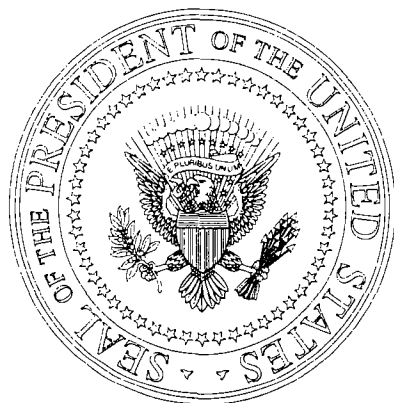
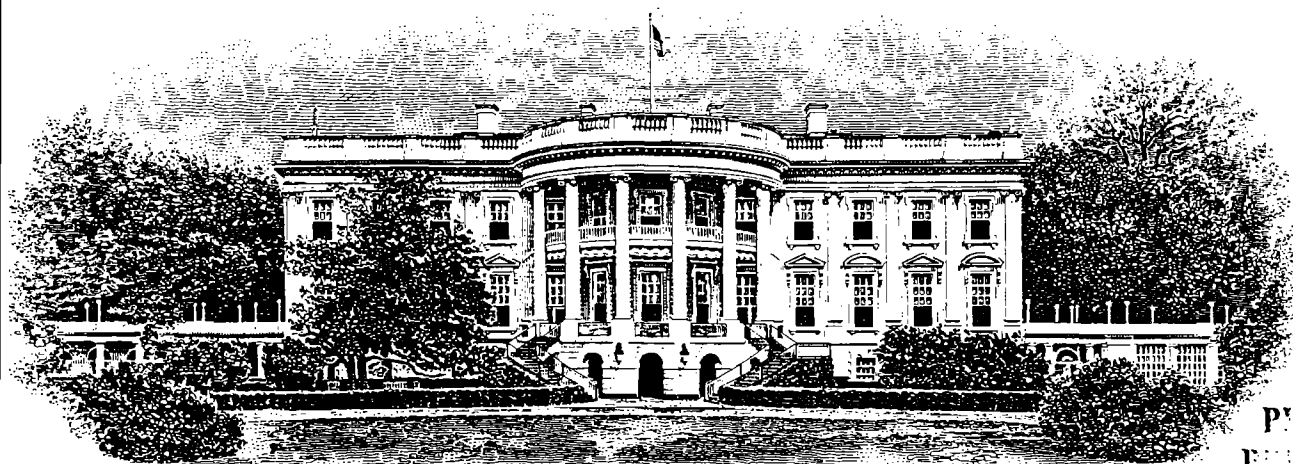


RITAIN



The White House



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HRC Remarks
Groups in attendance
Seating Chart

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press paper
fact sheet

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Lszooey@aol.com
03/20/2000 01:19:33 AM

Record Type: Record

To: Devorah R. Adler/OPD/EOP
cc: Ann O'Leary/OPD/EOP
Subject: Re: new draft

devorah -- the dinner party went way too long! i was scared to fax chris so late, in case the phone rings through the house. so, here's the new draft...if i don't get it to him before he leaves the house tomorrow morning, could you forward it? thanks, as always, for all your help!

FIRST LADY HILLARY RODHAM CLINTON
REMARKS FOR PRESS EVENT AFTER MEETING
TO DISCUSS TREATMENT FOR
CHILDREN WITH BEHAVIORAL AND EMOTIONAL DIFFICULTIES
THE WHITE HOUSE
MARCH 20, 2000

Thank you, Secretary Shalala for your comments and for, yes, refusing to sit still, whenever our children's health is at stake. I want to welcome you all and thank you for coming.

I am here today with not only Secretary Shalala, but also Surgeon General David Satcher, FDA Director Jane Haney [Hay-nee], NIMH director Dr. Steve Hyman, representatives from the Education Department, physicians, parents, educators, counselors and other children's experts.

We just came from a meeting where we talked about what more we can all do to ensure that children with emotional and behavioral problems get the diagnosis and treatment they need --when they need it. Today's meeting and the announcements around it, are important steps, but they are certainly not the last steps we will take in meeting this goal.

When our children come to us hurt or sick, there is nothing more terrifying for a parent than not knowing how to make it better. If they have a broken arm, we want to fix it. If they have a deadly disease, we want to cure it. And, it's no different if their problem lies in their head or their heart.

Thanks in large part to the leadership of Tipper Gore, the President's mental health advisor, we have come a long way in our battle to bring mental illness out of the shadows and make sure it is treated just as seriously as physical illness. More and more often, those treatments are including psychotropic drugs, even for young children. And that is the issue we are here to discuss today.

As many of you know, the Journal of the American Medical Association recently reported that the number of preschoolers who are taking psychotropic drugs increased dramatically from 1991 to 1995. We know that the increase for Ritalin alone was 150 percent, and the use of antidepressants increased over 200 percent. Now, I'm no doctor, but, as a parent and children's advocate, these results concerned me. And I know they concerned Dr. Hyman and countless other experts.

Let me be clear: We are not here to bash the use of these medications. They have literally been a godsend for countless adults and young people with mental illnesses. And research suggests that when children with emotional and behavioral disorders are left untreated, they may fail to reach their full potential later in life.

But, we do have to ask some serious questions about the use of prescription drugs in all children. We must ask: How are we diagnosing, treating, and caring for children with behavioral and emotional conditions? Do we have the best tools to make the most accurate diagnosis? When it comes to drug treatments for children, why are we seeing great variations by community and race? And what effects do overuse and underuse of those medications have on children?

We need to ask: Why aren't we doing a better job of combining drugs, when necessary, with family therapy and other behavior modifications? And what about the effects on our very youngest children, who haven't been tested for these prescription drugs, and whose brains are in their most critical stage of development? These are tough questions. And none of us have all the answers.

But, as Secretary Shalala made clear, we are building on a record, not starting from scratch. We have already taken critical steps over the past few years to ensure that drugs are being tested and labeled specifically for children. And, in doing so, we have learned that finding the right prescription for a child is not always just a matter of decreasing the dosage.

And we also learned quite a bit from the first-ever Surgeon General's report on Mental Illness, which came out in December. It grew out of the White House Conference on Mental illness, led by Tipper Gore. And, it taught us that the stigma of mental illness is often worse for children, who are not little adults; that too many health care professionals lack training in this area; and that we must increase public awareness about children's mental health.

But, clearly we must do more. We know the questions being raised are very difficult. They won't be answered overnight. And they certainly won't be answered by the government or health care professionals or educators or parents acting alone. Every single person with a stake in our children's

health has an important role to play. And so, I am very pleased today to announce some of the immediate steps we are taking to make sure that children with mental illnesses get the right care, at the right time.

As our meeting made clear, we already know a lot about the proper diagnosis and treatment of emotional and behavioral problems in children. But, that critical information has not reached many of the people who need it most. Here are a few of the things we are doing to change that:

Today, the NIMH is releasing a new, easy-to-understand fact sheet that parents can use to make the right decisions about their children's treatment for these conditions. The Education Department will soon release an information kit to help parents and teachers better care for children with ADHD.

and full
And I want to thank both the American Academy of Pediatrics and the American Academy of Family Physicians for all they are doing on this issue. This spring, the American Academy of Pediatrics will give all of their 55,000 members up-to-date guidelines for diagnosing and treating children with emotional and behavioral problems. And, as part of their year-long focus on mental health, the American Academy of Family Physicians is sponsoring continuing education courses about these conditions for their 90,000 members.

Now, quite frankly, there are some areas where we still do not know enough. And, that's especially true when it comes to giving prescription drugs to our very youngest children.

over
I am very pleased that NIMH will dedicate \$5 million to conduct a landmark study examining ADHD and Ritalin use in preschoolers. This study will look at the gap between what we are finding out in the science labs and what is happening in clinical practice - so we can ensure that children get the best possible care.

In addition, the FDA will look at some common psychotropic drugs and begin a process to find out what dosage levels, if any, are appropriate for very young children. This information will be included on the labels of these medications. And the studies on them will address the obvious ethical issues that arise when you examine the use of prescription drugs in such a vulnerable group.

Finally, I am delighted that this fall the Office of the Surgeon General will coordinate a National Conference for the Treatment of Children with Behavioral and Mental Disorders. It will bring together Administration experts, parents, advocates, educators, researchers, health care professionals and consumers.

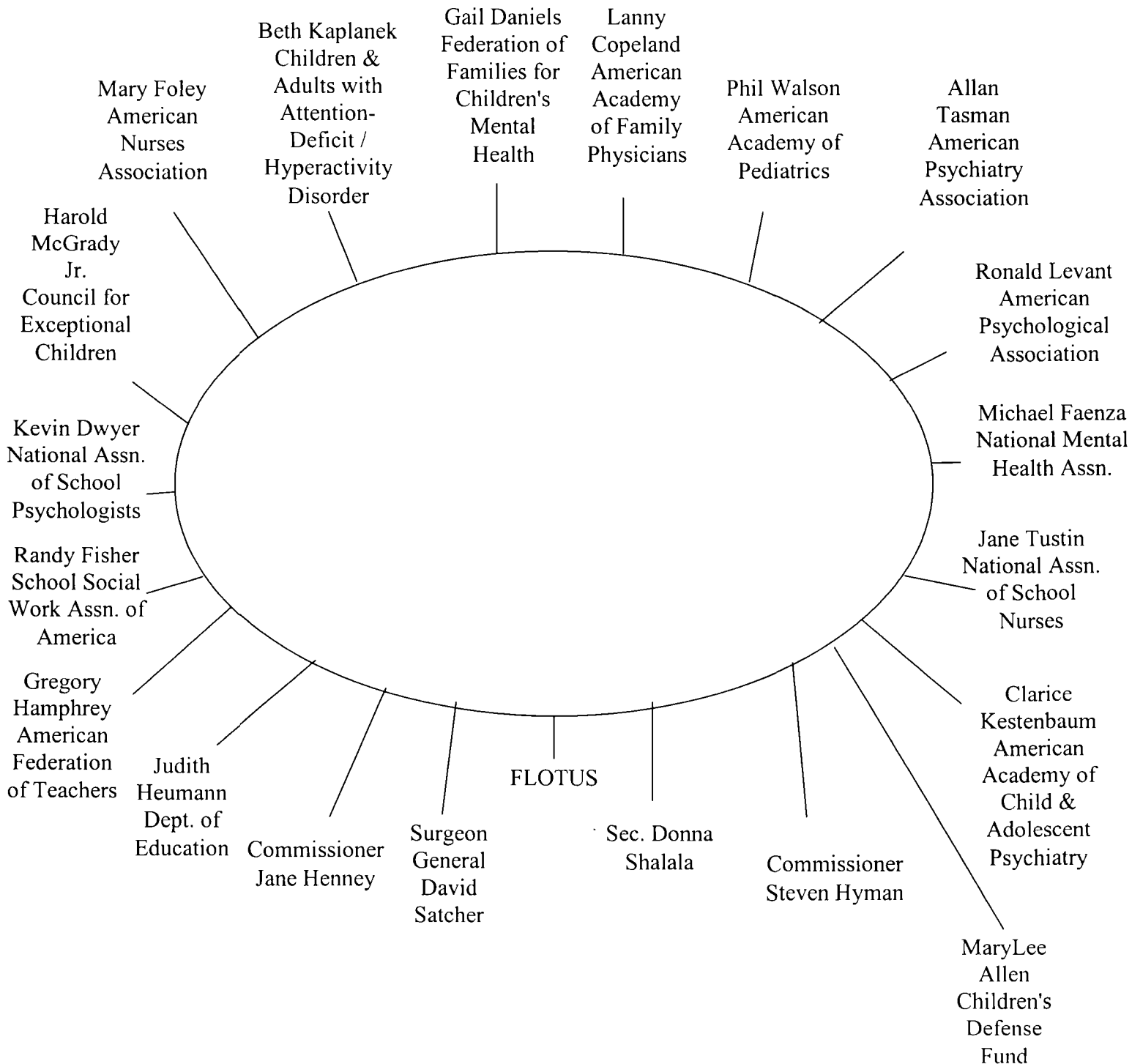
It will look at the challenges we all still face in caring for children with mental illnesses. And it will help us develop long term strategies that each of us can use to help young people get the childhoods and chance in life they all deserve.

We know that when a child is sad or misbehaving, it is never easy for a parent to figure out why or what to do. Some of these young people have

problems that are symptoms of nothing more than childhood or adolescence. Some of them need a parent to love them, or a person to simply listen to them talk about their pain. And yet, some of them do have severe behavioral or emotional problems that may be greatly helped by prescription drugs. These children are waiting for our help - and today we are taking important steps to provide it.

It is my great hope that this meeting will move us closer to the day when we are able to heal the hearts and minds of all children as effectively as heal the rest of their bodies. And I want to thank everyone who has come here today to help make that possible.

First Lady
Meeting on the Safe Use of Medications for
Young Children with Emotional & Behavioral Conditions
March 20, 2000
Map Room
10:00 a.m.



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- **Failure to treat emotional and behavioral disorders can have severe life-long consequences.** Studies suggest that many children with untreated emotional and behavioral conditions fail to reach their full potential. Untreated mental illness has a negative impact on the developing brain, causing lifelong emotional and social damage. Children with these types of problems are at significantly higher risk for anti-social activities later on than those without behavioral problems. It is evident that an accurate early diagnosis, education, support, and medication, if necessary, can overcome many early problems and help prevent long-term negative behavior.
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- **More research is necessary to ensure informed treatment decisions.** Many of the drugs being prescribed for very young children have not been tested in children under the age of 16; few have been tested for children under the age of six. More research is necessary to ensure that providers and parents have necessary information, especially about the impact of medication on brain development, to make appropriate treatment decisions.

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NEW PRIVATE SECTOR COMMITMENT TO ENSURING APPROPRIATE DIAGNOSIS OF EMOTIONAL AND BEHAVIORAL CONDITIONS IN YOUNG CHILDREN. Today, the First Lady will praise and highlight the new efforts of the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) to ensure appropriate diagnosis and effective treatment of children with emotional and behavioral conditions. This spring and fall, the AAP will distribute new clinical practice guidelines on the diagnosis and evaluation of children with attention deficit disorders to every one of their 55,000 members. In addition, as part of their focus on mental health in the year 2000, the AAFP will sponsor education courses nationwide for their over 89,000 members on how to address the problems of young children with emotional and behavioral conditions.

HILLARY ROHDAM CLINTON'S LONGSTANDING COMMITMENT TO CHILDREN.

For over 25 years, Hillary Clinton has fought to raise awareness and support policies that protect children. She was a strong advocate for: the passage of the Children's Health Insurance Program, the Family and Medical Leave Act; new regulatory and statutory authority for pediatric labeling; administration efforts to improve child care. The new pediatric labeling regulations and the FDA Modernization Act enacted by the Clinton Administration have improved the information available to both parents and physicians about the appropriate use of medications for children. In the 18 months since these initiatives have been implemented, research has been completed on 19 drugs, resulting in new safety information being added to six drugs with changes expected for the other 13. Studies of an additional 125 drugs are already underway.

TREATMENT OF YOUNG CHILDREN WITH MENTAL CONDITIONS

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Although progress has been made in diagnosing the mental illnesses that begin in childhood, children's brains are in a state of rapid change and growth, and diagnosis and treatment of mental disorders must be viewed with this in mind. While some problems are short lived, others are persistent and very serious, and parents should seek help for their children. Treatment decisions should be weighed for risks and benefits, and each child should be viewed individually.

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Stimulants

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<u>Brand Name</u>	<u>Generic Name</u>	<u>Approved Age</u>
Adderal	amphetamines	3 and older
Cyclert	pemoline	6 and older
Dexedrine	dextro-amphetamine	3 and older
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Anti-Depressant and Anti-Anxiety Medications

These medications are used for depression and for anxiety disorders, including obsessive compulsive disorder.

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Luvox	fluvoxamine	8 and older (OCD)
Sinequan	doxepin	12 and older
Tofranil	imipramine	6 and older (bedwetting)
Zoloft	sertraline	6 and older (OCD)

Other medications that are used to treat these disorders in children include Effexor (venlafaxine), Paxil (paroxetine), Prozac (fluoxetine), Serzone (nefazodone), and Wellbutrin (bupropion). They are not labeled for pediatric use.

Anti Psychotics

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Neurontin	gabapentin	12 and older (for seizures)
Tegretol	carbamazepine	any age (for seizures)

Research on the effectiveness of these and other medications in children and adolescents with bipolar disorder are ongoing. In addition, studies are investigating various forms of psychotherapy, including cognitive-behavioral therapy, to complement medication treatment for this illness in young people.

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March 20, 2000

Curbing Use of Psychiatric Drugs for Children

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By **ROBERT PEAR**

WASHINGTON, March 19 -- The White House will announce a major effort on Monday to reverse a sharp increase in the number of preschool children using Ritalin, Prozac and other powerful psychiatric drugs, administration officials said today.

As part of the initiative, they said, the government will inform parents and teachers about the risks of such drugs, the Food and Drug Administration will develop new drug labels, the National Institutes of Health will begin a huge nationwide study of Ritalin use in children under the age of 6, and the ~~White House~~ will hold a ✓ conference this fall on the diagnosis and treatment of mental illness in very young children.

Hillary Rodham Clinton and federal health officials plan to meet on Monday with parents, psychiatrists, pediatricians, psychologists, nurses and social workers to discuss the issue.

Then the administration plans to issue a statement declaring that "the use of medication is not generally the first option for a preschool child with a psychiatric disorder."

In a study last month in the Journal of the American Medical Association, researchers reported that there had apparently been an acute increase in the number of preschoolers taking psychotropic drugs, particularly stimulants like Ritalin and antidepressants like Prozac.

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Ritalin is called a stimulant because it belongs to a family of drugs that stimulate the central nervous system and increase a person's alertness and ability to pay attention. Researchers say 20 percent of white boys are taking the drug in some suburban school districts.

The study caused concern among parents and medical experts alike, and the administration is now trying to address that concern.

In an interview, Dr. Steven E. Hyman, director of the National Institute of Mental Health, said, "As a rule of thumb, doctors, psychologists and social workers should attempt to modify the behavior of a child and deal with family crises before drugs are prescribed."

The government has prepared a new guide for parents on the treatment of young children with mental disorders. "When medication is used, it should not be the only strategy," but should be part of an overall treatment plan, the guide says. Parents and doctors may want to consider behavioral therapy for the child, family therapy and other techniques to help manage the child's symptoms, the document says.

Administration officials said the initiative was inspired mainly by Mrs. Clinton, who they said wanted to announce some immediate steps after seeing the immense public concern about the use of powerful pills to treat toddlers with emotional and behavioral disorders.

Mrs. Clinton is running for the United States Senate in New York, but White House officials said it would be cynical to believe that her motives were only political. They noted that for years she has been interested in children's issues, including the testing and labeling of drugs for children. Health officials and medical experts said the government's concern was well founded.

"Everything Mrs. Clinton does is related to her campaign, but this initiative has substance too," a federal health official said. "We want doctors and parents to think about these issues."

In an editorial in the *Journal of the American Medical Association* last month, Dr. Joseph T. Coyle, chairman of the psychiatry department at Harvard Medical School, said children with behavioral disorders were "increasingly subjected to quick and inexpensive pharmacologic fixes," even though "there is no empirical evidence to support psychotropic drug treatment in very young children."

Indeed, Ritalin carries a warning that says, "Ritalin should not be used in children under 6 years, since safety and efficacy in this age group have not been established."

Dr. Hyman said the National Institute of Mental Health would spend \$6 million in the next five years to study whether Ritalin is safe and effective in treating preschoolers with the impulsive, aggressive behavior traits known as attention deficit hyperactivity disorder -- the most commonly diagnosed psychiatric disorder in children.

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In the study, Dr. Hyman said, hundreds of girls and boys at research centers around the country will receive Ritalin, behavior therapy or some combination of the two.

Dr. Hyman said the problem was not simply that children were being overmedicated, but that they were not being appropriately evaluated and treated. "In some communities," he said, "too few children are receiving medications, just as in other communities, too many are getting medications."

Government scientists said they recognized that drug therapy could sometimes provide relief to young children. "If a kid is engaged in aggressive behavior, self-mutilation, head banging, and is otherwise uncontrollable, you should try medication," Dr. Hyman said.

Certain drugs are widely prescribed for young children even though they have not been studied, approved or labeled for such use. The Food and Drug Administration does not regulate the practice of medicine; after a drug is approved for one purpose, doctors often prescribe it for other purposes.

The White House said, for example, that some medications used to treat depression and anxiety disorders in children, like Paxil, Prozac and Wellbutrin, were not labeled for pediatric use.

In addition, the White House said, Zoloft has been approved to treat obsessive-compulsive disorder in children 6 and older, while Luvox has been approved for the same condition in children 8 and older. But both drugs are used in younger children.

Drug labels often do not specify the proper doses for children. The White House said the food and drug agency would soon specify how drug companies should conduct the research needed to develop "pediatric dosage information" that can be included on the labels of Ritalin, clonidine and other drugs used to treat hyperactivity and other attention deficit disorders in young children.

Dr. Jane E. Henney, the commissioner of food and drugs, said that in the last year her agency had sent letters to seven companies asking them to study the effects of antidepressants in children 7 to 18 years old. The government, she said, is analyzing ways in which research on younger children can be scientifically and ethically conducted.

Dr. Hyman said: "Lots of mood disorders and anxiety disorders begin in childhood. But the younger a child is, the more difficult it is to make a diagnosis of mental disorder with certainty. It is quite difficult to diagnose attention deficit hyperactivity disorder in children under 6 because they are usually not articulate, their brains and behavior are changing rapidly, and they are very reactive to their environment."