure. Note that the mercury has caused disintegration of tubulin microtubule structure.

These new findings reveal important visual evidence as to how mercury causes neurodegeneration. More importantly, the study provides the first direct evidence that low-level mercury exposure is, indeed, a precipitating factor that can initiate—

[End of videotape presentation, stopped mid-sentence.]

Mr. BURTON. OK. Here's the point—and you're talking to a layman, not a scientist, but I can see, and we've looked at these things before, and I've had the finest minds around the world before this committee. Mercury causes a degeneration in the brain tissues. It's a contributing factor, according to many, many scientists, in Alzheimer's and autism and other neurological problems in children.

Now, it doesn't take a rocket scientist to be able to see that we need to get that substance out of anything going into the body. You in health agencies took it out of mercurochrome. You took it out of topical dressings. The reason you did that was because you said it leaches into the skin and can cause neurological problems.

Yet, you're still sticking it into our kids and we have an epidemic that has gone from 1 in 10,000 to 1 in 250 kids in this country, and we're going to have to take care of those people. It's going to be a nuclear bomb on our economy at some point in the future.

Now, you're talking about today Ritalin and how we need Ritalin and how all these kids in schools and these young kids are having to get it because of the way they act. A lot of that may be caused

by the introduction of mercury and other toxic substances into the body, so it seems to me logically that the first step you take in the health agencies is get mercury and these toxic substances out of our vaccines.

We have not done that here in the United States, and really, much to my chagrin, in most of the vaccines we're exporting to Third World countries we're keeping it in there. We're not even trying to take it out, which means we're going to be causing these problems all around the world.

Now, all I'd like to end up saying to you, from my perspective, is: let's get mercury out of all of these vaccines. Let's look at whether or not the amalgams, as was indicated—we all have fillings in our teeth, and these amalgams—and I've already had my mouth tested. I had five of these amalgams taken out. But I had a very high rate of mercury vapor when I chewed and everything that was getting out in my mouth, and that would leach into the brain. Maybe that's part of my problem. I don't know.

But the point is: why don't we start, as our health agencies, to look at getting mercury out of any substance that goes into the human body or is in close proximity to it? And then, after we do that, we may not need to be giving these kids these mind-altering drugs, because many of them may not be adversely affected.

Now, if you do that and you start informing our educational institutions of the criteria that should be used before you start giving these kids Ritalin, I think you'll solve a lot of these problems. And I also think our health agencies ought to take a hard look at whether or not pharmaceutical companies should have influence on the dispersion of these things and the usage of these things by using their money to create a wider body of users, which is what they're doing.

I know that a lot of—there's a revolving door over at the health agencies where people go to the pharmaceutical companies, come over to health agencies, and go back, and we've looked at their financial disclosure forms and we've seen some things that were very curious there—people on Advisory Committees that have a vested interest in getting products passed into the mainstream of use here in this country.

I'm not going to talk any more about this, but I hope that those of you from our health agencies who have heard what we had to say today, what I had to say, will take that message back, because it is going to be a broken record. It ain't going to go away as long as I am in Congress and as long as we have committees like this.

I've talked enough. Do any of my colleagues have any more questions for this gentleman?

Mrs. JOANN DAVIS OF VIRGINIA. Just one quick question, Mr. Chairman.

In your research, have you found any difference in—any discrepancies in boys versus girls with ADHD?

Dr. NAKAMURA. There are differences in behavior, but they both respond to Ritalin.

Mrs. JOANN DAVIS OF VIRGINIA. I guess "discrepancy" is not the word I wanted. Do there seem to be more boys, more girls?

Dr. NAKAMURA. Definitely more boys.

Mrs. JOANN DAVIS OF VIRGINIA. By a wide majority?

Dr. NAKAMURA. Four to one.

Mrs. JOANN DAVIS OF VIRGINIA. Thank you.

Mr. BURTON. Mr. Gilman.

Mr. GILMAN. Just one question, Mr. Chairman.

Doctor, would your NIH consider a long-term study, a study of the long-term effects of Ritalin? I don't think any study has been undertaken, from the testimony we've heard.

Dr. NAKAMURA. Right. We have an ongoing study of Ritalin which is anticipated to be long term—that is, we will follow children for many years.

Mr. GILMAN. That's encouraging. Thank you very much. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Horn, anything else?

Mr. HORN. No. Just on the last point made by Mr. Gilman, have you got the National Academy of Science and Medicine? Are they doing it, or is it simply done within the NIH?

Dr. NAKAMURA. It's being funded by the NIH. The National Academy of Science doesn't actually conduct studies, they review studies.

Mr. HORN. Well, it might be worthwhile to get some people that are not completely involved within NIH and take a look. That's exactly what they're there for. We use them all the time here.

Dr. NAKAMURA. OK.

Mr. BURTON. Thank you, Dr. Nakamura. We have some questions we'd like to submit for the record. If you'd consent to answer those and send them back to us, we'd appreciate it.

Dr. NAKAMURA. Absolutely.

Mr. BURTON. OK. Thank you very much.

Dr. NAKAMURA. Thank you.

Mr. BURTON. We have one more panel, and this last panel consists of: E. Clarke Ross, CEO of Children and Adults with Attention Deficit Hyperactivity Disorder; David Fassler, a doctor who is a representative of the American Psychiatric Association and American Academy of Child and Adolescent Psychiatry.

Do you gentleman have an opening statement? Let me swear you in.

Do you swear to tell the whole truth and nothing but the truth so help you God?

Mr. ROSS. Yes.

Mr. FASSLER. Yes.

Mr. BURTON. Do you want to start, Mr. Ross?

Mr. GILMAN. Mr. Chairman, if I might interrupt, I have to go to another meeting. Could I ask just one question of Mr. Ross before I have to leave?

Mr. BURTON. Sure.

Mr. GILMAN. Mr. Ross, isn't it true that CHADD received a grant award of \$750,000 from the CDC to establish and operate the National Resource Center on ADHD?

Mr. ROSS. Yes. We were awarded a \$750,000 grant from the Centers for Disease Control and Prevention to operate a National Resource Center on ADHD.

Mr. GILMAN. And have your membership been made aware that those funds came from a pharmaceutical company?

Mr. ROSS. The money did not come from pharmaceutical companies. The CDC funds came from an appropriation of Congress administered by the Centers for Disease Control and Prevention.

Mr. BURTON. If the gentleman would yield—

Mr. GILMAN. I would be pleased to.

Mr. BURTON. If the gentleman would yield, you did get \$748,000 from Novartis.

Mr. ROSS. Of our budget, 18 percent currently—

Mr. BURTON. No. You got that money?

Mr. ROSS. Over a 3-year period in the mid-1990's before I was there we did.

Mr. BURTON. Did you get \$100,000 last year?

Mr. ROSS. We got \$700,000 from the pharmaceutical industry in its entirety in the last year, which is 18 percent of our budget. I didn't bring a breakout of each company, but it is on our Web site, it is in our IRS returns, and I'm happy to provide it to the committee. But 18 percent of our budget is derived, like most every other voluntary health agencies in America, whether it's the Epilepsy Foundation, diabetes, cancer, heart, or the National Health Council, which is the umbrella group. We try to diversify our funding and we try to receive corporate funding as well as membership donations and Federal funds.

Mr. GILMAN. One last comment on that. The DEA stated that \$748,000 to CHADD from 1991 to 1994 came from the manufacturer of Ritalin; is that correct?

Mr. ROSS. The then owner, which has subsequently become Novartis, gave CHADD roughly that amount of money in that 3-year period. Yes.

Mr. GILMAN. Was that made known to your membership?

Mr. ROSS. Yes. It is on our Web site. You'll see who all our corporate donors are, how much they give, and the totality of our budget.

Mr. GILMAN. Thank you.

Thank you, Mr. Chairman.

Mr. BURTON. Proceed, Mr. Ross.

**STATEMENTS OF E. CLARKE ROSS, CHIEF EXECUTIVE OFFICER OF CHADD—CHILDREN AND ADULTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER, LANDOVER, MD; AND DAVID FASSLER, M.D., REPRESENTATIVE, AMERICAN PSYCHIATRIC ASSOCIATION, AND AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY, WASHINGTON, DC**

Mr. ROSS. I'm here today to talk not only as the CEO of CHADD, but as the father of an 11-year-old son with inattentive type ADHD, anxiety disorder, and a variety of other challenges and learning disorders, and a boy who has a history of challenges. He had seizures, unprovoked seizures, when he was 21 months old. At Johns Hopkins University at Kennedy Krieger we've had a complete blood metabolic workup when he was 3 or 4 years old to try to determine things like mercury, lead, and other possible contributions to his challenges. Andrew has a series of developmental problems. Inattentive ADHD was not recognized until he was 4 in his first group learning situation, and teachers noticed that he was in-

attentive. He did not pay any attention to what was going on around him.

So I'm here to speak as a parent of an 11-year-old son that we deal with daily with major challenges, and that experience, as well as the CEO of CHADD.

What CHADD does—and I do have a written statement that I'd like to have in the record—what CHADD does is disseminate the science-based information, and that's why the Centers for Disease Control and Prevention have given us a grant to do that, and we rely on things like the U.S. Surgeon General Report on Mental Health and the ADHD, and Dr. Nakamura and NIMH, and the National Institutes of Health, and the professional societies like American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, the American Academy of Pediatrics. That's what 20,000 family members of CHADD rely on the science, the Federal agencies and the professional community.

The highest importance at the moment are guidelines that have been mentioned before. The American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry have issued best practice treatment guidelines on how to assess and treat ADHD, and the recommendation of the Surgeon General, the recommendation of NIMH, and the recommendation of the two professional academies is what's called a multimodal treatment. It is not medication as a first entry, it is a multimodal treatment, which are behavioral interventions, counseling interventions, special education interventions, and, if needed, medication use. We've done all of that in our family with our son, Andrew.

We have also tried a variety of other complementary or so-called "alternative interventions." None of them have done harm, but none of them have had any impact, and medication actually did have an impact on Andrew, our son.

Andrew's life is filled with dedicated clinicians, from a pediatrician to a child psychiatrist to a child psychologist to a neurologist to a speech pathologist and to a team of educators. Without their collective support, I cannot imagine where Andrew would be today. Andrew is making steady progress. He is dealing with his anxiety. He is dealing with his inattentiveness. He's dealing with his learning challenges, but he has major challenges, and for those who want to dismiss the professional community, the 20,000 family members in CHADD rely on the psychiatrist and the pediatrician and the psychologist for their professional advice, and my wife and I rely on our clinical team and we appreciate our clinical team, and they've made a huge difference in Andrew's quality of life and his future.

So we didn't fabricate disorders in Andrew. At age 11 months he broke his ankle, and was put in a cast. When the cast came off we all—I've had a couple broken ankles in my life. When the cast comes off we all have pain and stiffness as we try to push that ankle down. Andrew's ankle never went down. Andrew's ankle stayed in the position of the cast. And so we went to Johns Hopkins University Medical Center. Andrew has some developmental challenges, and he happens to have inattentive type of ADHD.

The multimodal treatment study of NIMH showed that 69 percent of children with ADHD have co-occurring disorders, so this

complicates the entire picture. Is it ADHD? Is it bipolar disorder? Is it anxiety disorder? Is it learning disabilities? Is it a reaction to allergies and mercury? These are very complex assessments to be made in a child, and the reason we at CHADD and the 20,000 members of CHADD advocate the pediatrician and child and adolescent psychiatry guidelines, which Dr. Fassler will talk about, is that they are a comprehensive assessment. It's not a 10-minute review and then medication.

At age 4, when teachers told us Andrew was not paying attention in the class and was very distractible, we went to a psychiatrist. The psychiatrist recommended Ritalin. We were not prepared to do that at age 4 and we said, "No, we're going to try other interventions," and we tried a whole host of other interventions.

By age 7, with all these other interventions tried, Andrew was still inattentive, he was still easily distractible, and so we tried Ritalin, which actually didn't even work, and we tried Dexedrin, which also didn't work. Then we tried Adderall, and Adderall had an immediate impact on Andrew's ability to attend to his day, to use a checklist so he can organize his immediate day, whether it's getting ready for school, going to bed at night, or in school. Parents don't rush—some may, but parents—the 20,000 members of CHADD—don't rush in and say, "Give us medication. We just want medication." Their children have functional challenges in their child in their daily life and they want help and they rely on the professional community and they rely on the science.

In our case, we took 3 years of reluctance to medicate, but when we medicated we had this immediate impact that was positive.

So the question is: should we have medicated at age 4 or should we have waited until age 7? That's every family's individual decision in consultation with their doctor. We waited, and that was our decision, and Andrew had a lot of problems from age 4 to 7 but that's hindsight. Every family has to figure that out.

The statistics show that stimulant medication works in 25 to 90 percent of children, so if you reverse that it doesn't work in 10 to 25 percent of children and there are going to be side effects, and you have to seriously think about that and know that. Ms. Weathers' point about informed consent is basic to a family. We need to know what the positive attributes of an intervention are, including medication, and we need to know the possible side effects, and communicate not every 4 months with your doctor, but communicate a couple times a month with the doctor on dose level, side effects. And we have that relationship in our family with our clinical team.

Mr. BURTON. Mr. Ross, would it be possible for you to sum up so we can get on with the questions?

Mr. ROSS. Yes.

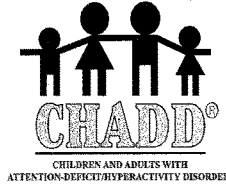
Mr. BURTON. I know you have a lot that you want to tell us about, and we'll be glad to get to that.

Mr. ROSS. I've made all the major points I want to make—the importance of the science, the importance of a clinical team, the

importance of comprehensiveness, the importance of the pediatricians and child and adolescent psychiatry guidelines and how complex this is, because many of the children have co-occurring disorders. So I'll rest.

Mr. BURTON. Thank you, Mr. Ross.

[The prepared statement of Mr. Ross follows:]



**Statement to the House Committee on Government Reform  
September 26, 2002**

**“Attention Deficit/Hyperactivity Disorders – Are Children  
Being Over Medicated?”**

**Statement by E. Clarke Ross, Chief Executive Officer, CHADD  
(Children and Adults with Attention-Deficit/Hyperactivity Disorder)  
8181 Professional Place, Suite 201, Landover, Maryland 20785**

Mr. Chairman and Members of the Committee: My name is Clarke Ross. I am the Chief Executive Officer of CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder).

Headquartered in the greater Washington area, CHADD is the nation’s leading advocacy organization serving individuals and families dealing with AD/HD. Under the guidance of the world’s leading AD/HD experts, CHADD works to improve the lives of those with AD/HD and their families through advocacy, education, research and support. CHADD currently serves 20,000 dues-paying members in 246 chapters located in 37 states and Puerto Rico.

CHADD educates the public about AD/HD primarily through dissemination of practices, policies, research and published papers issued by the nation’s leading scientific and medical institutions. This includes the publications and research of the United States Surgeon General, the National Institutes of Health, the National Institute of Mental Health, and the professional societies of physicians and other treating professionals and researchers in the mental health field.

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Of utmost importance to CHADD are the evidence-based assessment and treatment guidelines of the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry. This body of evidence-based research emphasizes the importance of what is known as “multi-modal treatment.”

Multi-modal treatment includes parent training in diagnosis, treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required.

Also of interest to CHADD are complementary interventions used in the treatment of AD/HD. While CHADD is not opposed to complementary interventions, it strongly believes further research is necessary and advocates that NIH, NIMH, and others in the research community conduct further investigation to determine the efficacy of these complementary interventions.

#### **The Story of One 11 Year Old Boy – Andrew Ross**

Perhaps even more important than my role as CEO of CHADD, is my role as father to an eleven-year-old son, Andrew, diagnosed with the inattentive type of AD/HD, an anxiety disorder, and other related co-occurring learning disorders.

Like many families facing AD/HD and related conditions, my wife and I, over time, have employed a wide array of interventions, including several considered complementary in nature, which are described in greater detail further in this statement. None of the complementary interventions we employed were harmful. But perhaps most significant, none of them have demonstrated an impact. Moreover, none of them are supported by the evidence-based research to which we are firmly committed.

In short, the multi-modal approach described above -- parent training in diagnosis, treatment and specific behavior management techniques, an appropriate educational

program, individual and family counseling when needed and, for us, medication provided and continue to provide the support that Andrew needs in order to thrive and flourish.

### **Background**

Andrew was born following a complicated delivery. When at age 11 months, he broke his ankle (which would not heal properly), follow-up assessments documented significant hypotonia and sensory integration challenges. At 21 months, he experienced his first unprovoked seizure with a pattern of seizures continuing for the next several years. Two EEGs later, many problems were confirmed. By two and still not speaking, Andrew's pediatrician referred him to the State of Maryland's Early Education Program. For the next several years he received intensive speech and language and sensory integration services. Andrew also has dysgraphia, which can best be described as a difficulty in automatically remembering and mastering the sequence of muscle motor movements needed in writing letters or numbers. Fortunately, with intensive assistance from the school occupational therapist, Andrew has largely overcome his dysgraphia.

By four, when Andrew entered a more formal education program, teachers began noting significant learning problems stemming directly from his inability to focus. He received numerous independent professional assessments, each affirming that his disabilities significantly impeded his ability to function at the level of his classmates. Andrew has always had difficulty with what now is referred to as "executive functioning" – brain actions of self control where he is unable to think ahead and consider "if-then" behaviors and their consequences.

My son does not have an occasional problem with distraction and attention. He has ongoing, continuous daily problems that result in overwhelming difficulties in many areas of his life.

No well-meaning parent sets out to medicate his or her child. Nor did we. But over time, given Andrew's learning and functional problems, we accepted the advice of child

psychiatrists who felt our son would benefit from medication. Today, Andrew takes both a medication for attention issues and a medication designed to reduce his anxiety. A series of behavioral management and learning assistance programs also are used and are an essential part of his overall treatment program.

At age four, a child psychiatrist recommended that Andrew try a stimulant medication. We initially said no, as we wanted to first try other interventions. But by the time Andrew was seven, we said yes to stimulant medication. The other interventions had not worked in helping him pay attention. We now were ready to try medication.

We actually tried three medications before we found one that worked. The first two did not help his attention (nor did they have any side effects), but the third one did have significant results. To this day Andrew takes Adderall.

Andrew began using Prozac two and a half years ago because of a severe anxiety problem. He is anxious about many things. As one example of many, Andrew was so afraid of flying insects that three summers ago he would not go outside despite his love of baseball and basketball. A combination of behavioral interventions, cognitive training and medication has helped to reduce his anxiety. He remains uncomfortable with flying insects and bristles stiffly when they are around, but generally speaking he now can function quite normally. But his anxiety was not singularly confined to flying insects. Andrew is anxious about many things and many situations. As such, my wife and I are constantly developing behavioral interventions to deal with these varied anxieties.

Medication obviously is not perfect. For example, Andrew initially experienced a significant loss in appetite. Today, however, he only experiences a loss of appetite at lunch, proof that there are continual tradeoffs in the beneficial use of medication and side effects from such use. On the plus side, however, with the assistance of special education personnel and a multimodal treatment approach in place, including medication, Andrew can now better attend to learning in class, is less phobic, and demonstrates more socially appropriate behaviors with children his age.

As the parent of a child with multiple challenges, I resent those who suggest that my son needs only a little more discipline, structure, and learning. In direct contrast to the publications issued today by some of the hearing witnesses, I want to emphatically say that my son's problems are neither "lies" nor "frauds" nor the "failures of his parents." Andrew has a biologically based brain disorder that we and an extensive network of dedicated clinicians face and address on a daily basis. Andrew's life is filled with dedicated clinicians – from pediatrician, to child psychiatrist, to child psychologist, to neurologist, to speech pathologist, to a team of educators. Without their collective support, I cannot imagine where Andrew would be today.

As mentioned previously, we employ a variety of complementary approaches. These include visualizing and verbalizing training, sensory integration therapy, and visual tracking. Andrew responds best in small learning groups where constant feedback and support is provided. We use Dr. Thomas Phelan's 1-2-3 Magic approaches each and every day. And every day Andrew consumes fish oil supplements (Omega-3 Fatty Acids). But as noted above, while certainly not harmful, none of these interventions (other than 1-2-3 Magic) have yielded any immediate or even long-lasting positive impact upon Andrew.

The good news is that Andrew is making progress. The strides are slow yet steady. And like most families in similar circumstances, we are resolved to living life one day at a time. I share my wife's and my story with the hope that those unfamiliar with AD/HD will appreciate the complexity and difficulty of identifying and implementing key medical strategies designed to help children like our son Andrew.

### **The Evidence-Based Science**

In looking at the broader AD/HD picture – particularly with respect to the emergence of evidence-based science—it is essential to note the following key milestones:

- In 1998, the American Medical Association published an exhaustive review of the scientific literature concerning AD/HD, concluding that the disorder is real and that while there may be instances of over diagnosis, *there is a greater problem of under diagnosis.*
- In 1999, the National Institute of Mental Health (NIMH) published its first results from The Multimodal Treatment Study of Children with Attention-Deficit/Hyperactivity Disorder, a multicenter study evaluating the leading treatments for ADHD, including various forms of behavior therapy and medications, in nearly 600 elementary school children. The results indicate that long-term combination treatments as well as medication management alone are both significantly superior to intensive behavioral treatments and routine community treatments in reducing AD/HD symptoms.
- In 1999, the U.S. Surgeon General released the landmark Report on Mental Health, which devotes an entire section to the evidence-based science behind AD/HD. Among the important findings are that stimulants are highly effective for 75-90% of children with AD/HD, while the most effective interventions for AD/HD are multimodal treatment—which involves the use of medication with psychosocial, behavioral and related interventions. Finally, "recent reports found little evidence of over diagnosis of AD/HD or over prescription of stimulant medications. Indeed fewer children (2-3% of school-aged children) are being treated for AD/HD than suffer from it."
- First in 2000 for assessment, and then in 2001 for treatment, the American Academy of Pediatrics (AAP) published clinical practice guidelines for AD/HD. These groundbreaking guidelines include endorsement of stimulant medications when appropriate monitoring and behavior interventions are also used.

- In 2002, the American Academy of Child and Adolescent Psychiatry (AACAP) published practice parameters for the use of stimulant medications in the treatment of children, adolescents and adults. The parameters rely on an evidence-based medicine approach derived from a detailed literature review and expert opinion.

#### **Some Children are Treated Inappropriately; Some Children are Under-Treated**

In reviewing the developments above, it is simultaneously essential to note that both U.S. Surgeon General's reports on mental health (1999 on mental health research, and the 2001 report on race and culture) emphasize that some children are inappropriately identified while many children are *never* identified.

It therefore also becomes essential to comment upon public alarm that "AD/HD is over-identified and over-medicated" because of the over 700% increase in the use of stimulant medication in the school age population over the past decade. Before resorting to alarmist reactions, let us first examine the prevalence rate.

- The U.S. Surgeon General estimates the school-age prevalence of AD/HD to be between 3 and 5%. Even with the over 700% increase in stimulant medication use over the past decade, only 2 to 2.5 % of the school-age population currently receive stimulant medication. If medication is an appropriate component of multi-modal treatment intervention (as the science informs us), then over half of those suffering the effects of AD/HD are not being effectively treated.
- The 3-to-5% prevalence rate may actually be a conservative rate. Two published studies by the Mayo Clinic of Rochester, Minnesota, one in the January 2001 issue of the Journal of the American Medical Association and the other in the March 2002 issue of the Archives of Pediatrics and Adolescent Medicine documented that 7.5% of all children presenting for any kind of medical treatment in Rochester over a seven year period had AD/HD.

What is particularly alarming to CHADD is the tremendous variance of stimulant medication prescribing practices across the nation. While Dr. Julie Zito of the University of Maryland and Dr. Gretchen LeFever of Eastern Virginia Medical School have published studies about the significant variance within Maryland and Virginia, probably the single most informative published study was the May 6, 2001 Cleveland Plain Dealer article, "Ritalin Prescribed Unevenly in U.S." The paper's reporters studied for one full year the actual prescriptions written in every county in the nation. Some counties had 5% of the total school-age population and 20% of school-age boys on stimulant medication while other counties had practically no one receiving a stimulant medication. CHADD remains alarmed with this variance of practice.

CHADD believes that the single most important reason for such variance is the absence in clinical practice of the use of the AAP and AACAP evidence-based assessment and treatment guidelines. That is why CHADD is tirelessly working to educate the public about the AAP and AACAP guidelines and to advocate that physicians using such guidelines be financially reimbursed by health insurance payers at a higher rate than physicians not using such guidelines.

We also need better research about the prevalence of AD/HD and the number of children actually receiving such medication. While the Cleveland Plain Dealer and others have studied the numbers of prescriptions written, we really have no excellent database on actual numbers of children receiving such medications on a regular basis. Certainly, we must protect the confidentiality of individual children and their families, but we also need better aggregate data on overall usage.

For example, consider the data. The United States General Accounting Office in 2001 stated that there were 46.6 million public school students. Three-to-five percent of this total would be between 1.4 to 2.3 million children, not including students in both private school or home-school settings. If we use the Mayo Clinic 7.5 % prevalence rate, then 3.26 million school age children would be expected to have AD/HD – an appropriate number given such rates. CHADD commends the Centers for Disease Control and

Prevention (CDC) for recognizing the need to better assess accurate prevalence rates, including funding for three prevalence studies.

**CHADD Reiterates Key Role Physicians, Teachers, and Families Play in Recognizing and Treating AD/HD**

CHADD is concerned that without proper context, and when sensationalized, alarmist statements and reports create confusion among the general public, patients and families, thus undermining the seriousness of AD/HD and the proven safety and efficacy of stimulant medications when properly administered by appropriate professionals.

CHADD believes that all families should have access to the best, evidence-based science in the diagnosis and treatment of AD/HD. We are therefore concerned when legislation is proposed that undermines this critical access—including the elimination of a teacher's freedom to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations. Likewise, CHADD is appalled when children are inappropriately prescribed medication that they do not need. This is of particular concern when small subsets of children suffer significant side effects.

CHADD believes that legislation must not limit or undermine the ability of a medical professional, within their scope of practice, from treating AD/HD based on the most widely accepted evidence-based science. CHADD encourages all families and physicians to follow best practice assessment and treatment guidelines being uniformly implemented throughout the nation, specifically the current American Academy of Pediatrics (AAP) and American Academy of Child and Adolescent Psychiatry (AACAP) guidelines. Using the force of law and agencies of government—particularly criminal penalties—to monitor and enforce best practice treatment guidelines is an ineffective approach at best and disastrous approach at worst. Instead, ongoing training and education in the diagnosis and treatment of AD/HD should be encouraged among all physicians.



Teachers are frequently the first to recognize learning, functioning, and behavioral problems in the school setting and therefore should be able to advise parents of such observations. CHADD believes that professionals should act within their professional scope of practice. Thus, school personnel should not recommend the use of medication. Medication assessment and prescription is the role of the physician and—under limited circumstances—in a few states, other treating professionals too. However, teachers should be able to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations.

Because students spend a significant portion of their day in the classroom, the vital role that teachers play in providing observations to the diagnosing professionals cannot be underestimated. Effective communication among teachers, professionals and parents is essential and strongly encouraged. CHADD advocates a multi-modal approach to the treatment of AD/HD, including parent training in diagnosis, treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required. Medication is used to improve the symptoms of AD/HD. Research shows that children and adults who take medication for the symptoms of AD/HD attribute their successes to themselves, not to the medication.

#### **Denial of AD/HD Refuted**

The organized interests at this hearing claiming that AD/HD is a “biological lie” also state that there are no “biological imbalances” and “no laboratory tests established as diagnostic” for AD/HD. They go on to claim that AD/HD is a “100 percent fraud.”

But science tells us a different story. The Surgeon General’s report (page 144) concludes “AD/HD is the most commonly diagnosed behavioral disorder in childhood and occurs in three to five percent of all school-age children. The exact etiology of AD/HD is unknown, although neurotransmitter deficits (such as the dopamine transmitter), genetics,

and perinatal complications have been implicated.” The NIH Panel Consensus statement declares: “Although an independent diagnostic test for AD/HD does not exist, there is evidence supporting the validity of the disorder.”

As previously stated, the NIMH MTA Study further documented that only 31% of the children with AD/HD have AD/HD alone with no other disorder. The study found that 40% of children with AD/HD had oppositional defiant disorder, 34% had anxiety disorder, 14% had conduct disorder, and 4% had a mood disorder. Those dismissing the existence of AD/HD repeatedly ignore these characteristics. A May 22 study by the Centers for Disease Control and Prevention (CDC) documented that half of the school age population with AD/HD also had a learning disability.

The existence of co-occurring disorders complicates assessment, complicates treatment, and increases the possibility of an inaccurate diagnosis. This only further reiterates the importance of the AAP and AACAP best practice guidelines.

### **Closing**

I have devoted over 30 years of my professional life assisting individuals with cerebral palsy, schizophrenia, bipolar disorder, AD/HD, and other mental disorders. I find it frustrating and disheartening that I have to defend recognized science against science fiction. This is demeaning to those suffering from these disorders and to the millions of families who devote their lives caring for and supporting their loved ones.

The science speaks for itself. Even more important are the stories of untold millions who have either been helped by appropriate interventions – or worse, been denied access to the treatment they deserve. Instead of wasting precious time, energy and resources defending a disorder that clearly exists, why can't we simply move forward in applying the science to clinical practice and educational settings to make life better for those faced with these challenges? Why do some policy makers continue to play to those who claim

that there are no mental disorders, that there is no science, and that anyone's science fiction is equivalent to the evidence-based science?

The reality that children and adolescents can and do suffer from AD/HD and other debilitating brain disorders, just as adults do, is finally being widely recognized. That is why we must continue educating others and ourselves about the broad spectrum of childhood mental disorders. We must continue joining forces with the scientific institutions and others. And we must do everything within our means to ensure that our children receive the tools they need to live a meaningful life, regardless of their disability, challenge or disorder.

#### **E. Clarke Ross**

As required by committee rule 12 and as requested in the committee's September 20 letter of request, the following biographical information is provided:

- Clarke Ross currently serves as the Chief Executive Officer of CHADD – Children and Adults with Attention-Deficit/Hyperactivity Disorder.
- Previous positions include Deputy Executive Director for Public Policy, NAMI – National Alliance for the Mentally Ill; Executive Director, American Managed Behavioral Healthcare Association; Assistant Executive Director for Federal Relations and then Deputy Executive Director, National Association of State Mental Health Program Directors (NASMHPD); Assistant Professor of Public Administration, Troy State University-European Region (Weisbaden, Germany); and Director of Governmental Activities, UCPA – United Cerebral Palsy Associations.
- Clarke Ross is a Fellow of the American College of Mental Health Administration (ACMHA). His doctorate is in public administration from the George Washington University. A former VISTA volunteer, he has taught graduate classes for Central

Michigan University since 1983 and also for both the University of Maryland and Southeastern University.

- Dr. Ross is the editor of a textbook on managed behavioral health care – Aspen Publisher's 2001 Managed Behavioral Healthcare Handbook. Dr. Ross also is the author of the chapter on managed care in Mental Health, United States, 2000, the resource published every other year by the Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services.
- He is the father of an eleven-year-old son with special challenges.

#### **CHADD Federal Government Revenue and Other Income Sources**

As required by committee rule 12 and as requested in the committee's September 20 letter of invitation:

- CHADD is a family membership organization with over 20,000 members organized through 246 chapters in 37 states and Puerto Rico. Our web site, [www.chadd.org](http://www.chadd.org), provides an overview of the information and services we provide as well as a list of our chapters.
- With a significant federal government \$750,000 grant in August 2002, CHADD operates with a \$3.935 million annual budget. As of August 2002, the composition of the budget is: members dues and contributions: 30%; annual conference revenue: 19%; revenue from publications and related educational products and information: 7%; federal government support, 19%; and non-governmental and non-pharmaceutical grants and donations: 7%. Total pharmaceutical financial support of CHADD is 18% of CHADD's budget. This ratio of multiple funding sources is typical of national voluntary health agencies in America.

**CHADD's revenue sources from the federal government are:**

- Centers for Disease Control and Prevention (CDC) \$750,000 grant to establish and operate a National Resource Center on AD/HD.
- Center for Mental Health Services \$150,000 subcontract with the American Institutes for Research to conduct community forums and increase participation within CHADD for the purposes of cultural competence and diversity promotion in order to better educate the public about AD/HD and related childhood mental disorders.
- Centers for Mental Health Services \$20,000 subcontract with Triumph-Technologies to conduct focus groups of families and adults with AD/HD to learn and document their unmet needs for services and supports.

**CHADD recognizes that membership and support of members through local chapters is a key factor in assisting and advocating for persons with AD/HD.**

**CHADD also operates under a statement of "Ethical Principles for Acceptance of Support."**

- An excerpt from that statement reads: "While CHADD is committed to achieving a diversified base of corporate support and actively seeks contributions from businesses and corporations with no direct financial interest in AD/HD, CHADD believes it is ethically sound to request business concerns that profit from AD/HD to devote a portion of those profits to support charitable endeavors that will benefit people with AD/HD. At the same time, CHADD is committed to avoiding a conflict of interest or even its appearance in accepting financial support from corporations with vested interests in how consumers, the health care community, and education professionals regard their products. To assure that conflicts of interest do not occur, CHADD's Board of Directors has determined that acceptance of substantial restricted or unrestricted gifts from commercial enterprises and foundations, and CHADD's

subsequent relationship with these donors, shall be governed by a strict set of ethical principles that requires mutual agreement by CHADD and its donors.” The complete statement is available from our web site, [www.chadd.org](http://www.chadd.org).

- As a member of the National Health Council, CHADD complies with the good operating practices for the entire voluntary health agency movement. Information on the National Health Council is available from [www.nationalhealthcouncil.org](http://www.nationalhealthcouncil.org).

E. Clarke Ross, September 23, 2002

Mr. BURTON. Dr. Fassler.

Dr. FASSLER. Thank you.

My name is David Fassler. I'm a Board-certified child and adolescent psychiatrist practicing in Burlington, Vermont. I'm a clinical associate professor in the Department of Psychiatry at the University of Vermont College of Medicine. I currently serve as the president of the Vermont Association of Child and Adolescent Psychiatry. I'm also a trustee of the American Psychiatric Association and a member of the Governing Council of the American Academy of Child and Adolescent Psychiatry.

First of all, let me thank Representative Burton and the committee for the opportunity to appear here today. My testimony is on behalf of the APA and the Academy, and I'd appreciate if my written remarks are entered into the record.

The American Psychiatric Association is a medical specialty society representing over 38,000 psychiatric physicians. The American Academy of Child and Adolescent Psychiatry is a national professional association representing over 65,000 child and adolescent psychiatrists who are physicians with at least 5 years of specialized training after medical school emphasizing the diagnosis and treatment of mental illness in children and adolescents.

I'm happy to be able to talk to you about the diagnosis and treatment of attention deficit hyperactivity disorder, or ADHD, and to underscore some of the comments that you've already heard.

As a psychiatrist, when I think of ADHD, I think first of the faces of children and families who I've seen over the years. I think, in particular, of a 7-year-old boy who was about to be left back in second grade due to his disruptive behavior. The teachers have labeled him "difficult to control." The other kids just call him weird. He has few friends and he's already convinced that he's bad and different. And I think of a 12-year-old girl with an IQ of 130. She's not disruptive, but she's failing seventh grade. And I think of a 28-year-old administrative assistant who was relieved and appreciative when he received an accurate diagnosis and appropriate treatment for his longstanding condition. But I also remember his anger and frustration because, in his words, he missed out on 20 years of his life.

As you've already heard, according to NIMH, the National Institute of Mental Health, attention deficit hyperactivity disorder, or ADHD, is the most commonly diagnosed psychiatric disorder of childhood. It's estimated to affect approximately 5 percent of school-aged children, although published studies have identified a prevalence rate as high as 12 percent in some populations. As you've heard, it occurs between three and four times more often in boys than in girls.

We also know that ADHD does run in families and, contrary to previous beliefs, it doesn't always go away as you grow up. In fact, the latest research indicates that as many as half of all kids with ADHD continue to have problems into adulthood. This is actually one of the reasons we see an increase in the overall use of medication. We are now recognizing and treating more adults with ADHD.

I've brought for the committee the Diagnostic and Statistic Manual of Mental Disorders, the DSM-IV, which you've heard discussed

today and which is central to our understanding of a formal diagnosis of ADHD.

The key features, as has been explained, include inattention, hyperactivity, and impulsivity. I want to underscore one of the other elements that Dr. Nakamura spoke about, and that's that the symptoms must be interfering in the child's life at home, at school, or at work, or at work for an adult, or with their friends, with their peers, in two of those settings. So it's not just that you're agitated or you're active, but that it is really interfering with your life, with your ability to function in those settings.

The diagnostic criteria are quite specific and they are well established within the field. They are the product of extensive and numerous research studies conducted at academic centers and clinical facilities throughout the country. I've brought a number of the studies which have already been mentioned from the AMA, the Academy, Academy of Pediatrics, and the Surgeon General's report.

In addition, we now have a substantial body of research literature about both the genetic markers and the neuroanatomical abnormalities associated with this disorder, and you started to hear about some of it, some of the MRI, the CAT scan, the PET scan studies, and I think within the next year or two we will even be able to use some of these in a more diagnostic way.

Let me be very clear. ADHD is not an easy diagnosis to make and it's not a diagnosis that can be made in a 5 or a 10 or a 15-minute office visit. Many other problems, including hearing and vision problems, anxiety disorders, depression, learning disabilities, toxicity with heavy metals, can all present with signs and symptoms which look similar to ADHD. There's also a high degree of comorbidity, meaning that over half of the kids who have ADHD also have a second psychiatric problem.

As we heard this morning, the diagnosis of ADHD really requires a comprehensive assessment by a trained clinician. I don't think any of us you've heard today would disagree with that.

In addition to direct observation, the evaluation includes a review of the child's developmental, social, academic history, medical history, including evaluating the child for other medical conditions, including things like hyperthyroidism, the toxicities. We really need to rule those things out. It also should include input from the child's parents and teachers and a review of the child's records.

Schools play a critical role in identifying kids who are having problems, but, as you've heard already today, schools should not be making diagnoses and they should not be dictating treatment.

ADHD is also a condition which should not be taken lightly. Without proper treatment, a child with ADHD may fall behind in school work, may have problems at home and with friends. It can have long-term effects on the child's self esteem. It can lead to other problems in adolescence, including an increased risk of substance abuse that you've heard about, increased risk of adolescent pregnancy, increased risk of accidents including car accidents in adolescence, school failure, and an increased risk of trouble with the law.

The treatment of ADHD should be comprehensive and individualized to the needs of the child and the family. Medication, including methylphenidate or Ritalin, can be extremely helpful to many



children, but, consistent with the opening comments from Mrs. Davis, medication alone is rarely the appropriate treatment for complex child psychiatric disorders such as ADHD. Medication should only be used as part of a comprehensive treatment plan, which will usually include individual therapy, family support and counseling, and work with the schools.

In terms of methylphenidate, we have literally hundreds of studies over 30 years clearly demonstrating the effectiveness of this medication on many of the target symptoms of ADHD. As you've also heard, it is generally well tolerated by children with minimal side effects. Nonetheless, I share the concern that some children may be placed on medication without a comprehensive evaluation, an accurate and specific diagnosis, or an individualized treatment plan.

Let me also be very clear that I am similarly concerned about the many children with ADHD and other psychiatric disorders who would benefit from treatment, including treatment with medication, if appropriate, but who go unrecognized and undiagnosed and who are not receiving the help that they need.

Let me turn specifically to the question of over-diagnosis and over-treatment.

Just last week, a review article written by Peter Jenson was published which addressed this issue in detail. I have included Dr. Jenson's article in the background materials. Dr. Jenson is currently at Columbia University. He was formerly the associate director for child and adolescent research at the National Institute of Mental Health. He reviews all of the available scientific studies on this issue. He notes that most studies and media reports have not been based on actual diagnostic data, where people actually sat and interviewed children and reviewed records, but they've relied, instead, on information from an HMO or Medicaid medication data base.

Dr. Jenson and his colleagues actually performed comparative evaluations on 1,285 children in four communities—Atlanta; New Haven; Westchester; and San Juan, Puerto Rico—to determine the prevalence of ADHD, as well as the forms of treatment utilized. The results were that 5.1 percent of children and adolescents between the ages of 9 and 17 met the diagnostic criteria for ADHD, yet only 12.1 percent of these children, or approximately 1 in 8, were being treated with medication. So the majority of children with ADHD in this carefully controlled study were not being treated with medication, suggesting that, at least in these communities, medication is currently under-prescribed.

These authors also found 8 children out of these 1,285 who were receiving medication who did not meet the full diagnostic criteria for ADHD, although they did have high levels of ADHD symptoms.

Dr. Jenson concludes—and I would concur—that on the basis of these results there is no evidence of widespread over-treatment with medication. On the contrary, it appears that, at least in these communities, the majority of children with ADHD are not receiving what we would consider to be appropriate and effective treatment.

There's a second study from the Mayo Clinic in Rochester, Minnesota, which is in the background materials. In the interest of time, I will skip the details, other than to mention that in that

study of all children on medication for ADHD, only 0.2 percent, which is 2 children in 1,000, had no evidence of the disorder whatsoever. So, again, the second study, carefully conducted study, simply doesn't support the argument that ADHD is generally over-diagnosed or over-treated.

This is not to say that over-diagnosis or over-treatment doesn't happen in any areas or any communities, which is why we all need to continue our collective efforts to improve public awareness and to ensure access to comprehensive assessment services and individualized treatment using the kinds of evidence-based guidelines which you have been hearing about and which have now been developed.

Mr. BURTON. Dr. Fassler, can you summarize? We have some votes on the floor.

Dr. FASSLER. I am summarizing with my recommendations.

The APA and the Academy would offer the following specific recommendations for your consideration.

First, we fully support and would underscore the importance of accurate diagnosis and treatment which requires access to clinicians with appropriate training and expertise and sufficient time to permit a comprehensive assessment.

Next, we fully support the increased emphasis of the FDA and the NIMH on research on the appropriate use of medication in the psychiatric treatment of children and adolescents, and we welcome the expanded clinical trials and the longitudinal studies which you have been hearing about.

We also fully support the passage of comprehensive parity legislation at both the State and the Federal level.

We fully support and welcome all efforts to sustain and expand training programs for all child mental health professionals, including programs for child and adolescent psychiatrists.

And, finally, we fully support and appreciate the efforts of the current Administration, through the New Freedom Commission on Mental Health, to focus increased attention on the diagnosis and treatment of all psychiatric conditions, including those which affect children and adolescents.

In summary, let me emphasize that child psychiatric disorders, including ADHD, are very real and diagnosable illnesses which affect lots of kids. The good news is that they are also highly treatable. We can't cure all the kids we see, but with comprehensive, individualized intervention we can significantly reduce the extent to which their conditions interfere with their lives.

The key for parents and teachers is to identify kids with problems as early as possible and to make sure that they get the help that they need.

Thank you.

Mr. BURTON. Thank you, Doctor.

[The prepared statement of Dr. Fassler follows:]

**AMERICAN ACADEMY OF  
CHILD & ADOLESCENT  
PSYCHIATRY**

**American Academy of Child and Adolescent Psychiatry**

**American Psychiatric Association**

**Statement for the**

**House Government Reform Committee**

**September 26, 2002**

**2154 Rayburn House Office Building**

**Washington, DC**

**ADHD: Are We Over-Medicating Our Children?**

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### **Introduction**

My name is David Fassler. I'm a board certified child and adolescent psychiatrist practicing in Burlington, Vermont, and a member of the leadership boards for the American Academy of Child and Adolescent Psychiatry and the American Psychiatric Association. First, let me thank Representative Burton for the opportunity to appear before the Committee on Government Reform to testify regarding treatment of the psychiatric disorder attention-deficit hyperactivity disorder (ADHD). My testimony today is on behalf of the American Academy of Child and Adolescent Psychiatry (AACAP) and the American Psychiatric Association (APA). I ask that my written remarks be entered into the record.

The American Academy of Child and Adolescent Psychiatry (AACAP) is a medical membership association established by child and adolescent psychiatrists in 1954. Now over 6,500 members strong, the 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. AACAP supports research, continuing medical education and access to quality care. Child and adolescent psychiatrists are physicians fully trained in psychopharmacology. Child and adolescent psychiatrists prescribe medications as one part of a comprehensive treatment plan, which includes ongoing medical assessment, and individual and family therapy for treating psychiatric disorders in children and adolescents.

The APA is a medical specialty society, representing over 38,000 psychiatric physicians. AACAP is a national, professional association representing over 6,500 child and adolescent psychiatrists, who are physicians with at least five years of specialized training after medical school emphasizing the diagnosis and treatment of mental illness in children and adolescents.

### **General Status of Children's Mental Health**

The Surgeon General's 2000 report on children's mental health estimated that 20%, or about 14 million American children and adolescents aged 9 to 17, have a diagnosable mental or emotional illness. Of this number, fewer than one in five children receive treatment. Barriers to accessing treatment and services include a lack of affordability, lack of availability of specialists, including child and adolescent psychiatrists and psychiatrists, and stigma. The stigma carried by mental illnesses is often worse in children than in adults. Parents often worry that medications will stigmatize their child. The growing numbers of children and adolescents with mental illnesses underscore the importance of increased study of children's mental illnesses and the critical need for more effective treatment options, including new medications.

As a child and adolescent psychiatrist practicing in a mostly rural area, I understand the barriers to access to treatment for families dealing with a child's mental illness. This hearing presents an opportunity to examine one disorder that is most often diagnosed in childhood, and it also offers us a chance to look at where we are as a country when it comes to providing mental health services. This Congress is also considering whether to make parity for mental illnesses the law, and doing this would advance the timely assessing, diagnosing and treating of children with attention-deficit/hyperactivity (ADHD) disorder. We must be sure that this will be done accurately and appropriately.

### **Attention-deficit/hyperactivity, the Disorder**

It is important that this hearing's record contain accurate information about ADHD and its prevalence and the diagnosis and the treatment, including the use of medications. Research on this disorder is ongoing and extensive, and new findings are a constant, but children and adolescents showing symptoms that raise concerns should have access to timely assessment, appropriate diagnosis and treatment that is safe and effective. The periodic waves of media-attention questioning this disorder's prevalence and treatment are confusing to the public and understandably perplexing to legislators. Some reports on ADHD are carefully researched, balanced articles, defining the disorder and its treatment and educating readers. Other publications have caused confusion and spread misinformation. This hearing can make legislators and the public better able to judge the validity of information and clarify the myths about mental disorders such as ADHD.

*From the AACAP Practice Parameters for the Assessment and Treatment of Children, Adolescents, and Adults With Attention-Deficit/Hyperactivity Disorder*

Attention-deficit/hyperactivity disorder is one of the most common psychiatric disorders of childhood and adolescence. Recent clinical experience and research document the continuation of symptoms into adulthood. The literature on ADHD is voluminous, with literature searches revealing hundreds of studies on the disorder. As with all illnesses, mental or physical, research is ongoing with findings integrated into practices as they are made available through training or publication. The AMA's Council on Scientific Affairs 1997 report responded to a request from physicians that the AMA study the increasing number of diagnoses of ADHD and address public concern regarding possible over-prescription of ADHD medications." The report, which is in the AACAP background materials, examines current research and current practice.

ADHD is a condition with onset in childhood, most commonly becoming apparent during the first years of elementary school. ADHD may be associated with a number of co-morbid psychiatric conditions as well as with impaired academic performance and with both patient and family emotional distress.

### **Epidemiology of ADHD**

According to the National Institute of Mental Health (NIMH), Attention Deficit Hyperactivity Disorder, or ADHD, is the most commonly diagnosed psychiatric disorder of childhood. It's estimated to affect approximately 5 percent of school-age children, although published studies have identified a prevalence rate as high as 12% in some populations. It occurs three times more often in boys than in girls.

We also know that ADHD runs in families, and contrary to previous beliefs, it doesn't always go away as you grow up. In fact, the latest research indicates that as many as half of all children with ADHD continue to have problems into adulthood. This is actually one of the reasons there is an increase in the overall use of medication: adults are now being recognized and treated for ADHD.

### **Understanding and Diagnosing ADHD**

The key features of the diagnosis include: inattention, hyperactivity and impulsivity. The symptoms must also be interfering with the child's life at home, in school, at work or with their friends. The diagnostic criteria are specific and well established within the field. They

are the product of extensive and numerous research studies conducted at academic centers and clinical facilities throughout the country. (see attached AMA Council on Scientific Affairs (CSA) Report 5-A-97; AACAP Practice Parameters for the Assessment and Treatment of Children, Adolescents and Adults with Attention Deficit Hyperactivity Disorder; AACAP Practice Parameters on the Use of Stimulants; the AAP Guidelines; and the 1999 Surgeon General's Report on Mental Health.)

ADHD is not an easy diagnosis to make, and it's not a diagnosis that can be made in a 5 or 10 minute office visit. Many other problems, including anxiety disorders, depression and learning disabilities can present with signs and symptoms that look similar to ADHD. There's also a high degree of co-morbidity, meaning that over half the children who have ADHD also have a second significant psychiatric problem.

The diagnosis of ADHD requires a comprehensive assessment by a trained clinician. In addition to direct observation, the evaluation includes a review of the child's developmental, social, academic and medical history. It should also include input from the child's parents and teachers, and a review of the child's records. Schools play a critical role in identifying kids who are having problems, but schools should not make diagnoses or dictate treatment. ADHD is also a condition that should not be taken lightly. Without proper treatment, a child with ADHD may fall behind in schoolwork and have problems at home or with friends. It can also have long-term effects on a child's self-esteem, and lead to other problems in adolescence, including an increased risk of substance abuse, adolescent pregnancy, school failure and trouble with the law.

The treatment of ADHD should be comprehensive, and individualized to the needs of the child and family. Medication, including methylphenidate or Ritalin, can be extremely helpful for many children, but medication alone is rarely the appropriate treatment for complex child psychiatric disorders such as ADHD. Medication should only be used as part of a comprehensive treatment plan, which will usually include individual therapy, family support and counseling, and work with the schools on an individualized education plan (IEP) tailored to help the child succeed academically.

In terms of methylphenidate, there are literally hundreds of studies clearly demonstrating the effectiveness of this medication on many of the target symptoms of ADHD. (see attached AMA CSA Report and NIH Consensus Statement on the Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder.) It is also generally well tolerated by children, with minimal side effects. Nonetheless, there are concerns that some children may be placed on medication without a comprehensive evaluation, accurate and specific diagnosis or an individualized treatment plan. There are similar concerns about the many children with ADHD and other psychiatric disorders, who would benefit from treatment, including treatment with medication, but who go unrecognized and undiagnosed, and who are not receiving the help that they need.

**General Epidemiology and Prevalence of ADHD**

Current estimates indicate that 10 percent of boys and 2 percent of girls have ADHD, so general prevalence is estimated at 6 to 9 percent of the school-age population in the United States. ADHD accounts for one third to one half of referrals for mental health services for children. There is a strong male predominance, with an almost 10 to one ratio for diagnosis boys to girls. The reported number of people with ADHD in the United States was over 2 million in 1995, up from 900,000 in 1990. The rapid increase in these numbers and in the

prescribing of medications, specifically Ritalin, for the treatment of ADHD, has raised questions about accurate diagnosis and treatment. Medical associations such as the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association and the American Academy of Pediatrics have developed guidelines for diagnosing and treating ADHD. The AACAP has developed educational materials for parents and educators to help them understand this disorder and judge the accuracy of the diagnosis and the course of the treatment plan. Because child and adolescent psychiatrists are the only medical specialty with specific training in the diagnosing of childhood and adolescent mental illnesses, a special effort has been taken by the AACAP to inform the public and the media about ADHD.

#### **Recent Prevalence Data**

As recently as last week, a review article by child and adolescent psychiatrist Peter Jenson, M.D., addressed this issue in detail. Dr. Jenson's article is included in the background materials. Dr. Jenson is currently the Ruane Professor of Child Psychiatry at Columbia University. He was formerly the Associate Director for Child and Adolescent Research at the National Institute of Mental Health. He notes in his article that most studies and media reports have not been based on actual diagnostic data, but have relied instead on HMO or Medicaid medication databases. Dr. Jenson and his colleagues actually performed comparative evaluations of 1,285 children in 4 communities (Atlanta, New Haven, Westchester and San Juan, Puerto Rico) to determine the prevalence of ADHD, as well as the forms of treatment utilized. The results were that 5.1% of children and adolescents between the ages of 9 and 17 met the diagnostic criteria for ADHD; yet only 12.1% of these children were being treated with medication, suggesting that at least in these communities, medication is currently under-prescribed. These authors also found 8 children who were receiving medication who did not meet the full diagnostic criteria for ADHD, although they did have high levels of ADHD symptoms. Dr. Jenson concludes that on the basis of these results, there is no evidence of widespread over-treatment with medication. On the contrary, it appears that, at least in these communities, the majority of children with ADHD are not receiving what we would consider to be appropriate and effective treatment.

#### **Prescribing Practices: Are Children Being Overmedicated?**

The issue of prescribing practices also enters into the discussion of diagnosing ADHD or any other mental illness. It is established that there are regional, professional and demographic variations in actual prescribing patterns and practices, which would lead to making a case for both "under-" and "over-prescribing," i.e. appropriate and inappropriate use of medications. Dr. Jensen states that, "...it is essential for clinicians and prescribers to separate fact from fancy concerning actual prescribing practices. Such information should serve not only to define gaps in research knowledge, but also to heighten professionals' awareness about evolving practice trends, so that more informed discussion could take place in professional and public arenas." The APA, AACAP and American Academy of Pediatrics have all developed practice parameters and guidelines for treating ADHD. The organizations have also included distribution of the parameters as part of the concerted effort to make updated diagnostic information easily available. One example of reducing geographic differences is the recent purchase of the AACAP's ADHD practice parameters by the state of North Carolina for distribution to clinicians who work in public health in that state. The results of this exercise are not available yet, but it reveals how serious officials are about the issue of accurate diagnosis and treatment of the children within their jurisdictions.

One disturbing prescribing practice, is that of prescribing presumptively rather than after a thorough assessment. This practice can be adjusted as parameters and guidelines become accessible to physicians who are not trained to treat children with mental illnesses. It will also be assisted by additional training support. In a study released in 2000, a survey of office visits to physicians throughout the United States, found that the proportion of visits by children or adolescents ages 0 to 17 years with a diagnosis of ADHD that also resulted in a prescription of psychostimulant medication had increased significantly between 1989 and 1996.

When looking at prevalence, the prescribing practices must be considered as part of the discussion. Understanding children's mental illnesses and how to diagnose and treat is not a constant, especially when prescribing medications. The base of research and the data attached to it advance the numbers of children recognized and referred and, thus, the number diagnosed and treated. This is progress. A key part of this progress is to assure the public that the diagnosis is accurate and the treatment effective.

The possibility of misunderstandings about the nature of ADHD prescribing practices reflects the need for ongoing research to assure the public further that these conditions exist and that children and adults do not have to endure the symptoms that keep them from developing naturally. To the extent one believes that such conditions are rare or do not exist in children, any amount of prescribing of psychotropic agents is likely to be viewed as "over-prescribing." Some research shows that up to 21% of children between the ages of 9 and 17 have diagnosable mental or addictive disorders (Shaffer et al, 1996). Dr. Jensen addresses the issue of "over-prescribing" in his most recent article (Jensen, 2002), "Without awareness of the reality of childhood mental illness and the impact that these conditions exert on children's development, the myth will persist among many persons that psychotropic medications should not be used at all with children. This "one-size-fits-all" assumption likely does great harm in delaying many parents and professionals in making informed treatment choices. The accusatory question sometimes heard by parents—"Are you drugging your child?"—suggests double standards for the use of psychotropic medications. Although ADHD and other childhood behavioral/emotional disorders can be just as devastating as other life-long ailments, such as asthma and diabetes, psychotropic agents that have been proven effective are often not even considered. However, as when treating asthma or diabetes, delaying effective treatments of childhood behavioral/emotional disorders also poses significant risks, such as enduring declines in functioning and disturbances in development. In many instances, psychotropic medications constitute an essential tool to assist suffering children and their families."

#### **Status of Understanding and Diagnosing ADHD And Learning Disabilities**

Ten to twenty percent of the school-age population has an abnormal difficulty with academic work. These youngsters fall into several broad categories: (1) some have mental retardation -- that is, they have subnormal intellectual capacities, and therefore they will always function below normal levels; (2) some have emotional problems that stand in the way of learning and cause academic difficulties; and (3) some have average or above-average intelligence, but still have academic difficulties because of the way their brain or nervous system functions. Although such children may have problems with physical disabilities such as impaired vision, hearing, or both, their learning problems are not caused by these impairments. The person we call "learning disabled" falls into this third group,



often called the “neurological group.” They represent between 3 and 10 percent of the school-age population. (Silver)

Children and adolescents with learning disabilities may have one or more of a group of associated disorders. ADHD also falls within this group of neurologically-based disorders. Some individuals with ADHD or a learning disability might have a tic disorder called Tourette’s disorder; some may have an obsessive-compulsive disorder; and, some may have a seizure disorder. Most develop secondary emotional, social, and family problems because of the frustrations and failures they experience. These emotional, social, and family problems are referred to as “secondary” to emphasize that they are the consequence of the academic difficulties and not the cause of the difficulties. (Silver)

Often, more than one of these problems will occur in the same child. Diagnosing the specific disorder and any secondary disorder is tremendously important and must be done by professionals, such as child and adolescent psychiatrists, who have special training to accurately assess the symptoms as they appear in all areas of the child’s life. For ADHD, the most frequent pattern found is associated learning disabilities and secondary emotional, social, and family problems. (Silver)

#### **Terminology History**

In the early 1940s, a fourth group was identified, children who had difficulty learning because of a presumed problem with their nervous system. The initial researchers noted that these students had the same learning problems as individuals who were known to have brain damage (e.g., after trauma or surgery to the brain). Yet, these students looked normal; thus, it was considered that they also had brain damage, but that the damage was minimal. The term *minimal brain damage* was introduced.

Initially, observations and testing revealed that no evidence of damage to the brain could be found in most of these children. This evidence regarding brain damage remains accurate; however, recent research using magnetic resonance imaging (MRI) and positron emission tomography (PET) found that total brain size in subjects with ADHD is approximately 5 percent smaller than in age- and gender-matched control subjects. Analyzing this newly discovered difference and the related questions about overall brain volume will contribute key information in the near future.

In the 1950s, the term *minimal brain dysfunction*, was used to identify children with learning difficulties, including hyperactivity. Professionals from different disciplines began the contemporary research that would lead to the diagnosis of ADHD. The labeling of disorders from this research caused some confusion since different disciplines used different terms, including dyslexia, dysgraphia and dyscalculia, but eventually the primary term became *learning disability*. In 1968, professionals studying children with hyperactive, distractible behavior established the medical classification system as *hyperkinetic reaction of childhood*.

By 1980, that term was changed to attention-deficit disorder (ADD). In 1987, the term attention-deficit/hyperactivity disorder (ADHD) replaced attention-deficit disorder and was accepted as the classification for children who have distractibility, but ADHD can include inattention as a primary issue. The term ADD no longer exists. The rapid changes in terminology indicate the intensity of research into this childhood disorder. With continued

support, research efforts should deliver new insights and terminology on a regular basis. (Silver)

We now know that learning disabilities and ADHD are two separate but related disorders, and that academic difficulties caused by other emotional, social, and/or family problems are also diagnosed and treated differently. We also know that children with auditory or visual problems can exhibit the symptoms of ADD, and the mental disorder diagnosis can be applied mistakenly when clinicians do an insufficient assessment and analysis of all the symptoms. The importance of accurate diagnosis cannot be overstated.

#### **Recognition and Diagnosis of ADHD**

One of the primary reasons for this hearing is to examine the increase in the numbers of children and adolescents diagnosed with ADHD. One of the first areas to be examined is the accuracy of the diagnosis. The diagnosis of ADHD cannot be made using a simple checklist of symptoms or reacting to initial comments from a parent or a teacher. We are learning from the ongoing research into ADHD how to more accurately diagnose the disorder, but there is no question that the diagnosis is the key to appropriate treatment and effective outcomes. A child or adolescent with ADHD will have one or more of three types of disorders: hyperactivity, inattention (distractibility), and/or impulsivity. Some will have only one of these disorders; some will have two; some will have all three. Critical to the diagnosis is the understanding that ADHD is neurologically-based and, for most individuals, has been present since birth. Thus, the behaviors reflective of the disorder have been present throughout the child or adolescent's life and are present throughout each day; that is, they are chronic and pervasive.

This concept of chronic and pervasive behavioral patterns is critical to the diagnosis. Such emotional problems as anxiety or depression can result in an individual being restless, inattentive, and irritable (thus impulsive). Certain learning disabilities can result in an individual being inattentive. However, with anxiety, depression, or a learning disability, the hyperactivity, distractibility, and/or impulsivity begins at a certain time or occurs during certain situations. For example, a child is described as hyperactive and inattentive in the fourth grade. It is noted that no previous teacher described the child as such. A more detailed clinical exploration shows that the child's parents separated during the summer between third and fourth grade.

#### **What are the symptoms of ADHD?**

Currently, a child who has ADHD has been diagnosed according to the following criteria: **DSM-IV Diagnostic criteria for Attention-Deficit/ Hyperactivity Disorder**

*A. Either (1) or (2):*

*(1) six (or more) of the following symptoms of inattention have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:*

##### *Inattention*

- (a) often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities*
- (b) often has difficulty sustaining attention in tasks or play activities*
- (c) often does not seem to listen when spoken to directly*
- (d) often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace (not due to oppositional behavior or failure to understand instructions)*

- (e) often has difficulty organizing tasks and activities
- (f) often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or home work)
- (g) often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)
- (h) is often easily distracted by extraneous stimuli
- (i) is often forgetful in daily activities
- (2) six (or more) of the following symptoms of **hyperactivity/impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

Hyperactivity

- (a) often fidgets with hands or feet or squirms in seat
- (b) often leaves seat in classroom or in other situations in which remaining seated is expected
- (c) often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness)
- (d) often has difficulty playing or engaging in leisure activities quietly
- (e) is often "on the go" or often acts as if "driven by a motor"
- (f) often talks excessively

Impulsivity

- (g) often blurts out answers before questions have been completed
- (h) often has difficulty awaiting turn
- (i) often interrupts or intrudes on others (e.g., butts into conversations or games)

*B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.*

*C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).*

*D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.*

*E. The symptoms do not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder and are not better accounted for by another mental disorder (e.g., Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).*

Longitudinal studies show that between fifty and seventy percent of children will continue to have ADHD as adults. Even for those who improve at puberty, the residual emotional, social, and family problems might persist into adolescence and adulthood if not addressed. It is now understood that in about fifty percent of individuals, ADHD is inherited. Thus, there is a high likelihood that one or both parents also have ADHD or had ADHD as a child. Perhaps some of these studies suggesting parents of children with ADHD have a higher probability of emotional and work difficulties is explained by their unrecognized ADHD.

Another set of research findings suggest that girls with ADHD are more likely to be missed than boys. These findings are especially true for girls who are only inattentive. Boys, when struggling and frustrated, are more likely to act out and misbehave; thus, boys are more likely to be evaluated. Girls, under the same conditions, are more likely to become passive and withdrawn; thus, they are missed.

### **The Outcome of ADHD**

If a child or adolescent with ADHD is not identified and treated, he or she is at great risk for developing serious emotional or behavioral problems. Being unable to attend to learning, there is the risk of academic underachievement and failure, and friendships may suffer. The child experiences more failure than success and is criticized by teachers and family who do not recognize a health problem. These problems increase during adolescence. Some outcomes studies on these unrecognized individuals suggest a higher risk of school drop out, substance abuse, delinquency, or other serious problems. In November 2000, the Coalition for Juvenile Justice estimated in their annual report that 50 – 75% of teenagers in the juvenile justice system nationwide have a diagnosable mental disorder and these numbers appear to be growing. Thus, it is critical that children with mental illnesses, including ADHD, be identified and diagnosed early. With the proper treatment, the outcome is much more likely to be positive.

### **Treatment of ADHD**

The treatment of ADHD must involve several models of help, including individual and family therapy, including cognitive and behavioral therapy, parent education, the use of appropriate behavioral management programs, modification to the child's educational plan, and the use of appropriate medications. Such a multimodal approach is needed because children and adolescents with ADHD frequently have multiple areas of difficulty. As with learning disabilities, the total person must be understood in his or her total environment. Educators, family members and others around a child with ADHD have to understand what is causing the distractibility, loss of concentration, frustration and depression linked to this disorder. Cognitive therapy can help build self-esteem, reduce negative thoughts and improve problem-solving skills. Parents can learn management skills such as issuing instructions one step at a time rather than issuing multiple requests at once. Educational modifications, which all students with ADHD are entitled to under the Individuals With Disabilities Education Act (IDEA) can address the symptoms of ADHD along with any coexisting learning disabilities.

Evaluation by a child and adolescent psychiatrist or psychiatrist specializing in children's disorders is appropriate for any child or adolescent with emotional and/or behavioral problems. Most children and adolescents with serious emotional and behavioral problems need a comprehensive psychiatric evaluation. Unfortunately, access to comprehensive psychiatric evaluations has declined during this age of managed care. Incentives to diagnose quickly and provide a treatment plan based on a rushed evaluation contribute to the statistics that show an ever increasing prevalence rate and more use of stimulant medications.

Comprehensive psychiatric evaluations usually require several hours over one or more office visits for the child and parents. With the parents' permission, other significant people (such as the family physician, school personnel or other relatives) may be contacted for additional information. The comprehensive evaluation frequently includes the following:

- Description of present problems and symptoms
- Information about health, illness and treatment (both physical and psychiatric), including current medications
- Parent and family health and psychiatric histories

- Information about the child's development
- Information about school and friends
- Information about family relationships
- Psychiatric interview of the child or adolescent
- If needed, laboratory studies such as blood tests, EKG, x-rays, or special assessments (for example, psychological, educational, speech and language evaluation)

The child and adolescent psychiatrist then develops a formulation. The formulation describes the child's problems and explains them in terms that the parents and child can understand. Biological, psychological and social parts of the problem are combined in the formulation with the developmental needs, history and strengths of the child or adolescent.

Time is made available to answer the parents' and child's questions. Parents are often worried about how they will be viewed during the evaluation. Child and adolescent psychiatrists are there to support families and to be a partner, not to judge or blame. They listen to concerns, and help the child or adolescent and his/her family define the goals of the evaluation. Parents should always ask for explanations of words or terms they do not understand, and ask questions about the side effects of the medication, how the medication works, and how long it will be before improvement is noted.

When a treatable problem is identified, recommendations are provided and a specific treatment plan is developed. Child and adolescent psychiatrists are specifically trained and skilled in conducting comprehensive psychiatric evaluations with children, adolescents and families.

#### **Prescription of Medications as Part of the Treatment Process**

Prescribing psychoactive medications for children and adolescents requires the judgment of a physician, such as a child and adolescent psychiatrist, or psychiatrist, with training and qualifications in the use of these medications in this age group. Certainly any consideration of such medication in a child or infant below the age of five should be very carefully evaluated by a clinician with special training and experience.

Most medications prescribed for children under age 12 do not as yet have specific approval by the Federal Drug Administration (FDA); such approval requires research demonstrating safety and efficacy. Such research, so far, lags behind the clinical use of these medications. To date, no study has been completed to determine the optimal range of effective doses for preschoolers with ADHD. To address this knowledge gap, two years ago the NIMH began PATS, the Preschoolers with ADHD Treatment Study, currently being conducted across six sites around the country. Other efforts to address the deficiency in pediatric drug research include the development of Research Units of Pediatric Psychopharmacology (RUPP), the Food and Drug Administration's (FDA) pediatric studies program, recently reauthorized under the Best Pharmaceuticals for Children Act (P.L. 107-109), and the 1997 Pediatric Rule requiring studies of medications prescribed for children and adolescents. The combination of the FDA program and the Pediatric Rule has seen a dramatic increase in the number of pediatric clinical trials, from just eleven between 1990 and 1997, to over 400 since 1998. Long-term studies are needed to adequately determine the safety and efficacy of psychoactive medications. In making decisions to prescribe such medications the physician -

specifically the child and adolescent psychiatrist - should consider data from studies in adults in treating the target disorder and/or symptomatology, any clinical or anecdotal reports of use in child and adolescent patients, studies conducted outside the United States and the experience of colleagues.

It is important to balance the increasing market pressures for efficiency in psychiatric treatment with the need for sufficient time to thoughtfully, correctly, and adequately, assess the need for, and the response to medication treatment. Monitoring on-going use of psychoactive medications requires sufficient time to assess clinical response, side effects and to answer questions of the child and family. The use of brief medication visits (e.g. 15-minute medication checks) is unacceptable as a substitute for ongoing individualized treatment. The role of psychosocial interventions, including psychotherapy, must be evaluated, and such interventions must be included in the treatment plan.

Medication to treat ADHD must be seen as part of a multimodal approach that includes education, therapy, and behavioral management. If the clinician establishes this diagnosis, it is presumed that the behaviors are neurologically based. Therefore, since ADHD is not a school disability but a life disability, the need for medication must be assessed for each hour of each day. To place a child or adolescent on medication only during school hours on school days will result in the individual doing better in school. However, he or she may continue to have difficulties within the family and in interactions with peers. Medication holidays, which were used to counter fears that the drugs would stunt growth or cause other physical complications, are no longer a treatment recommendation. (Silver)

Research clearly demonstrates that medication can be an effective part of treatment for ADHD. A National Institutes of Mental Health (NIMH) study found that a combination of therapy (specifically behavior modification and social skill building) and medication were the most effective modes of treatment for children with ADHD aged 7 to 9. A child should have had a complete physical examination within the last year before a stimulant is prescribed. This baseline of the physical condition will be used for comparison when the medication is taken over time. Most children should take ADHD medication for a minimum of nine to twelve months. There are medications other than Ritalin prescribed for ADHD, but it is the first choice for effective treatment. (Koplewicz) Ritalin is also the focus of media attention because of the increase in the number of prescriptions written over the last five years. Oversight of this increase should involve an examination of who is prescribing the medication, what diagnostic method was used to establish the disorder, and what does the treatment plan involve other than the medication.

#### **Methylphenidate (Ritalin)**

There are more than 200 studies showing that the stimulant Ritalin (generic name: methylphenidate) works effectively for children with ADHD. Stimulants have been used in the treatment of ADHD for more than 90 years. Adults feel more focused and alert after a cup of coffee in the morning. This is basically how Ritalin, and newer stimulants such as Adderall and Concerta, work for children with ADHD. Ritalin and other stimulants increase the alertness of the brain and nervous system, stimulating it to produce more dopamine and norepinephrine. The medication increases the child's attention and reduces excess fidgetiness and hyperactivity, allowing him to focus on his work. Children with ADHD who take Ritalin make fewer errors on a variety of tasks than untreated children do. They

are less impulsive and more attentive, both in the classroom and in social situations. (Koplewicz)

A myth surrounding the treatment of ADHD is the “paradoxical calming effect” of stimulants such as Ritalin. It is a commonly held misconception that if a stimulant calms a child, then he must have ADHD; if he didn’t have the disorder, the thinking goes, the medication would not have any effect. That is not true. Stimulants increase attention span in normal children as well as those with ADHD.

#### **Treatment Providers**

Currently, treatment for children and adolescents with ADHD can be provided by primary care physicians or by specialists, including child and adolescent psychiatrists, psychiatrists, neurologists, and pediatricians. Other mental health providers who can treat ADHD but do not prescribe medications are psychologists, social workers, and school psychologists.

Different medical specialists see substantially different sectors of the ADHD population. Neurologists tend to see children with ADHD who have seizures and mental retardation. Psychiatrists treat ADHD with personality disorders and concomitant psychiatric illnesses, and child and adolescent psychiatrists are trained to treat specific child and adolescent characteristics and levels of severity. Pediatricians typically treat children with ADHD who have less severe characteristics.

One of the barriers to treatment for children and adolescents with mental illnesses, including ADHD, is the lack of available specialists trained in the diagnosis and treatment of these disorders. In particular, there is a critical national shortage of child and adolescent psychiatrists. There are about 7,000 child and adolescent psychiatrists nationally while the prevalence rate for children and adolescents with mental illnesses is between 15 and 20 million. Data on this professional shortage comes from several sources including the Council on Graduate Medical Education (COGME), a committee of the Department of Health and Human Services and the Bureau of Health Professions. The COGME report concluded that by 1990, the nation should have over 33,000 child and adolescent psychiatrists. The Bureau of Health Professions projected that between 1995 and 2020, the use of child and adolescent psychiatrists will increase by 100%, with general psychiatry’s increase at 19%.

An increase in the numbers of all children’s mental health professionals can help reduce one of the barriers to treatment for the families of children with ADHD. The AACAP recommends congressional action in this effort, including passage of the Children’s Mental Health Service Expansion Act, H.R. 5078, bipartisan legislation sponsored by Reps. Kennedy (D-RI) and Ros-Lehtinen (R-FL), which would encourage individuals to enter all children’s mental health professions through the creation of education incentives.

#### **A Final Word: Are We Over Diagnosing ADHD?**

About ten to fifteen years ago a concerted effort was made to educate professionals, parents, and teachers about ADHD. There was concern that too many children in adolescence were missed. A national parent organization, Children and Adults with Attention Deficit Disorder (CHADD), was formed along with other regional organizations. Literature became available to parents and teachers explaining ADHD. Books for the public were written and published. The topic of ADHD became popular in both the print and electronic

media. As a result, more children and adolescents have been diagnosed with ADHD. With the increased awareness that the disorder can continue into adulthood, more adults have been diagnosed. The general opinion is that more cases are being diagnosed because parents and teachers are recognizing the behaviors and referring to physicians and because more physicians are correctly making the diagnosis.

Studies at the American Psychiatric Association and elsewhere are currently underway to examine the treatment patterns of psychiatry, child and adolescent psychiatry, and other physicians for patients with ADHD. Studies of longer-term outcomes are also being developed.

#### **RECOMMENDATIONS**

The American Academy of Child and Adolescent Psychiatry and the American Psychiatric Association submit the following recommendations for the committee's consideration:

- In order to assure accurate diagnosis and treatment, policies should be approved that support access to clinicians with appropriate training and expertise, and allow sufficient time for a comprehensive assessment.
- To provide access to nondiscriminatory insurance coverage, support is needed for comprehensive parity legislation at both the state and federal level so there are fewer barriers to keep children from getting the kind of comprehensive evaluations and individualized treatment they need. The strong support for parity recently voiced by President Bush is appreciated.
- Support is recommended for all efforts to sustain and expand training programs for all child mental health professionals, including programs for child and adolescent psychiatrists.
- That opposition be given to legislation that recognizes only the disruptive behavior and offers punitive resolutions rather than recognizing the reasons for the behavior and offering help through federal health and education services.
- To assure safety in prescribing by all physicians, federal support is needed 1) for the increased emphasis of the FDA and the NIMH on research on the appropriate use of medication in the psychiatric treatment of children and adolescents, and 2) for expanded clinical trials and longitudinal studies for all medications prescribed for children.
- And finally, support and appreciation should be given to the efforts of the current administration, through the New Freedom Commission on Mental Health, to focus increased attention on the diagnosis and treatment of all psychiatric conditions, including those that affect children and adolescents.

#### **SUMMARY**

The prevalence rate for children and adolescents with mental disorders is estimated between 12 and 20 percent – the wide difference of opinion is indicative of the difficulties in measuring numbers across uneven access to treatment and quality of care. Conservatively, there are 15 million American youngsters needing treatment and services at any one time.



Only about 20% of these children ever receive any treatment or find their way into a service system that can meet their needs. This rate has not changed significantly for over a decade, yet the question is still raised as to whether there may be too many diagnoses of ADHD and too many prescriptions for stimulants. It is appropriate to look into an issue that receives this much attention, but it is also appropriate to remember that concerns about overdiagnosis can be addressed with better education about the disorder, better training for the providers of treatment, more research into the diagnosis and treatment, and a comprehensive service delivery system. No one -- not children, adolescents or adults -- can be assured an early identification, accurate diagnosis and appropriate treatment until the skills, resources, and governmental support are available. Too many families have to deal with mental illnesses without support, diagnosis, treatment or resources to buy medications. The issue of paramount importance to this debate is the lack of access to affordable treatment for mental illnesses for children, adolescents and their families.

In summary, child psychiatric disorders, including ADHD, are very real and diagnosable illnesses, and they affect thousands of children and adolescents. The good news is that they are also highly treatable. While it is not currently possible to cure all children, with comprehensive, individualized intervention, there can be a significant reduction in the extent to which this disorder interferes with their lives. The key for parents and teachers is to identify kids with problems as early as possible, and make sure they get accurate and effective treatment.

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Mr. BURTON. I'd like to ask you a whole bunch of questions, but, unfortunately, we've got two votes on the floor, and you've been here all day. I don't want to keep you all any longer than we have to.

We have 6 million children that are using these drugs right now. I don't know how we got through all this when I was younger, but we did, and the society did fairly well.

Did you find any mercury in your son's blood work?

Mr. ROSS. No. We were hoping to find some toxic element so that we could have a simple explanation for the fact that he was having seizures and that he had hypertonia and a lot of problems.

Mr. BURTON. OK. But you—

Mr. ROSS. No, we did not find.

Mr. BURTON [continuing]. Found no mercury?

Mr. ROSS. No.

Mr. BURTON. Had he had all of his childhood vaccines?

Mr. ROSS. Yes. We contracted with our pediatrician 2 months before we delivered Andrew, and he has had the same pediatrician and—

Mr. BURTON. So he had all of his childhood vaccinations?

Mr. ROSS. He had all of his childhood vaccinations. Now, he was tested when he was 3 or 4, and he's had subsequent vaccinations.

Mr. BURTON. Well, but the thing is, I wonder if you could contact your pediatrician and find out the lot numbers of those vaccinations. I am just curious. I would just like to see those, because mercury has been in these childhood vaccinations for 30, 40 years, and if he got a number of these vaccinations, as my grandson did, it's hard for me to believe that he didn't get some mercury injected into him.

Mr. ROSS. Well, what the doctor would have told me is not there wasn't some; he would have told me if it was abnormal. We were told there was not abnormal levels of mercury, lead, and a whole bunch of things. So I don't know. I don't know. I didn't see the actual test results and I'm not a physician.

Mr. BURTON. I think most parents who have had these shots given to their children and who have autistic children would really argue with what is an acceptable level of mercury in the body. That's a subjective thing, and it may vary from person to person, so that's something that I'm sure would be debated.

You agree, Dr. Fassler, that there ought to be a thorough analysis of a child before they go on medication?

Dr. FASSLER. Yes. My bottom line would be that kids need a comprehensive evaluation before there is any treatment plan in place, and that parents need to be advocates for kids to try to make sure that—

Mr. BURTON. I don't think anybody disagrees with that.

Dr. FASSLER. Right.

Mr. BURTON. And your organization also agrees with that?

Mr. ROSS. Yes. Every child should have a complete and—

Mr. BURTON. Well, why is it then—

Mr. ROSS [continuing]. Comprehensive assessment.

Mr. BURTON. Why is it then that around the country we have school corporations that have this checklist where a teacher checks off the problems with the child, the child is taken to a doctor, and

it is a perfunctory thing for the doctor to say, "Well, it appears as though he needs Ritalin," and they write out a prescription for that. That's not a thorough examination.

Dr. FASSLER. And that's not something that I think either of us or any of us who you've heard would support. There are checklists where teachers report what they're seeing in the classroom, but there shouldn't be a diagnosis made just on the basis of reviewing that checklist.

Mr. BURTON. My grandson never had a complete psychological analysis. He became autistic, as I said, right after getting all these shots. And yet the school recommended, because he was difficult—he was in a special ed class—that he should be put on Ritalin, and they had a doctor also subscribe to that. Of course, he wasn't put on Ritalin. We didn't allow that, and he seems to be doing all right on other ways that we're dealing with him. But the fact of the matter is, in my own personal experience that was the case—recommendation by the teacher and the doctor went along with that.

How do we educate our educators around the country to understand that this has to be something that's done in a very thorough manner before you start putting these kids on these drugs?

Dr. FASSLER. I think it is an excellent point and I think collectively we need to work on getting that message to the schools, and part of it is our job going into the schools, teaching teachers about the kinds of things to look for and when kids should be referred.

I think we need to do a better job at recognizing the signs and symptoms earlier and getting help for kids before they have major problems, because often we all wait too late, and we may see things in adolescence that we may have been able to help earlier in life.

Mr. BURTON. Let me just say that I hope you and CHADD and our health agencies will figure out some way—I don't know how much time is left—will figure out a way to make sure that every school corporation, every superintendent of public instruction in all 50 States understands that there should be a thorough analysis before they put these kids on these drugs.

Dr. FASSLER. I don't think—

Mr. BURTON. If you would do that, I think you would eliminate a lot of the problems.

The other thing is I hope you'll all agree that we shouldn't be introducing mercury or other toxic substances into people's bodies, whether they're kids or adults. If we could get that point across, we might solve a lot of these problems.

I have a lot of questions I'd like to submit to you for the record, Dr. Fassler and Mr. Ross.

I would also like to end by saying, Mr. Ross, I do—we had what was called the "Keating Five" here in Washington. We had five Senators that met with Mr. Keating on the savings and loan crisis, and I don't believe any of those Senators really intentionally did anything wrong, but the appearance of impropriety was very great and they got a heck of a lot of bad publicity when the savings and loan debacle took place. And for you to get hundreds of thousands of dollars from Novartis, which manufactures Ritalin, and your organization does advocate that children should use that, it gives the appearance—

Mr. ROSS. We do not advocate any brand drug.

Mr. BURTON. Well, I—

Mr. ROSS. We advocate a multimodal treatment which may include medication—

Mr. BURTON. I understand.

Mr. ROSS [continuing]. And the products are never discussed.

Mr. BURTON. Regardless—I understand, but the appearance is that they're feeding you to deal with this problem in that way, and I would just suggest, if there was a better way to fund your organization, even if it is only 18 percent, it would be helpful, because if you were in the U.S. Senator or the House and that happened, you would have a heck of a problem.

With that, let me just say to you I really appreciate your being here. We will submit questions for the record and we would appreciate your response.

Thank you.


Mr. ROSS. Thank you.

Dr. FASSLER. Thank you very much.

Mr. BURTON. We are adjourned.

[Whereupon, at 2:26 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statements of Hon. Constance A. Morella, Hon. Dennis J. Kucinich, Hon. Marge Roukema, and additional information submitted for the hearing record follows:]



**Morella Opening Remarks for Attention Deficit/Hyperactive  
Disorder (ADHD) Hearing**

I welcome today's hearing on attention deficit/hyperactive disorder and whether we are over-medicating our children. The Committee is rightly bringing in witnesses who have perspectives from all sides of the debate. I think it is essential that we both listen to arguments from those who believe attention deficit disorder is not a brain disorder and those that believe it is and warrants medication along the lines of Ritalin. Considering there has been a 500% increase in the use of Ritalin in the United States since 1990 and roughly 4-6 million children may be using it daily, we must ascertain the root causes of ADHD and how best to alleviate its effects.

It is also important though that this debate focus on what sound research has shown us about this particular disorder and this particular problem and not let any general views or perceptions of psychiatry and psychiatric drugs skew viewpoints away from today's topic. I know some of the witnesses today have skeptical views about psychiatry in general and I hope to determine whether those views are based on facts or feelings.

I look forward to today's hearing and yield back my time.

**Opening Statement  
Rep. Dennis Kucinich  
September 26, 2002**

**"Attention Deficit/Hyperactivity Disorders- Are We Over-Medicating Our Children?"**

I would like to begin by thanking Chairman Burton for his recognition of the need for Congressional attention to and action on the problem of overmedication of children for Attention Deficit/Hyperactivity Disorder (ADHD). I am grateful to him for providing the necessary leadership on the overmedication of children, a frightening phenomenon that is already compromising many children's lives. It is my intention that under his leadership this Committee will begin the process of slowing the rate at which we are medicating our young citizens and compromising their autonomy, their individual paths of physical and mental development.

My thanks also to the witnesses who have lent us their expertise and the wisdom of their experiences to better equip this Committee to address the possible problem of overmedication of children.

I question whether we should be medicating up to 6 million children, as reported by the American Medical Association. The United States consumes 90% of the world's supply of Ritalin, as the Lexington Institute states using information from a United Nations report. This should raise a red flag. Even more concerning is the increasing frequency with which we are medicating our very young children; one study by the American Medical Association reported up to 3 fold increases in the medication of 2 to 4-year olds, as well as "a great increase" in stimulant treatment for ADHD with such drugs as Ritalin in the 4 to 15-year old age group.

In tackling this issue we must first look at what is called Attention Deficit/Hyperactivity Disorder, a



phenomenon whose legitimacy as a disease is disputed by some in the medical community, including our witness today Dr. Mary Ann Block. This skepticism stems from fact that symptoms of ADHD are quite ambiguous. According to the American Academy of Pediatrics, the key symptoms of ADHD involve displays of "inattention, hyperactivity, and impulsivity." Furthermore, children with ADHD may experience "significant functional difficulties, such as academic underachievement, troublesome interpersonal relationships with family members and peers, and low self-esteem." Clearly these criteria are vague and, if indeed present, could be the result of any number of factors in a child's life. In branding children who are excitable and have trouble focusing on tasks as having a disorder, we may be stifling aspects of their personalities and intellects, or permitting other issues to go unaddressed. One must be very careful in treating such a disorder with large amounts of very potent, serious medication, as this may result in irreparable damage to children at such a delicate time in their lives.

Statistics on the substantial rise in the diagnosis of ADHD and administration of drugs for treatment take on very ominous meanings when one considers the types of drugs we are talking about. The Drug Enforcement Agency classifies Ritalin as a Schedule II narcotic as described in the Controlled Substances Act. Schedule II narcotics are those that have a high potential for abuse with severe liability to cause psychic or physical dependence, but have some approved medical use. The American Medical Association reports that Ritalin produces many of the same effects as cocaine or other amphetamines. The Drug Enforcement Agency goes so far as to say that humans cannot distinguish between cocaine, and Ritalin, or methylphenidate, when they are administered the same way at comparable doses.

What does this mean for children being administered such narcotics? According to the Food and Drug Administration, common side effects of Ritalin include loss of appetite, abdominal pain, weight loss

during long-term therapy, insomnia, nervousness. Such medications can also inflict increased blood pressure, nausea and vomiting, Tourettes-like jerking fits, fluctuations in blood pressure, liver damage, and hallucinations and psychosis. Furthermore, the long-term effects of Ritalin and other Schedule II narcotics are unknown.

Apart from the individual consequences of prescribing Schedule II narcotics to children, there are ramifications on the societal level as well. These ramifications stem from the linkage of ADHD medication to violence. The Citizens Commission on Human Rights International and Dr. Mary Ann Block represent for this committee those activists and members of the medical community who are pointing out links to future narcotic abuse among children prescribed Schedule II medications, thus exacerbating the societal problem of drug addiction.

I feel that the administration of Schedule II narcotics should be a major decision between the child, his or her parents or guardians, and medical professionals, and should be made with complete understanding of the possible side effect and long-term consequences and a time frame for the drug therapy. Administration of such drug therapy should also be made with great caution, when all other components of a child's life have been analyzed and other courses of action have been explored.

Furthermore, I believe we should also explore the influence of drug companies on physicians. As Dr. Mary Ann Block details in her book "No More ADHD," in order to fully address the overprescription of Ritalin and other Schedule II narcotics, the relationship between prescribing physicians and pharmaceutical corporations must be critically examined. The medical community should not have a financial incentive to administer Ritalin and the like to our children. And just as drug companies should be prevented from wielding undue influence on the prescriptions doctors issue, so to should

schools be prevented from coercing parents to medicate their children. The testimony of Ms. Weathers vividly illustrates how some schools have been overstepping their bounds in this respect.

We in Congress, as well as those in the medical and educational communities, must acknowledge that the very powerful and potentially dangerous narcotics being dispensed to our children at incredibly high rates are altering their chemistry, physiology, personality, and overall development in ways we do not fully understand. Should we be taking such chances with our young citizens, especially at such formative stages in their lives? We must recognize and honor the rights of our nation's children by critically examining the current alarming trends of overmedicating children and by helping to create a new system of addressing their needs. Some components of this new system could be new and more personalized teaching methods, tutoring, training more teachers with specialization in dealing with a range of behaviors, individual and family counselling, examination of children's sleep patterns, allergies, and diet, and in general a more holistic view of children's lives considering their issues at school, at home, and with friends.

Today I am proud to join my fellow members of Congress and those witnesses kind enough to participate in this hearing in acknowledging that this issue merits scrutiny, and that for the sake of our children we must initiate a review of a system that may currently compromise their mental and physical health and autonomy.

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**Congress of the United States**  
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**Testimony of Congresswoman Marge Roukema**  
**Committee on Government Reform Hearing**  
**“ADHD—Are Children Being Over-Medicated?”**  
**September 26, 2002, 10:00 a.m.**

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While I am not a Member of this Committee, the subject of today’s hearing is of particular interest to me in light of my continued work to ensure that the mental health needs of our nation’s children are met. I want to thank the Chairman for allowing me the opportunity to submit this testimony for the record. I have long been an advocate of mental health services for youth. Federal statistics show that one in ten children has a serious mental health disorder, but that only one-third of these children get any care. Even less receive appropriate care. The lack of appropriate mental health interventions can produce devastating results for children, including disrupted social and educational development, academic failure, substance abuse problems, or juvenile justice system involvement.

My understanding is that the purpose of this hearing is to examine whether there are pressures or incentives that in any way encourage physicians to diagnose children with disorders commonly treated with psychotropic medications. I commend the Chairman for exploring this issue because I believe that Congress should pay more attention to children suffering from mental illness. In that light, I am particularly concerned that this hearing is providing a forum for individuals to purport their anti-psychiatry rhetoric and to legitimate their misguided convictions. I am hopeful that my colleagues who serve on this Committee will rely on nearly

thirty years of sound science when analyzing Attention Deficit/Hyperactivity Disorder and children's use of psychotropic medications.

Let me be clear: I too am concerned about children who are prescribed with Ritalin as a "quick-fix" for bad behavior. I am concerned with reports by parents that teachers and principals are pressuring them to resort to psychotropic medications. Parents should not be pressured by doctors or teachers to have their children use Ritalin or any other medication. In fact, last Congress, Mr. Schaffer and I introduced, H. Res. 459, which expresses the sense that Congress should examine the "provision for school children of prescriptions for psychotropic drugs."

I firmly believe, however, that rather than targeting the medications, what we in Congress should be examining is how children's mental health needs have historically been ignored or not treated in the right way. The bottom line is that we need to provide children who have mental health disorders with appropriate services. I am extremely concerned with the number of children who have mental health disorders that are not receiving proper treatment.

I strongly believe that doctors, parents, and teachers need to fully understand the effect of psychotropic medications on children; that parents and students should understand the variety of medical and non-medical treatment options available before settling on Ritalin or any other similar prescription; and that if Ritalin is prescribed, then health professionals, parents, and teachers should work together to monitor its effectiveness and ensure its proper usage.

The anti-psychiatry rhetoric presented at the hearing today will serve primarily to scare or discourage parents who are seeking help for their children. In that respect, it puts children at risk, particularly when suicide today ranks as the third-leading cause of death for youth. The suicide rate for adolescents between the ages of 15 and 24 is nearly triple the rate it was 40 years ago. Our common goal should be the highest standard of evaluation and appropriate treatment.

Some children do not need to be on medication. They should be identified through better evaluations before any treatment is begun. But many children are not being screened at all. Some children need treatment and are not getting it. Their entire lives will be affected by the failure to identify and treat their illnesses now, when intervention can make a difference. This should be one of Congress' paramount concerns.

In that light I am especially pleased that there is a bipartisan majority of this Committee, who, recognizing the importance of access to appropriate mental health treatment have signed on as co-sponsors of H.R. 4066, the "Mental Health Equitable Treatment Act of 2002" which would eliminate discriminatory insurance co-payments for mental health care and improve access to specialists in the care of brain disorders.

#### **Research about Diagnosis and Treatment of ADHD**

The landmark 1999 Surgeon General's Report on Mental Health provides the current national baseline for understanding mental illnesses and treatment options. Almost 21 percent of children ages nine to 17 today suffer from mental or addictive disorders. ADHD is the most commonly diagnosed and one of the most studied psychiatric diagnosis in children. Its prevalence is approximately three to five percent of school-aged children. However, far fewer children, two to three percent, are being treated for ADHD. Treatment rates are much lower for selected groups such as girls, minorities, and children receiving care through public service systems.

The Surgeon General's Report discusses the diagnostic criteria and practice parameters for ADHD. A diagnosis of ADHD requires the presence of impairing ADHD symptoms in multiple settings for at least six months. Although fidgeting and not paying attention are

common childhood behaviors, the diagnostic criteria for ADHD are reserved for children in whom such frequent behavior produces persistent and pervasive dysfunction. Access to a trained physician is key to accurate diagnosis and treatment.

The reason for the recent controversy around psychotropic medications is that there is a demand by our society for quick cures for all illnesses. Ritalin, in some instances, although not a cure, results in rapid changes in behavior. It calms hyperactivity and improves attention to work in some children. Therefore, if a child is acting up, not attending to work, and seems overactive, parents, teachers, and physicians alike think about Ritalin use. Because of these remarkable changes in some children, there is a tendency for parents and for school personnel to press for its use. However, when Ritalin is used in these cases, it will only be successful in a certain number of situations, most of which can not even be predicted by a competent physician. Furthermore, there are a number of psychiatric and neurological conditions that include hyperactivity and attention deficits where Ritalin will be totally ineffective. For this reason, it is important that a neurologist and psychiatrist do a careful evaluation before Ritalin is prescribed. Some pediatricians who take a special interest in this illness may also be competent to evaluate the proper treatment.

Let me be clear -- No child should be given medication for any condition without first having a complete medical examination and history. As Dr. Fassler will testify, research has shown that clinically-appropriate medication therapies should be used only as part of an integrated and comprehensive treatment plan. If medications such as Ritalin are being used as a "quick-fix" or not being implemented as part of a comprehensive treatment plan, this is a problem.

**Conclusion**

The medical field is in consensus that accurate diagnoses require careful physical examinations and extended behavioral observation. They cannot be made in a 20-minute office visit, and medication should not be regarded as a “quick fix” to make a problem go away. Successful treatment takes time. It requires choices made by parents, working with an appropriate physician. It also deserves the support of schools and communities. Parents, as advocates, should not be able to “force” physicians to prescribe Ritalin for their children.

I remember the testimony of Ms. Weathers during a hearing on the Education Committee two years ago. What happened to her son Michael was a tragedy. Ms. Weather’s case illustrates that children’s mental health needs are not being appropriately addressed by the current system. The Congress should support early assessment, diagnosis and appropriate treatment of mental illness and work to ensure that cases such as this are eliminated.

We should not be sending the message to millions of parents around the country with children suffering from ADHD that their child’s condition is not “real” and that their child’s behavior is the result of bad parenting. We need to further investigate whether Ritalin is being inappropriately used or abused by children.

I strongly urge the Members of this Committee to ensure that their inquiry is focused on the legitimate and serious issues surrounding children suffering from ADHD -- whether those making diagnosis decisions are adequately trained, and whether parents are pressured to utilize behavioral medications to facilitate the management of their children’s behavior in school. As the Committee addresses these issues, I caution Members to base their analyses and conclusions on sound principles of medicine and science, and not on anecdotal non-evidence or pseudo-science, however well-intentioned or sincerely believed.





AMERICAN  
PSYCHOLOGICAL  
ASSOCIATION

**Testimony of the American Psychological Association for the hearing  
record of the House Committee on Government Reform**

**Attention Deficit Disorder/Hyperactivity Disorders—Are Children  
Being Overmedicated?**

**September 26, 2002**

**Submitted by**

**Raymond D. Fowler, Ph.D.**

**Chief Executive Officer**

The American Psychological Association (APA) commends Chairman Burton for holding this hearing on the treatment of children with Attention Deficit/Hyperactivity Disorders (ADHD). Proper diagnosis and treatment of mental disorders in children is important to many parents, teachers, and health professionals across the nation. APA recognizes the need to assess reports about dramatic increases in the use of psychotropic medications with young children, and your interest in ensuring that children with emotional and behavioral conditions are properly diagnosed and treated.

APA is the world's largest scientific and professional organization representing psychology, with a membership of 155,000 researchers, educators, clinicians, consultants, and students. Psychology is unique among health and human service professions, because it is both a scientifically grounded, academic discipline and a health care service-oriented profession.

Many psychologists are on the front-line working on behalf of our nation's children, particularly children with behavioral and emotional challenges. APA's commitment to children's mental health is evidenced by the number of divisions of the membership devoted to children's concerns, including divisions of developmental psychology, clinical child psychology, pediatric psychology, school psychology, and family psychology. That commitment is further demonstrated by APA's governance structure, which includes the Committee on Children, Youth and Families, as well as various task forces devoted to family and adolescent issues.

In the United States, 1 in 10 children and adolescents suffers from mental disorders severe enough to cause some level of impairment. In any given year, up to 3 percent of children and 8 percent of adolescents are affected by depression, and as many as 13 percent of young people experience anxiety disorders. However, according to the National Institute of Mental Health (NIMH), ADHD is the most frequently diagnosed psychiatric disorder of childhood.

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This disorder, which is characterized by poor concentration, impulsivity, and/or hyperactivity, can create difficulties with peers and in multiple settings, such as home and school. ADHD has also been shown to have long-term adverse effects on academic performance, vocational success, and social-emotional development.

The number of children diagnosed with and treated for disruptive disorders, including ADHD, has markedly increased over the last decade. Concurrent with this trend is a growing debate about the best way to prevent, diagnose and treat such problems in children. This is particularly true regarding very young children. A study published in the *Journal of the American Medical Association* in February 2000 showed that the number of preschool children (ages 2 - 4) receiving stimulants, such as Ritalin, and other psychiatric medications "rose drastically from 1991 to 1995." This study raised concerns because so little is known about the safety and effectiveness of these medications, and because few of these drugs are approved by the U.S. Food and Drug Administration for prescription to young children.

For parents, especially parents of a child who has been diagnosed with a behavioral or emotional disorder or who suspect their child has been suffering from such a problem, concerns about the use of psychotropic medications present serious dilemmas. How should parents make decisions about what course of treatment is the best one for their child?

#### **Importance of Appropriate Assessment and Diagnosis**

The first step in successfully treating any mental disorder is an accurate diagnosis. With young children, many factors make proper diagnosis more difficult. Contributing to this difficulty is the lack of access to qualified mental health professionals, and the difficulty obtaining reimbursement for a comprehensive assessment by a qualified professional.

In order to diagnose children with disruptive disorders accurately, health professionals need an understanding both of normal child development and childhood disorders. While all children develop at their own pace, there are developmentally appropriate stages through which children progress. Children in these stages, regardless of their chronological age, exhibit certain behaviors. For example, certain stages of development are characterized by shy behavior, while others are characterized by more motor activity and exploratory behavior.

While teachers, school administrators, or primary care physicians may suggest that a child's behavior could improve if he/she takes a psychotropic medication, a thorough evaluation and diagnosis by an appropriately trained and credentialed mental health professional should take place before any such decision is made. This will help determine if the child's behavior is truly outside the normal range and if ADHD is the best diagnosis. For example, a qualified mental health professional could distinguish between ADHD and other disorders, such as anxiety or depression, which may have similar symptoms and behaviors, but call for different treatment approaches. In addition, knowledge and consideration of the social environments in which a child functions-- what the child is experiencing at home and at school-- makes an essential contribution to a more complete understanding of any child and contributes greatly to an accurate diagnosis.

Psychological assessment is an important contribution to any collaborative effort to diagnose and treat childhood behavioral disorders. Psychological assessment provides data to help distinguish between possible alternate diagnoses and improves intervention outcomes by: describing current functioning across a range of environments; confirming or refuting clinical impressions; identifying treatment needs; identifying appropriate interventions; and providing a means of monitoring treatment progress.

### **Behavioral Treatment as an Important Part of the Treatment Plan**

Parents, teachers, physicians, and mental health providers all strive for the same goal: to help the child function at his or her best. It is no surprise that treatment programs, which can take many forms, work best when specifically tailored to the needs of the individual child and when they include a comprehensive approach to services. Such programs may include psychotherapy, such as cognitive-behavior therapy, and/or behavioral management training, parent education, social skills training, and family support service. If it is determined that a child needs medication, it is often most effective when employed in conjunction with behavioral and other interventions.

Recent research supports the use of comprehensive treatment strategies. A 1998 Consensus Development Conference on ADHD sponsored by the National Institutes of Health indicated that stimulant medications, such as Ritalin, can be very helpful over the short-term in treating core clinical symptoms of ADHD. However, the addition of behavioral treatments resulted in improved functioning in areas such as social skills and academic achievement. In December 1999, the NIMH released the results of a large study of elementary school children, ages 7 to 9, which evaluated the safety and relative effectiveness of the leading treatments for ADHD. Conclusions indicated that the use of stimulants alone was more effective than behavioral therapies in controlling the core symptoms of ADHD in attention, hyperactivity/impulsiveness, and aggression. In other areas of functioning, such as anxiety symptoms, academic performance, and social skills, the combination of stimulant use with intensive behavioral therapy was consistently more effective than either treatment alone. In addition, families and teachers reported higher levels of satisfaction for treatments that included behavioral therapy components.

Medical interventions have clearly proven effective for older children and adults who suffer from ADHD. However, not much is known about the long-term effects of stimulants such as Ritalin, and some studies indicate that stimulants have weak and/or unreliable therapeutic effects on many co-occurring emotional and behavioral problems of children with ADHD, such as depression and anxiety disorders. Furthermore, we know little about safety and effectiveness of stimulants for use in children under the age of six, and little about the potential impact of taking psychotropic medication on a child's developing brain. We also know little about the degree to which gains made while taking medication are sustained after medication usage stops.

### **Summary and Recommendations**

ADHD is a problem of great concern to all of us whether we are policymakers, parents, or mental health care providers. While we know little about the best treatment for very young children with this disorder, we do know a great deal about effective interventions for school-age children with the disorder. We know that proper diagnosis is a critical first step to effective treatment. We know that medication works best when used in conjunction with other interventions, such as behavioral psychotherapy, parent education, and behavioral interventions. We also know that for many children barriers may exist to the best treatments because of lack of access to treatment and because of gaps in our scientific knowledge.

To address the problems of access, several issues are critical to consider. First, families need to be able to access an expert in child behavior who can make a thorough assessment and diagnosis. Once a correct diagnosis of ADHD is made, families need access to the best treatment for their child, including psychotherapy and behavioral interventions. While medical interventions have clearly proven effective for many children, in many cases the use of pharmacological intervention alone is either inappropriate or inadequate. For these reasons, we believe that the best way to diagnose and treat children is through the integrated collaboration of pediatricians, family physicians, psychologists and other health and mental health professionals, parents, and teachers, according to the training, skills and capacities of each and as indicated by a child's individual

needs. Unfortunately, provisions in many health insurance policies hinder families from taking these steps and often force them to make medication their first, and sometimes only, treatment option. Families need better options in helping their children, including health insurance that covers the full array of services research has indicated will help their child.

In addition to addressing the concerns about access to the best treatment, gaps in our knowledge about ADHD must also be addressed. In particular, more research is needed to assess the long-term effects of medication, behavioral therapies, and their combination, on children. Studies of the effect of treatments, including medication, are especially needed for girls and for children under the age of six.

While we need to understand more about the use of psychotropic medications, we also need to understand more about childhood disorders within the context of the family and peers, school, home, and community. This will help us determine how children with different sets of symptoms and needs respond to different types of interventions. The development of early interventions for young children is another area where more research is greatly needed. Finally, further research is needed to help us understand more about how effective interventions may be developed and implemented within various health care settings. NIMH needs additional support to continue to expand research in understanding, treating and preventing children's mental disorders, and to build a cadre of trained scientists and clinical trials networks to do this crucial research.

Many gaps remain in our response to behavioral and emotional disorders in children. It is increasingly clear that the failure to recognize and treat emotional and behavioral disorders in children and adolescents can have devastating results. We know that untreated mental health problems in childhood are related to substance abuse, juvenile delinquency, suicide, and further problems in adulthood. Developing our knowledge base about childhood disorders, such as ADHD, through investment in research is an investment in the future. Helping children access appropriate, comprehensive mental health services for diagnosis and treatment of ADHD and other disorders is an investment in the life of every child and family who needs help. We can afford to do no less.

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Dr. Mary Ann Block, top-selling author, goes further in her new book, *No More ADHD*. She questions the very existence of the ADHD diagnosis with compelling and fact-based arguments. Dr. Block takes the reader on a shocking journey behind the scenes of the mental health profession to expose the origin of the ADHD label and explains how children's attention and behavior symptoms can be the result of real and explainable health and learning problems.

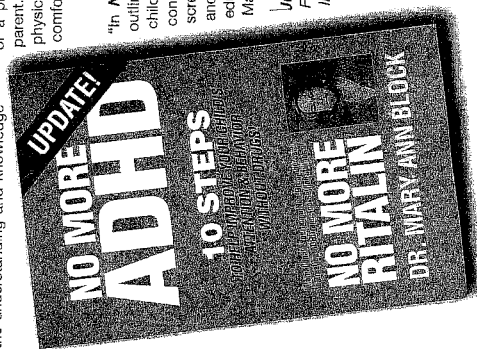
Dr. Block is an international expert and healthcare leader on the treatment of attention and behavior problems without drugs. Her book provides a natural and practical approach to children's health and debunks theories that ADHD is a "chemical imbalance in the brain" or a "mental disorder." She exposes the dangers of psychiatric drugs frequently prescribed for this condition and summarizes the most common causes of attention and behavior symptoms.

While others are debating the pros and cons of the psychiatric drugging of children, Dr. Block has spent her medical career working in the trenches, helping to get children off these drugs and keep them off. A mother who knows all too well how the health system can fail a child, Dr. Block was compelled to go to medical school at the age of 39 to save her daughter after she was made seriously ill by inappropriate drugs used for a wrong diagnosis. Today she brings to her patients the understanding and knowledge of a physician and the sensitivity and respect of a parent. What Dr. Block learned as a mother and a physician is in this book and may help bring hope and comfort to other parents.

"In *No More ADHD*, Dr. Mary Ann Block clearly outlines reasonable solutions to the 'problems' of childhood. This is a must read for parents who are concerned about their children. Do not, and I scream do not, trust psychologists, psychiatrists and the current drug-pushing culture of modern education. There are superior alternatives and Dr. Mary Ann Block has a book full of them."

**Julian Whitaker, M.D.**  
 Founder and Director of the Whitaker Wellness Institute and top-selling author.

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### Help the Campaign to Educate our Leaders

CCHR® is creating a tidal wave of well-educated and powerful opposition to psychiatry labeling and drugging children. From politicians, to policy-makers, to better-informed teachers and newly enlightened parents, united we can eradicate harmful psychiatric meddling in our children's lives. *You can help too.* Buy one or more copies of *No More ADHD* for CCHR to donate to a community leader today. This book contains all the vital information necessary for those who can and will make a difference.

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by continuous heavy chugging from a very early age, can the "afflicted" child possibly make it through life.

**Labeling for Profit**

Jana Dineen, a Canadian psychologist and author of *Manufacturing Victims*, says psychology is neither a science nor a profession, but an industry that turns healthy people into victims to give itself a constant source of income.

Psychiatry's *Diagnosis and Statistical Manual of Mental Disorders (DSM)*, their cookbook of "mental illnesses," is no more scientific or reliable than reading tea leaves. Professors Herb Kutchins and Stuart A. Kirk in *Scientific American* say that the DSM "is primarily about being a guide to filling out insurance forms."

As Dr. Baughman states, "We are not over-diagnosing or misdiagnosing ADHD-ADHD is a total, 100 percent fraud. The twenty millions of school children around the world who are being drugged have no disease. Had the vast majority of these children learned to read properly utilizing phonics they would never have been labeled as having ADHD or any other learning disorder."

Driven by huge financial incentives, the "virtue" of "learning disorders" in the country today is no more than a profit-making industry, with children and parents paying the price.

**Some Solutions**

- It is a fact that undiagnosed, untreated physical conditions often manifest as a "psychiatric symptom." Advise reactions to common prescription drugs can also create unwanted behavior. According to Dr. Doris Rapp, a board-certified environmental medical specialist, pediatric allergist and author of *The New York Times Best Seller, Is This Your Child?*, "A wide variety

Nor are these "disorders" the results of a "chemical imbalance" in the brain. In 1996, psychiatrist David Kaleler stated: "Patients (have) been diagnosed with 'chemical imbalances' despite the fact that no test exists to support such a claim and...there is no real conception of what a correct chemical balance would look like."

New York psychiatrist Ron Lefter says, "There's no biological imbalance. When people come to me and say, 'I have a biochemical imbalance,' I say, 'Show me your lab tests. There are no lab tests. So what's the biochemical imbalance?' While a California psychiatrist says of psychiatry, "...What they have done is medicalize many problems that don't have demonstrable, biological causes." Jeffrey A. Schaler, Adjunct Professor of psychology from Philadelphia also warns that "legislators and the general public should not be hoodwinked... behaviors cannot be diseases."

**When "Normal" is Redefined as Living on Drugs**

You probably have your own idea of what a "normal" sort of life is. Does it involve the consumption of addictive, mind-altering and potentially dangerous, psychiatric drugs? Does it involve total reliance on such drugs to remain normal? Well, to the average psychiatrist and psychologist, nothing could be more normal. In fact, when a child is diagnosed with ADD/ADHD and other licit/licitous behavior "disorders," he is most often prescribed methylphenidate (Ritalin), an amphetamine-like drug classified as a Schedule II drug—the exact classification covering morphine, opium and cocaine.

By such wordplay, psychiatrists and psychologists have thoroughly duped well-meaning parents, teachers and politicians alike—that "normal" active childhood behavior is no longer normal, that it is a mental *illness*. And further, that only

**ADHD – The "virus" of the 90's**

Over-activity, fatigue, head-wetting, inappropriate behavior, depression, screaming, irritability, stomping feet, won't sit still, tossing toys, knowing objects your child has turned from a Dr. Sebel! to a Mr. Hyde before your very eyes. You've had it! You're in tears.

The worst thing to do at this point is to see a psychiatrist who tells you that your child has a serious mental disease: Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD). Or to listen to a school psychologist telling you that your child has a "Learning Disorder (LD).

Dr. Fred A. Baughman Jr., a pediatric neurologist and fellow of the American Academy of Neurology, has discovered and described real diseases. Finding no abnormality, no sign of disease in children said to have ADD/ADHD and "learning disabilities," he writes of these as "inventions, continuances and a fraud."

Children, he said, "believe they have something wrong with their brains that makes it impossible for them to control themselves without using a pill." This is reinforced by "heaving the most important adults in their lives, their parents and teachers, believe this as well.

"These make-up disorders," he adds, "along with others including Severe Emotional Disorder, Dyslexia or Dyscalculia (special arithmetic disorder), have never been validated as brain diseases," Kevin P. Dwyer, assistant executive director of the National Association of School Psychologists in the U.S., said that the way "learning disorders" are diagnosed is "not a science. We're not sophisticated enough to do a perfect diagnosis," he revealed. Even the American Psychiatric Association (APA) admits that there are "...no laboratory tests that have been established as diagnostic" for ADHD.



**Attention Deficit/Hyperactivity Disorder-Are We Over-Medicating Our Children?**

Testimony for the record of hearing held by the U.S. House Committee on Government Reform held September 26<sup>th</sup>, 2002

International Center for the Study of Psychiatry and Psychology IDEA Task Force  
 Karen R. Effrem, M.D., chairperson and lead author  
 Doretta Hegg, M.A.  
 Grace Jackson, M.D.  
 Bob Jacobs, Psy.D.

**INTRODUCTION:** The International Center for the Study of Psychiatry and Psychology Task Force on IDEA thanks the Committee and Chairman Burton for holding this hearing on this important topic and appreciates the opportunity to submit testimony for the record. ICSPP was founded by psychiatrist Dr. Peter Breggin and is a group of concerned professionals and lay people that oppose coercive psychiatric treatment in all of its forms. We would strongly answer in the affirmative the question used in the title of this hearing. Not only are children being over-medicated, but as you will see from this testimony, there is little benefit or wisdom and many risks in medicating children at all. We will answer that question as well as describe our understanding of the origins of the problem, the problems with and the consequences of over-medication of children along with recommendations for change.

**ARE WE OVERMEDICATING OUR CHILDREN WITH "ADHD"?** - We believe that the answer to that question is a resounding "YES!" Here are some statistics showing both the skyrocketing rates of psychiatric diagnosis for children and the appallingly high rates of psychiatric medication in children:

- ❖ **Astronomical increase in rates of diagnosis of children since 1991** – 1991 is when mental and emotional disorders, particularly ADHD were added to the diagnoses covered by the Individuals with Disabilities Education Act (IDEA). These mental and emotional "disorders" can be "treated" by the schools at very low cost to them. The parents have to purchase the medication while the schools receive the funding and expend few or no other funds to help the child in any other way. Here are some examples of this alarming trend from various reports:
  - According to a 2002 report by President Bush's Commission on Special Education entitled *A NEW ERA: Revitalizing Special Education for Children and their Families*, 90% of students served under IDEA have "high incidence" disabilities such as mental, emotional, specific learning disabilities or "other health impairments."<sup>1</sup>
  - The "other health impairment" category has "increased 319% in the last ten years" (since mental and emotional disorders were added to IDEA in 1991). "Some of the growth in the OHI category is the result of the growth in children identified as having ADHD, where a physician's signature is generally sufficient to trigger the eligibility process."<sup>2</sup>
  - Using just the state of Minnesota as an example, the rate of designation for emotionally and behaviorally disturbed children has increased 36% and OHI, which includes ADHD, has increased 830% since 1991.<sup>3</sup>

❖ **Skyrocketing use of psychotropic drugs in children –**

- Prescription of psychotropic drugs, particularly Ritalin, for 2 to 4 year old children, increased 300% between 1991 and 1995.<sup>4</sup> Ritalin (methylphenidate), along with amphetamine and methamphetamine are in the stimulant class of psychiatric medications. Ritalin is the drug most commonly used on children labeled ADHD.
- Data on “‘drug mentions’ that occur during a hospital or office visit when a doctor provides or prescribes a medication, or orders it refilled” was analyzed by the National Center for Health Statistics for a Sacramento Bee story. According to that data, stimulants such as Ritalin were mentioned 5.3 million times in the year 2000, which was nearly twice as often as they were mentioned in 1995-1996.<sup>5</sup>
- According to the National Ambulatory Medical Care Survey performed by the Center for Disease Control’s National Center for Health Statistics, the prescription of central nervous system drugs had the highest increase for children, up an alarming 327% between 1985 and 1999. The study finds that the stimulant drug Ritalin was among the most frequently mentioned drugs in this class during children’s visits in 1999.

**WHAT FACTORS ARE CONTRIBUTING TO THE DRUGGING OF CHILDREN?** – There are a number of factors that are contributing to the over-diagnosis and the over-medication of children. These include lack of awareness of, and failure to examine, other medical/nutritional, societal, and educational issues, including federal mandates that may be contributing to emotional and behavioral problems in the classroom:

❖ **Medical**

- Other undiagnosed illnesses<sup>6</sup>
- Reactions to medications for almost any illness<sup>7</sup>
- Nutritional/Metabolic<sup>8</sup>
  - Artificial colors in food
  - Hypoglycemia
  - Food allergies and intolerances
  - Vitamin and mineral deficiencies
  - Hormonal imbalances - esp. thyroid
  - Amino acid imbalances
  - Essential fatty acid deficiencies
  - Inherited metabolic disorders
- Environmental allergies and toxicity<sup>9</sup>
  - Pesticides and chemicals used in homes and schools
  - Pollution
  - Radon
  - Hormones and antibiotics in meat
- Heavy metal toxicity
  - Lead
  - Mercury - from vaccines and dental fillings<sup>10</sup>
  - Cadmium
- Vaccine Reactions<sup>11</sup>
- Overuse of antibiotics / yeast<sup>12</sup>

## ❖ Educational –

- **IDEA** - This “special education” legislation was passed in 1975 to allow all children with disabilities access to public education. All children with disabilities were to receive a “free appropriate public education” in the “least restrictive environment.” Congress promised to pay forty percent of the expenses to allow that access, but has never paid more than about seventeen percent. This has resulted in a huge un-funded mandate for the states. IDEA started with payments to schools for children with physical disabilities, such as blindness, cerebral palsy, and orthopedic problems. In 1991, the criteria were changed to include children with mental and emotional disorders. The definition of a child with a disability in the law, particularly regarding mental and emotional problems is terribly vague: “a child with mental retardation... serious emotional disturbance ...autism, traumatic brain injury, other health impairments or specific learning disabilities...”<sup>13</sup> “ADHD” the most common mental or behavioral label given to children, is in the “other health impairment” category. The criteria for emotional disturbance, while trying to maintain the aura of clinical credibility, are appallingly vague. These criteria are completely in the eye of the beholder, and with the states and schools having incentives to identify children; it is rather like a fox guarding the henhouse. These criteria also leave open the possibility that a child could be labeled for political reasons. For example, what standards are to be applied, and who is authorized to determine whether or not a child displays “inappropriate types of behavior or feelings under normal circumstances,” a “pervasive mood of unhappiness or depression,” or an “inability to build or maintain satisfactory interpersonal relationships with peers and teachers”?? Although well intentioned, the Individuals with Disabilities Education Act has resulted in perverse financial and policy incentives for too many children to be labeled with mental and emotional disorders and learning disabilities according to criteria which are extremely vague, controversial, and too easily misinterpreted. Besides burdening a child with a label that will stay for the rest of one’s academic and employment career, far too many children are placed on powerful medications. These drugs have dangerous side effects with no long-term research to expose potential harm from chronic/acute use
- **ILLITERACY** – “up to 90 percent of children identified as Specific Learning Disabilities have reading as their primary area of difficulty”<sup>14</sup>
- Increase in per pupil funding for schools (IDEA and Elementary and Secondary Education Act) – Schools may exempt IDEA children from the federally mandated assessments that determine the majority of federal funding states and school districts receive based on “adequate yearly progress” under the ESEA<sup>15</sup>. This is done frequently for minority students, which is one reason so many minority students are labeled as emotionally disturbed or mentally retarded.<sup>16</sup> The per pupil funding in IDEA was changed in the 1997 reauthorization to prevent over-labeling, but that did not go into effect until 2000, so it is unclear that it has helped.

- Outcome based education via federal mandates (Goals 2000, School to Work, and ESEA) – These mandate the teaching of a psychosocially based curriculum<sup>17</sup> that creates cognitive dissonance in children when taught by the schools to believe things other than those on which they have been raised.<sup>18</sup> This curriculum also deprives poor children of the academic basics that they desperately need to obtain a better life. The boredom and frustration can lead to behavior problems and even violence.<sup>19</sup>
  - Attempt to gain correct thought and action based on federal curriculum – Much personal and psychological data is collected on students via surveys and assessments.<sup>20</sup> One example from the Cornell Review and Fox News, which documented in January, 2002 is a stunning example of grading based on attitudes, which could easily lead to labeling for special education: “School officials in Ithaca, N.Y., are requiring that first- and second-graders there be graded on their tolerance, reports the Cornell Review. The kids will get grades based on how well they ‘respect others of varying cultures, genders, experiences, and abilities.’ The grade will appear on report cards under the heading ‘Lifelong Learning Skills.’ It appears well before social studies, science, reading, or writing.” Lifelong Learning is part of the School to Work program, which also passed in 1994. STW tracks children into jobs chosen by big business and the government. Success in this system depends not on what one knows, but rather what one thinks and believes.<sup>21</sup>
  - Effort to gain academic advantage (e.g. untimed tests)
  - Boring, ineffective, and unsafe classrooms
- ❖ **Societal**
- Behavior control tool for parents and teachers
  - Societal changes and pressures
    - Divorce
    - Daycare
    - Teen parenthood
    - “Hurried” child
  - Temptation for people to want to receive Social Security disability income
  - Feminism – The War Against Boys<sup>22</sup>
  - Drug company profits

**WHAT ARE THE PROBLEMS WITH LABELING AND MEDICATING CHILDREN?** – The four main problems are that there are no concrete criteria for diagnosis, dangerous side effects of the drugs, lack of effectiveness of the drugs, coercion of parents, and an invalid screening process with the resulting labels having profound and long-lasting harmful effects on the children.

- ❖ **No concrete tests or reproducible criteria for diagnosis** - As ICSP IDEA task force member, Bob Jacobs, Psy.D., has stated in his Australia-based report on ADHD for the Queensland Youth Affairs Network entitled Queensland’s Children at Risk, “The undisputed clinical reality in July of 2002 is this: Physicians are identifying a “disease” based SOLELY on reports and observations of behavior. The only “tests” are questionnaires about the child’s behavior, usually completed by the parents or teachers whose frustration with the child prompted the doctor visit in the first place. There is no confirmatory physical examination, EEG, CT-scan, X-ray, PET scan or any other diagnostic instrument because there is nothing to look for. By all standards of medicine these are healthy children whom we are arbitrarily declaring “sick” because people are not happy with their behavior.” Here are several other reports and statements from around the world to confirm that clinical reality:
- The New Era report says that children with these “high incidence” ‘disorders’ “cannot be identified on the basis of acuity, physical or neurological findings.”<sup>23</sup>

- The 2001 World Health Report by the World Health Organization states, “Childhood and adolescence being developmental phases, it is difficult to draw clear boundaries between phenomena that are part of normal development and others that are abnormal.”
- The 1999 Surgeon General’s Report on Mental Health says, “The diagnosis of mental disorders is often believed to be more difficult than diagnosis of somatic or general medical disorders since there is no definitive lesion, laboratory test or abnormality in brain tissue that can identify the illness”
- “Finally, why must the APA (American Psychiatric Association) pretend to know more than it does? DSM IV (the fourth edition of the Diagnostic and Statistical Manual) is the fabrication upon which psychiatry seeks acceptance by medicine in general. Insiders know it is more of a political than scientific document.”<sup>24</sup>

❖ **Harmful side effects of psychotropic drugs used in children without long term safety studies –**

- According to research highlighted by psychiatrist, Dr. Peter Breggin in his book *Talking Back to Ritalin*,<sup>25</sup> these medications actually cause the same symptoms they are supposed to treat – hyperactivity, impulsivity and inattention, which can lead to a vicious cycle of incorrect and dangerous dosage increases.
- These drugs work by altering brain function, causing a short-term change in behavior that may actually interfere with learning. They produce rote compliance in structured environments at the cost of spontaneity, creativity and social interaction. The stimulant drugs also impair flexible problem-solving and divergent thinking. James Swanson, a researcher for the U.S. Department of Education and leading Ritalin advocate, stated in a 1992 review of the medical literature that this type of “cognitive toxicity may occur at commonly prescribed clinical doses of stimulants,” and in up to 40% of patients.<sup>26</sup>
- Other very worrisome side effects include sleeplessness, weight loss, growth retardation including decreased brain growth, heart damage including cardiac arrest, atrophy (shrinkage) of the brain, psychosis, and violence.<sup>27</sup> Particularly concerning is a 1986 study that showed cortical atrophy in 50% of a group of 24 young adults who had been on Ritalin for several years in their childhood.<sup>28</sup> Neither the Food and Drug Administration nor the pharmaceutical manufacturers have ever followed up this study. Dr. Breggin reiterates this concern by saying, “Brain structural abnormalities found in children diagnosed with ADHD and treated with stimulants – to the extent that they are valid findings – are almost certainly due to the stimulants and other psychiatric medication to which they have been exposed. These studies add to the accumulating evidence that psychostimulants cause irreversible brain damage.”<sup>29</sup>
- Psychosis is one manifestation of the kind of brain damage that can occur from use of the stimulants. The risk of psychosis is listed in the package insert, but receives little attention from physicians and is rarely discussed with parents. Psychosis may happen as a toxic reaction to the stimulant medications or as they are withdrawn after long-term use. Previously thought to occur in 1% of patients on the stimulants, a 1999 study from the *Canadian Journal of Psychiatry* showed that the incidence of drug-induced psychosis is closer to 9% and that is probably an underestimate.<sup>30</sup> A 1993 study by Koek and Colpaert states that Ritalin “induces a psychopathology that seems to mimic schizophrenic psychosis more closely than amphetamines and cocaine.”<sup>31</sup> These schizophrenic-like and manic-like reactions to stimulants are thought to lead to violence as well as depression and suicide.<sup>32</sup> All

four of the perpetrators of the major school shootings were taking psychiatric drugs, some including Ritalin, at the time of their crimes.<sup>33</sup>

- The package insert for Ritalin confirms that there are no long-term studies on the effects of these medications on young children's growing brains. It says in the "WARNING" section, "Sufficient data on safety and efficacy of long-term use of Ritalin in children are not yet available," and Ritalin should not be used in children under six years, since safety and efficacy for this age group have not been established." Yet, both of these warnings are routinely ignored as described by the Zito study in Problem 2 above.
- ❖ **Lack of effectiveness of the medications** - There has never been a single long-term study showing academic or social benefit of the stimulant medications. Here are a few of many examples from the medical literature:
- The 1999 Surgeon General's report said, "However, psychostimulants do not appear to achieve long-term changes in outcomes such as peer relationships, social or academic skills, or school achievement." Obviously Ritalin and other members of its class are making learning more difficult, which is not what is wanted for special needs children served under IDEA or in any classroom.
  - "Stimulants do not produce lasting improvements in aggressivity, conduct disorder, criminality, education achievement, job functioning, marital relationships, or long-term adjustment."<sup>34</sup>
  - "Long term efficacy of stimulant medication has not been demonstrated for *any* (original emphasis) domain of child functioning."<sup>35</sup>
- ❖ **Coercion of parents to drug their children** - ICSP IDEA task force member, Doretta Hegg, M.A., founder of C.H.I.L.D., sees repetitive intimidation and suggestive coercion employed by schools that panic parents into putting their child on a psychotropic medication. Here are a few examples from around the country:
- In New York, Patricia Weathers, as you have heard in testimony,<sup>36</sup> and the Carroll<sup>37</sup> families were threatened or charged with child abuse for wanting to take their sons off of stimulant medications following adverse reactions. The Carroll family was ordered by a judge to continue the medication despite the drug's severe adverse effects on Kyle's sleep and appetite. According to New York Post reporter Douglas Montero, "Assemblyman Felix Ortiz, the Brooklyn Democrat trying to create a law banning educators from verbally prescribing Ritalin, said that since last week, his office has received 63 phone complaints from parents."<sup>38</sup>
  - Neil Bush, brother of President George W. Bush, stated that he endured pressure from a private school in Houston to medicate his son Pierce with Ritalin for ADHD incorrectly diagnosed by the school. "There is a systemic problem in this country, where schools are often forcing parents to turn to Ritalin," said Bush, 47, who spent years researching the issue. "It's obvious to me that we have a crisis in this country." Neil Bush also said, "The problem is, it isn't the kids that are broken. It's the system that is failing to engage children in the classroom," and "My heart goes out to any parents who are being led to believe their kids have a disorder or are disabled."<sup>39</sup>
  - Paul Johnston of West Virginia began kindergarten as an exuberant and very normal five year old until the teacher began pressuring his parents to have him evaluated for ADHD. The parents were coerced into starting him on Ritalin, and he was eventually "treated" with a total of *sixteen* different psychotropic medications and experienced seven hellish years of drug-induced psychosis. He was finally released from an institution after a court battle and was carefully withdrawn from the medication by Dr. Breggin.<sup>40</sup>

- Daniel Salazar's parents, Raul and Yolanda, were threatened with removal of Daniel from their home in Florida if they did not give Daniel psychiatric drugs.<sup>41</sup>
- ❖ Invalid screening process for behavioral and emotional disorders with resulting labels having profound, long-lasting negative effects on a child – Early intervention programs within the field of mental health engender serious dilemmas. The contemporary example of pre-psychotic treatment programs was analyzed by ICSPP IDEA Task Force member Grace Jackson, M.D. and may be used to illustrate a variety of methodological flaws associated with premature screening and preventive pharmacology for attention deficit disorder, which in some studies has been used as a marker for schizophrenic psychosis.<sup>42</sup>
  - Specificity: Problems with specificity arise from the use of screening instruments that incorrectly identify healthy individuals as abnormal. In many investigations, the use of ambiguous features to identify patients (or pre-patients) has led to inappropriate labeling and treatment.
  - Validity: Due to the complex or vague nature of symptoms used to define categories of mental disease, it is frequently impossible for health professionals to agree upon the presence of pathology, the onset or resolution of illness, or the advisability or effectiveness of particular interventions, such as treatment with psychostimulant medication.
  - Amplification: The emerging and expanding use of “subthreshold” or “pre-syndromal” symptoms to identify individuals at risk for specific disorders appears to amplify the prognostic implications of irrelevant or even normal mental states, by identifying them as precursors of severe disease.
  - Kindling: By suggesting that unmedicated symptoms inevitably progress to serious and specific disease, researchers ignore the fact that many individuals fail to develop the conditions that the kindling model predicts. Furthermore, there is little evidence to substantiate the claim that the best method of disease prevention lies in the early administration of treatments that would otherwise be reserved for the true disease. [The fallacious reasoning here would recommend that bone fractures be prevented by early casting; breast cancer, by preventive mastectomy; and diabetes, by preventive use of insulin.]
  - Results of Labeling: Regardless of the benevolent intentions that inspire them, all interventions with diagnostic labels give rise to potentially adverse consequences:
    - Self-fulfilling prophecy (the Pygmalion effect) - suggests that individuals fulfill others' conscious and unconscious expectations, be they positive or negative.
    - Special attention (the Hawthorne effect) - suggests that individuals are strongly influenced by the mere process of being observed. It reminds us that the true potential of an individual might have far less to do with innate capacities than with the social forces and relationships to which he or she is exposed.
    - Stigma – When it is associated with the pronouncement of a specific disorder, stigma can be devastating, due to ensuing restrictions in education and employment opportunities; disruption in critical relationships; the ability to obtain and afford medical insurance and most importantly, destruction of self-confidence and self-esteem. To do this to a young child at the beginning of the academic career would be especially damaging. Additionally, because federal education mandates are causing academic achievement to be closely linked to psychological parameters such as attitudes, values, and

beliefs, screening will allow political issues to factor into the realm of already less than valid psychiatric diagnosis and coercive treatment.

**RECOMMENDATIONS:**

- 1) **Change the financial and policy incentives for schools to label children with mental and emotional disorders or learning disabilities that have vague criteria** – Data need to be collected and evaluated to make sure that the 1997 changes to IDEA are working to prevent schools labeling children to receive more funding. Amendments to the Elementary and Secondary Education Act (ESEA) are needed that will prevent a special education label just so schools can exclude special education children in assessment scores to increase federal funding. Both of these will help IDEA funds to go to the children who truly need them, those with more verifiable, less controversial disorders.
- 2) **Limit acceptable emotional disorders under IDEA to those with demonstrable organic etiology** – IDEA's mandates should be limited only to valid medical conditions, in order to prevent the harm of inappropriate labeling, and the ensuing
- 3) **treatment employing powerful, potentially dangerous psychiatric drugs**
- 4) **Investigate dangers of psychiatric medications, such as cortical atrophy, psychosis, violence, suicide, and cardiac arrest** – Congress should exercise its legitimate oversight authority of the Food and Drug Administration and call for thorough investigations into the role of these drugs in the problems listed.
- 5) **Prohibit and penalize coercion of parents to drug their children** – Withholding federal IDEA funds or making schools financially responsible for the costs of withdrawing children from psychotropic medication and any adverse effects of those drugs are penalties that are being discussed. Although some physicians are too eager to prescribe these medications, at least the decision should be removed from unqualified school personnel to parents and their family physician without threat of child abuse charges, or threat of losing their children by removal from the home, expulsion from school, or inappropriate placement into alternative educational environments.
- 6) **Safeguard the rights of parents and children, by emphasizing the need for fully informed consent and by demanding that prescribers disclose the risks and potential adverse effects associated with the use of psychoactive medications** - No parent should have to find out about the potential for cardiac arrest, growth retardation, cortical atrophy, psychosis, violence, or suicide because it happens to their child.
- 7) **Ensure that other reasons for behavior or academic problems are discussed before psychotropic drugs are suggested** – The list above, though incomplete, is quite long. no child has emotional or behavioral problems due to a natural, metabolic deficiency of any psychotropic drug. Ensuring that other causes are identified and appropriately managed will preserve the responsible allocation and delivery of scarce funds to those children who truly need them.



- 8) **Focus on academic issues instead of expanded behavioral screening** – According to special education teacher, Mary Sue Laing, “EARLY [ACADEMIC SCREENING and] INTERVENTION is of the utmost importance in assisting students, especially young students. A month is a long time in the life of a little child. Intervention should consist of using highly structured methods that teach the student how to read, write, and do math correctly from the beginning. In reading, only methods that teach the sound-symbol relationship should be used. Visual guessing in reading, invented spelling, and free play with math manipulatives are inadequate methods for students who experience learning difficulties.” It is these activities upon which schools must concentrate. Given the inaccuracy of the process and the invalidity of the diagnoses, especially ADHD, expanded behavioral screening will result in more children receiving labels with the harm described above and treated with psychotropic drugs with all of the dangerous side effects also described above.
- 9) **Strictly enforce the 2001 Protection of Pupil Rights Amendments in the ESEA that that require notice and right of parental inspection of curriculum and physical or psychological evaluations, including surveys, of students in school, as well as opting their children out of these procedures and related curriculum.**<sup>43</sup>
- 10) **Strictly enforce the 2001 amendments to the ESEA that prohibit assessments based on attitudes, values, and beliefs of students and their families.**<sup>44</sup>

<sup>1</sup> Presidential Commission Report - *A NEW ERA: Revitalizing Special Education for Children and their Families* 7/02, p. 21 at <http://www.ed.gov/initiatives/commissionsboards/whspecialeducation/reports/pcsefinalreport.pdf>

<sup>2</sup> *Ibid.*, p.23

<sup>3</sup> MN Dept of Children Families and Learning data from annual reports on students receiving IDEA funds

<sup>4</sup> Zito, JAMA, Vol. 283, No. 8, 2/23/00

<sup>5</sup> See *Pills or Patience?* Sacramento Bee, 6/23/02 at <http://www.sacbee.com/content/news/story/3313233p-4344565c.html>

<sup>6</sup> See any pediatric or internal medicine text book

<sup>7</sup> See any edition of the *Physician's Desk Reference* or pharmacology textbook

<sup>8</sup> See, for example, Murray, M. and Pizzorno, J., (1998) *Encyclopedia of Natural Medicine*, Revised 2<sup>nd</sup> Edition, Rocklin, CA, Prima Publishing pp. 273-281

<sup>9</sup> See, for example, Rapp, D., (1996) *Is This Your Child's World? – How You Can Fix the Schools and Homes That Are Making Your Children Sick*, New York, Bantam

<sup>10</sup> Cave, S., (2001) *What Your Doctor May NOT Tell You About Children's Vaccinations*, New York, Warner Books, p. 39-56

<sup>11</sup> *Ibid.*, pp. 57-78

<sup>12</sup> Crook, W., (1991) *Help for the Hyperactive Child*, Jackson, TN, Professional Books

<sup>13</sup> Public Law 105-17, Section 602(3)(A)(i)

<sup>14</sup> *A New Era*, p. 22

<sup>15</sup> See The No Child Left Behind Act of 2001, Section 1111, (b)(2)(C)

<sup>16</sup> See (2002) *Minority Students in Special and Gifted Education*, Washington D.C., National Academy Press, <http://books.nap.edu/books/0309074398/html/index.html>, especially Chapter 2

<sup>17</sup> See the Goals 2000 chapter of Quist, A. *The Seamless Web*, 1999 Mankato, MN Maple River Education Coalition at [http://mredcopac.org/Seamless%20Web/chap\\_01.pdf](http://mredcopac.org/Seamless%20Web/chap_01.pdf)

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<sup>19</sup> Brunner, M., (1993) *Retarding America, Imprisoning Potential*, Halcyon House as quoted in Eakman p. 385

<sup>20</sup> See Eftrem, K. Data Privacy Chapter of Quist, A., (1999) *The Seamless Web*, Mankato, MN Maple River Education Coalition at [http://www.edwatch.org/seamless\\_web.htm](http://www.edwatch.org/seamless_web.htm)

<sup>21</sup> See Chapman, M., and Bachmann, M., *US Policy embraces State-Planned economy*, Maple River Education Coalition at <http://mredcopac.org/upda0219.htm>

<sup>22</sup> See Sommers, C. (2001) *The War Against Boys: How Misguided Feminism is Harming Our Young Men*, Touchstone *A NEW ERA*, p. 21

<sup>24</sup> Mosher, Loren, M.D., Psychiatrist, former Chief of the National Institute of Mental Health's Center for the Study of Schizophrenia, quoted in *Death from Ritalin: The Truth Behind ADHD*, available at

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<sup>25</sup> Breggin, P. (2001). *Talking Back to Ritalin*, revised edition. Cambridge, MA: Perseus Publishing, p. 32

<sup>26</sup> *Ibid.*, pp. 49-50

<sup>27</sup> *Ibid.*, p. 32

<sup>28</sup> Nasrallah, H., et al., *Psychiatry Research* 17:241-246, 1986 as quoted in *ibid.*, p.67

<sup>29</sup> *Ibid.*, p. 69

<sup>30</sup> Cherland and Fitzpatrick, *Canadian Journal of Psychiatry*, October, 1998, as quoted in *ibid.*, p. 45

<sup>31</sup> Koek, W., and Colpaert, F.C., *Journal of Pharmacology and Experimental Therapeutics*, Vol. 267, p. 181-191, 1993 as quoted in *ibid.*, p. 46

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<sup>33</sup> See Farber, B., *The Link Between Anti-depressants and Mayhem*, Newsmax.com, July 2, 2001 at <http://www.newsmax.com/archives/articles/2001/7/2/181622.shtml>

<sup>34</sup> *Textbook of Psychiatry (1995)*, American Psychiatric Press

<sup>35</sup> NIMH collaborative multisite, multimodal treatment study of children with ADHD, 1995

<sup>36</sup> Montero, D., *I was forced to dope my kid*, New York Post, 8/7/02 at

<http://www.nypost.com/news/regionalnews/54243.htm>

<sup>37</sup> Karlin, R., *Court orders couple to give son drug (Ritalin) after school turns parents in*, Albany Times Union, 7/19/00

<sup>38</sup> Montero, D., *Bush's Bro: My Son was a Victim of School Rx*, New York Post, 8/14/02 at

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<sup>39</sup> *Ibid.*

<sup>40</sup> *A Parent's Nightmare: Losing a Child to Drug-Induced Psychosis*, Education Reporter, June, 2002 at

<http://www.eagleforum.org/educate/2002/june02/drug-induced.shtml>

<sup>41</sup> Eakman, B., *Uncle Sam's Classroom*, originally published September, 2000 in *Chronicles* at

[http://www.beverlyc.com/classroom\\_20000821.html](http://www.beverlyc.com/classroom_20000821.html)

<sup>42</sup> NIMH document PKT 00-0016, October 1995, "Multimodal Treatment Study of Children with ADHD," entitled "Cooperative Agreement for Multi-Site Multimodal Treatment Study of Children With ADHD (MTA): Investigator William E. Pelham, Ph.D., Western Psychiatric Institute & Clinic, University of Pittsburgh. Grant Title: *Pharmacologic and Psychosocial Treatment for ADHD* (UoIMH50467-01) as quoted from Eakman, B., (1998) *Cloning of the American Mind – Eradicating Morality Through Education*, Lafayette, LA, Huntington House, p. 103 and discussed on pp. 98-100 and 173-175

<sup>43</sup> See The No Child Left Behind Act of 2001, Section 1061

<sup>44</sup> *Ibid.*, Sections 1111(b)(3)(C)(xiv) and 411(b)(5)(A), which say, "... objectively measure academic achievement, knowledge, and skills, and be tests that do not evaluate or assess personal or family beliefs and attitudes, or publicly disclose personally identifiable information

**STATEMENT OF JIM MCNULTY**  
**ON BEHALF OF NAMI—**  
**THE NATIONAL ALLIANCE FOR THE**  
**MENTALLY ILL**  
**ON**  
**“ATTENTION DEFICIT/HYPERACTIVITY DISORDERS -- ARE CHILDREN BEING**  
**OVERMEDICATED?”**  
**SUBMITTED TO THE**  
**COMMITTEE ON GOVERNMENT REFORM**  
**U.S. HOUSE OF REPRESENTATIVES**  
**SEPTEMBER 27, 2002**

Chairman Burton, Representative Waxman and members of the Committee, I am Jim McNulty, President of NAMI—The National Alliance for the Mentally Ill. On behalf of NAMI, I submit these comments for the record. NAMI is deeply concerned that the Committee held the hearing to largely recycle bad science and trivialize the need for early identification and treatment of mental illnesses in children and adolescents. In doing so, the Committee missed a wonderful opportunity to examine childhood mental disorders and emerging scientific consensus about how best to respond to the needs of children who suffer from these illnesses. Public policy involving treatment of Attention Deficit Hyperactivity Disorder (ADHD) and other brain disorders must be founded on science, not science-fiction or religious ideology. Public policy on health issues must be shaped by scientific evidence. The best available research and the most knowledgeable experts should guide congressional oversight and legislative action on the diagnosis and treatment of psychiatric disorders in children.

Who is NAMI?

NAMI, the National Alliance for the Mentally Ill, is the leading family member and consumer grassroots membership organization in the nation dedicated to improving the lives of individuals with severe mental illnesses and their family members. NAMI was founded in Madison, Wisconsin in 1979 and currently has over 220,000 members, 50 state organizations and over 1,200 local affiliates. Through these chapters and affiliates in all 50 states, NAMI supports education, outreach, advocacy and research on behalf of persons with serious brain disorders such as schizophrenia, manic depressive illness, major depression, severe anxiety disorders and major mental illnesses affecting children, including ADHD. NAMI families know all too well the barriers that exist in accessing quality treatment for their children struggling with mental illnesses, however, these families can also speak of how their lives, and the lives of their children, have been dramatically improved by effective treatment.

### The Legacy of Failure in this Country to Treat Childhood Mental Illnesses

Before addressing the content of the hearing, it is critically important to frame NAMI's testimony in the context of the legacy of failure in this country to treat childhood mental illnesses. Also, it is appropriate to address the treatment of ADHD in the broader context of childhood mental illnesses because research shows that 69% of children with ADHD have one or more co-occurring disorders. (NIMH, Multi-modal Treatment Study of Children – MTA, 1999)

Contrary to the suggestion at the hearing that we are overdiagnosing and overtreating children with ADHD in this country, well-documented studies and reports make clear that we have repeatedly failed to provide gravely needed treatment and services to children with ADHD and co-occurring mental illnesses. This country is experiencing a health care crisis as a result of our failure to identify and treat children in need of mental health services. In 2000, the Surgeon General convened a conference of experts and issued a report on children's mental health. The report identified that 1 in 10 children and adolescents in this country suffer from mental illness severe enough to cause impairment. Yet, in any given year, only 1 in 5 children receive mental health services. The unmet need for treatment and services for children remains as high today as it was 20 years ago.

The World Health Organization Global Burden of Disease Study indicates that by the year 2020, childhood neuropsychiatric disorders will rise proportionally by over 50% to become one of the five most common causes of morbidity, mortality, and disability among children.

Our nation lacks a unified infrastructure to address the needs of children and adolescents with mental illnesses and their families. Consequently, families often have nowhere to turn in their hour of greatest need. NAMI is frequently contacted by families across the country who often have nowhere to turn for mental health services for their child when they have exhausted their private insurance benefits for mental health coverage (most insurers place discriminatory caps on mental health benefits). Most of these families do not qualify for Medicaid benefits. These families are often told by state agencies and others that they can access critically needed treatment by relinquishing custody of their child to the state. NAMI's 1999 report – *Families on the Brink, The Impact of Ignoring Children with Serious Mental Illness* – documented the prevalence of the custody relinquishment problem. In *Families on the Brink*, 23% of respondents to NAMI's national survey of parents and caregivers, reported being told that they would have to relinquish custody of their child to access services. 20% of the respondents reported they ultimately relinquished custody of their child to the state. This is a well-documented problem that is receiving increasing media attention. Understandably, families are shocked to learn that their family must be torn apart and they must give up custody to access mental health treatment for their child.

Some families also report being told that to access treatment or services for their child, they should either call the police and have their child arrested or leave the child at a hospital or treatment center. An arrest means that the child may receive services through the juvenile justice system and parental abandonment means that the child will be referred to the child welfare system and will most likely receive some treatment.

On the education front, Congress promised to fund the Individuals with Disabilities Education Act (IDEA) at 40%, however has never lived up to that promise. Most schools fail to provide school personnel with basic training and education to understand the early warning signs and symptoms of mental illnesses, despite the high prevalence rates of the disorders. Without an adequate investment in education for students with disabilities, especially those with mental illnesses, and appropriate training for school personnel, we will continue to see unacceptably poor outcomes for these students.

So rather than hold a hearing on the issue of overtreating and overmedicating children with ADHD – for which there is little scientific evidence -- this Committee should focus future efforts on the more immediate crisis of unidentified and untreated mental illnesses in children and adolescents.

### The Tragic Consequences of Untreated Mental Illnesses in Children and Adolescents

Everyday, thousands of families struggle to get treatment and support services for their children with mental illnesses. Unfortunately, many of these children cannot access the treatment and services they need. As a society, we frequently abandon these children and their families who are trying to help them. The tragic consequences of the failure to provide treatment for many children with ADHD and co-occurring disorders are staggering. What happens to children and adolescents with mental illnesses who fail to get treatment? They end up in the criminal justice system where it is estimated that 60-75% of the youth in our country's juvenile justice facilities suffers from a diagnosable mental illness. (Coalition for Juvenile Justice)

The consequences can also be deadly. Suicide is the third leading cause of death in adolescents. (CDC, 1999) The evidence is strong that as many as 90% of children and adolescents who commit suicide have a diagnosable mental disorder. (Surgeon General, 1999).

For children, the failure to diagnose and treat a mental illness early often results in the loss of critical developmental years. Many children fail in school, are unable to develop friendships and become isolated from their peers. Their inability to participate in school results in their failure to earn a diploma and ultimately in the chance to lead an independent and productive life.

Families often face unthinkable stress and financial ruin when a child requires intensive treatment and there is no coverage or programs available to serve the child. Several families testified before Congress about the financial devastation in support of the Family Opportunity Act. Families are also torn apart when they are forced to relinquish custody to secure critically needed treatment and services. This has a dramatic adverse effect on the child being given up and the siblings who often fail to understand why this happens.

Research increasingly is showing that the failure to intervene and provide early treatment for many mental illnesses accelerates the course of the illnesses and may result in increased damage to the functioning of the brain.

Without proper attention and a real commitment for change at the national, state and local levels -- the tragedies that result from unidentified and untreated mental illnesses in children and adolescents will not improve.

### Broad Scientific Agreement Exists on the Most Effective Treatment for ADHD

The knowledge and tools to help these children recover and thrive are available right now. Attention Deficit Hyperactivity Disorder is one of the most extensively studied childhood mental disorders. There is broad scientific agreement that ADHD is a brain disorder, based on decades of NIMH-sponsored research. In 1999, the U.S. Surgeon General's seminal Report on Mental Health contained an entire chapter on childhood mental disorders, including ADHD. ADHD is a relatively well defined disorder in which a child shows cognitive deficits (particularly difficulties attending to an activity long enough to function successfully) and hyperactive behavior. When appropriately trained professionals perform careful evaluations the disorder can be diagnosed with good reliability. Unfortunately, far too many children never receive this kind of careful evaluation. A lack of insurance coverage and discriminatory caps on mental health coverage, restrictions under managed care, a profound shortage of trained professionals (currently there are approximately 6,300 child and adolescent psychiatrists in this country with a level of need at 32,000), poor training of professionals who work with children -- including school personnel and primary care practitioners -- and many other factors result in a failure to identify and intervene with treatment for children with ADHD and co-occurring disorders.

#### NIMH Multi-modal Treatment Study of ADHD

The Surgeon General's report documented broad scientific consensus that multi-modal treatment -- medication used together with multiple psychosocial interventions in multiple settings -- is the most effective intervention for ADHD. Additionally, both the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry, emphasize the importance of multi-modal treatment, including parent training in diagnosis, treatment and behavior management techniques, educational supports, individual and family counseling and, when necessary, medication. In other words, medications for ADHD are not an "either-or" proposition, but rather an essential component of a good treatment plan.

The most recent and most definitive study of the treatment of ADHD is the NIMH Multi-modal Treatment Study of ADHD. This study compared 14-month outcomes of 579 children randomly assigned to one of four treatment conditions - medication management alone, behavioral treatment alone, a combination of medication and behavioral treatments, and standard treatment in the community. The study demonstrated once again that medication has a substantial positive impact on symptoms and behavior at home and at school. Moreover, the study demonstrated that behavioral strategies have a useful role in effective treatment. These results are completely consistent with the evidence from decades of study.

#### Surgeon General's Report Addresses Overdiagnosis and Overmedication

The Surgeon General included a separate section in the seminal report on mental health to probe the issue of whether there is an overdiagnosis of ADHD or overmedication for the illness in children. Contrary to some of the testimony provided in this hearing, recent reports have found

little evidence of either the overdiagnosis of ADHD or the overprescription of stimulant medications. In fact, overall just the opposite is true. Fewer children (2 to 3% of school-aged children) are being treated for ADHD than suffer from it. This suggests that there are many children who could be helped but are not being properly identified, diagnosed or treated.

The available evidence from numerous studies -- examining the issue of whether ADHD is overdiagnosed and whether children are overmedicated -- suggests that ADHD is not overdiagnosed across the country, since as many as half of all children with ADHD are not being diagnosed and treated in any given year. (see *Report on Emotional & Behavioral Disorders in Youth*, Columbia University, Fall 2002 -- summarizing the research and studies) NAMI recognizes that overdiagnosis and overmedication likely occurs in certain regions. What is critically needed to address those cases is better education and training for providers and families. There must also be a commitment to address the profound shortage of qualified mental health providers in this country to treat children and adolescents.

#### IDEA and ADHD

Research shows that **only** 40% of children with well-defined ADHD are receiving special education services provided under the Individuals with Disabilities Education Act (IDEA). In order for children to be successful they must have access to a comprehensive range of evidence-based services, especially those that combine intensive school-based services with access to high-quality mental health treatment, including behavioral therapy, parent training and appropriate medication. (MTA Cooperative Group) Students with access to the proper services and supports achieve greater outcomes in not only daily schoolwork and testing, but also with peer relations and social development. There are some good examples of evidence based practices in our communities and schools, however, these practices often fail to be widely disseminated and implemented.

#### Preschool Children and Psychotropic Medications

Mr. Chairman, witnesses at the hearing testified about their concerns related to medicating preschool children. NAMI shares these concerns and believes that any decision to treat preschool children with psychotropic medication requires strong justification and documentation of the failure of other treatment alternatives. Relatively little to no scientific research exists to guide the use of psychiatric medications in pre-school children. It therefore is especially important that children at this age receive a thorough evaluation by well-trained child specialists and that other therapies always be considered. Particularly for very young children, intensive therapy should be provided before considering the use of medication. NAMI has supported the Surgeon General's recommendations to push for more prevention and early intervention services which are fundamental to lowering future health care costs and promoting the opportunity for children with mental illnesses to achieve independence and economic self-sufficiency as adults. Some children manifest the signs and symptoms of a serious mental disorder at an early age. Failure to intervene early can result not only in the loss of a childhood, but also lost potential—and loss of a child's future. For some young children, medication is appropriate and has proven highly effective in dramatically improving the quality of their lives. In some cases, it has saved lives.

Given the unacceptably high number of children and adolescents with ADHD and other mental illnesses who fail to be identified and treated, our focus should be on better education and training for providers, school personnel and families and disseminating the most current research and evidence-based information on ADHD and other mental disorders affecting children. We must address the sad reality that only 1 in 5 children suffering from a mental illness, including ADHD, receives treatment.

### Actions that should be taken to prevent further tragedies.

NAMI continues to ask Congress to act on the U.S. Surgeon General's call to address the health care crisis in this country by improving early recognition and appropriate identification of mental illnesses within all of the systems serving children and adolescents (schools, primary care, juvenile justice, child welfare and others). Future hearings should focus on ensuring that federal, state and local governments make a real commitment to developing systems that meet the treatment needs of children and adolescents with mental illnesses and their families. It is unacceptable that so many children fall through the cracks.

Congress should keep its promise to provide full funding for IDEA. Congress must make an appropriate investment in the special education system in this country to ensure that children with disabilities, especially those with mental illnesses, are given a fair chance for an appropriate education. NAMI families tell us that school personnel often fail to understand the basics about early-onset mental illnesses. It is hard to imagine how school personnel can be expected to address the education needs of children with mental illnesses without adequate training. We must invest in school-based training so that school personnel can recognize the signs and symptoms of mental illness and can develop the skills to effectively work with these students. Also, schools should make a commitment to the early identification of students with mental health needs early in the school years, just as schools identify students with visual, auditory and other health concerns. High dropout rates among students with mental illnesses are correlated to shortages of qualified personnel.

Congress should increase its commitment to fund research to continue progress in understanding early onset mental illnesses, including ADHD. NAMI supports increases in federal funding for research on childhood mental illnesses and continued research in child psychopharmacology.

Congress should address the profound shortage of qualified mental health providers in this country to serve children and adolescents and their families. This shortage presents a real barrier to children accessing critically-need treatment and services. Families are often told that they must wait 6 months or longer for their child to see a qualified mental health provider.

Congress should focus on promoting awareness of early-onset mental illnesses and recognizing the serious adverse impact that untreated mental illnesses can have on families and reducing the stigma that families often face with a child is diagnosed with a mental illness.

### Conclusion



Mr. Chairman, this hearing presented an ideal opportunity for the Committee to engage informed scientists in a thoughtful discussion about the current status of research on ADHD and other childhood mental disorders and how best to properly diagnose and treat these disorders. Unfortunately, the hearing provided an opportunity for those whose quest it is to discredit the very existence of ADHD and the value of medication in treating ADHD and other mental illnesses to further perpetuate the stigma of childhood mental illness. This type of misinformation only serves to further stigmatize mental illnesses and perpetuates the shame that so many families feel when their child suffers from a mental illness. It harms families by making it harder for them to make informed treatment choices for their child.

I would respectfully suggest that the committee focus its attention in the future on why children with these illnesses are not being identified or provided with treatment and services that they so desperately need to succeed in school – and ultimately in their lives.



FOR IMMEDIATE RELEASE  
September 25, 2002

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## NAMI CONDEMNS CONGRESSIONAL HEARING FOR PROMOTING "BAD SCIENCE"

*House Hearing with Lisa Marie Presley  
Trivializes Challenge of Mental Illnesses,  
Putting Children at Risk*

Arlington, VA—The **National Alliance for the Mentally Ill (NAMI)** criticized the House of Representatives' Committee on Government Reform for scheduling a hearing tomorrow on the "Overmedication of Hyperactive Children"—late in the waning days of the legislative session—that "will largely recycle bad science and trivializes the need for early identification and treatment of mental illnesses in children and adolescents."

"It seems to happen every election year," said NAMI national executive director **Richard C. Birkel**, Ph.D. "On September 29, 2000, it was a hearing by the oversight subcommittee of the House Committee on Education and the Workforce on essentially the same topic. This week, on September 26, it's the full Government Reform Committee."

"Two years ago the U.S. Surgeon General identified the urgent need for early intervention to help children at risk. President Bush's "New Freedom" Commission on Mental Health held hearings this past summer and soon will release its preliminary report on the need for improvements in the nation's overall treatment system."

"Meanwhile, Congress has yet to pass legislation to help American families simply by providing parity for mental illnesses in health insurance plans—which House leaders blocked in 2001—but which the President since has pledged to see enacted this year."

"The Committee needs to get its priorities straight. We know what's needed to provide necessary treatment for our children. The real problem is that as a society we are not providing it. Too many children continue at risk, while an endless sideshow questions the overwhelming scientific consensus."

The witness list for the House hearing includes **Lisa-Marie Presley** as spokesperson for the Citizens Commission on Human Rights, an organization originally founded by the Church of Scientology. In a letter to **Committee Chairman Dan Burton (R-IN)**, NAMI observed: "Public policy involving treatment of attention deficit-hyperactivity disorder (ADHD) and other brain disorders must be founded on science, not science fiction or religious ideology."

(more)

NAMI Condemns "Bad Science"  
September 25, 2002  
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"For children, treatment requires partnerships between parents, physicians, and teachers. Medication is not an either/or choice and should be considered in conjunction with a range of treatment options. Policy choices should not distort scientific consensus or prevent or discourage families from getting the help that they need."

"The nation's goal should be to offer the highest standard of evaluation and appropriate treatment. Some children may not need to be on medication, but many children with ADHD and other disorders are not being screened at all."

"Many children need treatment and are not getting it. Unfortunately, their entire lives will be affected by the failure to identify and treat such conditions."

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*With more than 220,000 members and 1200 state and local affiliates nationwide, the National Alliance for the Mentally Ill (NAMI) is the nation's leading grassroots organization dedicated to improving the lives of persons with severe mental illnesses such as schizophrenia, bipolar disorder (manic-depression), major depression, obsessive-compulsive disorder and severe anxiety disorders.*

**STATEMENT FOR THE RECORD  
HOUSE GOVERNMENT REFORM COMMITTEE  
U.S. HOUSE OF REPRESENTATIVES**

**NATIONAL MENTAL HEALTH ASSOCIATION  
Michael M. Faenza, MSSW, President and CEO**

**Hearing on Attention-Deficit Hyperactivity Disorder or ADHD**

The National Mental Health Association (NMHA), the country's oldest and largest advocacy organization addressing all aspects of mental health and mental illness, representing more than 54 million children and adults who have a mental disorder, is pleased to provide a perspective on Attention-Deficit Hyperactivity Disorder (ADHD).

ADHD is a mental disorder marked by a persistent pattern of inattention and/or hyperactivity and impulsivity that is more frequent and severe than is typically observed in individuals at a comparable level of development.

Two critical considerations should be noted in taking inventory of ADHD and its impact on the development of children: (1) significantly fewer children are being treated for ADHD than suffer from it despite overwhelming evidence that ADHD can be successfully treated; and (2) children who do not receive needed treatment services for ADHD are at serious risk during a critical period in their brains' development of failing to reach their optimal growth and maturation potential.

ADHD is one of the most common reasons children are referred for mental health services. Despite the number of referrals, nearly four in five children who need mental health treatment do not receive care. The Surgeon General's 2000 report on children's mental health estimated that 20 percent of children and adolescents have a diagnosable mental or emotional illness. In the world's richest country, the tremendous gap between those in need of treatment and those who receive it borders on irresponsibility.

Several factors contribute to this treatment gap: the stigma associated with mental illnesses (which is often worse in children than in adults); a lack of affordability of services; insurance discrimination against mental illnesses; lack of availability of mental health service providers; and a battered, worn-down public mental health system. The existence of barriers to effective treatment is particularly troubling given the enormous growth in our understanding of mental disorders, including ADHD, and the development of effective treatments, including psychotropic medications, which are available to treat these illnesses.

According to the National Institutes of Mental Health (NIMH), ADHD is the most extensively studied mental disorder of children. There is compelling evidence that children and adolescents with ADHD are more likely than children without the disorder to suffer from other mental disorders, i.e. over half the children who have ADHD also have a second mental disorder. About one-half of all young people with ADHD have

oppositional defiant disorder; about one-quarter have an anxiety disorder; as many as one-third have depression and one-fifth have bipolar disorder. Adolescents with untreated ADHD are at risk for substance abuse disorders. Research shows that young people treated for ADHD have lower rates of substance abuse than children who go untreated.

Under the Diagnostic and Statistical Manual of Mental Disorders, DSM-IV, to be diagnosed with ADHD, a child must show symptoms in at least two settings, such as home and school, and the symptoms must interfere with the child's ability to function at home or school for at least six months. Symptoms often go unnoticed until a child enters school. There are three main types of ADHD. One type is characterized by inattentiveness, another by hyperactive or impulsive behavior, and the third combining signs of both types.

The symptoms of ADHD begin to manifest themselves in children by the age of seven. Although the number of boys diagnosed with ADHD is significantly higher than girls (nearly four times higher in boys), the condition tends to be greatly underdiagnosed among young females, according to several recently published studies. The researchers found that girls with ADHD often exhibit academic and social impairment, tend to be rejected by their peers and find it harder to make and keep friends. In total, it is estimated to affect approximately 5 percent of school-age children, although published studies have identified a prevalence rate as high as 12% in some populations.

NIMH concedes that diagnosing childhood mental disorders is not as advanced as our capacities for diagnosing adult disorders. While not necessarily an easy diagnosis to make, ADHD can be accurately diagnosed through implementation of effective diagnostic approaches in practice settings. The diagnosis of ADHD requires a comprehensive assessment by a trained mental health professional. In addition to direct observation, the evaluation includes a review of the child's developmental, social, academic and medical history. It should also include input from the child's parents and teachers. Good treatment starts with an accurate diagnosis. An accurate diagnosis relies on the presence of a range of symptoms and difficulties that prevent the child from performing at an appropriate level for his or her age and intelligence level.

Symptoms of ADHD—such as trouble sitting still, paying attention to details, and listening—can make school difficult for a child with ADHD. Although most children with ADHD have normal or above-normal intelligence, 40 to 60 percent have serious learning difficulties. Many others have specific problems with schoolwork or maintaining good grades, and face particular challenges with assignments and tests that require focused attention or lengthy writing, or have time limits. On a social level, children with ADHD often have trouble developing meaningful relationships with peers and family members. Other children may find it frustrating to play with a child who has ADHD, because classic symptoms include difficulty following rules, waiting one's turn, or excessive talking.

Treatment for ADHD is effective for most children. Early identification, diagnosis and treatment help children reach their full potential. The most effective treatments for ADHD include a combination of medication, behavioral therapy, and parental support and education. Nine out of ten children respond to medication, and 50 percent of children who do not respond to an initial medication will respond to a second. When ADHD co-occurs with another disorder, such as depression or anxiety, a combination of medication and psychotherapy is shown to be particularly effective. Although the value of medication has been well documented, parents should be encouraged to discuss any concerns about medication use with the child's doctor.

Several studies indicate that between fifty and seventy percent of children will continue to have ADHD as adults. Although children may improve at puberty, the residual emotional, social, and family problems might persist into adolescence and adulthood if not addressed. It is now understood that in about fifty percent of individuals, ADHD is inherited. Even with treatment, symptoms may take time to improve.

The Surgeon General's mental health report recommends a course of treatment that includes support and education of parents, appropriate school placement, and pharmacology. The report highlights two major types of treatment: psychosocial treatment, including behavioral modification, and pharmacological treatment, as well as multimodal treatment, the combination of psychosocial and pharmacological treatments.

In addition, there is evidence demonstrating the effectiveness of psychotropic medications for some mental disorders, for some children. There are published pediatric studies on the ten top-selling psychotropic medications, and, on the basis of hundreds of randomized controlled trials, stimulants have been shown to be highly effective for 75% to 90% of children with ADHD. In 1999, the National Institute of Mental Health completed its first major clinical trial to focus on a childhood mental disorder, the NIMH Multi-modal Treatment Study of Children with ADHD. This study concluded that long-term combination treatment (medication plus cognitive-behavioral psychotherapy), as well as carefully monitored medication alone, was superior to psychotherapy alone. As the results of this study suggest, for some children with mental health problems, psychotropic medications may be extremely effective.

There is anecdotal evidence that some children who are diagnosed with, and get psychotropic medication for, ADHD may not need them, but would benefit from other interventions. In our view, when children develop mental health symptoms, treatment should be sought from a qualified child and adolescent mental health clinician for a comprehensive evaluation. When medication therapies are clinically appropriate, they should be part of an integrated and comprehensive treatment plan that involves families in every respect.

Failure to provide appropriate treatment for certain mental disorders – including ADHD – poses a risk to brain integrity and function. A child who cannot pay attention and who cannot learn is at risk of learning delays and academic failures that lead to early school drop out. Children with ADHD who are untreated may also be at increased risk for some

medical and social problems such as reckless driving, drug and alcohol abuse, smoking, academic failure, difficulty in making relationships and trouble with the law. For example, estimates of the prevalence of emotional, behavioral, and mental disorders among children in state custody (e.g. children in foster care or in juvenile justice facilities) are even higher than among youth in the general population.

As the nation recognizes that mental health is fundamental to public health, we are coming to realize that four out of the ten leading causes of disability for persons age 5 and older are mental disorders. Medical and public awareness of the problem of ADHD has grown considerably so that individuals, who were underdiagnosed in the past, are being identified and treated.

The enormous advances occurring in the brain sciences will contribute to an increased understanding of ADHD and other brain disorders. NMHA continues to advocate for increased funding for research and treatment of all mental disorders including ADHD. With increased funding for our public mental health system and passage of mental health parity, we can begin to address the incredible treatment gap that exists in this nation.

A range of effective treatments exists for children who exhibit a variety of emotional, behavioral, and mental disorders including ADHD, depression, and conduct disorder. Evidence suggests that community-based approaches tend to be superior to more restrictive alternatives (such as residential treatment) and that family involvement as partners in treatment is essential. We can successfully treat ADHD, a very real mental disorder. We have the knowledge to treat this illness.

# Otter Creek Associates

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September 27, 2002

Congressman Dan Burton  
2185 Rayburn HOB  
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Dear Congressman Burton,

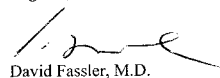
Thank you for inviting me to appear before the Committee on Government Reform. I appreciate your interest in the issue of Attention Deficit-Hyperactivity Disorder. Despite the diversity of views expressed, I am confident that all the witnesses who testified would agree that children need comprehensive evaluations prior to any diagnosis or the consideration of treatment alternatives. There was also broad agreement that parents need to be advocates for their kids, and that parents and children deserve full information about the risks and benefits about any proposed intervention.

I was also quite intrigued about your comments about mercury, and about the experiences within your own family. I've taken the liberty of collecting several additional articles on this topic, which I thought might be of interest. I have enclosed copies for your review.

While you and I may have somewhat differing views with respect to ADHD, I very much appreciate and applaud your willingness to ask difficult and controversial questions and to advocate for research to help us understand the etiology of complex child psychiatric disorders such as autism. As a physician, I am well aware that we certainly do not have all the answers. It's when we think we do, or when we stop asking questions that we're really in trouble!

Thanks again for inviting me to appear before the Committee. Please feel free to call on me again if I can be of any further assistance.

Regards,



David Fassler, M.D.

*An Affiliation of Independent Practitioners*



to stabilize the Medicare part A trust fund through the baby boom years under the program's current structure.<sup>3</sup>

#### Conclusion

Nothing in Medicare's financial condition compels ending its entitlement to basic-defined coverage at affordable rates. While it is possible to introduce more private insurance options within Medicare without compromising the basic program structure, the premium-support model fails to address certain key problems raised by the model. Medicare's financial challenge can only be overcome if that challenge is confronted in the context of meeting Medicare's other challenges. Ignoring the need for a stable program could lead to disintegration of Medicare, large increases in uninsurance among the elderly, and economic instability as Americans continue to struggle to cope with substantially increasing health care costs.

**Acknowledgment:** We thank Jeff Levi, PhD, and Kathleen Malley, JD, PhD, for their thoughtful reviews and comments and Daniel Hawkins for his able reference assistance.

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#### EDITORIALS

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## Limiting Infant Exposure to Thimerosal in Vaccines and Other Sources of Mercury

Neal A. Halsey, MD

**I**N LATE JUNE OF THIS YEAR, THE FOOD AND DRUG ADMINISTRATION (FDA) revealed that some infants who receive multiple doses of vaccines containing thimerosal could be exposed to total amounts of mercury that exceed some federal guidelines.<sup>1</sup> Thimerosal is a mercury-containing preservative used in some *Haemophilus influenzae* type b (Hib), diphtheria and tetanus toxoids with acellular pertussis (DTaP), hepatitis B, influenza, and other vaccines.<sup>2</sup> Federal agencies, the American Academy of Pediatrics (AAP), international agencies, and vaccine manufacturers have responded quickly to address the concern.<sup>1,3,4</sup> However, more can be done to maintain public confidence in vaccines and to reduce childhood exposures to mercury from all sources.

Some confusion has occurred because of uncertainty regarding the applicability of guidelines for long-term exposures to methylmercury from environmental sources to intermittent exposures to ethylmercury, a breakdown product from thimerosal. Based on the limited data available, experts have con-

cluded that the toxicity of ethylmercury may be similar to methylmercury. Guidelines for limiting exposure to methylmercury in foods (primarily fish) are based on the assumption that exposure will continue over long periods of time. The long half-life of methylmercury (average, 50 days) results in accumulation that could be harmful to the developing fetal brain, which is much more susceptible to organomercurial compounds than the adult brain.<sup>5</sup> The doses thought to be able to be consumed on a daily basis without harm vary among agencies: 0.1 µg/kg per day for the Environmental Protection Agency (EPA),<sup>6</sup> 0.3 µg/kg per day for the Agency for Toxic Substances Disease Registry,<sup>7</sup> and 0.4 µg/kg per day for the FDA.<sup>8</sup> The World Health Organization provides a provisional tolerable weekly intake of 3.3 µg/kg for the general population,

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See also p 1725.

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but the dose for pregnant women and infants would be smaller.<sup>9</sup> The EPA estimates that 7% of women of childbearing age in the United States consume 0.1 µg/kg per day or more of mercury from fish harvested in high risk areas, and 1% of women consume 0.37 µg/kg per day or more.<sup>9</sup> Mercury accumulated in these women is transferred to their children prenatally and in breast milk; subsequent exposures to organomercurials from other sources, including biologic products, are presumed to be additive to their baseline body loads.

Exposure to ethylmercury from vaccines containing thimerosal in the first 6 months of life ranges from 0 to 187 µg based on which vaccines are administered.<sup>2</sup> Since many vaccines do not contain thimerosal, most children receive less than the total amount of mercury indicated in the guidelines during the first 6 months of life. If all thimerosal-containing vaccines are given, the total exposures exceed the EPA guidelines, and possibly other guidelines, for the smallest infants. There are safety or uncertainty factors (10-fold for the EPA) built into the guidelines, and experts believe there is no evidence of harm from exposure to thimerosal in vaccines.<sup>12</sup> However, clinicians are uncertain as to how much mercury can be safely given at 1 time when multiple thimerosal-containing vaccines are administered simultaneously.

Data from 2 recent studies examining the relationship between methylmercury exposure and neuropsychological outcome in children suggest that intermittent large exposures may pose more risk than small daily doses. Faeroese children at age 7 years who had been exposed in utero to intermittent bolus doses of methylmercury were found to have subtle neurologic impairments based on domain-specific neuropsychological testing.<sup>10</sup> The total exposures during pregnancy were in the range that was not associated with impairments by global IQ testing in Seychellois children aged 5.5 years who had been exposed to smaller daily doses.<sup>11</sup> The investigators from the 2 studies disagree over what exposures are safe, but a review by a panel of independent scientists found no major methodological problems in either of the studies.<sup>12-14</sup> Differences in testing methods and age at evaluation might explain some of the differences; follow-up studies will provide more information. The controversy resembles that in studies of lead toxicity where sequential studies over many years provided evidence for subtle effects with progressively lower exposures and resulted in increasingly lower acceptable limits of exposure.<sup>15</sup> Additional studies are being planned to evaluate the possible effects of mercury exposure from vaccines.

The FDA sent a letter to vaccine manufacturers on July 1, 1999, requesting plans to remove thimerosal from vaccines or justify the continued use of this preservative.<sup>1</sup> The AAP and the US Public Health Service issued a statement on July 7 calling for elimination or reduction of thimerosal in vaccines for children and recommending deferral of the first dose of hepatitis B vaccine for infants born to hepatitis B virus surface antigen (HBsAg) negative women until age 2 to 6 months.<sup>1</sup>

A parallel review of these issues in Europe resulted in the European Agency for the Evaluation of Medicinal Products issuing a statement on July 8 promoting the use of vaccines without thimerosal for infants and toddlers within the shortest possible time frame.<sup>3</sup> The AAP issued a more detailed statement on July 14<sup>1</sup> that provided physicians with the mercury content in vaccines, background information on mercury toxicity, advice for reducing mercury exposures from all sources, and specific guidelines for the use of hepatitis B vaccines. The AAP also urged the FDA and manufacturers to rapidly reduce the mercury content of vaccines.<sup>2</sup> In a remarkably short time, the FDA approved a request from Merck on August 27 to market a thimerosal-free hepatitis B vaccine for use in infants. SmithKline Beecham also has submitted a request for approval of products with little or no thimerosal.<sup>3</sup> The Centers for Disease Control and Prevention (CDC) and the AAP have strongly encouraged physicians to resume neonatal hepatitis B vaccination of infants born to HBsAg negative women with products that have reduced or no thimerosal.<sup>2,5</sup>

Some clinicians apparently were confused by the rapid changes in hepatitis B guidelines. Infants born to women who are HBsAg positive or whose hepatitis status is unknown should be vaccinated at birth regardless of the availability of thimerosal-free vaccines because the high risk of acquiring hepatitis B infection and increased likelihood of becoming a carrier far outweigh theoretical concerns about the amount of mercury in a single dose of this vaccine.<sup>1,5</sup> The CDC has emphasized the need for immunization of all newborns in populations at increased risk for hepatitis B infections from contacts early in life.<sup>3</sup> Most countries have initiated programs to administer hepatitis B immunization at birth or in the first few weeks of life because this is the optimal strategy for preventing hepatitis B transmission.<sup>16,17</sup> Immunization at birth provides early and long-term protection of neonates against infection by HBsAg positive mothers who were missed by screening programs and HBsAg carriers among families, friends, and other contacts.<sup>18</sup>

In this issue of THE JOURNAL, Lauderdale and colleagues<sup>19</sup> present evidence that neonatal hepatitis B vaccination may have additional benefits. They found that children given the first dose of vaccine in the first month of life, presumably mostly at birth, were more likely to complete the 3-dose series and to receive their first dose of DTaP vaccine at age 2 months than children who began hepatitis B immunization at an older age. Since the availability of hepatitis B vaccine in nurseries is a hospital decision, the data suggest that the birth dose helps influence parents to complete the series and seek other vaccines on time. Prospective controlled studies are needed to determine if early immunization truly increases on-time immunization at older ages or if this is a result of enrollment in a more proactive health care program.

Are preservatives like thimerosal necessary in vaccines? The FDA regulations require preservatives in multidose vials of most vaccines (with the exception of certain live vi-

ral vaccines) to protect against inadvertent contamination from repeated puncture of the seal.<sup>20</sup> Thimerosal does not prevent all bacterial contamination, as evidenced by clusters of disease from group A streptococcus infections traced to multidose diphtheria toxoid, tetanus toxoid, and pertussis (DTP) vaccine vials that were contaminated after opening.<sup>21</sup> The use of single-dose vials or prefilled syringes for vaccines should be encouraged because this eliminates errors in preparation as well as the need for preservatives for most vaccines. Thimerosal is used during production of some vaccines and in many cases can be removed leaving trace amounts (<0.3 µg) of mercury that have no biologic effect.<sup>22</sup> Such products should be considered equivalent to thimerosal-free products. Alternative preservatives are one option for multidose vials, especially in developing countries where the need to keep costs low is an essential component of the success of the World Health Organization's Expanded Program on Immunization. The use of new combination products will reduce exposure to preservatives by decreasing the number of injections needed to deliver recommended vaccines.

How should physicians deal with the uncertainties during the transition to the elimination or reduction of thimerosal in vaccines? On October 20, 1999, the Advisory Committee on Immunization Practices of the CDC decided not to give a general preference for thimerosal-free vaccines for administration to infants. The CDC and AAP have indicated that hepatitis B vaccines containing no or trace amounts of thimerosal should be preferentially used for infants during the first 6 months of life. I believe that this preference should be extended to Hib and DTaP vaccines for infants (especially premature infants) whenever possible. The list of mercury content in vaccines is kept up-to-date on the Institute for Vaccine Safety Web site ([www.vaccinesafety.edu](http://www.vaccinesafety.edu)) to assist physicians in vaccine choices. If supplies are limited, exposure to no more than 1 thimerosal-containing vaccine at each visit would reduce exposures while ensuring that infants are fully protected against diseases, including influenza in high-risk infants. Elimination of thimerosal or other preservatives will be more difficult for influenza vaccines produced in eggs because a preservative helps ensure protection against contamination. The small amount of thimerosal in influenza vaccines does not constitute an undue risk for older children and adults, especially for high-risk individuals in whom complications from influenza constitute a major health burden.

The AAP encourages parents to follow local fish advisories to reduce children's exposure to mercury.<sup>2</sup> Since mercury exposures from other sources may be additive, special care should be taken not to administer additional mercury from vaccines to small infants in populations in which pregnant women may consume more than the maximum recommended amounts of mercury. Thimerosal has been eliminated from latex paints, and merthiolate, a concentrated form of thimerosal used as an antiseptic, is no longer used because of serious toxic effects from these products in in-

fants.<sup>23</sup> Congress deserves credit for mandating the review of thimerosal in biological products, but needs to ensure that the agencies responsible for vaccine safety have the resources and freedom from undue regulation to allow them to carry out their mandates. The FDA needs highly qualified scientists and resources to address the increasingly complex scientific issues involved in vaccine production. Therefore, health care professionals should be concerned that the research budget for the Center for Biologics and Evaluation Research has been reduced to one third the level that it was in 1994.<sup>24</sup> Availability of the safest vaccines now and in the future requires support for scientists working at federal agencies responsible for vaccine safety. In late June and early July, when decisions needed to be made rapidly, officials from the CDC could not officially consult with the Advisory Committee on Immunization Practices because statutes prevent such meetings without posting a notice in the *Federal Register*.<sup>25</sup> Exceptions should be made to allow the CDC and other agencies to address urgent situations.

The public has become intolerant of unnecessary exposure to real and theoretical risks for children from all sources as evidenced by demands to make food products, toys, seat belts, and air bags as safe as possible.<sup>26</sup> Reducing or eliminating exposure to mercury from all sources, including industrial contamination of waterways that leads to accumulation of mercury in fish, should be a national priority.<sup>27</sup> Further reductions or elimination of mercury in vaccines will help maintain public confidence by demonstrating a commitment to provide the safest vaccines possible for protecting children against disease.

**Acknowledgment:** I am grateful to Leslie Ball and Robert Ball for comments and technical support.

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## Fair Conduct and Fair Reporting of Clinical Trials

Drummond Rennie, MD

**M**ETA-ANALYSIS, DONE PROPERLY, IS A SYSTEMATIC effort to search for and winnow out all the best evidence and show how well a given intervention works. It is crucially dependent on the identification of all available data from clinical trials. In 1989, Gøtzsche,<sup>1</sup> who was performing a meta-analysis of 244 trials of nonsteroidal anti-inflammatory drugs in rheumatoid arthritis, drew attention to a practice that seemed to subvert the normal process of publication as well as of meta-analysis. Excluding abstracts, letters, and brief versions, Gøtzsche found 44 multiple publications of 31 of the clinical trials, 20 trials published twice, 10 three times, and 1 trial 5 times, with the overall proportion of multiple publications being at least 18%. The fact that the data had been published elsewhere was not noted in 32 of the 44 articles. Indeed, in about half of them, the first author and number of authors were different, and in half there were important discrepancies between the various versions of the same trial. Gøtzsche<sup>1</sup> pointed out that "some cases were so difficult to detect that in a meta-analysis they might have been mistaken for separate trials."

In 1996, Huston and Moher<sup>2</sup> found the same problem when they attempted to perform a meta-analysis of the effects of the antipsychotic agent risperidone. They had a frustrating time. They identified 20 articles and several unpublished reports describing randomized, double-blind trials, but after a search they described as "vexing," "bewildering," and "intolerably time-consuming" they concluded that there were probably only 7 small trials and 2 large trials, 1 of the latter being reported "in part, transparently, and not so transparently in six different publications . . . the authorship was different for each." Huston and Moher wrote: "Multiple renditions of the same information is self-serving, wasteful, abuses

the volunteer time of peer reviewers, and can be profoundly misleading; it brings into question the integrity of medical research."<sup>2</sup> It certainly does. Who, for example, designed the trial in the first place? Why aren't all the names of those who did the work of the study consistently cited as authors? This practice, if it merely inflated the bibliographies of the researchers and distorted the process of promotion, might seem somewhat academic, but it has more pernicious effects. Huston and Moher took objection to a practice that "made a mockery of editors and the peer review system." While editors may be strong enough to withstand such mockery, other objections were more telling. The practice gave "an artificial impression of wide support for the efficacy of an intervention."<sup>3</sup> The multiple counting of the same data and patients would lead to a confirmatory bias in favor of the intervention.

The authors of this case study, and others,<sup>3</sup> did not attempt to quantify the extent by which this unfortunate behavior might influence the estimate of the effect of the intervention reported in the meta-analyses. Tramer and colleagues<sup>4</sup> took the process further when they examined full reports of 84 trials presumably involving 11 980 patients, investigating the effect of ondansetron on postoperative emesis. They found that data from 9 trials had been published in 14 reports, without any clear cross-reference, so there were really only 8645 patients in 70 trials. Seventeen percent of published, full reports of randomized trials were duplicates, and data from 3335 patients (28%) were reported twice. Most crucially, these authors found that inclusion of these duplicate data led to a 23% overestimation of the efficacy of ondansetron. Moreover, the covert duplicate publication was not easy to uncover: it had not been noticed by the expert authors of at least 8 subsequent articles, reviews, or book chapters.

See also p 1752.

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American Medical Association

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## Vaccination for Children

### **Institute Of Medicine Finds No Link Between Thimerosal In Vaccines And Neurodevelopmental Disorders In Children**

#### **But precaution dictates that thimerosal exposure should be decreased**

The Institute of Medicine (IOM) has released a report entitled "Thimerosal-Containing Vaccines and Neurodevelopmental Disorders" (click here for a PDF file, requiring the free Adobe Reader). This report is the second study in a series on vaccine safety was sponsored by the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases. Comments from these two agencies on this report are available as a Word file.

The report concludes that current scientific data does not show a link between the mercury-containing preservative thimerosal and neurodevelopmental disorders in children. However, the report also states that current data could also not disprove such a link. Thus, even though very few current given to children in the United States today still contain thimerosal, prudence dictates that precautionary measures be taken to decrease thimerosal exposure even further.

Thimerosal is used in some vaccines and other pharmaceutical products to prevent bacterial contamination. Vaccines against measles, mumps, and rubella; varicella; and polio have never contained the preservative. However, until recently, several other vaccines on the recommended childhood immunization schedule in the United States did. They are now manufactured without thimerosal, but an unknown, probably small number of vaccine doses for hepatitis B; diphtheria, tetanus, and pertussis; and haemophilus influenzae type B, a form of bacterial meningitis, are still on clinic shelves. These supplies should not be used when alternatives are available, said the committee that wrote the report.

Most children in the United States being immunized today and in the future are unlikely to receive a vaccine that contains thimerosal. While the health effects of thimerosal are uncertain, vaccines protect against real, proven threats to unvaccinated infants, children, and pregnant women.

As another precaution, policy-makers in the United States should consider changing existing policies to reduce exposure to thimerosal as much as possible. For example, professional societies and government agencies should review their policies about nasal sprays, eye drops, and other products that contain thimerosal and are used for infants, children, and pregnant women, the report says.

In 1999 the U.S. Public Health Service, the American Academy of Pediatrics, and the American Academy of Family Physicians issued precautionary recommendations limiting mercury exposure of infants and young children, a measure that prompted development of thimerosal-free versions of routine childhood vaccines. By mid-2000, thimerosal-free vaccines against hepatitis B and bacterial meningitis were widely available. A combination vaccine for diphtheria, pertussis, and tetanus also is available today without thimerosal.

The preservative is still used in a few vaccines, including influenza vaccine, which is given annually during the viral flu season to adults and some children. The CDC recommends that protecting pregnant women and high-risk children during flu season take precedence over any possible risk from thimerosal exposure.

IOM Press Release on Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (Word file)

Thimerosal Fact Sheet for you and your patients (Word file)

[Questions and Answers on thimerosal, vaccines, and vaccine safety \(Word file\)](#)

[Statement to the Press from Marie McCormick, MD, IOM Committee Chair \(Word file\)](#)

[Comments on the IOM report from the CDC and the National Institutes of Health \(Word file\)](#)

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Last updated: May 08, 2002  
Content provided by: L.J Tan, PhD, Senior Scientist

AMERICAN ACADEMY OF  
CHILD & ADOLESCENT  
PSYCHIATRY

September 16, 2002

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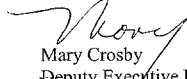
Dear Beth:

Thank you for meeting with Lynda Tenhundfeld, M.D., Nuala Moore, and me, and the representatives from the American Academy of Pediatrics and Children and Adults with ADHD (CHADD), on September 11, to discuss the possible causes of ADHD, medical treatment options available, and the consequences of failing to treat this serious disorder. American Academy of Child and Adolescent Psychiatry (AACAP) members appreciate the information Rep. Burton, as chair of the Committee on Government Reform, can bring to the public's understanding of Attention Deficit Hyperactivity Disorder and the lack of access to treatment that many families have for the mental disorders of childhood and adolescence.

We offer the AACAP's resources to this effort, including recommendations for witnesses for a September hearing. We would be pleased to provide you with the names of AACAP members fully trained in the diagnosis and treatment of ADHD for consideration. Please let me know if you have any specific requests regarding ADHD, medications used to treat this illness, or other children's mental health issues in preparation for this hearing.

In response to your questions about medications used for specific age groups in children and adolescents, I have enclosed a listing of priority drugs for study that the AACAP and American Psychiatric Association (APA) submitted to the Food and Drug Administration (FDA) in 1998. Thanks again for your interest in this issue.

Sincerely,



Mary Crosby  
Deputy Executive Director

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Enclosure

American Academy of Child & Adolescent Psychiatry  
American Psychiatric Association  
Priority Pediatric Psychotropic Drug Testing List

DRUG NAME	INDICATIONS	AGE
<b>Stimulant:</b> <i>Ritalin/methylphenidate</i>	ADHD	3 - 5 years (has had clinical trials in the 6 years and above age group)
<b>SSRIs:</b> <i>Prozac/fluoxetine</i>	Depression/OCD	6 and older
<i>Zoloft/sertraline</i>	Depression	6 and older
<i>Paxil/paroxetine</i>	Depression/OCD	6 and older
<i>Luvox/fluvoxamine</i>	Depression	6 and older
<i>Effexor/venlafaxine</i>	Depression	6 and older
<b>Atypical Antidepressant:</b> <i>Wellbutrin/bupropion</i>	ADHD/Depression	6 and older
<b>Alpha Adrenergic Agents:</b> <i>Catapres/clonidine</i>	ADHD, PTSD, Tourettes, tics	3 and older
<i>Tenex/guanfacine</i>	ADHD, PTSD, Tourettes, tics	3 and older
<b>Mood Stabilizers:</b> <i>Lithium</i>	Bipolar disorder, Aggression	6 and older
<i>Tegretol/carbamazepine</i>	Bipolar disorder, Aggression	6 and older
<i>Depakote/valproate</i>	Bipolar disorder, Aggression	6 and older
<b>Antipsychotics:</b> <i>Orap/pirnozide</i>	Tourettes	6 and older
<i>Risperidal/risperidone</i>	Psychosis, PDD	6 and older
<i>Zyprexa/olanzapine</i>	Psychosis, PDD	6 and older
<i>Clozari/clozapine</i>	Psychosis, PDD	6 and older
<i>Inapsine/droperidol</i>	Aggression, Severe agitation	6 and older



DRUG NAME	INDICATIONS	AGE
<b>Anxiolytics:</b>		
<i>BuSpar/bupirone</i>	Anxiety, Aggression	6 and older
<i>Klonopin/clonazepam</i>	Panic	8 and older
<i>Xanax/alprazolam</i>	Panic	8 and older
<i>Ativan/lorazepam</i>	Panic	8 and older
<b>Tricyclics:</b>		
<i>Tofranil/imipramine</i>	ADHD, Panic	6 and over
<i>Pamelor/nortriptyline</i>	ADHD	6 and over
<i>Norpramin, Pertofrane/desipramine</i>	ADHD	6 and over
<b>Miscellaneous:</b>		
<i>Inderal/propranolol Other beta blockers</i>	Aggression, PTSD	8 and older
<i>Naltrexone</i>	PDD	3 and older



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**Press Releases 2002**

FOR IMMEDIATE RELEASE

**House Hearing Causes Concern for CHADD**

Date: 09-25-2002

Contact: Peg Nichols or Winnie Imperio, 301-306-7070, ext. 102 or 117 or peg\_nichols@chadd.org or winnie\_imperio@chadd.org

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Landover, MD - On Thursday, September 26, the House Committee on Government Reform, chaired by Representative Dan Burton (R-IN), will conduct a hearing entitled "Attention Deficit/Hyperactivity Disorders - Are Children Being Over Medicated?"

Four of the five witnesses -- invited by Representative Burton -- are reported to spokespersons for or persons associated with the Citizens Commission on Human Rights (CCHR), an affiliate established 1969 by the Church of Scientology. CHAD is concerned that four witnesses associated with the hearing share the belief that AD/HD is a lie and a fraud. They include:

- \* Lisa Marie Pressley
- \* Bruce Wiseman
- \* Dr. Mary Ann Block
- \* Patricia Weathers

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As further context of the CCHR's philosophy, among their publications currently in circulation are "Psychiatry Betraying Families: The Hoax of ADD/ADHD and Other Learning Disabilities," "Psychiatry: Shattering Your World with Drugs," and "The Hoax of Learning and Behavior Disorders."

The fifth witness, invited at Mr. Burton's request, is Mr. Neil Bush, the President's brother, whose son was incorrectly diagnosed with AD/HD.

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Through the efforts of Representative Henry Waxman (D-CA) to ensure a balanced discussion, Clarke Ross, CEO of CHADD and Dr. David Fassler, representing the American Academy of Child and Adolescent Psychiatry (AACAP) and the American Psychiatric Association (APA), also have been asked to testify. It is expected that the National Institute of Mental Health will also send a witness.

**ACTION REQUESTED**

Please review the testimony below and share your concerns with Rep. Burton about the lack of balance in this hearing. You are also encouraged to cc a copy of the letter to your own U.S. Representative.

Mr. Burton can be contacted at:

Dan Burton  
Indiana-6th, Republican  
2185 Rayburn HOB  
Washington, DC 20515-1406

phone: 202-225-2276  
 fax: 225-0016  
 No e-mail address available

Contact information for representatives from your own state can be obtained through the THOMAS database at: <http://clerk.house.gov/members/index.php>

#### FULL TESTIMONY OF E. CLARKE ROSS, CHIEF EXECUTIVE OFFICER, CHADD

Statement to the House Committee on Government Reform September 26, 2002  
 "Attention Deficit/Hyperactivity Disorders - Are Children Being Over Medicated?"

Statement by E. Clarke Ross, Chief Executive Officer, CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder) 8181 Professional Place, Suite 201 Landover, Maryland 20785

Mr. Chairman and Members of the Committee: My name is Clarke Ross. I am the Chief Executive Officer of CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder).

Headquartered in the greater Washington area, CHADD is the nation's leading advocacy organization serving individuals and families dealing with AD/HD. Under the guidance of the world's leading AD/HD experts, CHADD works to improve the lives of those with AD/HD and their families through advocacy, education, research and support. CHADD currently serves 20,000 dues-paying members in 246 chapters located in 37 states and Puerto Rico.

CHADD educates the public about AD/HD primarily through dissemination of practices, policies, research and published papers issued by the nation's leading scientific and medical institutions. This includes the publications and research of United States Surgeon General, the National Institutes of Health, the National Institute of Mental Health, and the professional societies of physicians and other treating professionals and researchers in the mental health field.

Of utmost importance to CHADD are the evidence-based assessment and treatment guidelines of the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry. This body of evidence-based research emphasizes the importance of what is known as "multi-modal treatment."

Multi-modal treatment includes parent training in diagnosis, treatment and special behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required.

Also of interest to CHADD are complementary interventions used in the treatment of AD/HD. While CHADD is not opposed to complementary interventions, it strongly believes further research is necessary and advocates that NIH, NIMH, and others in the research community conduct further investigation to determine the efficacy of these complementary interventions.

#### THE STORY OF ONE 11-YEAR-OLD BOY: ANDREW ROSS

Perhaps even more important than my role as CEO of CHADD, is my role as father to an eleven-year-old son, Andrew, diagnosed with the inattentive type of AD/HD, an anxiety disorder, and other related co-occurring learning disorders.

Like many families facing AD/HD and related conditions, my wife and I, over time, have employed a wide array of interventions, including several considered complementary in nature, which are described in greater detail further in this statement. None of the complementary interventions we employed were harmful.

statement. None of the complementary interventions we employed were harmful. But perhaps most significant, none of them have demonstrated an impact. Moreover, none of them are supported by the evidence-based research to which we are firmly committed.

In short, the multi-modal approach described above -- parent training in diagnosis and treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed and, for us, medication provided and continue to provide the support that Andrew needs in order to thrive and flourish.

#### BACKGROUND

Andrew was born following a complicated delivery. When at age 11 months, he broke his ankle (which would not heal properly), follow-up assessments documented significant hypotonia and sensory integration challenges. At 21 months, he experienced his first unprovoked seizure with a pattern of seizures continuing for the next several years. Two EEGs later, many problems were confirmed. By two and still not speaking, Andrew's pediatrician referred him to the State of Maryland's Early Education Program. For the next several years he received intensive speech and language and sensory integration services. Andrew also has dysgraphia, which can best be described as a difficulty in automatically remembering and mastering the sequence of muscle motor movements needed in writing letters or numbers. Fortunately, with intensive assistance from the school occupational therapist, Andrew has largely overcome his dysgraphia.

By four, when Andrew entered a more formal education program, teachers began noting significant learning problems stemming directly from his inability to focus. He received numerous independent professional assessments, each affirming that his disabilities significantly impeded his ability to function at the level of his classmates. Andrew has always had difficulty with what now is referred to as "executive functioning" - brain actions of self control where he is unable to think ahead and consider "if-then" behaviors and their consequences.

My son does not have an occasional problem with distraction and attention. He has ongoing, continuous daily problems that result in overwhelming difficulties in many areas of his life.

No well-meaning parent sets out to medicate his or her child. Nor did we. But over time, given Andrew's learning and functional problems, we accepted the advice of child psychiatrists who felt our son would benefit from medication. Today, Andrew takes both a medication for attention issues and a medication designed to reduce his anxiety. A series of behavioral management and learning assistance programs also are used and are an essential part of his overall treatment program.

At age four, a child psychiatrist recommended that Andrew try a stimulant medication. We initially said no, as we wanted to first try other interventions. But by the time Andrew was seven, we said yes to stimulant medication. The other interventions had not worked in helping him pay attention. We now were ready to try medication.

We actually tried three medications before we found one that worked. The first two did not help his attention (nor did they have any side effects), but the third one has had significant results. To this day Andrew takes Adderall.

Andrew began using Prozac two and a half years ago because of a severe anxiety problem. He is anxious about many things. As one example of many, Andrew was so afraid of flying insects that three summers ago he would not go outside despite his love of baseball and basketball. A combination of behavioral interventions, cognitive training and medication has helped to reduce his anxiety. He remains

uncomfortable with flying insects and bristles stinky when they are around, but generally speaking he now can function quite normally. But his anxiety was not singularly confined to flying insects. Andrew is anxious about many things and many situations. As such, my wife and I are constantly developing behavioral interventions to deal with these varied anxieties.

Medication obviously is not perfect. For example, Andrew initially experienced a significant loss in appetite. Today, however, he only experiences a loss of appetite at lunch, proof that there are continual tradeoffs in the beneficial use of medication and side effects from such use. On the plus side, however, with the assistance of special education personnel and a multimodal treatment approach in place, including medication, Andrew can now better attend to learning in class, is less phobic, and demonstrates more socially appropriate behaviors with children his age.

As the parent of a child with multiple challenges, I resent those who suggest that my son needs only a little more discipline, structure, and learning. In direct contrast to the publications issued today by some of the hearing witnesses, I want to emphatically say that my son's problems are neither "lies" nor "frauds" nor the "failures of his parents." Andrew has a biologically based brain disorder that we have an extensive network of dedicated clinicians face and address on a daily basis. Andrew's life is filled with dedicated clinicians - from pediatrician, to child psychiatrist, to child psychologist, to neurologist, to speech pathologist, to a team of educators. Without their collective support, I cannot imagine where Andrew would be today.

As mentioned previously, we employ a variety of complementary approaches. These include visualizing and verbalizing training, sensory integration therapy, a visual tracking. Andrew responds best in small learning groups where constant feedback and support is provided. We use Dr. Thomas Phelan's 1-2-3 Magic approaches each and every day. And every day Andrew consumes fish oil supplements (Omega-3 Fatty Acids). But as noted above, while certainly not harmful, none of these interventions (other than 1-2-3 Magic) have yielded any immediate or even long-lasting positive impact upon Andrew.

The good news is that Andrew is making progress. The strides are slow yet steady. And like most families in similar circumstances, we are resolved to living life one day at a time. I share my wife's and my story with the hope that those unfamiliar with AD/HD will appreciate the complexity and difficulty of identifying and implementing key medical strategies designed to help children like our son Andrew.

#### THE EVIDENCE-BASED SCIENCE

In looking at the broader AD/HD picture - particularly with respect to the emergence of evidence-based science-it is essential to note the following key milestones:

\* In 1998, the American Medical Association published an exhaustive review of the scientific literature concerning AD/HD, concluding that the disorder is real and that while there may be instances of over diagnosis, there is a greater problem of under diagnosis.

\* In 1999, the National Institute of Mental Health (NIMH) published its first results from The Multimodal Treatment Study of Children with Attention-Deficit/Hyperactivity Disorder, a multicenter study evaluating the leading treatments for ADHD, including various forms of behavior therapy and medication in nearly 600 elementary school children. The results indicate that long-term combination treatments as well as medication management alone are both significantly superior to intensive behavioral treatments and routine community treatments in reducing AD/HD symptoms.

\* In 1999, the U.S. Surgeon General released the landmark Report on Mental Health, which devotes an entire section to the evidence-based science behind AD/HD. Among the important findings are that stimulants are highly effective for 75-90% of children with AD/HD, while the most effective interventions for AD/HD are multimodal treatment-which involves the use of medication with psychosocial behavioral and related interventions. Finally, "recent reports found little evidence over diagnosis of AD/HD or over prescription of stimulant medications. Indeed fewer children (2-3% of school-aged children) are being treated for AD/HD than suffer from it."

\* First in 2000 for assessment, and then in 2001 for treatment, the American Academy of Pediatrics (AAP) published clinical practice guidelines for AD/HD. The groundbreaking guidelines include endorsement of stimulant medications when appropriate monitoring and behavior interventions are also used.

\* In 2002, the American Academy of Child and Adolescent Psychiatry (AACAP) published practice parameters for the use of stimulant medications in the treatment of children, adolescents and adults. The parameters rely on an evidence-based medicine approach derived from a detailed literature review and expert opinion.

#### SOME CHILDREN ARE TREATED INAPPROPRIATELY; SOME CHILDREN ARE UNDEI TREATED

In reviewing the developments above, it is simultaneously essential to note that both U.S. Surgeon General's reports on mental health (1999 on mental health research, and the 2001 report on race and culture) emphasize that some children are inappropriately identified while many children are never identified.

It therefore also becomes essential to comment upon public alarm that "AD/HD is over-identified and over-medicated" because of the over 700% increase in the use of stimulant medication in the school age population over the past decade. Before resorting to alarmist reactions, let us first examine the prevalence rate.

\* The U.S. Surgeon General estimates the school-age prevalence of AD/HD to be between 3 and 5%. Even with the over 700% increase in stimulant medication use over the past decade, only 2 to 2.5 % of the school-age population currently receive stimulant medication. If medication is an appropriate component of multimodal treatment intervention (as the science informs us), then over half of those suffering the effects of AD/HD are not being effectively treated.

\* The 3-to-5% prevalence rate may actually be a conservative rate. Two published studies by the Mayo Clinic of Rochester, Minnesota, one in the January 2001 issue of the Journal of the American Medical Association and the other in the March 20 issue of the Archives of Pediatrics and Adolescent Medicine documented that 7.5% of all children presenting for any kind of medical treatment in Rochester over a seven year period had AD/HD.

\* What is particularly alarming to CHADD is the tremendous variance of stimulant medication prescribing practices across the nation. While Dr. Julie Zito of the University of Maryland and Dr. Gretchen LeFever of Eastern Virginia Medical School have published studies about the significant variance within Maryland and Virginia probably the single most informative published study was the May 6, 2001 Cleveland Plain Dealer article, "Ritalin Prescribed Unevenly in U.S." The paper's reporters studied for one full year the actual prescriptions written in every county in the nation. Some counties had 5% of the total school-age population and 20% school-age boys on stimulant medication while other counties had practically no one receiving a stimulant medication. CHADD remains alarmed with this variance in practice.

CHADD believes that the single most important reason for such variance is the absence in clinical practice of the use of the AAP and AACAP evidence-based assessment and treatment guidelines. That is why CHADD is tirelessly working to educate the public about the AAP and AACAP guidelines and to advocate that physicians using such guidelines be financially reimbursed by health insurance payers at a higher rate than physicians not using such guidelines.

We also need better research about the prevalence of AD/HD and the number of children actually receiving such medication. While the Cleveland Plain Dealer and others have studied the numbers of prescriptions written, we really have no excellent database on actual numbers of children receiving such medications on regular basis. Certainly, we must protect the confidentiality of individual children and their families, but we also need better aggregate data on overall usage.

For example, consider the data. The United States General Accounting Office in 2001 stated that there were 46.6 million public school students. Three-to-five percent of this total would be between 1.4 to 2.3 million children, not including students in both private school or home-school settings. If we use the Mayo Clinic 7.5 % prevalence rate, then 3.26 million school age children would be expected have AD/HD - an appropriate number given such rates. CHADD commends the Centers for Disease Control and Prevention (CDC) for recognizing the need to better assess accurate prevalence rates, including funding for three prevalence studies.

#### CHADD REITERATES KEY ROLE PHYSICIANS, TEACHERS, AND FAMILIES PLAY IN RECOGNIZING AND TREATING AD/HD

CHADD is concerned that without proper context, and when sensationalized, alarmist statements and reports create confusion among the general public, patients and families, thus undermining the seriousness of AD/HD and the proven safety and efficacy of stimulant medications when properly administered by appropriate professionals.

CHADD believes that all families should have access to the best, evidence-based science in the diagnosis and treatment of AD/HD. We are therefore concerned when legislation is proposed that undermines this critical access-including the elimination of a teacher's freedom to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations. Likewise, CHADD is appalled when children are inappropriately prescribed medication that they do not need. This is of particular concern when small subsets of children suffer significant side effects.

CHADD believes that legislation must not limit or undermine the ability of a medical professional, within their scope of practice, from treating AD/HD based on the most widely accepted evidence-based science. CHADD encourages all families and physicians to follow best practice assessment and treatment guidelines being uniformly implemented throughout the nation, specifically the current American Academy of Pediatrics (AAP) and American Academy of Child and Adolescent Psychiatry (AACAP) guidelines. Using the force of law and agencies of government, particularly criminal penalties-to monitor and enforce best practice treatment guidelines is an ineffective approach at best and disastrous approach at worst. Instead, ongoing training and education in the diagnosis and treatment of AD/HD should be encouraged among all physicians.

Teachers are frequently the first to recognize learning, functioning, and behavior problems in the school setting and therefore should be able to advise parents of such observations. CHADD believes that professionals should act within their professional scope of practice. Thus, school personnel should not recommend the use of medication. Medication assessment and prescription is the role of the physician and-under limited circumstances-in a few states, other treating professionals too. However, teachers should be able to recommend a

professionals too. However, teachers should be able to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations.

Because students spend a significant portion of their day in the classroom, the role that teachers play in providing observations to the diagnosing professionals cannot be underestimated. Effective communication among teachers, professionals, and parents is essential and strongly encouraged. CHADD advocates a multi-modal approach to the treatment of AD/HD, including parent training in diagnosis, treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required. Medication is used to improve the symptoms of AD/HD. Research shows that children and adults who take medication for the symptoms of AD/HD attribute their successes to themselves, not to the medication.

#### DENIAL OF AD/HD REFUTED

The organized interests at this hearing claiming that AD/HD is a "biological lie" state that there are no "biological imbalances" and "no laboratory tests establish as diagnostic" for AD/HD. They go on to claim that AD/HD is a "100 percent fraud."

But science tells us a different story. The Surgeon General's report (page 144) concludes "AD/HD is the most commonly diagnosed behavioral disorder in childhood and occurs in three to five percent of all school-age children. The exact etiology of AD/HD is unknown, although neurotransmitter deficits (such as the dopamine transmitter), genetics, and perinatal complications have been implicated." The NIH Panel Consensus statement declares: "Although an independent diagnostic test for AD/HD does not exist, there is evidence supporting the validity of the disorder."

As previously stated, the NIMH MTA Study further documented that only 31% of the children with AD/HD have AD/HD alone with no other disorder. The study found that 40% of children with AD/HD had oppositional defiant disorder, 34% had anxiety disorder, 14% had conduct disorder, and 4% had a mood disorder. Those dismissing the existence of AD/HD repeatedly ignore these characteristics. A May 22 study by the Centers for Disease Control and Prevention (CDC) documented that half of the school age population with AD/HD also had a learning disability.

The existence of co-occurring disorders complicates assessment, complicates treatment, and increases the possibility of an inaccurate diagnosis. This only further reiterates the importance of the AAP and AACAP best practice guidelines.

#### CLOSING

I have devoted over 30 years of my professional life assisting individuals with cerebral palsy, schizophrenia, bipolar disorder, AD/HD, and other mental disorders. I find it frustrating and disheartening that I have to defend recognized science against science fiction. This is demeaning to those suffering from these disorders and to the millions of families who devote their lives caring for and supporting their loved ones.

The science speaks for itself. Even more important are the stories of untold millions who have either been helped by appropriate interventions - or worse, been denied access to the treatment they deserve. Instead of wasting precious time, energy, and resources defending a disorder that clearly exists, why can't we simply move forward in applying the science to clinical practice and educational settings to make life better for those faced with these challenges? Why do some policy makers continue to play to those who claim that there are no mental disorders, that there is no science, and that anyone's science fiction is equivalent to the evidence-based science?




The reality that children and adolescents can and do suffer from AD/HD and other debilitating brain disorders, just as adults do, is finally being widely recognized. That is why we must continue educating others and ourselves about the broad spectrum of childhood mental disorders. We must continue joining forces with scientific institutions and others. And we must do everything within our means to ensure that our children receive the tools they need to live a meaningful life, regardless of their disability, challenge or disorder.

E. Clarke Ross, September 23, 2002

###

With over 20,000 members and 200 chapters nationwide, CHADD works to improve the lives of people affected by AD/HD through collaborative leadership, advocacy, research, education and support: CHADD CARES. For additional information about AD/HD or CHADD, please contact CHADD National Call Center at 1-800-233-405 or visit the CHADD website at [www.chadd.org](http://www.chadd.org).

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8181 Professional Place, Suite 201,  
Landover, MD 20785

**CHADD National Call Center (800) 233-4**  
**Business (301) 306-7070 FAX (301) 306-7**

For questions about AD/HD or CHADD, please see the Frequently Asked Questions.  
For more information or comments, please e-mail us at [national@chadd.org](mailto:national@chadd.org)  
For comments or problems with this web site, contact [webmaster@chadd.org](mailto:webmaster@chadd.org)  
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## Your Role in Helping Children With ADHD

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To be successful in school, and in life, one must be able to pay attention and to control behavior and impulses. These areas are the same areas in which the child with attention deficit hyperactivity disorder (ADHD) has trouble.

You will best be able to help your students with ADHD succeed by learning as much as possible about the condition. This site will aid you in understanding the many aspects of children with ADHD and help you guide them in the classroom and with other school-related activities. The resources section of this site will provide you with access to an even wider range of information. The site is a guide only; the child's doctor and the professional staff of your school system should be available to help you with specific planning.

### Why You?

A conservative estimate on the incidence of ADHD in the United States is about 3 to 5 percent of grade school children. More boys than girls have been diagnosed with the disorder—the ratio is about 4 to 1. As a teacher, you are likely to have a child or an adolescent with ADHD and/or learning disabilities (LD) in your classroom. Depending on the size of your class, you may have more than one such child.

The disorder usually starts at about age 3, but the symptoms are not usually recognized until the child reaches school age because classrooms demand more structured behavior ie as age-appropriate attention span and concentration. Difficulties in learning are often a part of ADHD, and for classroom purposes, they can be considered together. The symptoms of ADHD-hyperactivity, short attention span, easy distractibility, impulsive behavior and emotional changeability-and signs of learning disability may be first recognized in the classroom.

The classroom teacher may be the first to start asking questions.

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### Helping the Student With ADHD

Some of your students may be able to receive special education services under the Individuals with Disabilities Education Act (IDEA). To get this help, the child's parents will need to talk with school officials about what special help might meet the child's needs. Additionally, you can direct your student's parents to the Parents section of this site for information on their child's right to an education as well as other valuable ADHD information.

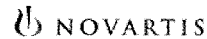
Most students with ADHD are helped by changes in the classroom called "adaptations."

### Common Classroom Adaptations for Children With ADHD

- **The student with ADHD needs clear rules.** Be sure the student knows the rules, schedules, and assignments. If possible, post the rules where they can be seen by the whole class so that you do not need to single out the child. The student with ADHD needs to know schedules and assignments. Have regular times for specific tasks. If changes are made in the schedule, call attention to the change several times. If possible, post the new time.
- **Be sure the student knows how to follow a schedule.** If you post assignments and schedules or have a book for the purpose, be sure the student knows how to use the schedule that you have assembled.

- **The student with ADHD needs to know how to study and learn.** Teach study skills and learning strategies and review them with the student frequently.
- **Students with ADHD need exercise-frequently.** Help the student channel physical activity. Schedule regular breaks for movement-exercise at the desks and walking as a class around the room as well as gym class. Let the student do some of the work standing at the board or be the one to hand out books or papers, clean the board, run errands, and tidy the room.
- **Students with ADHD need specific instructions, carefully given.** Instructions should be given both out loud and in writing. Give instructions for each task step by step. Some students with ADHD can do a full task more easily if they do each step as a separate task. Check with the student to make sure your instructions are understood and being followed.
- **Computers make many tasks easier for the child with ADHD.** If possible, let the student work on a computer. The student may be better able to focus and to concentrate on the information rather than handwriting and neatness.
- **There's more to schoolwork than academics.** ADHD interrupts art, sports, social activities, and relationships as much as it does reading, writing, and arithmetic. Be aware of the effect of ADHD on these areas and consider what adaptations might help improve the child's chances of success.
- **The child's parents are an important part of the teaching process.** Work with parents to create and activate the educational plan that is best for the student. Keep the parents informed about how the student is doing at school and ask questions about behavior at home. Talk to the school administration about how to improve the situation.
- **The student with ADHD may have emotional problems.** Sadness, depression, anxiety, disruptive behavior, and social problems may coexist with ADHD. Be aware of the possibility, learn about how the student is being treated, and if there is any way you can help.
- **The student with ADHD may be taking medication.** If your student is taking medication for ADHD or related problems, your help may be needed with the scheduling of medication, noting of side effects, and handling of an emergency.
- **The student with ADHD needs your help... and respect.** Although you may have to make adaptations and do things in new ways to meet the needs of your students with ADHD, you should have high expectations for them. Your thoughtful planning and patience will maximize your students' chances of success in school-and life.

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## What Can I Do for Myself?

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### Your Role in ADHD

The treatment most often suggested for ADHD is a combination of medication, some type of psychotherapy, including behavior modification, parental counseling, and treatment of any coexisting learning disorder. Teachers are often in a position to notice changes in a child's behavior due to treatment, and as a result, you can provide information and aid to the child, his or her parents, other school personnel, and anyone else involved in the child's care.

Children who take medications have regular checkups, and doctors usually ask that parents talk regularly with their child's teacher(s) to see how the child is doing. These talks are especially important when medicine is first started, restarted, or when the dosage is changed. By keeping the lines of communication open and having conversations with parents about their children's treatment, you can take an active role in the management of your student's condition.

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### Your Role in Medication

The treatment section of this site, *How is ADHD Treated?* discusses the types of medication used for the treatment of ADHD. However, just knowing about the medicines is not enough. School policy will determine your degree of involvement in supporting the treatment of the child taking medication for ADHD, but the following may prepare you for the observations you may need to make and the questions you may be asked to answer. Remember, your observations are important.

- Know if a child is taking medication, what the medication is, and if medication has to be taken during school hours. Talk with the school nurse as necessary. In some schools the teacher may meet with or talk to the child's doctor or therapist to gain information about the child's treatment. Write down any information you are given and ask questions until you have a firm understanding of what is required of you. As with all medicines, it is important that medicine for ADHD be taken exactly as directed.
- Know the timing of a child's medication so you can observe variations during the day. For example, note if the child becomes slightly hyperactive and irritable for a brief period when the medicine wears off.
- Know what changes to expect in a child just starting medicine-for example, is the child more attentive, better about completing tasks, etc.?
- Know what side effects may occur with any particular medication and what actions you need to take if any do occur. For example, does the child complain of headache or stomachache?
- Be aware of how the child's behavior and school performance change with long-term use of the medication. Is the child better able to function in school, and is he or she improving in relationships with peers? Has the child's self-esteem improved? You and the parents should know that a child's symptoms may crop up again, become exaggerated, or new one will arise when the child is under stress. Situations that are only annoying for most children can be quite stressful for a child with ADHD.
- Know when a child stops taking medication or starts to take a new medication or a new dosage, and what changes may occur. Nine out of 10 children improve on a "stimulant" drug, but

sometimes a medication will be tried for a week and if necessary the dosage or the medication may be switched.

- Some doctors take children off medicine from time to time to see how they will do. You should be aware of the change and the reason for it since you may be asked to help evaluate the behavior.
- Assumptions about medication based on single-case scenarios should not be made. Different doctors use medicines in slightly different ways and different children have different needs. Ask for specific instructions for medication for each child. A doctor works closely with each child to be sure the medication is appropriate.
- Recognize that the medications do not create the change in the child... they only make it possible for the child's strengths and natural abilities to show through the cloud of ADHD.
- Respect the child's confidentiality. Medical matters should only be discussed with those involved in the child's care.

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#### If parents ask...

If parents have questions about the doctor's or therapist's instructions, you can encourage them to ask their healthcare professional for clarification or further instructions. Make it clear that it is important for them and for their child to understand and follow the doctor's medical advice about medication and other therapies for ADHD. ADHD is a serious condition that may require the child to be on medication and undergo counseling for a long duration. If your school approves, you can refer the parents to an ADHD family support group or to supportive web sites such as this one.

There are many myths and facts about the treatment of ADHD that parents may ask you about. Many people think ADHD is related to eating sugar and food additives but excess sugar and food additives do not usually cause ADHD. Restricting foods containing artificial flavorings, preservatives, and sugars has been found by the National Institutes of Health (NIH) to help only about 5% of children with ADHD and these children are mostly either very young or have food allergies.

There are a number of alternative therapies offered for the treatment of ADHD. However, there is no scientific proof of the effectiveness of the following in treating children with ADHD.

The following is a list provided by the National Institute of Mental Health (NIMH):

- Biofeedback
- Restricted diet (mostly sugar, artificial coloring, and additives)
- Allergy treatment
- Inner ear medications
- Megavitamins
- Chiropractic adjustment and bone realignment
- Treatment for yeast infections
- Eye training or special colored glasses

If parents ask about the above treatments, you should inform them that the most effective demonstrated treatment involves a combination of medication, psychotherapy, and support from caregivers, including parents, other family members, and you.

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**Ritalin<sup>®</sup>** hydrochloride  
methylphenidate hydrochloride  
tablets USP



**Ritalin-SR<sup>®</sup>**  
methylphenidate hydrochloride USP  
sustained-release tablets

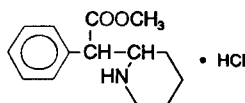


Rx only

### Prescribing Information

#### DESCRIPTION

Ritalin hydrochloride, methylphenidate hydrochloride USP, is a mild central nervous system (CNS) stimulant, available as tablets of 5, 10, and 20 mg for oral administration; Ritalin-SR is available as sustained-release tablets of 20 mg for oral administration. Methylphenidate hydrochloride is methyl  $\alpha$ -phenyl-2-piperidineacetate hydrochloride, and its structural formula is



Methylphenidate hydrochloride USP is a white, odorless, fine crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and in methanol, soluble in alcohol, and slightly soluble in chloroform and in acetone. Its molecular weight is 269.77.

*Inactive Ingredients.* Ritalin tablets: D&C Yellow No. 10 (5-mg and 20-mg tablets), FD&C Green No. 3 (10-mg tablets), lactose, magnesium stearate, polyethylene glycol, starch (5-mg and 10-mg tablets), sucrose, talc, and tragacanth (20-mg tablets).

Ritalin-SR tablets: Cellulose compounds, cetostearyl alcohol, lactose, magnesium stearate, mineral oil, povidone, titanium dioxide, and zein.

#### CLINICAL PHARMACOLOGY

Ritalin is a mild central nervous system stimulant.

The mode of action in man is not completely understood, but Ritalin presumably activates the brain stem arousal system and cortex to produce its stimulant effect.

There is neither specific evidence which clearly establishes the mechanism whereby Ritalin produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.

Ritalin in the SR tablets is more slowly but as extensively absorbed as in the regular tablets. Relative bioavailability of the SR tablet compared to the Ritalin tablet, measured by the urinary excretion of Ritalin major metabolite (■-phenyl-2-piperidine acetic acid) was 105% (49%-168%) in children and 101% (85%-152%) in adults. The time to peak rate in children was 4.7 hours (1.3-8.2 hours) for the SR tablets and 1.9 hours (0.3-4.4 hours) for the tablets. An average of 67% of SR tablet dose was excreted in children as compared to 86% in adults.

In a clinical study involving adult subjects who received SR tablets, plasma concentrations of Ritalin's major metabolite appeared to be greater in females than in males. No gender differences were observed for Ritalin plasma concentration in the same subjects.

## INDICATIONS

### **Attention Deficit Disorders, Narcolepsy**

**Attention Deficit Disorders** (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction.

Ritalin is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

### ***Special Diagnostic Considerations***

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors

and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

### **CONTRAINDICATIONS**

Marked anxiety, tension, and agitation are contraindications to Ritalin, since the drug may aggravate these symptoms. Ritalin is contraindicated also in patients known to be hypersensitive to the drug, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome.

Ritalin is contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result).

### **WARNINGS**

Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established.

Sufficient data on safety and efficacy of long-term use of Ritalin in children are not yet available. Although a causal relationship has not been established, suppression of growth (i.e., weight gain, and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Ritalin should not be used for severe depression of either exogenous or endogenous origin. Clinical experience suggests that in psychotic children, administration of Ritalin may exacerbate symptoms of behavior disturbance and thought disorder.

Ritalin should not be used for the prevention or treatment of normal fatigue states.

There is some clinical evidence that Ritalin may lower the convulsive threshold in patients with prior history of seizures, with prior EEG abnormalities in absence of seizures, and, very rarely, in absence of history of seizures and no prior EEG evidence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. In the presence of seizures, the drug should be discontinued.

Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking Ritalin, especially those with hypertension.

Symptoms of visual disturbances have been encountered in rare cases. Difficulties with accommodation and blurring of vision have been reported.

### **Drug Interactions**

Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents.



Human pharmacologic studies have shown that Ritalin may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic drugs (imipramine, clomipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Ritalin.

Serious adverse events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systemically evaluated.

### Usage in Pregnancy

Adequate animal reproduction studies to establish safe use of Ritalin during pregnancy have not been conducted. However, in a recently conducted study, methylphenidate has been shown to have teratogenic effects in rabbits when given in doses of 200 mg/kg/day, which is approximately 167 times and 78 times the maximum recommended human dose on a mg/kg and a mg/m<sup>2</sup> basis, respectively. In rats, teratogenic effects were not seen when the drug was given in doses of 75 mg/kg/day, which is approximately 62.5 and 13.5 times the maximum recommended human dose on a mg/kg and a mg/m<sup>2</sup> basis, respectively. Therefore, until more information is available, Ritalin should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

### Drug Dependence

Ritalin should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

### PRECAUTIONS

Patients with an element of agitation may react adversely; discontinue therapy if necessary.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe Ritalin should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with Ritalin is usually not indicated.

Long-term effects of Ritalin in children have not been well established.

### **Carcinogenesis/Mutagenesis**

In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 30 times and 2.5 times the maximum recommended human dose on a mg/kg and mg/m<sup>2</sup> basis, respectively. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 4 times the maximum recommended human dose on a mg/kg and mg/m<sup>2</sup> basis, respectively.

Methylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay or in the *in vitro* mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an *in vitro* assay in cultured Chinese Hamster Ovary (CHO) cells. The genotoxic potential of methylphenidate has not been evaluated in an *in vivo* assay.

### **ADVERSE REACTIONS**

Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. There have been rare reports of Tourette's syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: instances of abnormal liver function, ranging from transaminase elevation to hepatic coma; isolated cases of cerebral arteritis and/or occlusion; leukopenia and/or anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

## DOSAGE AND ADMINISTRATION

Dosage should be individualized according to the needs and responses of the patient.

### Adults

*Tablets:* Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

*SR Tablets:* Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

### Children (6 years and over)

Ritalin should be initiated in small doses, with gradual weekly increments. Daily dosage above 60 mg is not recommended.

If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

*Tablets:* Start with 5 mg twice daily (before breakfast and lunch) with gradual increments of 5 to 10 mg weekly.

*SR Tablets:* Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.

Ritalin should be periodically discontinued to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

## OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis, and dryness of mucous membranes.

Consult with a Certified Poison Control Center regarding treatment for up-to-date guidance and advice.

Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage. In the presence of severe intoxication, use a carefully titrated dosage of a *short-acting* barbiturate before performing gastric lavage. Other measures to detoxify the gut include administration of activated charcoal and a cathartic.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for Ritalin overdosage has not been established.

#### HOW SUPPLIED

**Tablets 5 mg** — round, yellow (imprinted CIBA 7)  
Bottles of 100.....NDC 0083-0007-30

**Tablets 10 mg** — round, pale green, scored (imprinted CIBA 3)  
Bottles of 100.....NDC 0083-0003-30

**Tablets 20 mg** — round, pale yellow, scored (imprinted CIBA 34)  
Bottles of 100.....NDC 0083-0034-30

Do not store above 30°C (86°F). Protect from light.

*Dispense in tight, light-resistant container (USP).*

**SR Tablets 20 mg** — round, white, coated (imprinted CIBA 16)  
Bottles of 100.....NDC 0083-0016-30

**Note:** SR Tablets are color-additive free.

Do not store above 30°C (86°F). Protect from moisture.

*Dispense in tight, light-resistant container (USP).*

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## Press Releases



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### Press Releases 2002

**FOR IMMEDIATE RELEASE**  
**House Hearing Causes Concern for CHADD**

Date: 09-25-2002

Contact: Peg Nichols or Winnie Imperio, 301-306-7070, ext. 102 or 117 or  
peg\_nichols@chadd.org or winnie\_imperio@chadd.org

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Landover, MD - On Thursday, September 26, the House Committee on Government Reform, chaired by Representative Dan Burton (R-IN), will conduct a hearing entitled "Attention Deficit/Hyperactivity Disorders - Are Children Being Over Medicated?"

Four of the five witnesses -- invited by Representative Burton -- are reported to spokespersons for or persons associated with the Citizens Commission on Human Rights (CCHR), an affiliate established 1969 by the Church of Scientology. CHADD is concerned that four witnesses associated with the hearing share the belief that AD/HD is a lie and a fraud. They include:

- \* Lisa Marie Pressley
- \* Bruce Wiseman
- \* Dr. Mary Ann Block
- \* Patricia Weathers

We'll keep you up to date on happenings in the world of AD/HD! Enter your email in the box below and click "subscribe"

As further context of the CCHR's philosophy, among their publications currently in circulation are "Psychiatry Betraying Families: The Hoax of ADD/ADHD and Other Learning Disabilities," "Psychiatry: Shattering Your World with Drugs," and "The Hoax of Learning and Behavior Disorders."

The fifth witness, invited at Mr. Burton's request, is Mr. Neil Bush, the President's brother, whose son was incorrectly diagnosed with AD/HD.

#### Help Areas

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Through the efforts of Representative Henry Waxman (D-CA) to ensure a balanced discussion, Clarke Ross, CEO of CHADD and Dr. David Fassler, representing the American Academy of Child and Adolescent Psychiatry (AACAP) and the American Psychiatric Association (APA), also have been asked to testify. It is expected that the National Institute of Mental Health will also send a witness.

#### ACTION REQUESTED

Please review the testimony below and share your concerns with Rep. Burton about the lack of balance in this hearing. You are also encouraged to cc a copy of the letter to your own U.S. Representative.

Mr. Burton can be contacted at:

Dan Burton  
Indiana-6th, Republican  
2185 Rayburn HOB  
Washington, DC 20515-1406

phone: 202-225-2276  
 fax: 225-0016  
 No e-mail address available

Contact information for representatives from your own state can be obtained through the THOMAS database at: <http://clerk.house.gov/members/index.php>

FULL TESTIMONY OF E. CLARKE ROSS, CHIEF EXECUTIVE OFFICER, CHADD

Statement to the House Committee on Government Reform September 26, 2002  
 "Attention Deficit/Hyperactivity Disorders - Are Children Being Over Medicated?"

Statement by E. Clarke Ross, Chief Executive Officer, CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder) 8181 Professional Place, Suite 201 Landover, Maryland 20785

Mr. Chairman and Members of the Committee: My name is Clarke Ross. I am the Chief Executive Officer of CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder).

Headquartered in the greater Washington area, CHADD is the nation's leading advocacy organization serving individuals and families dealing with AD/HD. Under the guidance of the world's leading AD/HD experts, CHADD works to improve the lives of those with AD/HD and their families through advocacy, education, research and support. CHADD currently serves 20,000 dues-paying members in 246 chapters located in 37 states and Puerto Rico.

CHADD educates the public about AD/HD primarily through dissemination of practices, policies, research and published papers issued by the nation's leading scientific and medical institutions. This includes the publications and research of United States Surgeon General, the National Institutes of Health, the National Institute of Mental Health, and the professional societies of physicians and other treating professionals and researchers in the mental health field.

Of utmost importance to CHADD are the evidence-based assessment and treatment guidelines of the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry. This body of evidence-based research emphasizes the importance of what is known as "multi-modal treatment."

Multi-modal treatment includes parent training in diagnosis, treatment and social behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required.

Also of interest to CHADD are complementary interventions used in the treatment of AD/HD. While CHADD is not opposed to complementary interventions, it strongly believes further research is necessary and advocates that NIH, NIMH, and others in the research community conduct further investigation to determine the efficacy of these complementary interventions.

THE STORY OF ONE 11-YEAR-OLD BOY: ANDREW ROSS

Perhaps even more important than my role as CEO of CHADD, is my role as father to an eleven-year-old son, Andrew, diagnosed with the inattentive type of AD/HD, an anxiety disorder, and other related co-occurring learning disorders.

Like many families facing AD/HD and related conditions, my wife and I, over time, have employed a wide array of interventions, including several considered complementary in nature, which are described in greater detail further in this statement. None of the complementary interventions we employed were harmful.

[http://www.chadd.org/press.cfm?cat\\_id=10&subcat\\_id=29&press\\_year=2002&press\\_id=52](http://www.chadd.org/press.cfm?cat_id=10&subcat_id=29&press_year=2002&press_id=52) 09/25/2002

statement. None of the complementary interventions we employed were harmful. But perhaps most significant, none of them have demonstrated an impact. Moreover, none of them are supported by the evidence-based research to which we are firmly committed.

In short, the multi-modal approach described above -- parent training in diagnosis treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed and, for us, medication provided and continue to provide the support that Andrew needs in order to thrive and flourish.

#### BACKGROUND

Andrew was born following a complicated delivery. When at age 11 months, he broke his ankle (which would not heal properly), follow-up assessments documented significant hypotonia and sensory integration challenges. At 21 months, he experienced his first unprovoked seizure with a pattern of seizures continuing for the next several years. Two EEGs later, many problems were confirmed. By two and still not speaking, Andrew's pediatrician referred him to the State of Maryland's Early Education Program. For the next several years he received intensive speech and language and sensory integration services. Andrew also has dysgraphia, which can best be described as a difficulty in automatically remembering and mastering the sequence of muscle motor movements needed in writing letters or numbers. Fortunately, with intensive assistance from the school occupational therapist, Andrew has largely overcome his dysgraphia.

By four, when Andrew entered a more formal education program, teachers began noting significant learning problems stemming directly from his inability to focus. He received numerous independent professional assessments, each affirming that his disabilities significantly impeded his ability to function at the level of his classmates. Andrew has always had difficulty with what now is referred to as "executive functioning" - brain actions of self control where he is unable to think ahead and consider "if-then" behaviors and their consequences.

My son does not have an occasional problem with distraction and attention. He has ongoing, continuous daily problems that result in overwhelming difficulties in many areas of his life.

No well-meaning parent sets out to medicate his or her child. Nor did we. But over time, given Andrew's learning and functional problems, we accepted the advice of child psychiatrists who felt our son would benefit from medication. Today, Andrew takes both a medication for attention issues and a medication designed to reduce his anxiety. A series of behavioral management and learning assistance program also are used and are an essential part of his overall treatment program.

At age four, a child psychiatrist recommended that Andrew try a stimulant medication. We initially said no, as we wanted to first try other interventions. But by the time Andrew was seven, we said yes to stimulant medication. The other interventions had not worked in helping him pay attention. We now were ready to try medication.

We actually tried three medications before we found one that worked. The first two did not help his attention (nor did they have any side effects), but the third one did have significant results. To this day Andrew takes Adderall.

Andrew began using Prozac two and a half years ago because of a severe anxiety problem. He is anxious about many things. As one example of many, Andrew was so afraid of flying insects that three summers ago he would not go outside despite his love of baseball and basketball. A combination of behavioral interventions, cognitive training and medication has helped to reduce his anxiety. He remains

uncomfortable with flying insects and bristles stumpy when they are around, but generally speaking he now can function quite normally. But his anxiety was not singularly confined to flying insects. Andrew is anxious about many things and many situations. As such, my wife and I are constantly developing behavioral interventions to deal with these varied anxieties.

Medication obviously is not perfect. For example, Andrew initially experienced a significant loss in appetite. Today, however, he only experiences a loss of appetite at lunch, proof that there are continual tradeoffs in the beneficial use of medication and side effects from such use. On the plus side, however, with the assistance of special education personnel and a multimodal treatment approach in place, including medication, Andrew can now better attend to learning in class, is less phobic, and demonstrates more socially appropriate behaviors with children his age.

As the parent of a child with multiple challenges, I resent those who suggest that my son needs only a little more discipline, structure, and learning. In direct contrast to the publications issued today by some of the hearing witnesses, I want to emphatically say that my son's problems are neither "lies" nor "frauds" nor the "failures of his parents." Andrew has a biologically based brain disorder that we have an extensive network of dedicated clinicians face and address on a daily basis. Andrew's life is filled with dedicated clinicians - from pediatrician, to child psychiatrist, to child psychologist, to neurologist, to speech pathologist, to a team of educators. Without their collective support, I cannot imagine where Andrew would be today.

As mentioned previously, we employ a variety of complementary approaches. These include visualizing and verbalizing training, sensory integration therapy, a visual tracking. Andrew responds best in small learning groups where constant feedback and support is provided. We use Dr. Thomas Phelan's 1-2-3 Magic approaches each and every day. And every day Andrew consumes fish oil supplements (Omega-3 Fatty Acids). But as noted above, while certainly not harmful, none of these interventions (other than 1-2-3 Magic) have yielded any immediate or even long-lasting positive impact upon Andrew.

The good news is that Andrew is making progress. The strides are slow yet steady. And like most families in similar circumstances, we are resolved to living life one day at a time. I share my wife's and my story with the hope that those unfamiliar with AD/HD will appreciate the complexity and difficulty of identifying and implementing key medical strategies designed to help children like our son Andrew.

#### THE EVIDENCE-BASED SCIENCE

In looking at the broader AD/HD picture - particularly with respect to the emergence of evidence-based science-it is essential to note the following key milestones:

\* In 1998, the American Medical Association published an exhaustive review of the scientific literature concerning AD/HD, concluding that the disorder is real and that while there may be instances of over diagnosis, there is a greater problem of under diagnosis.

\* In 1999, the National Institute of Mental Health (NIMH) published its first result from The Multimodal Treatment Study of Children with Attention-Deficit/Hyperactivity Disorder, a multicenter study evaluating the leading treatments for ADHD, including various forms of behavior therapy and medication in nearly 600 elementary school children. The results indicate that long-term combination treatments as well as medication management alone are both significantly superior to intensive behavioral treatments and routine community treatments in reducing AD/HD symptoms.



\* In 1999, the U.S. Surgeon General released the landmark Report on Mental Health, which devotes an entire section to the evidence-based science behind AD/HD. Among the important findings are that stimulants are highly effective for 75-90% of children with AD/HD, while the most effective interventions for AD/HD are multimodal treatment-which involves the use of medication with psychosocial behavioral and related interventions. Finally, "recent reports found little evidence over diagnosis of AD/HD or over prescription of stimulant medications. Indeed fewer children (2-3% of school-aged children) are being treated for AD/HD than suffer from it."

\* First in 2000 for assessment, and then in 2001 for treatment, the American Academy of Pediatrics (AAP) published clinical practice guidelines for AD/HD. The groundbreaking guidelines include endorsement of stimulant medications when appropriate monitoring and behavior interventions are also used.

\* In 2002, the American Academy of Child and Adolescent Psychiatry (AACAP) published practice parameters for the use of stimulant medications in the treatment of children, adolescents and adults. The parameters rely on an evidence-based medicine approach derived from a detailed literature review and expert opinion.

#### SOME CHILDREN ARE TREATED INAPPROPRIATELY; SOME CHILDREN ARE UNDEI TREATED

In reviewing the developments above, it is simultaneously essential to note that both U.S. Surgeon General's reports on mental health (1999 on mental health research, and the 2001 report on race and culture) emphasize that some children are inappropriately identified while many children are never identified.

It therefore also becomes essential to comment upon public alarm that "AD/HD is over-identified and over-medicated" because of the over 700% increase in the use of stimulant medication in the school age population over the past decade. Before resorting to alarmist reactions, let us first examine the prevalence rate.

\* The U.S. Surgeon General estimates the school-age prevalence of AD/HD to be between 3 and 5%. Even with the over 700% increase in stimulant medication use over the past decade, only 2 to 2.5 % of the school-age population currently receive stimulant medication. If medication is an appropriate component of multimodal treatment intervention (as the science informs us), then over half of those suffering the effects of AD/HD are not being effectively treated.

\* The 3-to-5% prevalence rate may actually be a conservative rate. Two published studies by the Mayo Clinic of Rochester, Minnesota, one in the January 2001 issue of the Journal of the American Medical Association and the other in the March 20 issue of the Archives of Pediatrics and Adolescent Medicine documented that 7.5% of all children presenting for any kind of medical treatment in Rochester over a seven year period had AD/HD.

\* What is particularly alarming to CHADD is the tremendous variance of stimulant medication prescribing practices across the nation. While Dr. Julie Zito of the University of Maryland and Dr. Gretchen LeFever of Eastern Virginia Medical School have published studies about the significant variance within Maryland and Virginia probably the single most informative published study was the May 6, 2001 Cleveland Plain Dealer article, "Ritalin Prescribed Unevenly in U.S." The paper's reporters studied for one full year the actual prescriptions written in every county in the nation. Some counties had 5% of the total school-age population and 20% school-age boys on stimulant medication while other counties had practically no one receiving a stimulant medication. CHADD remains alarmed with this variance practice.

CHADD believes that the single most important reason for such variance is the absence in clinical practice of the use of the AAP and AACAP evidence-based assessment and treatment guidelines. That is why CHADD is tirelessly working to educate the public about the AAP and AACAP guidelines and to advocate that physicians using such guidelines be financially reimbursed by health insurance payers at a higher rate than physicians not using such guidelines.

We also need better research about the prevalence of AD/HD and the number of children actually receiving such medication. While the Cleveland Plain Dealer and others have studied the numbers of prescriptions written, we really have no excellent database on actual numbers of children receiving such medications on regular basis. Certainly, we must protect the confidentiality of individual children and their families, but we also need better aggregate data on overall usage.

For example, consider the data. The United States General Accounting Office in 2001 stated that there were 46.6 million public school students. Three-to-five percent of this total would be between 1.4 to 2.3 million children, not including students in both private school or home-school settings. If we use the Mayo Clinic 7.5 % prevalence rate, then 3.26 million school age children would be expected have AD/HD - an appropriate number given such rates. CHADD commends the Centers for Disease Control and Prevention (CDC) for recognizing the need to better assess accurate prevalence rates, including funding for three prevalence studies.

#### CHADD REITERATES KEY ROLE PHYSICIANS, TEACHERS, AND FAMILIES PLAY IN RECOGNIZING AND TREATING AD/HD

CHADD is concerned that without proper context, and when sensationalized, alarmist statements and reports create confusion among the general public, patients and families, thus undermining the seriousness of AD/HD and the prove safety and efficacy of stimulant medications when properly administered by appropriate professionals.

CHADD believes that all families should have access to the best, evidence-based science in the diagnosis and treatment of AD/HD. We are therefore concerned w/ legislation is proposed that undermines this critical access-including the eliminat of a teacher's freedom to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations. Likewise, CHADD is appalled when children are inappropriately prescribed medication that they do not need. This is of particular concern when small subsets of children suffer significant side effects.

CHADD believes that legislation must not limit or undermine the ability of a medical professional, within their scope of practice, from treating AD/HD based on the most widely accepted evidence-based science. CHADD encourages all families and physicians to follow best practice assessment and treatment guidelines being uniformly implemented throughout the nation, specifically the current American Academy of Pediatrics (AAP) and American Academy of Child and Adolescent Psychiatry (AACAP) guidelines. Using the force of law and agencies of government particularly criminal penalties-to monitor and enforce best practice treatment guidelines is an ineffective approach at best and disastrous approach at worst. Instead, ongoing training and education in the diagnosis and treatment of AD/HD should be encouraged among all physicians.

Teachers are frequently the first to recognize learning, functioning, and behavior problems in the school setting and therefore should be able to advise parents of such observations. CHADD believes that professionals should act within their professional scope of practice. Thus, school personnel should not recommend the use of medication. Medication assessment and prescription is the role of the physician and-under limited circumstances-in a few states, other treating professionals too. However, teachers should be able to recommend a

professionals too. However, teachers should be able to recommend a comprehensive and complete medical assessment by persons licensed to perform such evaluations.

Because students spend a significant portion of their day in the classroom, the role that teachers play in providing observations to the diagnosing professionals cannot be underestimated. Effective communication among teachers, professionals and parents is essential and strongly encouraged. CHADD advocates a multi-modal approach to the treatment of AD/HD, including parent training in diagnosis, treatment and specific behavior management techniques, an appropriate educational program, individual and family counseling when needed, and medication when required. Medication is used to improve the symptoms of AD/HD. Research shows that children and adults who take medication for the symptoms of AD/HD attribute their successes to themselves, not to the medication.

#### DENIAL OF AD/HD REFUTED

The organized interests at this hearing claiming that AD/HD is a "biological lie" state that there are no "biological imbalances" and "no laboratory tests establish as diagnostic" for AD/HD. They go on to claim that AD/HD is a "100 percent fraud

But science tells us a different story. The Surgeon General's report (page 144) concludes "AD/HD is the most commonly diagnosed behavioral disorder in childhood and occurs in three to five percent of all school-age children. The exact etiology of AD/HD is unknown, although neurotransmitter deficits (such as the dopamine transmitter), genetics, and perinatal complications have been implicated." The NIH Panel Consensus statement declares: "Although an independent diagnostic test for AD/HD does not exist, there is evidence supporting the validity of the disorder."

As previously stated, the NIMH MTA Study further documented that only 31% of the children with AD/HD have AD/HD alone with no other disorder. The study found that 40% of children with AD/HD had oppositional defiant disorder, 34% had anxiety disorder, 14% had conduct disorder, and 4% had a mood disorder. Those dismissing the existence of AD/HD repeatedly ignore these characteristics. A May 22 study by the Centers for Disease Control and Prevention (CDC) documented that half of the school age population with AD/HD also had a learning disability.

The existence of co-occurring disorders complicates assessment, complicates treatment, and increases the possibility of an inaccurate diagnosis. This only further reiterates the importance of the AAP and AACAP best practice guidelines.

#### CLOSING

I have devoted over 30 years of my professional life assisting individuals with cerebral palsy, schizophrenia, bipolar disorder, AD/HD, and other mental disorders. I find it frustrating and disheartening that I have to defend recognized science against science fiction. This is demeaning to those suffering from these disorders and to the millions of families who devote their lives caring for and supporting their loved ones.

The science speaks for itself. Even more important are the stories of untold millions who have either been helped by appropriate interventions - or worse, been denied access to the treatment they deserve. Instead of wasting precious time, energy, and resources defending a disorder that clearly exists, why can't we simply move forward in applying the science to clinical practice and educational settings to make life better for those faced with these challenges? Why do some policy makers continue to play to those who claim that there are no mental disorders, that there is no science, and that anyone's science fiction is equivalent to the evidence-based science?

The reality that children and adolescents can and do suffer from AD/HD and other debilitating brain disorders, just as adults do, is finally being widely recognized. That is why we must continue educating others and ourselves about the broad spectrum of childhood mental disorders. We must continue joining forces with scientific institutions and others. And we must do everything within our means to ensure that our children receive the tools they need to live a meaningful life, regardless of their disability, challenge or disorder.

E. Clarke Ross, September 23, 2002

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With over 20,000 members and 200 chapters nationwide, CHADD works to improve the lives of people affected by AD/HD through collaborative leadership, advocacy, research, education and support: CHADD CARES. For additional information about AD/HD or CHADD, please contact CHADD National Call Center at 1-800-233-405 or visit the CHADD website at [www.chadd.org](http://www.chadd.org).

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**IS RITALIN AN ABUSED DRUG?:****DOES IT MEET THE CRITERIA OF A SCHEDULE II SUBSTANCE?**

Christine Sannerud and Gretchen Feussner

Methylphenidate (MPH, Ritalin®) is classified as a Schedule II stimulant under the Federal Controlled Substances Act (CSA). In order to place any substance under control in the United States requires very specific findings. For a Schedule II classification, the drug or other substance must (1) have a high potential for abuse, (2) have a currently accepted medical use in the United States and (3) show that abuse may lead to severe psychological or physical dependence. Studies that address the abuse liability of a drug and data relating to the separation of a drug from legitimate handlers combined with clinical experience of actual abuse represent valuable information about the abuse potential and dependence profile for a drug. This report will explore the scientific, medical and law enforcement data that explains why MPH has been placed in the same classification as other highly abusable substances like amphetamine, methamphetamine, methamphetamine and cocaine.

**ABUSE LIABILITY**

A good correlation exists between drugs that are abused by man and those that maintain self-administration in laboratory animals (Schuster and Thompson, 1969; Griffiths et al., 1980). There are a number of behavioral paradigms used in animals that are sensitive models of human drug abuse and reinforcing effects. Specifically, preclinical evaluations of psychomotor effects in laboratory animals using drug discrimination and intravenous self-injection

paradigms are considered useful for the prediction of human abuse liability of these compounds (Johanson and Balster, 1978; Preston et al., 1997).

### **Drug Discrimination**

Drug discrimination procedures provide an indirect measure of a drug's reinforcing effects and its abuse potential (Preston et al., 1997). The drug discrimination paradigm is based on the ability of psychoactive drugs to produce interoceptive stimuli, and the ability of nonhuman and human subjects to identify the presence of these stimuli and to differentiate among the constellations of stimuli produced by different drug classes. In drug discrimination studies, the drug stimuli function as a cue to make an operant response in order to receive a reinforcer. Repeated pairings of a reinforcer with only the drug-appropriate response can produce reliable discrimination between the drug and no-drug. This paradigm has been used extensively to characterize the behavioral profile of MPH.

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#### *Preclinical drug discrimination:*

Years of preclinical drug discrimination research show that MPH is (1) discriminable, (2) can be trained as a discriminative stimulus, and (3) generalizes to a number of psychomotor stimulants including cocaine, and d-amphetamine. Preclinical studies show that animals trained to discriminate d-amphetamine from saline showed generalization to MPH (Huang and Ho, 1974; Harris and Balster, 1971; Porsolt et al., 1982; Evans and Johanson, 1987; De la Garza and Johanson, 1987), animals trained to discriminate cocaine from saline show generalization to amphetamine and MPH (McKenna and Ho, 1980; Silverman and Schultz, 1989), and animals

trained to discriminate MPH from saline show generalization to amphetamine and cocaine (Perkins et al., 1991; Silverman and Ho, 1980) (see Table 1).

In rats, monkeys and pigeons trained to discriminate d-amphetamine from saline, MPH produces d-amphetamine-like effects (Huang and Ho, 1974; Harris and Balster, 1971; Porsolt et al., 1982; Evans and Johanson, 1987; De la Garza and Johanson, 1987) (see Table 1). MPH and other psychomotor stimulants, including l-amphetamine, methamphetamine, cocaine, and ephedrine all produced discriminative stimulus effects similar to those of d-amphetamine (Huang and Ho, 1974; Silverman and Ho, 1980; Porsolt et al., 1982; Rosen et al., 1986). However, MPH produced partial generalization to 2,5-dimethoxy-4-methylamphetamine (DOM) stimulus (Silverman and Ho, 1980). These data suggest that MPH produces amphetamine-like effects, but not DOM-like hallucinogenic effect.

MPH also produced amphetamine-like effects in nonhuman primates and pigeons trained to discriminate d-amphetamine from saline (De la Garza and Johanson, 1987; Evans and Johanson, 1987). In these studies, MPH produced amphetamine-like discriminative stimulus effects without producing changes in general activity. Similarly, in animals trained to discriminate cocaine from saline under a variety of operant schedules of reinforcement, MPH shares discriminative stimulus effects with cocaine when tested for generalization. In rats, MPH, d-amphetamine, l-amphetamine, and methamphetamine all substituted for cocaine, suggesting that these drugs produced effects similar to those of cocaine (Colpaert et al., 1979; McKenna and Ho, 1980; Silverman and Schultz, 1989).

The discriminative stimulus effects of MPH appear to be robust; MPH generalizes to cocaine and d-amphetamine across several training dose conditions. Specifically, MPH

generalizes to cocaine when the training dose of d-amphetamine or cocaine is high or low (Wood and Emmett-Oglesby, 1988; Emmett-Oglesby et al., 1983; Rosen et al., 1986). Thus, regardless of training condition, MPH substituted for the cocaine discriminative stimulus.

In other studies, MPH produced stimulus effects similar to dl-cathinone (Goudie et al., 1986) in rats and to the selective dopamine uptake inhibitor (1-{2-[bis(4-fluorophenyl)-methoxyethyl]-4-(3-phenylpropyl)piperazine (GBR 12909) in monkeys (Melia and Spealman, 1991). MPH completely substituted for the GBR 12909 stimulus as did high doses of cocaine, the cocaine analog (2 $\beta$ -carbomethoxy-3 $\beta$ -(4-fluorophenyl)tropane), and d-amphetamine. In addition to producing effects similar to cathinone, d-amphetamine and cocaine in generalization tests, MPH will serve as a training stimulus in drug discrimination studies, demonstrating its ability to produce and maintain discriminable stimulant-like effects that can be used to guide behavioral choice under different operant schedules of reinforcement (Perkins et al., 1991; Overton 1982).

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In summary, MPH produces discriminative stimulus effects similar to d-amphetamine, cocaine, and cathinone in laboratory animals (Table 1). Under cocaine and d-amphetamine training conditions, the stimulus effects produced by MPH completely substituted for the cocaine or d-amphetamine training stimulus. The psychomotor stimulant effects of MPH are robust and can be demonstrated under many different training conditions, and using several different species of nonhuman animal.

*Clinical Drug Discrimination Studies:*

MPH produces stimulant-like discriminative stimulus effects in humans (Heischman and



maintain high rates of self-injection in progressive ratio studies and is chosen over cocaine in preference studies. In clinical studies MPH is self-administered by humans and produces patterns of reinforcing and subjective effects similar to d-amphetamine. MPH and d-amphetamine produce similar patterns of subjective effects, including increases in rating of euphoria, drug liking and activity and decreases in sedation.

#### **Tolerance/Sensitization**

In preclinical studies, chronic administration of MPH produces tolerance to its disruptive and stimulus effects and shows cross-tolerance with d-amphetamine and cocaine (McNamara et al., 1993; Kolta et al., 1985; Emmett-Oglesby and Taylor, 1981; Emmett-Oglesby and Brewin, 1978; Wood and Emmett-Oglesby, 1983, 1988; Leith and Barrett, 1981). Like d-amphetamine and cocaine, chronic administration of MPH produces psychomotor stimulant toxicity, including aggression, agitation, disruption in food intake, weight loss, stereotypic movements and death (Downs et al., 1979; Wesson and Smith, 1978). This toxicity may be a result of sensitization to the drug's effects during chronic use.

#### **Dependence and Withdrawal Effects**

In animals, withdrawal from MPH has not been tested using behavioral paradigms. However, given MPH's pharmacological and behavioral similarities to cocaine and d-amphetamine, data suggest that withdrawal from chronic MPH would result in a withdrawal "anxiety" stimulus similar to that demonstrated after withdrawal from chronic cocaine administration (Wood and Emmett-Oglesby, 1988, 1989).

In humans, abstinence from psychomotor stimulants, such as d-amphetamine and cocaine, after chronic use results in the appearance of withdrawal signs within one to three days, including depression, sleep disturbances, anxiety, fatigue, anger/hostility, dysphoria, psychomotor agitation, confusion and drug craving (Gawin and Kleber, 1986; Gawin, 1989; Gawin and Ellinwood, 1988; Gawin et al., 1992; Weddington et al, 1990; Satel et al, 1991; Dackis and Gold, 1990; Watson et al 1992).

In summary, methylphenidate is a psychomotor stimulant structurally and pharmacologically similar to the amphetamines. In preclinical studies, methylphenidate, like d-amphetamine and cocaine, is self-administered by laboratory animals including rats, dogs, monkeys and baboons (Wilson et al., 1971; Johanson and Schuster, 1975; Risner and Jones, 1975; Griffiths et al., 1975; Spealman, et al., 1989). Methylphenidate produces discriminative stimulus effects similar to d-amphetamine and cocaine in laboratory animals (Huang and Ho, 1974; Evans and Johanson, 1987; Wood and Emmett-Oglesby, 1988). In preclinical studies, chronic administration of methylphenidate produces tolerance to its disruptive and stimulus effects and shows cross-tolerance with d-amphetamine and cocaine (Emmett-Oglesby and Taylor, 1981; Wood and Emmett-Oglesby, 1988; Leith and Barrett, 1981).

#### ACTUAL ABUSE

Some of the earliest published reports of MPH abuse were out of Sweden (Borg, 1961; Jorgensen and Kodahl, 1961; Noriek, 1960) where widespread abuse and misuse of MPH led to

its withdrawal from the Swedish market in 1968. Most of the U.S. literature cite case reports of individuals while only a few studies document abuse in certain groups or populations. The following literature summarizes the patterns and severity of abuse associated with MPH and provides pertinent citations concerning the medical consequences associated with that abuse.

In the early 1960s, many members of the scientific community felt that stimulants produce a form of addiction that is relatively benign and infrequent. Riox (1960) and McCormick and McNeal (1963) countered this view by providing detailed case reports of patients that abused MPH. These and subsequent case reports (Jaffe and Koschmann, 1970; Spensley and Rockwell, 1972; Brooks et al., 1974; Goyer et al., 1979; Keeley and Light, 1985; Jaffe, 1991) demonstrate that MPH is associated with patterns of abuse similar to other Schedule II stimulants. Like amphetamine and cocaine, abuse of MPH can lead to marked tolerance and severe psychological dependence. The pattern of abuse is characterized by escalation in dose, binge use followed by severe depression and an overpowering desire to continue the use of this drug despite negative medical and social consequences. The abuser may alter the mode of administration from oral use to intranasal or intravenous use to intensify the effects of the drug. Typical of other potent psychostimulants, high doses of MPH often produce euphoria as well as agitation, tremors, tachycardia, palpitations and hypertension. Psychotic episodes with schizophrenic characteristics and paranoid delusions characteristic of amphetamine-like toxicity have been associated with MPH abuse.

Throughout the 1970s and 1980s, several articles were published in the medical literature that document the serious medical consequences associated with parenteral abuse of MPH. Large amounts of talc used as a filler in MPH tablets lead to widespread obstruction of the

in pulmonary vascular bed when these tablets, intended for oral use, are crushed, diluted and injected intravenously. Pulmonary hypertension brought on by repeated i.v. injections of MPH was strongly associated to the deaths of numerous individuals in Oregon and Washington (Lewman, 1972); autopsy examination demonstrated a characteristic talc granulomatosis and morphologic evidence of severe hypertension. Other fatalities associated with intravenous MPH abuse have been reported (Levine et al., 1984 and Lundquest et al., 1987). Brooks et al. (1974) provided a study of the effects of MPH abusers who presented on the medical-surgical services for eikenella infections at injection sites. Problems created by intra-arterial injection of MPH were discussed by Smith et al. (1972). Chillar et al. (1982) presented two cases of hemiplegia brought on by intra-arterial injection of MPH. Arnett et al. (1976) presented a case of a patient with bacterial tricuspid valve endocarditis with septic embolic pneumonia resulting from intravenous MPH abuse. Elenbaas et al. (1976) and Zempenji and Colman (1984) reported osteomyelitis as a complication of parenteral MPH abuse. Other serious complications of MPH abuse have included osteomyelitis (Abino and Pandarinath, 1977), precocious puberty (Sherman et al., 1987), severe eosinophilia (Wolf et al., 1978), multiple organ failure (Muller et al., 1985), retinopathy (Gunby, 1979) and hepatic injury (Mehta et al., 1984). Carter and Johnson (1994) conducted a study to characterize intravenous pentazocine/methylphenidate abuse in emergency department patients. This drug combination has been reported in other case reports (Bryon et al., 1973; Kishorekumar et al., 1985; Lundquest et al., 1987) and is referred to as "T & Blues" or "T & Rs" among street addicts in many areas of the United States and Canada.

The use of MPH by methadone clients has been studied by Lewman (1972) who

estimated that about 20 percent of 360 addicts in methadone treatment at the Oregon Medical Center were injecting MPH regularly or on occasion. Raskind and Bradford (1975) found that methadone patients were more likely to abuse MPH than heroin street addicts. The methadone clients stated that MPH produced an intense "rush" that methadone did not and the "program" did not seem to know or care if patients were using MPH. Haglund and Howerton (1982) assessed the use of MPH among 192 consecutive admissions to a central intake unit for drug abuse treatment. More than half of the clients seeking treatment reported using MPH usually in combination with opioids. It is unknown whether MPH remains a popular drug among methadone patients as routine testing does not screen for MPH use.

Unlike cocaine, amphetamine and methamphetamine where illicit manufacturing account for the vast majority of available drugs for abuse, pharmaceutical products diverted from legitimate channels are the only sources of MPH available for abuse. The Drug Enforcement Administration (DEA) is unaware of any clandestine production of MPH; this fact probably reflects its rather arduous chemical synthesis. Diversion of MPH has been identified by drug thefts, illegal sales and prescription forgery. An analysis of drug thefts reported to the DEA indicates that MPH ranks in the top 10 most frequently reported controlled pharmaceuticals diverted from licenced handlers; most reports were generated by pharmacies and most thefts occurred during night break ins. Data from state and local law enforcement and DEA case files indicate that MPH is diverted in a number of ways by a wide range of individuals and organized groups: from health care professionals including physicians, pharmacists and nurses to organized drug trafficking rings involving multistate distribution. This profile is consistent with other highly abusable pharmaceutical substances that are in Schedule II of the CSA.

MPH diversion has been a particular problem in some states. For example, in Nebraska, investigative services for the state reported that MPH ranked among the top three pharmaceutical drugs most frequently submitted to crime laboratories for analysis from 1991 through 1994 and from April 1992 through January 1995, MPH ranked 6th among drugs involved in incidents of forged or altered prescriptions. In Ohio, from March 1979 to January 1994, MPH ranked second among pharmaceutical drugs reported for false or forged prescriptions and the Ohio Board of Pharmacy reported 18 separate cases involving pharmacists that were diverting this drug for sale or personal use.

In recent years, data from prescription audits, production quotas and sales data from the manufacturers indicate that the use of MPH has increased significantly in the United States. In 1995, the United Nations reported that the U.S. produced and consumed about 85 percent of the total world production of MPH (Fig 1). The primary use of this drug is for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children although there is a growing trend for MPH pharmacotherapy for the treatment of ADHD symptoms in adults. Because so many families with young children and adolescents are in daily contact with this drug, evidence of diversion and misuse/abuse in this setting is both noteworthy and alarming. Goyer et al. (1979), Fulton et al. (1988) and Jaffe (1991) are among the few literature articles that address the abuse of MPH within the context of ADHD treatment. However, a significant amount of data including school surveys, emergency room reports, data from poison control centers, data from adolescent treatment centers and law enforcement encounters all indicate a growing problem with the abuse of MPH among younger populations (DEA Reports, 1995, 1997). Since 1990, there has been a five-fold increase in the number of emergency room mentions for MPH in the

Drug Abuse Warning Network (DAWN) and a ten-fold increase for children 10 to 14 years of age who are just as likely to report MPH abuse as cocaine (Fig 2). The national survey Monitoring the Future conducted by the Institute of Social Research at the University of Michigan (also referred to as the high school survey) indicated that about 1 percent of all 1994 and 1995 high school seniors used Ritalin without a doctor's order during the previous year. Adolescent treatment centers have uniformly reported an increase in abuse of MPH although few adolescents report this drug as their primary drug of abuse.

Four different types of cases centering around the use of MPH for ADHD treatment have been reported by law enforcement personnel throughout the U.S.: 1) parents who sell or abuse MPH medication prescribed to their child; 2) adolescents that sell their own MPH medication or a sibling's medication to friends and classmates; 3) adolescents that abuse their own MPH medication or that of a friend by crushing the tablets and snorting the powder and 4) theft from home or school MPH supplies. The DEA held a conference in December, 1996 where adolescent abuse was discussed and possible contributing factors were explored (DEA report, 1997).

There is little doubt that MPH is associated with significantly less abuse and associated morbidity/mortality than cocaine or methamphetamine (both classified as Schedule II stimulants) and, as a consequence, many have used this information to argue that MPH does not have a high abuse potential. This disparity reflects the vastly different amounts of cocaine and methamphetamine produced by clandestine labs as well as uncontrolled street distribution of these drugs. In comparison, MPH production and distribution is highly regulated to help prevent diversion and subsequent abuse. It is interesting that the same disparity exists between pharmaceutical morphine and heroin but no one is suggesting that morphine be less highly

controlled.

In conclusion, MPH has been shown to have an abuse liability similar to other Schedule II stimulants including amphetamine, methamphetamine and cocaine. Actual abuse data indicates that the pattern of MPH abuse is similar to other potent psychostimulants and is diverted and abused to a similar extent as other pharmaceutical Schedule II substances. Taken collectively, the data indicates that MPH fits the profile of a Schedule II substance.

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U.S. Department of Justice  
Drug Enforcement Administration

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**METHYLPHENIDATE**  
**(A Background Paper)**

October 1995  
Drug and Chemical Evaluation Section  
Office of Diversion Control

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METHYLPHENIDATE BACKGROUND PAPER

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Summary

Methylphenidate is a Schedule II stimulant which is structurally and pharmacologically similar to the amphetamines. It is indicated for the treatment of Attention-Deficit/Hyperactivity Disorders (ADHD) and narcolepsy. Approximately 85 to 90 percent of all prescriptions for methylphenidate are written for young children and adolescents for the treatment of ADHD. Methylphenidate is available as the brand name product, Ritalin, manufactured by Ciba-Geigy, and as generic products manufactured by MD Pharmaceuticals.

The use of methylphenidate in the United States has increased dramatically in recent years. Since 1990, there has been a six-fold increase in the U.S. production and utilization of methylphenidate. This increase contrasts sharply with trends in medical practice seen in the rest of the world. According to the United Nations 1993 statistics on psychotropic substances (the latest data available from that body), the U.S. produces and consumes five times more methylphenidate than the rest of the world combined.

Internationally, methylphenidate is listed in Schedule II of the Convention on Psychotropic Substances, 1971, along with amphetamine and methamphetamine. Under treaty obligations, the United States must provide the United Nations International Narcotics Control Board (INCB) with data on the production, distribution and consumption of methylphenidate. The INCB has, on two recent occasions, written letters to U.S. officials expressing their concern about the sharp increase in the use of methylphenidate in the United States and has requested data on the legal requirements for the use of methylphenidate as well as data concerning trends in abuse and possible diversion from licit sources.

While stimulant pharmacotherapy for the treatment of ADHD in children is recognized by medical experts worldwide, no other nation prescribes stimulants in such volume to its children. Epidemiological data indicate that from 3-5 percent or more of all U.S. children are treated with methylphenidate for ADHD, frequently without the benefit of other services as recommended in treatment guidelines.

Support and advisory groups play an important role in the distribution of information regarding ADHD and its treatment. In recent years there have been large increases in membership in these organizations and participation in their activities. Children and Adults with Attention Deficit Disorder (CHADD) is the nation's largest ADHD support organization. CHADD has a membership of over 28,000 and has 600 chapters nationwide. CHADD sponsors parent support groups, convenes meetings featuring speakers, works with local school systems and provides information regarding ADHD related issues.

It has recently come to the attention of the DEA, that Ciba-Geigy (the manufacturer of the methylphenidate product marketed under the brand name Ritalin) contributed \$748,000 to CHADD from 1991 to 1994. The DEA has concerns that the depth of the financial relationship with the manufacturer was not well-known by the public, including CHADD members that have relied upon CHADD for guidance as it pertains to the diagnosis and



treatment of their children. A recent communication from the United Nations International Narcotics Control Board (INCB), expressed concern about non-governmental organizations and parental associations in the United States that are actively lobbying for the medical use of methylphenidate for children with ADHD. The INCB further stated that "financial transfer from a pharmaceutical company with the purpose to promote sales of an internationally controlled substance would be identified as hidden advertisement and in contradiction with the provisions of the 1971 Convention (Article 10, para 2)." In fact, a spokesman for Ciba-Geigy stated that "CHADD is essentially a conduit for providing information to the patient population". The relationship between Ciba-Geigy and CHADD raises serious concerns about CHADD's motive in proselytizing the use of Ritalin.

In conjunction with the American Academy of Neurology, CHADD has submitted a petition to reschedule methylphenidate from schedule II to Schedule III under the Controlled Substances Act (CSA). CHADD denies that the financial contributions received from Ciba-Geigy have any relationship to their action. The basis for this petition is that methylphenidate has a lower abuse potential than amphetamines and that Schedule II controls are unduly burdensome on manufacturers of methylphenidate, physicians who prescribe it and patients who receive methylphenidate. In accordance with procedures set forth in the CSA, the DEA has gathered available data regarding methylphenidate, conducted an initial review of this information, and submitted our findings to the Department of Health and Human Services for their scientific and medical evaluation. The DEA is awaiting their input for consideration in making a final determination on the scheduling of methylphenidate.

Of particular concern is that most of the ADHD literature prepared for public consumption by CHADD and other groups and available to parents, does not address the abuse potential or actual abuse of methylphenidate. Instead, methylphenidate (usually referred to as Ritalin by these groups) is routinely portrayed as a benign, mild substance that is not associated with abuse or serious side effects. In reality, however, there is an abundance of scientific literature which indicates that methylphenidate shares the same abuse potential as other Schedule II stimulants. Case reports document that methylphenidate abuse (like other Schedule II stimulants) can lead to tolerance and severe psychological dependence<sup>1</sup>. A review of the literature and examination of current abuse/trafficking indicators reveals a significant number of cases where children are abusing methylphenidate.

Whereas the majority of children experience only minor side effects under medically supervised controlled conditions, there are a significant number of case reports documenting more severe abuse. These reports and scientific studies of abuse potential are routinely down-played, if referenced at all. As a consequence, parents of children and adult patients are not being provided with the opportunity for informed consent or a true risk/benefit consideration in deciding whether methylphenidate therapy is appropriate.

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<sup>1</sup> (Jaffe, 1990)

Another area of concern is that children under the age of six are being treated with methylphenidate contrary to labeling guidelines<sup>2</sup>, in the absence of controlled studies suggesting that this is appropriate.<sup>3</sup> In addition, children are remaining on medication for longer periods of time, frequently into adolescence and adulthood. Given recent drug abuse trends which indicate that adolescents are abusing methylphenidate with serious consequences, the above issues require close consideration by health authorities.

This paper provides an overview of the growing availability and utilization of methylphenidate in the U.S. and outlines concerns regarding methylphenidate in light of its high potential for abuse. In preparing this paper, many data sources were reviewed including the scientific and medical literature, United Nations statistics on psychotropic substances, Drug Abuse Warning Network (DAWN) statistics and a number of data sources compiled by the DEA on drug thefts, manufacture and distribution, and investigative case files. Information was also supplied by law enforcement personnel, various state agencies and other interested parties.

### **Background**

#### **Overview of Attention Deficit Disorder**

The Merck Manual defines Attention Deficit Disorder as developmentally inappropriate inattention and impulsivity, with or without hyperactivity. ADHD is implicated in learning disorders and is diagnosed four times more frequently in boys than girls. Despite the frequent reference to ADHD as a neurobiological disorder, the cause of ADHD remains unknown.<sup>4</sup>

The primary signs of ADHD (with or without hyperactivity) are the display of inattention and impulsivity. ADHD with hyperactivity is diagnosed when signs of overactivity are obvious. Inattention is described as a failure to finish tasks started, easy distractibility, seeming lack of attention, and difficulty concentrating on tasks requiring sustained attention. Impulsivity is described as acting before thinking, difficulty taking turns, problems organizing work, and constant shifting from one activity to another. Hyperactivity is described as difficulty staying seated and sitting still, and running or climbing excessively.<sup>5</sup>

<sup>2</sup>Physicians Desk Reference, 1994

<sup>3</sup>[DEA found only four studies that addressed the use of methylphenidate in children under the age of six and only about 130 children were involved in the combined studies (Barkley, 1988; Barkley et al., 1984; Conners, 1975; Schliefer et al., 1975)].

<sup>4</sup>Brain imaging studies initially showed clear-cut reductions in glucose utilization in the premotor and prefrontal cortex, areas believed to be important in motor control and attentional processes, in hyperactive parents of hyperactive children (Zametkin et al., 1990). Subsequent studies, however, could not show the same deficits in hyperactive male adolescents (Zametkin et al., 1993) and no changes were observed in the global rate of glucose utilization after an acute dose of methylphenidate in hyperactive adults (Matochik et al., 1993).

<sup>5</sup>The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck & Company, Inc., Rahway, N.J. 1992

The American Psychiatric Association Diagnostic Criteria from DSM-IV lists symptoms of inattention, hyperactivity and impulsivity to be utilized in the diagnosis of the disorder. In order for a diagnosis of ADHD to be made, the symptoms must have persisted for at least 6 months to a degree that is maladaptive and inconsistent with the developmental level.<sup>6</sup>

### Overview of Methylphenidate

Methylphenidate is a Schedule II central nervous system (CNS) stimulant and shares many of the pharmacological effects of amphetamine, methamphetamine and cocaine. An abundance of literature indicates that methylphenidate is effective in the symptomatic management of narcolepsy and ADHD.

The beneficial effects of amphetamine administration to children with hyperactivity and behavioral problems was first reported in 1937.<sup>7</sup> Since that time, central nervous system (CNS) stimulants have been used in the United States for the management of a triad of symptoms including hyperactivity, distractibility and impulsivity that has come to be known as Attention Deficit Hyperactivity Disorder (ADHD). Methylphenidate hydrochloride is the most commonly used psychopharmacological agent in children for the treatment of ADHD with about 85 to 90% of all prescriptions of methylphenidate written for this indication. The first published pharmacological study on methylphenidate hydrochloride was by Meier in 1954. Methylphenidate was introduced into therapeutics that same year and has since become the focus of hundreds of scientific studies.

Approved for use in the treatment of Attention Deficit Disorders (previously referred to as minimal brain dysfunction) and narcolepsy, methylphenidate has also been used experimentally for the treatment of mild depression, apathetic or withdrawn senile behavior, and drug-induced lethargy.

Methylphenidate is a CNS stimulant like amphetamine and methamphetamine, and thus produces a number of effects including dose related increases in blood pressure, heart rate, respiration and body temperature, appetite suppression and increased alertness<sup>8</sup>. Weight loss and growth retardation are common side effects of chronic methylphenidate pharmacotherapy in youngsters although drug holidays on weekends and/or summers can usually compensate for these deficits<sup>9</sup>. Serious side effects include facial ticks and muscle twitching<sup>10</sup>. Other adverse effects of methylphenidate, particularly at higher than therapeutic doses, include excessive CNS stimulation, euphoria, nervousness, irritability, and agitation.

<sup>6</sup> American Psychiatric Association Diagnostic Criteria from DSM-IV, May 1994.

<sup>7</sup> Bradley (1937)

<sup>8</sup> (AMA Drug Evaluations, 1993)

<sup>9</sup> (Safer et al., 1972; 1975)

<sup>10</sup> (Stevenson and Wolraich, 1989)

Psychotic episodes, violent behavior, tolerance and severe psychological dependence are also reported when methylphenidate is abused. While it is uncertain as to how methylphenidate or other stimulants exert their effects on the CNS to bring about therapeutic efficacy in ADHD, a number of neurotransmitter systems are altered by both acute and chronic methylphenidate administration.

In the U.S., there are now three registered bulk manufacturers of methylphenidate: Ciba-Geigy which produces under the brand name of Ritalin, MD Pharmaceuticals which produces generic methylphenidate and the recent addition of Johnson Matthey who will be synthesizing methylphenidate for generic manufacture. Methylphenidate is available (as Ritalin and in the generic form) in 5, 10 and 20 mg tablets for oral consumption. Ritalin SR and a generic version are available as sustained release tablets of 20 mg for oral use.

FDA approved labeling states that methylphenidate is contraindicated in patients with marked anxiety, tension and agitation since the drug may aggravate these symptoms. Methylphenidate is contraindicated in patients known to be hypersensitive to the drug, patients with glaucoma and in patients with motor tics or with a family history or diagnosis of Tourette's Syndrome. In addition, methylphenidate should not be used in children under six years of age since safety and efficacy in this age group have not been established.<sup>11</sup>

#### **Trends in ADHD Treatment in the U.S.**

The use of methylphenidate has increased dramatically in the U.S. in recent years. The production and use of methylphenidate has increased almost 6-fold since 1990. For example, the aggregate production quota for methylphenidate has increased from 1,361 kg in 1985 to 10,410 kg in 1995 with the primary increases occurring in the last five years.

The United States now consumes more than 80 percent of the total world supply of methylphenidate or five times more than the rest of the world combined. While stimulant pharmacotherapy for the treatment of ADHD in children is recognized by medical experts worldwide, no other nation prescribes stimulants for its children in such volume. Epidemiological data indicate that from 3-5 % or more of all U.S. children are treated with methylphenidate for ADHD, frequently without the benefit of other services (e.g. behavioral modification training and psychotherapy) as recommended in treatment guidelines. Boys are 4 times more likely to be diagnosed with the disorder. Increased utilization is also supported by information from state studies, prescription audit systems and studies of patient visits.

#### **World Perspective**

Internationally, methylphenidate is viewed as having a very high potential for abuse and is listed in Schedule II of the Psychotropic Convention. Under treaty obligations, the

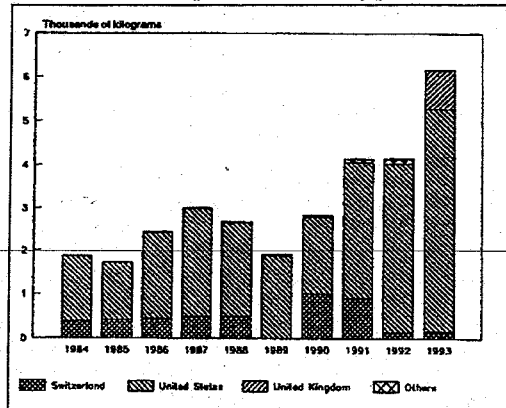
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<sup>11</sup>Physicians Desk Reference, 1994

United States must provide the United Nations with data on the production, distribution and consumption of methylphenidate. Methylphenidate is the only psychoactive substance listed in Schedule II under international treaty whose worldwide medical use has increased. According to the 1993 United Nations Report on Psychoactive Substances, the worldwide medical use of methylphenidate has increased from less than 3 tons in 1990, to more than 6 tons in 1993. This global trend largely reflects increased consumption of methylphenidate in the United States.

The United Nations International Narcotics Control Board (INCB) has, on two recent occasions, written letters to U.S. officials expressing their concern about the sharp increase in the use of methylphenidate in the United States and have requested data on the legal requirements for the use of methylphenidate (i.e. prescription in accordance with sound medical practice - Article 9 of the 1971 Convention) as well as data concerning trends in abuse and possible diversion from licit sources.

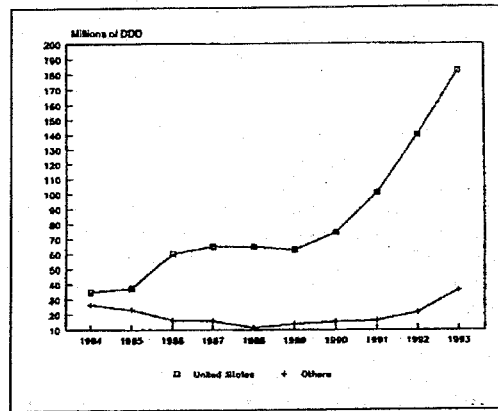
The following chart depicts world production of methylphenidate. As can be seen, there have been vast increases in U.S. production of methylphenidate in recent years<sup>12</sup>:



While U.N. data is not yet available, data for 1994 and 1995 will show substantial increases in U.S. production of methylphenidate.

<sup>12</sup> United Nations Statistical Report on Psychotropics 1993

The reported worldwide consumption of methylphenidate is depicted below.<sup>13</sup> The vast proportion of methylphenidate is consumed by the United States. In addition, U.S. consumption has increased dramatically in recent years.



#### Prescribing Patterns/Treatment Guidelines

A multimodal approach to the treatment of ADHD would incorporate the utilization of a stimulant such as methylphenidate as part of a total treatment program that includes other remedial measures (psychological, educational and social) for a stabilizing effect on individuals with ADHD. The utilization of behavioral therapy in conjunction with drug therapy is supported, in principle, by most practitioners. While most practitioners ascribe to such a multimodal approach to the treatment of ADHD, most children are prescribed methylphenidate chronically as their sole treatment.<sup>14 15</sup>

<sup>13</sup> United Nations Statistical Report on Psychotropics 1993

<sup>14</sup> (Kelleher et al., 1989; Wolraich et al., 1990).

<sup>15</sup> Using a 1985 National Ambulatory Medical Care Survey, Kelleher et al (1989) investigated the frequency of follow up arrangements and concurrent psychotherapy among U.S. children. They found that few providers reported referral or concurrent psychotherapy for patients receiving psychostimulants. Wolraich et al. (1990) reported a serious underuse of systematic behavior treatment in primary care practices. Wolraich and colleagues surveyed a random national sample of primary care physicians (the principal doctors to diagnose and treat ADHD children) and then directly screened 457 patients of 10 pediatricians and family practitioners in two small midwestern cities. They found that few other forms of therapy, such as behavior modification, were actually used by primary care physicians despite the fact that the majority of physicians in the national surveys and in the midwestern cities reported using behavior treatments. The authors concluded that, while efficacious, behavior modification usually requires a rigorous program to achieve significant benefits and that casual advice by the physician is not likely to be effective or be perceived by the patients as a behavior modification program. "The paucity of non-drug therapies used with children with a diagnosis of ADHD is of concern given the findings that suggest the

Diagnostic criteria established by the American Psychiatric Association are not applied uniformly<sup>16</sup> resulting in some children not being identified as having ADHD and others being falsely diagnosed with ADHD when other psychiatric problems may be overlooked. The manner in which a diagnosis of ADHD is made and the singular treatment approach of psychostimulant therapy contributes to claims that methylphenidate is overprescribed and used indiscriminantly in place of disciplinary measures at home and at school.

Long-term studies indicate that a multimodal treatment approach is necessary to achieve significantly improved outcomes for ADHD children. These studies indicate that treatment with psychostimulants alone does not improve the outcomes of most ADHD children<sup>17</sup>. These data suggest that there may be a serious underutilization of other treatment modalities and that the medical community may not be meeting the needs of many ADHD children. More promising outcomes have been reported when multimodal approaches are used in the treatment of ADHD<sup>18</sup>. However, data on physician prescribing practices imply that few general practitioners or pediatricians provide treatment other than pharmacotherapy with psychostimulants.<sup>19</sup>

Epidemiological data indicate that U.S. medical practitioners vary greatly in the diagnosis and treatment of ADHD. One study indicates that a small percentage of primary care physicians are writing nearly half of all methylphenidate prescriptions for children<sup>20</sup>. Another area of concern, is that children under the age of six are being treated with methylphenidate contrary to labeling guidelines<sup>21</sup> in the absence of controlled studies suggesting that this is appropriate.<sup>22</sup>

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importance of multimodality therapy for long-term beneficial outcomes" (Wolraich et al., 1990)

<sup>16</sup> (Kelleher et al., 1989; Wolraich et al., 1990)

<sup>17</sup> (for example: Akerman et al., 1977; Barkley, 1977; Blouin et al., 1978; Satterfield et al., 1987)

<sup>18</sup> For example, Satterfield et al., (1987) described the results of two prospective longitudinal studies of predelinquent hyperactive boys. One group of 80 boys was treated with methylphenidate alone (DTO group) and a second group of 50 boys received methylphenidate in addition to intensive psychological treatments (MMT group). The MMT group received individualized therapy for an average of 3.5 visits per month for 35 months. MMT mean follow up was 9.3 years or at 17.4 years of age. DTO mean follow up was 8.7 years or 17.6 years of age. The MMT group had significantly less delinquency and teenage antisocial behavior, they were more attentive in school and better adjusted at home and more globally improved compared to the DTO group. The authors concluded that medication may be necessary to facilitate impulse control so that the child can better apply what is learned in psychotherapy. While most clinicians ascribe to this theory and indications for use of methylphenidate in the PDR recommends a multimodal approach to therapy, few ADHD children are treated with anything other than psychostimulants.

<sup>19</sup> (Kelleher et al., 1989; Wolraich et al., 1990)

<sup>20</sup> Rappeley, 1995

<sup>21</sup> Physicians Desk Reference, 1994

<sup>22</sup> [DEA found only four studies that addressed the use of methylphenidate in children under the age of six and only about 130 children were involved in the combined studies (Barkley, 1988; Barkley et al., 1984; Conners, 1975; Schliefer et al., 1975)].

There is a considerable body of literature on the short-term efficacy of stimulant pharmacotherapy on the symptoms of ADHD<sup>23</sup>. From 60 to 90% of children have been judged as positive drug responders to methylphenidate medication. However, contrary to popular belief, stimulants like methylphenidate will affect normal children and adults in the same manner that they affect ADHD children<sup>24</sup>. Behavioral or attentional improvements with methylphenidate treatment therefore is not diagnostic of ADHD.

#### **Scheduling History of Methylphenidate**

In the United States, methylphenidate was placed in Schedule II of the Controlled Substances Act in 1971. This action was based, in part, on a review by the Department of Health and Human Services (DHHS). The recommendation by the Secretary reflected advice from the National Academy of Science/National Research Council Committee on Problems of Drug Dependence and the Commissioner of the Food and Drug Administration. Both recommended that methylphenidate be placed in Schedule II of the CSA. It was found that methylphenidate's pharmacological effects are essentially the same as those of amphetamine and methamphetamine and that it shares the same abuse potential as these Schedule II stimulants.

While Schedule II regulation prohibits prescription refills, Federal Law does not limit the number of dosage units per prescription nor prevent physicians from issuing several prescriptions at one time as long as they are dated when the physician issues them.

#### **Quota Setting Process and 1994 Methylphenidate Shortage**

Because methylphenidate is a Schedule II controlled substance, it is subject to quotas as outlined in Section 306(a) of the Controlled Substances Act (CSA). The CSA requires that the Attorney General establish limits or quotas on the amount of Schedules I and II controlled substances which may be produced in a calendar year. Quotas take into consideration the estimated change in medical requirements as provided by the Department of Health and Human services. Quotas are established to limit the diversion of drugs from legitimate channels while ensuring that legitimate medical need is satisfied. Each year an aggregate production quota (APQ) for each Schedule I and II substance is set based on sales and inventory needs. Each company is given a manufacturing quota (MQ) to provide for these needs. Adjustments may be made at any time throughout the year provided that

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<sup>23</sup> (for example: Davy and Rogers, 1989; Rostain, 1991; Stevenson and Wolraich, 1989). On laboratory measures of attention, impulsivity and learning, methylphenidate administration has routinely been found to improve ADHD children's performance on the order of about 25% compared to placebo levels of performance (Pelham, 1986; Swanson and Kinsbourne, 1979). Improvement is shown most clearly as a reduction in classroom disruptiveness and an increase in on-task behavior. Task irrelevant activities such as fidgetiness, finger tapping, and fine motor movements are reduced. In general, medicated children are less disruptive and more compliant than non-medicated children (Barkley et al, 1984).

<sup>24</sup> (Rapoport et al., 1978; Gittelman and Kenner, 1986)



adequate material remains within the APQ. Also, revisions to the APQ are made midyear based on the previous years' year-end data. These revisions take into consideration any changes in the company's needs up to that point in the year. Additionally, if these revisions prove insufficient, an interim notice may be published to satisfy additional legitimate needs.

The APQ for Schedule I and II controlled substances is published in the Federal Register as a proposal for public comment. Subsequently, these quotas are finalized through a second Federal Register Notice. Since 1983, these Federal Register Notices have required a review by the Office of Management and Budget (OMB) prior to publication. In 1988 additional reviews before publication of each Federal Register Notice were required by the Department of Justice, Office of Policy Development (OPD). Both reviews added to the amount of time required publish the aggregate production quotas. This was particularly troublesome in 1992 and 1993 when it took approximately two months for external reviews before certain quota Federal Register Notices could be published. Beginning in 1994, these external reviews by OMB and OPD were eliminated, thereby greatly reducing the time required for quota revisions.

#### **The Quota Process and Alleged Shortage**

In response to the delay created by the external review process in revising the 1993 aggregate production quota (APQ), Ciba-Geigy (the manufacturer of Ritalin) issued a press release and over 400,000 letters to health care professionals accusing the DEA of creating an impending shortage of their product, Ritalin. This was done at a time when it was known by Ciba-Geigy that a proposal was pending to increase the methylphenidate quota. The issuance of such statements caused great concern within the medical community, and created an environment of panic for parents of children being treated with methylphenidate. Groups such as CHADD were also notified of Ciba-Geigy's allegations. CHADD, in turn, urged parents to write their Congressional Representatives and to the DEA to voice complaints regarding DEA creating a shortage. In addition, many parents rushed to their physicians to get multiple prescriptions for methylphenidate in order to ensure they had several months supply on-hand. In short, Ciba-Geigy was contributing to a situation which promoted the increased sale of product through panic buying.

It should be noted that in 1993, DEA set APQs for more than 60 substances and established revised manufacturing quotas for more than 150 companies. The extended external review process affected each company yet only one company making one product chose to accuse DEA of failing to respond to their needs. All other companies worked with the DEA to ensure that adequate amounts of their products were available until the revisions could be completed. As a result of Ciba-Geigy's actions, the DEA sampled several distributors and pharmacy chains which indicated concern over their ability to obtain Ritalin and the generic form of methylphenidate. DEA could not conclude that a shortage of Ritalin or the generic form existed. MD Pharmaceuticals, the other manufacturer of methylphenidate products, maintained throughout that they had sufficient quota to

manufacture methylphenidate as long as the revision was published and an increase granted before the end of the year.

Although both manufacturers of methylphenidate (Ciba-Geigy and MD Pharmaceuticals) were granted revised quotas late in the year (October), neither company stopped manufacturing and sales continued. In addition, each company ended 1993 with inventory on hand.

In 1994 the manufacturing quotas were initially established and then subsequently revised twice during the year due to increased demand for methylphenidate. This is not surprising since there was increased publicity regarding Attention Deficit Disorder and treatment using Ritalin by CHADD and other advocacy groups. Both Ciba-Geigy and MD Pharmaceuticals were granted quotas near the end of 1994 which were the full amount each company requested. Ciba-Geigy ended 1994 with a substantial inventory on hand.

#### **Results of GAO Review**

In 1993, an external review process caused a 2-month delay in publishing the proposed revised 1993 APQs for several controlled substances. This created concerns about an impending shortage of some forms of methylphenidate. In response, CIBA-Geigy sent 400,000 letters to health care professionals and CHADD warned its members and Congress about this impending shortage. This created a near panic situation for patients who thought that they couldn't get their medicine because they were told that DEA failed to allow adequate amounts of methylphenidate to be produced. Fortunately no widespread shortage materialized in spite of the panic buying which was prompted. As a result of this incident, however, the oversight and review procedures for the establishment of quotas have been revised. Additionally a General Accounting Office (GAO) investigation was conducted in January 1995. The GAO report indicated that in 1993, all DEA's quota regulations had to be reviewed and approved by OPD (a unit within the Justice Department) and OMB before publication. Because OPD misplaced the Federal Register for the revision of 1993 APQ's, including that for methylphenidate, a 2-month delay in publishing the revised quota ensued. In February, 1994, OMB declared DEA quota regulations to be exempt from OMB centralized review. Under this new procedure, once the DEA Deputy Administrator approves either the proposed or final quota notices, they are forwarded directly to the Federal Register for publication. This new procedure eliminates the cause of the delays in publishing Federal Register Notifications that occurred in 1993 and there is no reason to believe that any such delays will occur in the future. Prompt publication of quota Federal Registers have occurred since the revised procedures were initiated and no shortages of any controlled substance have been a result of DEA not providing quotas to meet medical needs.

Current Industry Practices\Concerns**CHADD/Ciba-Geigy Relationship**

Children and Adults with Attention Deficit Disorders (CHADD) is the nation's largest ADHD support organization. CHADD was begun in 1987 by a small group of parents and professionals. Today, CHADD has grown to over 28,000 members and 600 chapters nationwide. CHADD works at the local, state and national levels. On the local level, CHADD sponsors parent support groups, convenes meetings featuring speakers, works with local school systems to ensure appropriate educational services for children with ADHD and publishes local newsletters. The national office of CHADD provides information on the latest developments in ADHD related issues.

A DEA review reveals that most of the ADHD literature prepared for public consumption and available to parents, does not address the abuse liability or actual abuse of methylphenidate. Instead, methylphenidate is routinely portrayed as a benign, mild stimulant that is not associated with abuse or serious side effects. In reality, however, there is an abundance of scientific literature which indicates that methylphenidate shares the same abuse potential as other Schedule II stimulants. Case reports document that methylphenidate abuse (like other Schedule II stimulants) can lead to tolerance and severe psychological dependence<sup>25</sup>. In addition, a review of the literature reveals cases where children are abusing methylphenidate.

Whereas the majority of children experience only minor side effects under medically supervised controlled conditions, the case reports documenting more severe abuse and scientific studies of abuse potential are routinely down-played, if referenced at all. As a consequence, parents of children and adult patients are not being provided with the opportunity for informed consent or a true risk/benefit consideration in deciding whether to initiate methylphenidate therapy.

It has recently come to the attention of the DEA, that Ciba-Geigy (the manufacturer of the methylphenidate product marketed under the brand named Ritalin) contributed \$748,000 to CHADD from 1991 to 1994.<sup>26</sup> The DEA has concerns that the depth of the financial relationship with the manufacturer was not well-known by the public, including CHADD members that have relied upon CHADD for guidance as it pertains to the diagnosis and treatment of their children. A recent communication from the United Nations International Narcotics Control Board (INCB), expressed concern about non-governmental organizations and parental associations in the United States that are actively lobbying for the medical use of methylphenidate for children with ADHD. The INCB further stated that "financial transfer from a pharmaceutical company with the purpose to promote sales of an internationally controlled substance would be identified as hidden advertisement and in

<sup>25</sup> (Jaffe, 1990)

<sup>26</sup> (\$100,000 in 1991, \$50,000 in 1992, \$200,000 in 1993 and \$398,000 in 1994).

contradiction with the provisions of the 1971 Convention (Article 10, para 2)."

In 1993 and 1994 when Ciba-Geigy warned of an impending shortage of Ritalin, CHADD was active in having its members write their Congressional Representatives to complain about the situation. In letters to members and interviews with the media, CHADD officials also were active in perpetuating concerns that a shortage of Ritalin was imminent. The DEA received more than 135 inquiries from Congressional Representatives. In these communications, CHADD routinely referred to a "Ritalin shortage" as opposed to a "methylphenidate shortage". The relationship between Ciba-Geigy and CHADD raises serious concerns about CHADD's motive in proselytizing the use of Ritalin through the use of the brand name as opposed to the generic name methylphenidate in its literature.

In conjunction with the American Academy of Neurology, CHADD has submitted a petition to reschedule methylphenidate from Schedule II to Schedule III under the Controlled Substances Act. Ciba-Geigy stands to benefit from a change in scheduling of methylphenidate. However, CHADD denies that the financial contributions received from Ciba-Geigy have any relationship to the scheduling petition.

**Advocacy Groups and Promotion of Methylphenidate  
Dissemination of Information which is Inconsistent with Scientific Literature**

The documentation in this report directly refutes the assertions that methylphenidate is a benign, mild stimulant that is not associated with abuse or serious side effects. The majority of the literature prepared for public consumption and available to parents does not address methylphenidate's abuse liability or actual abuse. The abuse reports demonstrate that even adolescents who are abusing methylphenidate do not view this activity as dangerous. Whereas the majority of children experience only minor side effects under medically supervised controlled conditions, as reported broadly in short-term efficacy studies, the smaller number of case reports documenting more severe abuse and scientific studies of abuse potential is down-played, if referenced at all. As a consequence, parents of children and adult patients are not being provided with the opportunity for informed consent or a true risk/benefit consideration in determining if they want their children or themselves taking methylphenidate.

**Current Public Health Concerns:**

**Abuse Liability of Methylphenidate**

**Summary**

Methylphenidate is a psychomotor stimulant structurally and pharmacologically related to the amphetamines. Studies and case reports indicate that methylphenidate has the same

dependence profile as other Schedule II stimulants. Like other Schedule II stimulants, abuse of methylphenidate can lead to tolerance and severe psychological dependence.<sup>27</sup> Psychotic episodes, violent behavior and bizarre mannerisms have been reported.<sup>28</sup> Intravenous<sup>29</sup> and intranasal abuse can result in serious medical complications.

### Studies

Methylphenidate produces d-amphetamine and cocaine-like reinforcing effects in both humans and non-human animals. Preclinical self-administration studies show that methylphenidate is self-administered by animals<sup>30</sup> under a variety of conditions, including when substituted for cocaine or d-amphetamine in drug-experienced animals or when initiated in drug-naïve animals. Methylphenidate has reinforcing efficacy similar to cocaine and d-amphetamine. In non-human primates, methylphenidate can maintain high rates of self-injection in progressive ratio studies and is chosen over cocaine in preference studies. In clinical studies methylphenidate is self-administered by humans and produces patterns of reinforcing and subjective effects similar to d-amphetamine. Methylphenidate and d-amphetamine produce similar patterns of subjective effects, including increases in rating of euphoria, drug liking and activity and decreases in sedation.

Drug discrimination procedures provide an indirect measure of a drug's reinforcing effects and its abuse potential.<sup>31</sup> Years of drug discrimination research show that methylphenidate is (1) discriminable, (2) can be used as a discriminative stimulus training drug, and (3) generalizes to a number of psychomotor stimulants including cocaine, and d-amphetamine.<sup>32</sup> In preclinical studies, chronic administration of methylphenidate produces tolerance to its disruptive and stimulus effects and shows cross-tolerance with d-amphetamine and cocaine.<sup>33</sup>

In animals, chronic or acute administration of high doses of psychomotor stimulants, such as methylphenidate, cocaine, and d-amphetamine and some substituted phenethylamines, produce a syndrome of behavioral effects characterized by aggression, agitation, disruption in food intake, visual tracking, stereotypies and death.<sup>34</sup>

In humans, methylphenidate produces behavioral, physiological, subjective, and

<sup>27</sup> Jaffe, 1990

<sup>28</sup> McCormick, McNeel, 1963; Spensley and Rockwell, 1972

<sup>29</sup> Hahn et al., 1969; Jaffe and Koschmann, 1970

<sup>30</sup> Wilson et al., 1971; Johanson and Schuster, 1975; Risner and Jones, 1975; Griffiths et al., 1975; Speelman, et al., 1989

<sup>31</sup> Preston et al., 1995

<sup>32</sup> Huang and Ho, 1974; Evans and Johanson, 1987; Wood and Emmett-Oglesby, 1988

<sup>33</sup> Emmett-Oglesby and Taylor, 1981; Wood and Emmett-Oglesby, 1988; Loith and Barrett, 1981

<sup>34</sup> Johanson et al., 1976; Nielsen et al., 1983; Griffiths et al., 1976; Dackis and Gold, 1990; Wesson and Smith, 1978; Lamb and Griffiths, 1987; Sannerud et al., 1995

reinforcing effects similar to those of d-amphetamine<sup>35</sup> including increases in rating of euphoria, drug liking and activity, and decreases in sedation. Methylphenidate produces stimulant-like discriminative stimulus effects in humans.<sup>36</sup>

Abstinence from stimulants, such as d- amphetamine and cocaine, after chronic use results in the appearance of withdrawal signs within one to three days, including depression, sleep disturbances, anxiety, fatigue, anger/hostility, dysphoria, psychomotor agitation, confusion and drug craving.<sup>37</sup> Case studies document the same type of syndrome with methylphenidate abstinence after chronic use.<sup>38</sup> Methylphenidate has been used experimentally to alleviate the abstinence syndrome associated with cocaine dependence.

It is clear that methylphenidate substitutes for cocaine and d-amphetamine in a number of behavioral paradigms and there is cross-stimulant sensitivity in animal studies. Taken together, studies suggest that a similar form of sensitization may be occurring in humans that are exposed to stimulants (e.g., methylphenidate) and that this drug history may predispose individuals to cocaine's reinforcing effects.<sup>39</sup> In a study of the incidence of cocaine use and abuse in adult subjects exposed to methylphenidate as children, medicated ADHD subjects who tried cocaine reported higher levels of drug dependence than non-medicated ADHD subjects and controls.<sup>40</sup>

#### Actual Abuse and Diversion of Methylphenidate

##### Actual Abuse

A review of the available literature shows that methylphenidate is associated with patterns of abuse similar to other Schedule II stimulants. Like amphetamine and cocaine, abuse of methylphenidate can lead to marked tolerance and psychic dependence. The pattern of abuse is characterized by escalation of dose, frequent episodes of binge use followed by severe depression, and an overpowering desire to continue the use of this drug despite medical and social consequences. The abuser may alter the mode of administration from oral use to snorting or intravenous injection to intensify the effects of the drug. Typical of other CNS stimulants, high doses of methylphenidate often produce agitation, tremors, euphoria, tachycardia, palpitations and hypertension. Psychotic episodes, paranoid delusions, hallucinations and bizarre behavior characteristic of amphetamine-like psychomotor stimulant toxicity have all been associated with methylphenidate abuse. Severe medical consequences,

<sup>35</sup> Martin et al., 1971; Smith and Davis, 1977; Brown et al., 1978; Chait, 1994

<sup>36</sup> Heischman and Henningfield, 1991

<sup>37</sup> Gawin and Kleber, 1986; Gawin, 1989; Gawin and Ellinwood, 1988; Gawin et al., 1992; Weddington et al, 1990; Satal et al, 1991; Dackis and Gold 1990; Watson et al 1992; Cottler et al., 1993

<sup>38</sup> Rioux, 1960; Spensley and Rockwell, 1972; Goyer et al., 1979; Keeley and Light, 1985; Jaffe, 1991

<sup>39</sup> Davidson et al., submitted

<sup>40</sup> Davidson et al., submitted

including death, have been reported. Case reports document that methylphenidate abuse can lead to marked tolerance and psychic dependence in children<sup>41</sup> and adults.<sup>42</sup> Although the majority of cases cited in the literature pertain to adult substance abusers, there are indications of adolescent abuse. The literature indicates that the addiction produced by methylphenidate abuse is neither benign nor rare in occurrence, and methylphenidate is more accurately described as producing severe dependence.

In the petition to reschedule methylphenidate, petitioners argue that children do not become dependent on methylphenidate. While that assessment is essentially true for a vast majority of youngsters that are being administered therapeutic doses of methylphenidate or d-amphetamine under a doctor's order, DEA's review indicates that children are abusing methylphenidate and abuse can lead to dependence and addiction.

Severe medical consequences including death have been associated with high doses of methylphenidate and where methylphenidate has been abused by snorting or intravenous injection.<sup>43</sup> Like other psychomotor stimulants, utilization of methylphenidate within normal therapeutic dose ranges for the treatment of narcolepsy and ADHD are associated with some risks.<sup>44</sup> Recent data suggest that pre-exposure to stimulants, including methylphenidate, in childhood may predispose these same individuals to the reinforcing effects of cocaine.<sup>46</sup> ADHD adults have a high incidence of substance abuse disorders.<sup>47</sup> With three to five percent or more of today's youth being administered methylphenidate on a chronic basis, these issues are of concern.

A significant body of literature is available that describes the actual abuse of methylphenidate and consequences associated with that abuse. Some of the earliest reported abuse cases came out of Sweden<sup>48</sup> where the widespread abuse of methylphenidate led to its withdrawal from the Swedish market in 1968.<sup>49</sup>

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Early reports of methylphenidate abuse in the United States are documented in the scientific and medical literature. Most of the U.S. abuse literature cite case reports of

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<sup>41</sup> Goyer et al., 1979; Jaffe, 1991

<sup>42</sup> Brooks et al., 1972; McCormick and McNeel, 1963; Rioux, 1960; Spensley and Rockwell, 1972

<sup>43</sup> For example: Arnett et al., 1976; Brooks et al., 1972; Chillar et al., 1982; Jaffe and Koschmann, 1970; Levine et al., 1984; Lewman, 1972; Lundquest et al., 1987; Stecyk et al., 1985

<sup>44</sup> United States Pharmacopeia, Drug Information for the Healthcare Professional

<sup>45</sup> Methylphenidate has been shown to alter a number of neurotransmitter systems (see Factor 2, Neurotransmitter effects). Neuroendocrine (Aarskog et al., 1977; Brown, 1977; Gualtieri et al., 1982; Janowsky et al., 1978; Weizman et al., 1987) and cardiac function (Amen and Werry, 1975; Ballard et al., 1976; Brown et al., 1984; Greenberg and Yellin, 1975; Safer, 1992; Safer and Allen, 1975; Wang et al., 1994) are altered with both acute and chronic dosing of methylphenidate. Long term effects of these system disturbances have not been documented and some controversy exists about the potential harm of chronic methylphenidate administration in children especially in regard to possible tics and dyskinesias, growth retardation, cardiac function in later life and substance abuse.

<sup>46</sup> Davidson et al., submitted; Schenk and Davidson, in press

<sup>47</sup> Biederman et al., 1993; Gualtieri et al., 1985; Levin and Kleber, 1995; Shekim et al., 1990; Spencer et al., 1994

<sup>48</sup> Borg, 1961; Jorgensen and Kodahl, 1961; Noriek, 1960

<sup>49</sup> Permen, 1970

individuals while limited studies were conducted on certain groups or populations. Methylphenidate has been abused orally, intranasally and intravenously. It has been used alone and in combination with narcotics producing the same kinds of effects as those seen with amphetamine alone or in combination with these same drugs. Throughout the 1970's and 1980's several articles in the medical literature documented the serious medical consequences associated with intravenous abuse of methylphenidate.<sup>50</sup> A number of papers documented the abuse of Talwin NX and Ritalin combination that was so prevalent in Kansas City, Missouri and other cities in the U.S. and Canada.<sup>51</sup> The prevalence of the use of methylphenidate among heroin addicts has been reported<sup>52</sup> as well as the use of methylphenidate among methadone clients.<sup>53</sup> Two citations in the literature documented the abuse of prescribed medication in adolescents treated for ADHD.<sup>54</sup>

High school surveys (1994 Texas School Survey and Monitoring for the Future) indicate an increased use of stimulants among high school students. Nationally, about 10% of 1994 high school seniors reported using amphetamines (designated as Benzedrine, Dexedrine, Methedrine, Ritalin, Preludin, Dexamyl and methamphetamine, specifically excluding non-prescription and over-the-counter drugs) without a doctor's order. Of those reporting using amphetamines nonmedically, 16.6% reported using Ritalin, up from 7.8% in 1993 and 3.5% in 1992, representing the greatest increase in use among drugs mentioned. For perspective, the report of Ritalin abuse by high school seniors indicates that more seniors in 1994 were using this drug nonmedically than those prescribed methylphenidate for ADHD. Additionally, of those seniors that admitted to using amphetamines without a doctor's order, 55.9% reported getting a little high to moderately high while 16% reported staying high for more than seven hours, indicating a more serious pattern of abuse.

The Drug Abuse Warning Network (DAWN) indicates that from 1990 through 1993, most DAWN emergency room mentions for methylphenidate involved whites (75% to 89%) who were taking the drug orally (90% to 96%) to commit suicide (47% to 67%). A significant number of these estimated episodes, 28 to 40%, were associated with abuse for dependence or psychological effects. The percentage of episodes involving youngsters between the ages of 10 and 19 increased from about 24% in 1990 to about 55% in 1993. Seattle, Washington, Washington D.C., and Detroit, Michigan reported the greatest percentage of mentions per 100,000 population. About 90% of the mentions in 1990 were for drug combinations compared to about 60% of the 1993 mentions suggesting increasing abuse of methylphenidate as a primary drug of abuse. Among those drugs listed in combination with methylphenidate, alcohol and at least one narcotic were consistently ranked among the top five most frequently mentioned. The high percentage of attempted suicides is

<sup>50</sup> For example: Brooks et al., 1972; Colman, 1984; Elenbaas et al., 1976; Lewman, 1972; Levine et al., 1984; Lindel et al., 1972; Lundquest et al., 1987

<sup>51</sup> Bryan et al., 1973; Carter and Watson, 1994; Kishorekumer et al., 1985; Lundquest et al., 1987

<sup>52</sup> Lewman (1972) and Haglund and Howerton (1982)

<sup>53</sup> Bradford (1975)

<sup>54</sup> Goyer et al., 1979 and Jaffe, 1991



consistent with the high frequency of depression associated with stimulant abuse. As a point of reference, only 6 DAWN emergency room mentions were associated with all Schedule III stimulants in 1992, and only one mention in 1993.

### Diversion

Methylphenidate has been in Schedule II of the CSA since 1971. This schedule provides the highest level of control available in the U.S. and is intended to limit diversion and abuse. Despite the unprecedented availability of other highly abusable stimulants like cocaine and methamphetamine, methylphenidate is still highly sought after by the drug abusing population. The abuse data documented herein all suggest that methylphenidate is abused by diverse segments of our population (from street addicts to children) and that significant amounts of methylphenidate have been diverted to illicit use.

Law enforcement data including STRIDE, theft reports, DEA case reports and reports submitted from various states indicate that even under Schedule II control, diversion and abuse of methylphenidate remains a problem in some segments of our population. Methylphenidate has been targeted by organized drug traffickers in several states, is among the top 10 controlled drugs involved in drug thefts and is diverted and abused by health professionals as well as street addicts. At least two states, Nebraska and Ohio, have experienced recent significant diversion and abuse of methylphenidate. The most recent trend in methylphenidate diversion centers around the use of this drug for the treatment of ADHD. Cases document parents abusing their child's medication, children selling or giving their medication to classmates and friends, adolescents crushing the methylphenidate tablets and snorting the powder (two deaths were associated with this activity in March of this year) and thefts of school supplies of methylphenidate.

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Unlike cocaine, amphetamine and methamphetamine where illicit manufacture and illegal importation into the U.S. account for practically all of the available drugs for abuse, pharmaceutical products diverted from legitimate channels are the only sources of methylphenidate available for abuse. The DEA is not aware of any clandestine production of methylphenidate, which probably reflects its rather arduous chemical synthesis. Diversion of methylphenidate has been identified by drug thefts, illegal sales by health care professionals and prescription forgery. Law enforcement encounters involving illegal activities with methylphenidate are also good indicators of the scope of its diversion and trafficking. The control of methylphenidate in Schedule II, which has the most stringent regulatory requirements and penalties associated with illegal activity, has certainly limited diversion and abuse of this drug. Nevertheless, the following information shows that methylphenidate is diverted and trafficked in a manner and amount similar to other legitimately produced Schedule II substances (e.g. morphine, meperidine, pentobarbital).

DEA maintains a data base of reports of stolen/missing controlled substances from pharmacies, practitioners, manufacturers, hospitals/clinics, distributors and any other licensed handler of controlled substances.

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The following table shows the total number of reports and mentions (units of medication, i.e. a bottle of 100, 20 mg tablets and a bottle of 500, 10 mg tablets would be considered two mentions) for methylphenidate and other CII substances provided for comparison of activity (data for 1990 through May, 1995).

SUBSTANCE, CONTROL STATUS	NUMBER OF REPORTS	NUMBER OF MENTIONS
AMPHETAMINE, CII	710	1325
FENTANYL, CII	640	858
PHENMETRAZINE, CII	34	39
<b>METHYLPHENIDATE, CII</b>	<b>1937</b>	<b>4592</b>
MORPHINE, CII	2118	4163
OXYCODONE, CII	3132	6886
HYDROMORPHONE, CII	1247	2151
HYDROCODONE, CII	2109	4575
MEPERIDINE, CII	2911	5380

In summary, a total of 1,937 instances of drug theft have been reported for methylphenidate since 1990, most reports were generated from pharmacies and most thefts were associated with night break ins. An analysis of the data entered into the system reveals that methylphenidate ranks in the top 10 most frequently reported pharmaceutical drugs diverted from licensed handlers.

Where methylphenidate diversion was documented, activities involved illegal sales of methylphenidate by health professionals, prescription forgery, and overprescribing of methylphenidate by physicians and pharmaceutical theft. Additionally it is important to note that despite Schedule II controls on methylphenidate and its predominant use in treating children and adolescents, methylphenidate is associated with the following types of criminal drug trafficking activities:

1. Street sales as determined by undercover buys
2. Multi-state distribution rings
3. Multi-drug distribution rings (with cocaine, LSD, marijuana, hydromorphone and diazepam)
4. Smuggling from Mexico
5. Distribution to and use by narcotic addicts

While DEA investigations and laboratory analyses generally involve wholesale level dealers, state/local investigations provide more information at the retail or user levels. DEA

does not routinely receive summaries of submissions of drug evidence to laboratories or law enforcement case reports from state and local agencies. However, a number of states have provided data to DEA concerning illicit activities with methylphenidate. Although this information is not from a systematic survey, it provides further support that methylphenidate is sought after by segments of the drug abusing community.

In summary, methylphenidate has been diverted in a number of ways by individuals and organized groups. Large quantities of methylphenidate have been obtained illegally by "doctor shoppers", organized theft rings, ADHD and narcolepsy scams, forged or altered prescriptions and through cooperating physicians or pharmacists. At least two states, Ohio and Nebraska, have identified themselves as having significant problems associated with methylphenidate diversion. Recent trends indicate that adolescents are giving and selling their prescription medication and youngsters are crushing the tablets and snorting the powder like cocaine. Two deaths in March, 1995 are known to have been associated with this practice.

As noted above, severe medical consequences have been associated with the abuse of methylphenidate. The recent trend in the abuse of methylphenidate among adolescents is particularly alarming because this is the group that has the greatest access to methylphenidate from legitimate prescriptions.

## Adverse Effects (Short and Long Term)

The potential adverse effects of methylphenidate and d- amphetamine are almost identical and are summarized in the table below:<sup>55</sup>

Organic system affected	Methylphenidate	Dextroamphetamine
Cardiovascular	Palpitation Tachycardia Increased blood pressure	Palpitations Tachycardia Increased blood pressure
Central nervous system	Excessive CNS stimulation Psychosis Dizziness Headache Insomnia Nervousness Irritability Attacks of Gilles de la Tourette or other tic syndromes	Excessive CNS stimulation Psychosis Dizziness Headache Insomnia Nervousness Irritability Attacks of Gilles de la Tourette or other tic syndromes
Gastrointestinal	Anorexia Nausea Vomiting Stomach pain Dry mouth	Anorexia Nausea Vomiting Stomach pain Dry mouth
Endocrine/metabolic	Weight loss Growth suppression	Weight loss Growth Suppression
Other	Leukopenia Hypersensitivity reaction Anemia Blurred vision	Skin rash or hives Blurred vision

Ahmann et al.(1993) evaluated Ritalin's side effects in a randomized double-blind placebo-controlled cross-over study with 234 children ages 5 to 15 who met the diagnostic criteria for ADHD. Five of the side effects studied, insomnia, decreased appetite, stomachache, headache and dizziness, increased during Ritalin therapy even at relatively low doses (0.3 mg/kg). This data is consistent with other studies.<sup>56</sup> Adverse effects of irritability and sadness have not been well studied, but have been reported in up to 22% of children receiving stimulant medication.<sup>57</sup>

<sup>55</sup> Data compiled from the United States pharmacopeia, Drug information for the healthcare professional, Rockville, MD: The United States Pharmacopeial Convention; 1990

<sup>56</sup> Barkley et al., 1990; Jacobvitz et al., 1990, McBride, 1988; Ullmann and Sleator, 1986; Wolraich et al., 1990

<sup>57</sup> Klein et al., 1980

The effects of methylphenidate on growth and the induction of motor tics have been matters of concern and controversy. Safer et al. (1972) was the first to report growth suppression in children receiving methylphenidate or dextroamphetamine. Subsequent studies have reported growth rebound when stimulant medication is temporarily discontinued.<sup>58</sup> However, the longer the drug treatment, the more severe growth suppression will be in adolescence and some drug-treated children are at risk for considerable growth decrements.<sup>59</sup> Several reports have indicated that tics may be induced or exacerbated by psychostimulants.<sup>60</sup> Stevenson and Wolraich (1989) estimated the risk of tic development in stimulant treated children to be about 1.3% or higher in children with a family history of Gilles de la Tourette's disease or other tic syndromes. Lipkin et al. (1994) reported that approximately 9% of children with ADHD treated with stimulant medication develop tics and dyskinesias, with less than 1% developing chronic tics or Tourette's syndrome.

The cardiovascular safety of stimulant therapy in children has been a concern of many physicians and researchers. Varying alterations in blood pressure and heart rate after methylphenidate administration have been reported.<sup>61</sup> A review by Safer (1992) indicated that in 15 controlled studies using test doses of methylphenidate, a significant elevation of resting heart rate was found in previously unmedicated children (mean + 11 beats/min), but with continued drug treatment, only a minor increase in heart rate was observed (mean + 4 beats/min). Both systolic and diastolic blood pressure increases have been noted but are usually minor after oral administration of therapeutic doses. Large increases in heart rate, diastolic and systolic blood pressure have been reported following i.v. administration and cardiovascular toxicity and death have been reported infrequently. Wang et al. (1994) reported that 0.5 mg/kg i.v. methylphenidate produced significant decreases in cerebral blood flow (CBF) in 5 healthy male subjects. Decrements in CBF were  $25 \pm 11\%$  after 5-10 minutes and  $20 \pm 10\%$  after 30 minutes. The authors concluded that the lack of regional effects suggest that the decrease in CBF is probably a direct vasoactive property of methylphenidate and proposed caution in administration of methylphenidate chronically or to subjects who may already be cardiovascularly compromised.

The possibility of drug abuse as a consequence of methylphenidate treatment remains unresolved. In a review of the literature, Hechtman (1985) concluded that there was no evidence to suggest that stimulant medication increases the likelihood of drug or alcohol use in adolescents. However, a number of recent studies, drug abuse cases, and trends among adolescents from various sources, indicate that methylphenidate use may be a risk factor for substance abuse. Reports of adults with ADHD have consistently demonstrated elevated rates of lifetime psychoactive substance use disorders (PSUD).<sup>62</sup> In particular, 17 to 45% of

<sup>58</sup> Safer et al., 1975; Satterfield et al., 1979

<sup>59</sup> Loney et al., 1981

<sup>60</sup> Pharmacopoeial Convention, 1990

<sup>61</sup> Aman and Werry, 1975; Ballard et al., 1976; Brown et al., 1984; Greenberg and Yellin, 1975; Safer and Allen, 1975

<sup>62</sup> Gualtieri et al., 1985; Shekim et al., 1990; Spencer et al., 1994; Biederman et al., 1993

ADHD adults had alcohol abuse problems or dependence and 9 to 30% had drug abuse problems or dependence. Recent prospective studies that have followed hyperactive children and normal controls into adulthood have found that hyperactive adults with a history of ADHD are more likely than controls to have substance-use disorders.<sup>63</sup> Chronic preexposure to stimulants, including methylphenidate, increases the rate of acquisition to cocaine self-administration in rats.<sup>64</sup> Further, treatment with methylphenidate in childhood, predisposes these same individuals as adults to cocaine's reinforcing effects.<sup>65</sup> Clearly, this is an issue that needs further research.

#### Risks of Abuse with Aging Treatment Population

In light of methylphenidate's abuse liability, it is important to note the tremendous increase in availability of this substance and the expanded population (adolescents and adults) receiving prescriptions for the treatment of ADHD. Prescription data as well as aggregate production quota information indicate that the use of methylphenidate has increased substantially in the past few years. For example, the aggregate production quota for methylphenidate has increased from 1,361 kg in 1985 to 10,410 kg in 1995 with the primary increases occurring in the last five years (almost a 6-fold increase since 1990). Epidemiological data indicate that approximately 85 to 90% of all prescriptions for methylphenidate are written for young children and adolescents.

Abuse data indicate a growing problem among school-age children. Children are remaining on medication for longer periods of time, frequently into adolescence and into adulthood. In addition, because so many families with young children and adolescents are in daily contact with this stimulant, a growing problem with abuse of methylphenidate in this setting has been documented.<sup>66</sup> The aging treatment population is of major concern given evidence of abuse by adolescents.

In addition, ADHD adults have a high incidence of substance abuse disorders.<sup>67</sup> With three to five percent or more of today's youth being administered methylphenidate on a chronic basis, these issues are of great concern.

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<sup>63</sup> Levin and Kleber, 1995

<sup>64</sup> Schenk and Davidson, in press

<sup>65</sup> Davidson et al., submitted

<sup>66</sup> Fulton et al. (1988), Goyer et al. (1979) and Jaffe et al. (1991)

<sup>67</sup> Biederman et al., 1993; Gualtieri et al., 1985; Levin and Kleber, 1995; Shekim et al., 1990; Spencer et al., 1994

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Diversion, Trafficking, and Abuse of Methylphenidate

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*Abstract:*

Since 1990, the use of methylphenidate (Ritalin®) for the treatment of ADHD in the United States has undergone considerable growth as the number of children and adults identified with serious problems with attention, impulsivity or hyperactivity escalates. The Drug Enforcement Administration has monitored this phenomena and has expressed concern about the emerging problem with the illicit use of methylphenidate among children. Data presented herein will show that methylphenidate has a high abuse potential, that abuse may lead to severe psychological addiction and that the expanded use of methylphenidate has resulted in a growing problem with the misuse/abuse of this drug among adolescents.

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*Introduction:*

Methylphenidate (MPH, Ritalin®) is classified as a Schedule II stimulant under the Federal Controlled Substances Act (CSA). The Drug Enforcement Administration (DEA) is the primary agency involved in enforcing the CSA and is, therefore, responsible for establishing manufacturing quotas for Schedule I and II substances, registering handlers of controlled substances and monitoring the distribution and use of these substances. The Schedule II classification requires that a drug or other substance have (1) a high potential for abuse, (2) a currently accepted medical use in treatment in the United States and show that (3) abuse may lead to severe psychological or physical dependence. Studies that address the abuse liability of a drug and data relating to the diversion of a drug from legitimate handlers combined with clinical experience of actual abuse provide critical information about the abuse potential and dependence profile for a drug. This paper will review the data that explains why MPH has been placed in this classification and provide data concerning the manufacture, distribution, diversion, trafficking and abuse of MPH.

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*Abuse liability Studies:*

Abuse liability studies provide information relating to the probability that a drug or other substance will be abused by man and are utilized to assess the abuse potential and dependence profile of a substance. Various behavioral paradigms including drug discrimination and self-administration analyses are sensitive models of human subjective and reinforcing effects. Although a comprehensive review of these studies has been published elsewhere,<sup>1</sup> a brief summary of these data will be provided herein.

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Preclinical research shows that MPH produces strong discriminative stimulus effects and will substitute for cocaine, *d*-amphetamine, cathinone, GBR12909 (a dopamine uptake inhibitor) and cocaine analogues across several training doses, species, and training conditions (Table 1). Animals trained to discriminate *d*-amphetamine from saline show generalization to MPH,<sup>2-6</sup> animals trained to discriminate cocaine from saline show generalization to amphetamine and MPH,<sup>7-11</sup> and animals trained to discriminate MPH from saline show generalization to amphetamine and cocaine.<sup>12,13</sup> These data suggest that MPH produces psychomotor stimulant effects in animal models that are amphetamine or cocaine-like in character.

In human drug discrimination studies, MPH substitutes for *d*-amphetamine and cocaine and produces similar patterns of subjective effects, including increased ratings of euphoria, drug liking and decreased sedation (Table 2). The physiological, subjective and behavioral effects of MPH have been studied in narcotic abusers,<sup>14</sup> psychiatric patients,<sup>15</sup> and normal subjects.<sup>16-19</sup> MPH administration produces increases in "positive" mood scores, and dose-dependently increases measures of "drug liking". Low and intermediate doses of MPH produce feelings of relaxation, well-being and contentment, whereas higher doses intensify these feelings and produce dysphoria, nervousness and anxiety. MPH also dose-dependently reduces appetite and decreases caloric intake. Similar subjective effects are seen with *d*-amphetamine and *d*-methamphetamine, suggesting that these drugs have similar mechanisms of action underlying their abuse potential.

Studies using self administration paradigms to evaluate the reinforcing effects of MPH in animals are summarized in Table 3. MPH maintains self-administration behavior in monkeys trained to self-administer intravenous cocaine<sup>20-23</sup> and in rats trained to self-administer

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of *d*-amphetamine.<sup>24</sup> In these studies, MPH substituted for the cocaine or *d*-amphetamine training dose and continued to maintain self-administration behavior. The reinforcing effects of MPH are potent. Drug naive animals readily acquire self-injection of MPH.<sup>25</sup> In rats, the rates of acquisition of MPH are faster than those of *d*-amphetamine, and faster than caffeine. In monkeys, unlimited access to MPH produces a higher rate of mortality than other drugs; 75% of the monkeys self-injecting MPH died, compared to 66% and 25% of the monkeys self-injecting cocaine and *d*-amphetamine, respectively. In dogs and monkeys, self-injection of cocaine, *d*-amphetamine and phenmetrazine produces a cyclic pattern of self-administration, as well as weight loss, stereotypy and death; this pattern of behavior and profile is characteristic of psychomotor stimulant abuse. In a choice procedure paradigm using three monkeys, MPH and cocaine were chosen over saline in >75% of the monkeys,<sup>30</sup> higher doses of each drug were chosen over lower doses and the preference for cocaine decreased as the dose of MPH increased. At the highest dose of MPH vs. cocaine, MPH was chosen by individual monkeys in 80-94% of the trials.

Preclinical studies have also shown that chronic administration of MPH produces hyperlocomotion, disruptive and stimulus effects and shows cross-tolerance with *d*-amphetamine and cocaine.<sup>31-36</sup> Like *d*-amphetamine and cocaine, chronic administration of MPH produces signs of stimulant toxicity, including aggression, agitation, disruption in food intake, weight loss, stereotypic movements and death.<sup>27,37</sup> These same effects have been well documented in humans.<sup>38-45</sup> These case reports demonstrate that high doses of MPH often produce euphoria as well as agitation, tremors, tachycardia, palpitations and hypertension. Psychotic episodes and paranoid delusions characteristic of amphetamine-like toxicity are associated with chronic MPH

abuse. The pattern of abuse is characterized by escalation in dose, binge use followed by severe depression and an overpowering desire to continue the use of this drug despite negative medical and social consequences. In addition, the Food and Drug Administration (FDA) Spontaneous Reporting System (SRS) shows that the administration of MPH can be associated with a number of CNS effects including: twitching, personality disorder, hyperkinesia, hostility, insomnia, nervousness, hallucination and psychosis. Other serious adverse drug effects reported to FDA include drug abuse, dependence, addiction and death.

Medical consequences associated with parenteral abuse of MPH are well documented. Pulmonary hypertension brought on by repeated intravenous injections of MPH was strongly implicated in the deaths of numerous individuals in Oregon and Washington.<sup>46</sup> Other fatalities associated with intravenous MPH abuse have been reported.<sup>47,48</sup> Brooks et al.<sup>49</sup> provided case reports of MPH abusers who presented on the medical-surgical services for eikenella abscesses at injection sites. Problems created by intra-arterial injection of MPH were discussed by Lindell et al.<sup>50</sup> Chillar et al.<sup>51</sup> presented two cases of hemiplegia brought on by intracarotid injection of MPH. Arnett et al.<sup>55</sup> presented a case of a patient with staphylococcal tricuspid valve endocarditis with septic embolic pneumonia resulting from intravenous MPH abuse. Elenbaas et al.<sup>56</sup> and Zemljenji and Colman<sup>57</sup> reported abscess formation as a complication of parenteral MPH abuse. Other serious complications of intravenous MPH abuse have included osteomyelitis,<sup>58</sup> precocious emphysema,<sup>59</sup> severe eosinophilia,<sup>60</sup> multiple organ failure,<sup>61</sup> retinopathy<sup>62</sup> and hepatic injury.<sup>63</sup>

In summary, MPH produces *d*-amphetamine and cocaine-like reinforcing effects in both humans and nonhuman animals. Preclinical self-administration studies show that MPH is self-



administered by animals under a variety of conditions, including when substituted for cocaine or *d*-amphetamine in drug-experienced animals or when initiated in drug-naive animals. MPH has reinforcing efficacy similar to cocaine and *d*-amphetamine. In nonhuman primates, MPH can maintain high rates of self-injection in progressive ratio studies and is chosen over cocaine in preference studies. MPH is self-administered by humans and the pattern of abuse is similar to the abuse pattern of other potent psychostimulants including amphetamine, methamphetamine and cocaine. Clinical data demonstrate that MPH abuse is associated with a number of CNS effects and may result in dependence and addiction.

*Manufacture and Distribution/Use:*

Each year, the DEA establishes an aggregate production quota (APQ) for MPH to meet the legitimate medical, scientific and industrial needs for the U.S. Since 1990, there has been a dramatic increase in the APQ for MPH: from 1,768 kg in 1990 to 14,442 kg in 1998. Domestic sales reported by the manufacturers increased nearly 5-fold during this same time period (Figure 1.). Prior to 1991, domestic sales of MPH reported by the manufacturers remained stable at approximately 2,000 kg per year. In 1997, domestic sales reached nearly 10,000 kg. This increase can be attributed to the increased use of MPH in the treatment of ADHD. According to IMS Health, National Disease and Therapeutic Index™, about 90 percent of all MPH prescriptions are for children diagnosed with ADHD although the use of MPH for adults with attentional problems has been escalating. IMS Health, National Prescription Audit Plus™ data suggest that prescriptions for MPH have leveled off in the past two years after significant increases earlier this decade (Figure 2). However, stimulant treatment for ADHD continues to

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rise as amphetamine products take a greater share of the market. Recent increases in the APQ for MPH reflect increased product development and new manufacturers entering the market. In 1990, there were only two bulk manufacturers for MPH; in 1998 there are seven. It should be noted that the use of psychostimulants in the treatment of ADHD in the U.S. is not in keeping with medical trends in other countries. According to the United Nations the U.S. produces and consumes about 90 percent of the entire world's supply of MPH ( Figure 3.). The International Narcotic Control Board (INCB) has expressed concern about this disparity.

Another data source that can be utilized to examine MPH use is the DEA ARCOS (Automation of Reports and Consolidated Orders System). This system tracks certain controlled substances like MPH from point of manufacture to a location where it will ultimately be dispensed to the consumer. Consumption is defined as those quantities received by pharmacies, hospitals/clinics, practitioners and teaching institutions. Assessed on a per capita basis, ARCOS data indicate that there is wide variability in the use of MPH from one state to another and one community to another within the states. For example, in 1997, Michigan used more than twice as much MPH than either New York or California. Within all three of these states there was more than a 5-fold difference between the consumption in the highest three digit zip code region and the lowest. These data are consistent with epidemiological studies using actual prescription data<sup>64,65</sup> that show areas of very low and very high prescribing of MPH. Those states with the highest levels of MPH use in 1997 are included in Table 4.

*Diversion and Trafficking:*

All Schedule II stimulants, including cocaine and methamphetamine, have medical utility

in the U.S. and pharmaceutical products containing these substances are available for medical use. Unlike cocaine and methamphetamine where illicit manufacturing and illegal smuggling into the U.S. account for the vast majority of available drug for abuse, pharmaceutical products diverted from legitimate channels are the only sources of MPH available (DEA is not aware of any clandestine production of MPH). Diversion of MPH has been identified by drug thefts, illegal sales and prescription forgery. Law enforcement encounters involving illegal activities with MPH are good indicators of the scope of its diversion and trafficking.

From January 1990 to May 1995, MPH ranked in the top 10 most frequently reported controlled pharmaceuticals diverted from licensed handlers with nearly 2,000 incidents of drug theft. Most reports were generated by pharmacies and most thefts occurred during night break-ins. From January 1996 to December 1997, about 700,000 dosage units were reported missing or stolen from licensed handlers. Night break-in, armed robbery and employee theft were the three major sources of the diverted MPH.

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The DEA does not routinely receive data from state law enforcement agencies or their forensic laboratories concerning drug related cases. However, what MPH data has been shared with DEA from state officials (primarily as a result of DEA's request for information when conducting a review in 1995) combined with data from DEA's own investigative case files and forensic laboratories, indicate that MPH is diverted in a number of ways by a wide range of individuals and organized groups: from health care professionals to organized drug trafficking rings. DEA case files show that MPH is associated with criminal drug trafficking activities including street sales, multi-state distribution rings, multi-drug distribution rings, smuggling from Mexico and distribution and use by narcotic addicts. The extent and severity of these

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activities is similar to other non-clandestinely produced Schedule II substances of comparable availability (i.e. morphine sulfate, meperidine, pentobarbital).

Law enforcement data indicate that a number of states have experienced significant problems with MPH diversion and abuse. In the 1970s and 1980s, MPH was extensively abused among street addicts and methadone clinic clients in Missouri, Oregon and Washington. Studies conducted in Washington<sup>66</sup> and Oregon<sup>66</sup> evaluated the extent and severity of this abuse. Intravenous abuse of MPH alone or in combination with narcotics was most commonly found. Talwin NX and Ritalin combination (referred to by addicts as "T & R") was trafficked in a number of states including Ohio, Kansas, Illinois and Missouri as well as major western Canadian cities. Abuse of this drug combination was also documented in the medical literature.<sup>48, 67-69</sup> For example, Carter and Watson<sup>69</sup> identified 29 emergency room patients that presented at the Truman Medical Center in Kansas City, Missouri from August 1987 to November 1992 with complications associated with abuse of this combination. In light of recent ~~diversion trends related to the treatment of ADHD, it is interesting to note that one of the first~~ "attention deficit scams" occurred in Missouri in the early 1980s and was associated with obtaining Ritalin for T&R traffickers. In this scam, Medicaid patients took their alleged ADD children to several doctors to obtain Ritalin prescriptions. The prescriptions were filled in numerous pharmacies to avoid detection and both the office visit and the medication were paid by Medicaid. The parents then sold the Ritalin (\$500/1000 tablets) to drug traffickers who combined a Ritalin tablet with a Talwin NX tablet and sold the set for anywhere from \$8 to \$50. Various permutations of this doctor shopping scam have been reported in Iowa, Ohio, New York, Wisconsin, Colorado and Illinois.

Various states have documented the diversion and trafficking of MPH in recent years. In Pennsylvania, the Pennsylvania State Police's Investigative Services for the State reported that MPH ranked among the top three pharmaceutical drugs most frequently submitted to crime laboratories for analysis from 1991 through 1993 and MPH ranked 6th among drugs involved in incidents of forged or altered prescriptions from April 1992 through January 1995. In Ohio, from March 1979 to January 1995, MPH ranked second among pharmaceutical drugs reported for false or forged prescriptions. The Ohio State Board of Pharmacy reported 18 separate cases involving pharmacists that were related to this drug. Except for one case of insurance fraud, all other cases involved Ohio pharmacists that were drug trafficking and diverting MPH for self-abuse. One pharmacist was arrested for crushing MPH and snorting the powder. From 1992 to 1995, the Washington State Board of Pharmacy identified 10 pharmacy technicians and pharmacists who were diverting MPH for their own use. A number of other medical professionals have diverted MPH for profit and personal use. For example, a physician in Ohio was writing fraudulent prescriptions to enable himself to receive Medicare reimbursement for office visits. In another case in Illinois, a physician was supplying fraudulent prescriptions to a group of individuals involved in a multi state drug trafficking ring. In California, from January 1990 through May 1995, DEA initiated nearly 200 MPH cases involving physicians and pharmacists. Cases ranged in severity from relatively minor infractions of the law to diverting large quantities of MPH to known drug abusers and drug traffickers.

Although diversion, trafficking and abuse of methylphenidate have been documented throughout the U.S. with some instances of a severe nature, the incidence of these activities in the general population has remained relatively stable. This is consistent with what the DEA would expect of a substance with a high abuse potential but no clandestine production, limited

prescription to adults, and stringent regulatory controls applied to its production, distribution and prescription. However, diversion and misuse/abuse of MPH medication intended for the treatment of ADHD is escalating and of particular concern to the DEA. Data relating to this will be reviewed in the next section.

#### *Issues Related to MPH Medication for ADHD*

There are very few articles in the ADHD-treatment literature that address the abuse potential of MPH and only a limited number of case reports have documented MPH abuse within the context of ADHD treatment,<sup>43,45,70</sup> In point of fact, the vast majority of articles in these professional journals fail to address this issue or will often comment that MPH is a mild psychostimulant that is not associated with drug abuse. However, a significant amount of data from school surveys, emergency room reports, poison control centers, adolescent drug treatment centers and law enforcement encounters all indicate a growing problem with the abuse of MPH among school children.

Since 1990, there has been a six-fold increase in the number of estimated drug abuse emergency room (ER) visits associated with the use of MPH in the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (DHHS-SAMHSA) Drug Abuse Warning Network (DAWN): in 1990 it was estimated that there were 271 ER visits while in 1996 the estimated number was 1,725. When these DAWN mentions are compared to other potent psychostimulants like methamphetamine (MAMP) and cocaine (COC), the total number of mentions for MPH pales in comparison (Figure 4). To a large extent, this disparity reflects the much greater availability of MAMP and COC. However, if DAWN data are

examined for children ages 10-14 years of age, a group that has much easier access to MPH as a result of the expanded use of MPH for ADHD treatment, an entirely different profile emerges for these drugs (Figure 5). In 1995 and 1996, 10-14 year old patients were just as likely to mention MPH use as cocaine in a drug abuse DAWN ER episode. Eighty five percent of the MPH cohort reported no other drug used in combination with MPH and in nearly 75 percent of the episodes patients reported drug use for psychic effects (44%) or recreational use (30%).

Survey data also indicate that a growing number of adolescents are misusing/abusing MPH. Monitoring the Future, a national school survey conducted by the Institute of Social Research at the University of Michigan, indicate that about 1 percent of all 1994 and 1995 high school seniors used Ritalin without a doctor's order during the previous year. In 1997, that percentage increased to 2.8. While 1997 statistics show a significant increase in illicit use, the percentages of high school seniors that have used Ritalin/MPH illicitly may be much higher. As explained by the authors,<sup>71</sup> 12th graders are asked about their use of Ritalin only if they answer that they used "amphetamines" non-medically in the prior 12 months. Failure to recognize that Ritalin is an amphetamine would mean that they would not respond to a question about Ritalin use and therefore not be counted. Indiana's drug use survey may reflect a more accurate prevalence. In 1997, Indiana University Prevention Resource Center Survey, representing a sampling of 44,232 students in 137 different schools, added questions relating to non-medical use of Ritalin in the general drug use section. Nearly 7 percent of all high school students reported using Ritalin non-medically at least once in the previous year and 2.5 percent reported using it on a monthly or more frequent basis.

Incidents that involve diversion of MPH medication intended for ADHD treatment have

been reported to DEA by a wide variety of sources. State and local law enforcement cases have identified four different types of illicit activities: 1). adults who divert children's medication for their own personal use or to sell or trade it for other drugs; 2). children who sell/give their own/siblings medication to friends and classmates; 3). adolescents who abuse their own medication or obtain it from friends or classmates; and 4). theft of school-held supplies of MPH.

Parents who "doctor shop" or abuse their children's medication is not a particularly new type of diversion as the earlier discussion on the "ADD scam" in Missouri documents. Recent law enforcement cases involving doctor shopping for MPH have been reported in Ohio, New York, Kentucky, Louisiana and Virginia. While Missouri has considerably less documented abuse of methylphenidate than in the 1980s, seven drug treatment centers reported that they had clients who were using their children's MPH prescriptions (documented in a 1995 survey on Ritalin conducted by the Missouri Department of Health).

As a result of DEA inquiries about adolescent misuse/abuse of MPH during the 1995 review, the DEA received numerous reports of students that gave, sold, traded and/or abused their own MPH medication or that of a sibling, friend or classmate. State and local law enforcement cases involving high school students in Iowa, Missouri, Michigan and Virginia were reported to DEA. In 1995, MPH was a contributing cause of death of a college freshman in Mississippi and the cause of death of a teenager in Virginia. In both instances MPH tablets were supplied by someone who had a legitimate prescription for the drug and the MPH tablets were crushed and snorted. Police reports of interviews with teenagers who were snorting MPH indicated that these youngsters did not view this activity as dangerous. Adolescent drug treatment centers in Michigan and Missouri reported having several clients who were abusing



MPH, but very few clients who identified MPH as their primary drug of abuse. The vast majority of incidents brought to DEA's attention involving students that were using MPH illicitly (selling, giving, trading, abusing) at school were not reported to law enforcement authorities at all but were handled by school officials and parents. Penalties frequently involved suspension or expulsion from school.

Schools in Connecticut, Michigan and Virginia reported break-ins and thefts of school-held supplies of MPH. In addition, law enforcement case files have documented the theft of this medication by school personnel. For example, a highly respected teacher was videotaped stealing MPH from the nurse's office the evening of an awards ceremony that was honoring him as "teacher of the year." In another incident, a school nurse who was responsible for safeguarding school supplies of medication, stole the children's MPH medication. In a school that required a student to provide proof of medication need (a doctor's prescription), the principal was discovered taking the MPH prescriptions and having them filled by pharmacies throughout the state for his own personal use. It is important to note that many schools have as much, if not more, MPH stored on a daily basis than many pharmacies but without the safeguards and accountability required of registered handlers.

At the conclusion of DEA's review in 1995, there was little doubt that children were diverting and using MPH illicitly. However, due to a number of factors including privacy issues relating to children and the lack of a formalized method to obtain state or local law enforcement data, it was difficult to determine how widespread this problem actually was. In other words, was this a random problem in certain areas or was it a more pervasive problem that was not being reported/captured by traditional sources of information? In order to address these questions, the

DEA conducted a survey in three states: Indiana, South Carolina and Wisconsin. These states shared two characteristics: ARCOS data indicated that all three states were considered high users of MPH and the DEA had not received a single anecdotal or law enforcement case involving illicit use of MPH by adolescents from these states. The high use criteria was made to eliminate any doubt about not finding cases because too few children were being treated with MPH. The second criteria was selected because it was felt a fair assessment required not knowing whether any ADHD-related MPH diversion or abuse would be found. Because it was postulated that traditional data sources like law enforcement case files, forensic laboratory reports and state controlled substances authorities could not provide the information sought, a number of non-traditional sources of information were explored. Interviews were conducted with physicians, adolescent treatment center personnel, school officials, nurses and teachers. Where available, poison control data and MPH prescription data were obtained. No effort was made to do a randomized sampling of the various sources of information. However, an effort was made to obtain information from communities of varying populations and locations within each state and the physicians who were interviewed were pediatric specialists for ADHD and child psychiatrists. Data were collected over a one week period in each state by this author and a trained DEA diversion investigator from each state. No attempt was made to do an exhaustive search of all possible cases related to MPH diversion as resources and time did not permit that type of investigation. The results were reported at a 1996 DEA conference on *Stimulant Use in the Treatment of ADHD*<sup>72</sup> and will be summarized herein.

All three states had incidents within the previous year that fit the profile of the types of diversion and misuse/abuse previously outlined. While there were not an overwhelming number

in each state, there was a sufficient number of events “unmasked” by this cursory examination to suggest that these activities are far from rare. Some examples of these incidents

are listed

below:

- a 14 year old sold his girlfriend’s MPH medication to an undercover agent
- a 16 year old crushed his MPH tablets and brought the powder to school
- an 18 year old female student was encountered with crushed MPH powder at school and admitted to abusing it for longer than a year
- a school nurse reported missing/stolen MPH from supplies held at school
- 12 high school students were trafficking MPH at school
- a student was stealing MPH medication from another student’s medication bottle. Although prescribed MPH, he said he needed more.

Examples include:

- a father brought a MPH tablet to the police for identification: son later admitted he was snorting Ritalin
- a 16 year old was arrested for marijuana possession and was found to be carrying 65 MPH tablets. He admitted to crushing the tablets and snorting the powder. He did not have a prescription for MPH.
- school officials reported MPH theft from the nurse’s office
- several students were suspended from school for distributing MPH on the school bus
- four male Citadel students were expelled for non-medical use of MPH

Examples also

- 12 students were suspended/expelled for selling MPH on the school bus
- a 13 year old boy was selling his brother’s medication at school
- a 16 year old male was found to be trading his MPH medication for marijuana
- a female student distributed her MPH medication on the school bus. She had left home with 60 tablets and arrived at school with 4
- three schools were broken into and MPH medication was taken

The information gathered from interviews combined with poison control data suggest that a number of factors may be contributing to the diversion and misuse/abuse of medication intended for ADHD treatment. For example, medications are kept in relatively unsecured areas at home and school. Keeping medication on the kitchen counter or table makes it accessible to other

siblings and children that visit. Many schools reported keeping medication in unlocked drawers or teacher's desks making theft at school relatively easy. Physicians rarely address drug abuse issues with parents or children: if parents are unaware of the abuse potential associated with a medication they are unlikely to take any special precautions. While many schools have rules against children carrying medication at school, those rules are variably applied especially for older students. In addition, very few schools have a nurse on duty to dispense medication and frequently untrained personnel are given this task. Some schools that reported missing/stolen medication could not identify the amounts missing or even which children were affected by the loss as no records or log books were maintained.

Adolescent drug treatment centers reaffirmed what had previously been reported to the DEA: there is a high incidence of illicit use of MPH among adolescents who are already abusing other drugs. In South Carolina one treatment center started requiring routine urine checks for MPH because the incidence of MPH abuse was so high. However, illicit use of MPH is not the exclusive domain of "bad kids." School officials seemed genuinely surprised by the actions of some of their better students who were identified as using MPH illicitly. In general, adolescents who want to use MPH for any reason (to get high, to lose weight, to stay up late and study) have little difficulty obtaining it. They don't need to rob a drug store, forge a prescription or make a visit to the local drug dealer.

*Conclusion:*

The DEA recognizes that psychostimulants like MPH and amphetamine are effective in treating the symptoms associated with ADHD. The present data indicate that chronic, oral, low-

dose stimulant medication in the treatment of properly diagnosed ADHD is generally not associated with children abusing their own medication. However, given the high abuse potential of these drugs and significant data that show they are being used illicitly by a growing number of children, the DEA remains concerned about the ease in which these drugs are available to individuals who choose to use them illicitly. The DEA concurs with other medical professionals who have urged the proactive efforts of many groups including physicians, parents, school personnel and law enforcement to curb the continued diversion, misuse and abuse of these medications. Failure to ensure medication compliance and continued lax handling of medication coupled with persisting efforts to have more children recognized and treated with stimulants is a formula for increased stimulant drug abuse among U.S. children.

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TABLE 1. EFFECTS OF AMPHETAMINE AND COCAINE ON THE BEHAVIOR OF TRAINED RATS

TRAINING/SPECIES	AMPHETAMINE DOSE (mg/kg/MI)	AMPHETAMINE EFFECTS (BEHAVIORAL)	COCAINE DOSE (mg/kg/MI)	COCAINE EFFECTS (BEHAVIORAL)	REFERENCES
<b>AMPHETAMINE-Trained</b>					
Rats	2.5	Yes		MPH=Methamphetamine=Cocaine=Ephedrine	Huang & Ho, 1974
Rats	0.5-2.0	Yes		MPH=Cocaine	Porsolt et al., 1982
Rats	0.1 - 10	Yes			Rosen et al., 1986
Rhesus monkeys	1.0 - 30.0	Yes		No changes in activity	Dela Garza & Johanson, 1987
Pigeons	0.1 - 3.0	Yes			Evans and Johanson, 1987
<b>COCAINE-Trained</b>					
Rats	2.5	Partial			McKeuna and Ho, 1980
Rats	4.5 and 6.0	Yes		MPH=Amphetamine	Silverman and Schultz, 1989
Rats	0.31-1.25	Yes		MPH=Methamphetamine=Cocaine	Colpaert et al., 1979
Rats	10	Yes		MPH=d-Amphetamine=Cocaine	Emmett-Oglesby et al., 1984; Wood and Emmett-Oglesby, 1988;
CATHINONE-Trained Rats	0.5 -4.0	Yes		MPH=Cathinone=Cocaine=Amphetamine	Goudie et al., 1986
GBR12909-Trained Rats	0.1 - 0.3	Yes		MPH=GBR=Cocaine=Cocaine Analogues=Amphetamine	Melia and Spealman, 1981
DOM-Trained Rats	2.5 and 5.0	Partial		MPH=Amphetamine	Silverman and Ho, 1980
MPH-Trained					
Rats	0.5-8.0	Yes		Dose-related increases	Perkins et al., 1981
Rats	15 and 40	Yes		Trained within 7-14 days	Overton, 1982

TABLE 2: REINFORCING EFFECTS OF METHYLPHENIDATE IN ANIMALS

TRAINING/Species	MPH DOSES TESTED (mg/kg/in)	MAINTAINED BEHAVIOR	OTHER EFFECTS	REFERENCE
<b>SUBSTITUTION: COCAINE TRAINED</b>				
Squirrel monkeys	0.01 - 0.3 mg/kg	Yes	Psychomotor stimulant effects	Spealman et al., 1989
Rhesus monkeys	0.025 - 0.4 mg/kg	Yes	1 MPH intake, 1 food intake	Wilson et al., 1971
Rhesus monkeys	0.05 mg/kg	Yes	Blocked by chlorpromazine	Wilson & Schuster, 1972
Rhesus monkeys	0.01 and 0.1 mg/kg	Yes	1 MPH intake, 1 food intake	Aigner & Balster, 1979
<b>SUBSTITUTION: AMPHETAMINE TRAINED</b>				
Rats	4 and 8 mg/kg	Yes	MPH blocked amphetamine	Nielsen et al., 1984
<b>PROGRESSIVE RATIO:</b>				
Baboons	0.1 - 0.8 mg/kg	Yes	Increasing responses for MPH MPH=Amphetamine	Griffiths et al., 1975
<b>CHOICE PARADIGM:</b>				
MPH vs COCAINE	0.1 - 0.8 mg/kg	Yes	MPH > Saline	Johanson and Schuster, 1975
Rhesus monkeys	0.075 vs 0.7 mg/kg	Yes	High MPH >> Low MPH doses	
Rhesus monkeys	0.075 - 0.7 mg/kg MPH vs 0.05 mg/kg Cocaine	Yes	High MPH >> Cocaine 0.5 MPH = 0.5 Cocaine	
<b>ACQUISITION PARADIGM:</b>				
Rhesus monkeys	0.1 mg/kg	Yes, MPH=Cocaine=Amphet.	Cyclicity, 1 stereotypies, 1 weight, Death	Downs et al., 1979
Dogs	0.025-0.4 mg/kg	Yes MPH=Amphetamine	Cyclicity, 1 stereotypies and locomotor activity	Risner and Jones, 1975
Dogs	0.025-0.4 mg/kg	Yes MPH>Amphetamine	Cyclicity, 1 stereotypies, locomotor activity and toxicity	Risner and Jones, 1976
Rats	1.0 and 0.32 mg/kg	Yes, MPH=Cocaine=Amphet.		Collins et al., 1984
Rats	0.33 mg/kg	Yes MPH>Cocaine		Dworkin et al., 1993

TABLE 3: DISCRIMINATIVE, REINFORCING AND SUBJECTIVE EFFECTS IN HUMANS

MPH DOSE (mg)	RESULTS	OTHER EFFECTS	REFERENCE
7.5-60 mg, po Stimulant Abusers	↑ "Positive" mood scores & Drug liking ↑ Stimulant subjective effects Identified as amphetamine (44%) or Cocaine (81%)	↑ Talkativeness, ↑ Drive ↑ Blood pressure, ↑ Heart rate ↑ Temperature	Heischman & Henningfield 1991
15-60 mg, sc Narcotic abusers	↑ "Positive" mood scores, ↑ Drug liking MPH-d-Amphetamine-Methamphetamine (7.5-30 mg) (15-30 mg)	Low: ↓ Relaxation, well-being, ↓ Appetite High: Nervousness, anxiety & dysphoria	Martin et al., 1971
20-40 mg po (mean = 31 mg) Normal Volunteers	MPH chosen on 28% of sessions Placebo chosen on 9% of sessions MPH = Amphetamine No increase on drug liking	↑ Activity level ↑ "Positive" mood scales ↑ Euphoria ↑ Toxicity, dysphoria	Chait, 1994
10 & 20 mg, po Psychiatrists and Psychologists	↑ Positive mood and subjective effects ↑ Talkative and friendly ↑ Euphoria	↑ Activity ↓ Anxiety	Smith & Davis, 1977
10 & 20 mg po Normal Volunteers	↑ Elation and ↑ Euphoria	MPH = Amphetamine	Brown, 1977, 1978
35 mg, iv Psychiatric patients	↑ "High" ↑ Euphoria	MPH = Amphetamine	Huey et al., 1980
45-60 mg, sc Cocaine abusers	MPH: ↓ Craving for Cocaine	Self-administered MPH	Kiantzian et al., 1984
60 mg MPH Dependent Patients	Disruptions in Behavior Affective and thought disorders	Maintained on MPH dose	Keeley & Light, 1985

TABLE 4: 1997 ARCOS

RANK	STATE	GRAMS PER 10K
1	DELAWARE	515
2	NEW HAMPSHIRE	485
3	VIRGINIA	481
4	IOWA	455
5	WISCONSIN	429
6	MICHIGAN	427
7	VERMONT	427
8	SOUTH DAKOTA	426
9	MONTANA	425
10	OHIO	416

1997 U.S. average = 311 grams per 10K population;  
Hawaii and California have the lowest (153 and 177, respectively)