

Ritalin

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**FIRST LADY HILLARY RODHAM CLINTON LAUNCHES NEW PUBLIC-PRIVATE  
EFFORT TO IMPROVE THE DIAGNOSIS AND TREATMENT OF CHILDREN WITH  
EMOTIONAL AND BEHAVIORAL CONDITIONS**

**March 20, 2000**

Today, First Lady Hillary Rodham Clinton, together with Secretary Shalala and representatives of parents and a broad range of health professionals, launched an unprecedented public-private effort to ensure that children with emotional and behavioral conditions are appropriately diagnosed, treated, monitored, and managed by qualified health care professionals, parents, and educators. Federal actions she will outline include: (1) the release of a new, easy to understand fact sheet about treatment of children with emotional and behavioral conditions for parents; (2) a new \$5 million funding commitment by the National Institute of Mental Health (NIMH) to conduct additional research on the impact of psychotropic medication on children under the age of seven; (3) the initiation of a process at the Food and Drug Administration (FDA) to improve pediatric labeling information for young children; and (4) a national conference on Treatment of Children with Behavioral and Mental Disorders to take place this fall. The First Lady will also highlight actions taken by the private sector to ensure appropriate diagnosis and effective treatment of these children. All of these actions build on the landmark work resulting from the first ever White House Conference on Mental Health and the release of the unprecedented Surgeon General's Report on Mental Health last year, both of which were spearheaded by Tipper Gore, the President's Mental Health Advisor.

**INAPPROPRIATE DIAGNOSIS AND TREATMENT OF BEHAVIORAL AND EMOTIONAL CONDITIONS HAVE ADVERSE CONSEQUENCES.** While progress has been made in diagnosing and treating these conditions, justifiable concerns have been raised about the inappropriate (both over and under) utilization of medications such as Ritalin, clonidine, and Prozac in very young children. Just as important, there is a lack of understanding amongst parents, teachers, and health professionals about the best diagnostic, pharmacological, and behavioral interventions now available. Recent studies published in the *Journal of the American Medical Association* reviewing selected provider data over a five year period found that:

- **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.
- **The number of preschoolers on anti-depressants increased by over 200 percent.** The number of children on tri-cyclic anti-depressants, often used to control bedwetting, increased 220 percent over five years. Given the difficulty of diagnosing depression in children this young and the relative normalcy of bedwetting in children this young, the increase in the use of this drug in preschoolers is troubling.

- **The number of children under the age of five on clonidine increased exponentially.** The 28-fold increase in children using clonidine, used in children with attention deficit disorders or children exhibiting disruptive behaviors, is notable, as the increase in its use occurred without research ensuring that it is safe and effective. Adverse effects, including rapid or irregular heartbeat and fainting, have been reported in children using the drug with other medications for attention-deficit disorder.
- **The number of children aged two through four taking stimulants such as Ritalin more than doubled.** The vast majority of preschoolers taking stimulants were on Ritalin to treat attention deficit disorders – as many as ninety percent in one study – and the number of these children increased by 150 percent over a five year period. Although there are a disproportionate number of boys taking medication for attention deficit disorders as opposed to girls (a ratio of 4:1), the number of girls being diagnosed and treated with attention deficit disorders increased over this time period; in one study, the proportion of girls taking stimulants increased by 60 percent.
- **Many children are inappropriately diagnosed and treated.** Studies indicate wide geographic and ethnic variation in the numbers of children receiving psychotropic drugs such as Ritalin. In one study, the percentage of children receiving Ritalin was as high as 10 percent – 2 to 3 times as high as the expected rate of attention deficit disorder. The percentage of boys receiving medication for attention deficit disorder in the fifth grade was as high as 20 percent. Other research indicates racial variations as well; a study of one Maryland HMO indicated that African-Americans children were 2.5 times less likely to receive Ritalin as white children. This wide variation in treatment patterns supports the need for more research to determine appropriate treatment protocols for children with emotional and behavioral disorders. Although little is known about the effects of over medication on children, unnecessary use of these medications can have adverse effects on the developing brain and the emotional and social development of young children.
- **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.

**NEW ACTION TO ENSURE BETTER DIAGNOSIS, TREATMENT, AND MANAGEMENT OF CHILDREN WITH EMOTIONAL AND BEHAVIORAL CONDITIONS.** At today's meeting, the First Lady will announce a series of public and private actions designed to address the challenges posed by children with emotional and behavioral conditions. Federal actions she will outline include:

- **Initiation of a process for the development of pediatric labeling information for psychotropic drugs used in young children.** Today, FDA will announce that it will work with its Pediatric Advisory Committee to design research protocols that will be used to develop new pediatric dosage information to be included on the labels of drugs such as methylphenidate, clonidine, and other drugs increasingly used in young children. These studies, which will begin after national research goals have been identified, will be designed to address ethical and scientific issues associated with the studies on this population.

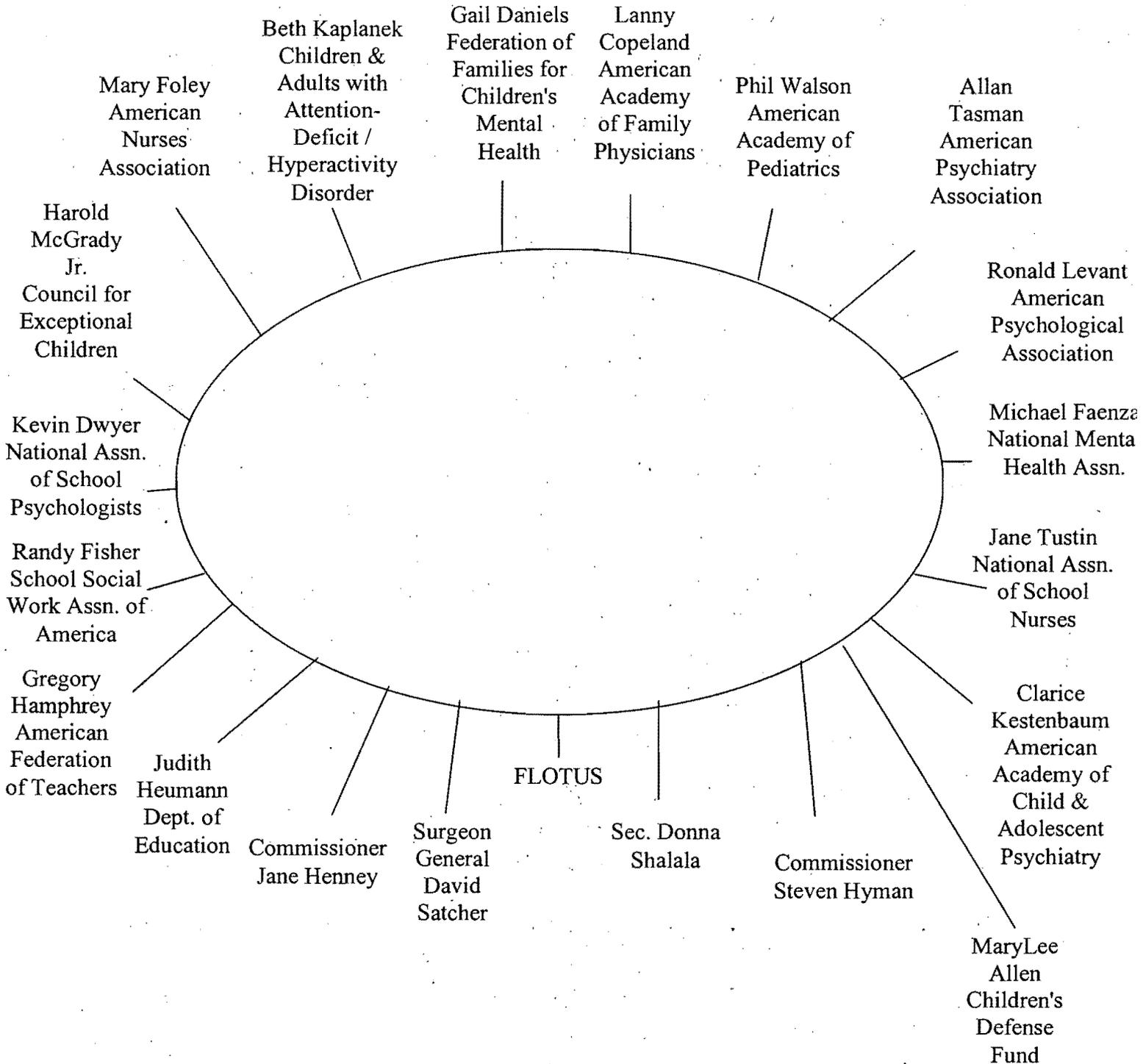
- **Announcement that NIMH will dedicate more than \$5 million to research on attention deficit disorder and Ritalin use in preschoolers.** Today, the National Institute of Mental Health announced that it plans to invest more than \$5 million in research on the use of medication to treat attention deficit disorder in preschool children. This research will assemble the latest information on the use of these drugs and identify discrepancies between clinical practice and current scientific evidence.
- **New efforts to provide parents with up-to-date information on the appropriate diagnosis and treatment of children with emotional and behavioral conditions.** This week, NIMH will release a new fact sheet to help parents of children with behavioral and emotional conditions understand the treatment options available and guide them in their decision-making process. This fact sheet includes easy to understand information on when to include medication in an overall treatment plan; how to help determine if a child's problems are serious; and when and how to get help. The Department of Education will also release an information kit on ways for teachers and parents of children with attention deficit disorders.
- **A national Conference on the Diagnosis and Treatment of Children with Behavioral and Mental Disorders.** This fall, the Office of the Surgeon General, together with NIMH and FDA, will coordinate a Conference on Treatment of Children with Behavioral and Mental Conditions. This national conference, which will build on the success of the recent White House Conference on Mental Health chaired by Tipper Gore, and the Surgeon General's Report on Mental Health, will include representatives of provider, consumer advocacy, and education communities. Topics of discussion include: developing research on treatments and services that can be used by providers nationwide; how best to determine the efficacy and safety of medications in young children; and ways to address the difficulty of accurate diagnosis in preschoolers. The Surgeon General will also release a report on children's mental health by the end of the year.

**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.

**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.**



**First Lady Hillary Rodham Clinton**  
**Meeting on the Safe Use of Medications for Young**  
**Children with Emotional and Behavioral Conditions**  
**March 20, 2000**

**List of Attendees**

MaryLee Allen, Director, Child Welfare & Mental Health Division, Children's Defense Fund  
Lanny R. Copeland, MD, Chairman of the Board, American Academy of Family Physicians  
Gail Daniels, President, Board of Directors, Federation of Families for Children's Mental Health  
Kevin P. Dwyer, MA, NCSPP, President, National Association of School Psychologists  
Michael M. Faenza, MSSW, President & CEO, National Mental Health Association  
Randy A. Fisher, President, School Social Work Association of America  
Mary E. Foley, MS, RN, President, American Nurses Association  
Gregory A. Humphrey, Special Assistant to the President, American Federation of Teachers  
Beth A. Kaplanek, RN, President Elect, Children and Adults with Attention-Deficit/Hyperactivity Disorder  
Clarice Kestenbaum, MD, President, American Academy of Child & Adolescent Psychiatry  
Ronald F. Levant, Ph.D., Board of Directors, American Psychological Association  
Harold James McGrady, Jr., MD, Council for Exceptional Children  
Allan Tasman, MD, President, American Psychiatry Association  
Jane Tustin, RN, MSN, CSN, President, National Association of School Nurses  
Phil Walson, Member, MD, AAP Committee on Drugs, American Academy of Pediatrics



Lszooney@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

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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 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.

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.

# **TREATMENT OF YOUNG CHILDREN WITH MENTAL CONDITIONS**

## **When to Get Help • People to Talk To • Learning About Medications**

### **A NOTE TO PARENTS**

There has been recent public concern over reports that increasing numbers of very young children are being prescribed psychotropic medications. Some parents are criticized for giving their children these medications, while others are criticized for not doing so. New studies are needed to tell us what the best treatments are for children with emotional and behavioral disturbances.

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.

### **WHEN TO GET HELP**

Changes in behavior can be of real concern to parents. It's important to recognize behavior changes, but also to differentiate them from signs of more serious problems. All children act out at times as part of typical development. Some children, however, experience significant changes that may indicate a more serious problem. But in some cases, children need help. Problems deserve attention when they are severe, persistent, and impact daily activities. Seek help for your child if you observe persistent problems such as sleep disturbances, changes in appetite, social withdrawal, or fearfulness; behavior that slips back to an earlier phase such as bedwetting; signs of depression; erratic and aggressive behavior, a tendency to be easily distracted or forgetful, or an inability to sustain attention; self-destructive behavior such as head banging; or a tendency to have frequent injuries. It's important to address concerns early – mental, behavioral, or emotional disorders affect the way your child grows up.

### **PEOPLE TO TALK TO IF YOU ARE CONCERNED ABOUT YOUR CHILD**

Remember that every child is different, and even normal development varies from child to child. If your child is in daycare or preschool, ask the teacher if your child has shown any troubling changes in behavior, and discuss this with your doctor. Ask your doctor questions and find out everything you can about the behavior or symptoms that worry you. Be sure to tell your doctor about extreme symptoms, such as self-injury, impulsive or aggressive behavior, hyperactivity, or social withdrawal.

Ask your doctor whether your child needs further evaluation by a specialist in child behavioral problems. A variety of specialists, including psychiatrists, neurologists, psychologists, behavioral therapists, social workers and educators may be needed to help your child. Consistent follow-up is critical to successful treatment.

### **LEARNING ABOUT MEDICATIONS**

The use of medication is not generally the first option for a preschool child with a psychiatric disorder. When medication is used, it should not be the only strategy. Family support services, educational classes on parenting strategies, behavior management techniques, and other approaches should be considered. If medication is prescribed, it should be monitored and evaluated closely and regularly. There are several categories of medications used for emotional and behavioral disorders: stimulants, anti-depressants, anti-anxiety agents, anti-psychotics, and mood stabilizers.

## Stimulants

There are four stimulant medications that are approved for use in the treatment of attention deficit hyperactivity disorder (ADHD), the most common behavioral disorder of childhood. Children with ADHD exhibit symptoms such as short attention span, excessive activity, and impulsivity that cause substantial impairment in functioning. If the child attends school, collaboration with teachers is essential. These medications are labeled for pediatric use.

<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
Ritalin	methylphenidate	6 and older

## Anti-Depressant and Anti-Anxiety Medications

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

<u>Brand Name</u>	<u>Generic Name</u>	<u>Approved Age</u>
Anafranil	clomipramine	10 and older (OCD)
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

These medications are used to treat schizophrenia, bipolar disorder, autism, Tourette's syndrome, and conduct disorders.

<u>Brand Name</u>	<u>Generic Name</u>	<u>Approved Age</u>
Haldol	Haloperidol	3 and older
generic only	Thioridazine	2 and older
Orap	Pimozide	12 and older

There are other medications used to treat these disorders in children, including clozaril (clozapine), Risperidal (risperidone), seroquel (quetiapine), Zyprexa (olanzapine). These drugs are newer (atypical) antipsychotics, and have fewer side effects. These medications are not labeled for pediatric use.

## Mood Stabilizers

These medications are used to treat bipolar disorder (manic depressive illness).

<u>Brand Name</u>	<u>Generic Name</u>	<u>Approved Age</u>
Cibalith-S	lithium citrate	12 and older
Depakote	divalproex sodium	2 and older (for seizures)
Eskalith	lithium carbonate	12 and older
Lamictal	lamotrigine	16 and older (for seizures)
Lithobid	lithium carbonate	12 and older
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.

**FOR MORE INFORMATION ON MENTAL DISORDERS IN CHILDREN  
CONTACT THE NATIONAL INSTITUTES OF MENTAL HEALTH 301 443 4513 / [www.nimh.nih.gov](http://www.nimh.nih.gov)**

# DRAFT FOR PARENTS

## Questions and Answers: Treatment of Children with Mental Disorders

### A Note to Parents

There has been recent public concern over reports that very young children are being prescribed psychotropic medications.

Some parents are criticized for giving their children these medications, while others are criticized for not doing so. The studies to date are incomplete, and much more needs to be learned about young children who are treated with medications for all kinds of illnesses. In the field of mental health, new studies are needed to tell us what the best treatments are for children with emotional and behavioral disturbances. For medications, we must also make sure that there are no negative consequences for the developing brain.

While there has been progress made in diagnosing the mental illnesses that begin in childhood, children 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 ways to help their children.

Not long ago, it was thought that many brain disorders such as anxiety disorders, depression, and bipolar disorder began only later in life. We now know they can begin in childhood. An estimated 6 to 9 million children and adolescents in the United States suffer from a serious

behavioral or emotional disturbance. Perhaps the most studied, diagnosed, and treated childhood-onset mental disorder is attention deficit hyperactivity disorder (ADHD), but even with this disorder there is a need for further research in very young children. Every decision about treatment should be weighed for risk and benefit, and each child should be viewed individually.

### Questions and Answers

*Q: What should I do if I am concerned about mental, behavioral, or emotional symptoms in my young child?*

A: Talk to your child's doctor. Ask questions and find out everything you can about the behavior or symptoms that worry you. Every child is different and even normal development varies from child to child. Sensory processing, language, and motor skills are developing during early childhood, as well as the ability to relate to parents and to socialize with caregivers and other children. If your child is in daycare or preschool, ask the caretaker or teacher if your child has been showing any worrisome changes in behavior, and discuss this with the doctor. Always bring extreme symptoms, such as self-injury, impulsive or aggressive behavior, persistent sadness,

hyperactivity, or social withdrawal, to the attention of the doctor.

*Q: How do I know if my child's problems are serious?*

A: Many everyday stresses cause changes in behavior. The birth of a sibling may cause a child to temporarily act much younger. It is important to recognize such behavior changes, but also to differentiate them from signs of more serious problems. Problems deserve attention when they are severe, persistent, and impact on daily activities. Seek help for your child if you observe persistent problems such as sleep disturbances, changes in appetite, social withdrawal, or fearfulness; behavior that slips back to an earlier phase such as bed wetting; signs of distress such as sadness or tearfulness; self-destructive behavior such as head banging; or a tendency to have frequent injuries. In addition, it is essential to review the development of your child, any important medical problem he/she might have had, family history of mental disorders, physical and psychological traumas or situations that may cause stress.

*Q: Whom should I consult to help my child?*

A: First, consult your child's pediatrician. Ask for a complete health examination of

# DRAFT FOR PARENTS

your child. Describe the behaviors that worry you. Ask whether your child needs further evaluation by a specialist in child behavioral problems. Parents may be faced with a patchwork of providers. Ultimately, a variety of specialists including physicians, behavioral therapists, and educators may be needed to help your child.

***Q: How are mental disorders diagnosed in young children?***

A: Most disorders are diagnosed by observing signs and symptoms. A skilled clinician will consider these signs and symptoms in the context of the child's developmental level, social and physical environment, and reports from parents and other caretakers or teachers. Very young children often cannot express their thoughts and feelings, which makes diagnosis a challenging task. The signs of a mental disorder in a young child may be quite different from those of an older child or an adult.

***Q: Won't my child just grow out of such problems?***

A: Sometimes yes, but in other cases children need help. Problems that are severe, persistent, and impact on daily activities should be brought to the attention of the child's doctor. Great care should be taken to help a child who is suffering, because mental, behavioral, or emotional disorders can affect the way the child grows up.

***Q: Are there situations in which it is advisable to use psychotropic medications in young children?***

A: Psychotropic medications may be prescribed for young children with mental,

behavioral, or emotional symptoms when the potential benefits of treatment outweigh the risks. Some problems are so severe and persistent that they would have serious negative consequences for the child if untreated, and psychosocial interventions may not always be effective by themselves. The more extreme the problems, the more likely it is that medication will be prescribed. However, the safety and efficacy of most psychotropic medications have not yet been studied in young children. As a parent, you will want to ask many questions and evaluate with your doctor the risks of starting and continuing your child on these medications. Learn everything you can about the medications prescribed for your child, including potential side effects. Learn which side effects are bothersome but tolerable, and which ones are threatening. In addition, learn and keep in mind the goals of treatment (e.g., change in specific behaviors). Although it has become common practice, combining multiple psychotropic medications should be avoided in very young children unless absolutely necessary. Any medication treatment should proceed with careful monitoring of benefits and adverse effects.

***Q: Does medication affect young children differently from older children or adults?***

A: Yes. Young children's bodies handle medications differently than older individuals and this has implications for dosage. The brains of young children are in a state of very rapid development, and animal studies have shown that the developing neurotransmitter systems can be very sensitive to medications. A great

deal of research is needed to determine the effects and benefits of medications in children of all ages. It is important to remember that serious untreated mental disorders themselves negatively impact brain development.

***Q: If my preschool child receives a diagnosis of a psychiatric disorder, does this mean that medications have to be used?***

A: No. Psychotropic medications are not generally the first option for a preschool child with a psychiatric disorder. The first goal is to understand (and if possible, to remediate) the factors that may be contributing to the condition. The child's own physical and emotional state is key, but many other factors such as parental stress or a changing family environment may influence the child's symptoms.

***Q: How should medication be included in an overall treatment plan?***

A: When medication is used, it should not be the only strategy. There are many services that you may want to investigate to develop a complete treatment plan for your child. Family support services, educational classes on parenting strategies, behavior management techniques, as well as family therapy and other approaches should be considered. If medication is prescribed, it should be monitored and evaluated closely and regularly.

***Q: Which mental disorders are seen in children?***

A: Mental disorders with possible onset in childhood include: anxiety disorders;

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attention deficit and disruptive behavior disorders; autism and other pervasive developmental disorders; eating disorders (e.g., anorexia nervosa); mood disorders (e.g., major depression, bipolar disorder); schizophrenia; and tic disorders. Enuresis and encopresis may be symptoms of a mental disorder.

*Q: Can family events such as a death in the family, illness in a parent, onset of poverty, or divorce cause symptoms?*

A: Yes. When a tragedy occurs or some extreme stress hits, every member of a family is affected, even the youngest ones. This should also be considered when evaluating mental, emotional, or behavioral symptoms in a child.

*Q: What difference does it make if a medication is specifically approved for use in children or not?*

A: The approval of a medication by the U.S. Food and Drug Administration (FDA) allows for doctors to prescribe the medication as they feel appropriate. In some cases there is extensive clinical experience in using medications for children or adolescents. However, everyone agrees that studies in children would be valuable for finding appropriate dosages and learning the effects of medications.

*Q: What does "off-label" use of a medication mean?*

A: Based on clinical experience and medication knowledge, a physician may prescribe to children a medication that has been FDA-approved for use only in adults. This use of the medication is called "off

label." Most medications prescribed for child mental disorders, including many of the newer medications that are proving helpful, are prescribed off label, because only a few of them have been systematically studied for safety and efficacy in children. Medications that have not undergone such testing are dispensed with the statement that "safety and efficacy have not been established in children."

*Q: Why haven't many medications been tested in children?*

A: In the past, medications were not studied in children because of ethical concerns about involving children in clinical trials. However, this created a new ethical problem: lack of knowledge about the best treatments for children. But in clinical settings, medications are being prescribed for children at increasingly early ages. The NIH and the FDA have begun examining the issue of research on medications in young children. New research approaches are being considered, and progress is being made to require such studies when a medication is undergoing FDA approval.

*Q: Does the FDA approve medications for different age groups among children?*

A: Yes. For example, Ritalin® is approved for children age 6 and older, whereas Dexedrine® is approved for children as young as 3. The lowest age for which the FDA approves a given medication is a function of the policies in effect at the time of initial approval and the specific requests of the drug manufacturer. Dexedrine® is an older medication than Ritalin®. When Ritalin®

was tested for efficacy by the pharmaceutical company that developed it, only children age 6 and above were involved; therefore, age 6 was established as the lower age limit for Ritalin®. There is no reason to believe that one medication is safer than the other based on differences in FDA approval.

*Q: What medications are used for which kinds of childhood mental disorders?*

A: There are several major categories of psychotropic medications: stimulants, antidepressants, anti-anxiety agents, antipsychotics, and mood stabilizers. For medications approved by the FDA for use in children, dosages depend on body weight and age.

■ *Stimulant Medications:* There are four stimulant medications that are approved for use in the treatment of attention deficit hyperactivity disorder (ADHD), the most common behavioral disorder of childhood. These medications have all been extensively studied and are specifically labeled for pediatric use. Children with ADHD exhibit such symptoms as short attention span, excessive activity, and impulsivity that cause substantial impairment in functioning. Stimulant medication should be prescribed only after a careful evaluation to establish the diagnosis of ADHD and to rule out other disorders or conditions. Medication treatment should be administered and monitored in the context of the overall needs of the child and family, and consideration should be given to combining it with behavioral therapy. If the child is of school age, collaboration with teachers is essential.

# DRAFT FOR PARENTS

## Stimulant Medications

Brand Name	Generic Name	Approved Age (children)
Adderal	amphetamines	3 and older
Cylert	pemoline	6 and older
Dexedrine	dextro-amphetamine	3 and older
Ritalin	methylphenidate	6 and older

▪ *Antidepressant and Antianxiety Medications:* These medications follow the stimulant medications in prevalence among children and adolescents. They are used for depression, a disorder recognized only in the last twenty years as a problem for children, and for the anxiety disorders, including obsessive-compulsive disorder (OCD). The

medications most widely prescribed for these disorders are the selective serotonin reuptake inhibitors (the SSRIs).

In the human brain, there are many "neurotransmitters" that affect the way we think, feel, and act. Three of these neurotransmitters that antidepressants influence are serotonin, dopamine, and

norepinephrine. SSRIs affect mainly serotonin and have been found to be effective in treating depression and anxiety without as many side effects as some older antidepressants. The following are the most commonly prescribed medications for children with depression or anxiety disorders (including OCD).

## Antidepressant and Antianxiety Medications

Brand Name	Generic Name	Approved Age (children)
Anafranil	clomipramine	10 and older (for OCD)
Effexor	venlafaxine	
Luvox (SSRI)	fluvoxamine	8 and older (for OCD)
Paxil (SSRI)	paroxetine	
Prozac (SSRI)	fluoxetine	
Serzone (SSRI)	nefazodone	
Sinequan	doxepin	12 and older
Tofranil	imipramine	6 and older (for bedwetting)
Wellbutrin	bupropion	
Zoloft (SSRI)	sertraline	6 and older (for OCD)

# DRAFT FOR PARENTS

■ *Antipsychotic Medications:* These medications are used to treat children with schizophrenia, bipolar disorder, autism, Tourette's syndrome, and severe conduct disorders. Some of the older antipsychotic medications have specific indications and dose guidelines for children. Some of the newer "atypical" antipsychotics, which have fewer side effects, are also being used for children. Such use requires close monitoring for side effects.

## Antipsychotic Medications

Brand Name	Generic Name	Approved Age (children)
Clozaril (atypical)	clozapine	
Haldol	haloperidol	3 and older
Risperdal (atypical)	risperidone	
Seroquel (atypical)	quetiapine	
(generic only)	thioridazine	2 and older
Zyprexa (atypical)	olanzapine	
Orap	pimozide	12 and older (for Tourette's syndrome). Data for age 2 and older indicate similar safety profile.

■ *Mood Stabilizing Medications:* These medications are used to treat bipolar disorder (manic depressive illness). However, because there is very limited data on the safety and efficacy of most mood stabilizers in youth, treatment of children and adolescents is based mainly on experience with adults. The most typically used mood stabilizers are lithium and valproate (Depakote®), which are often very effective for controlling mania and preventing recurrences of manic and depressive episodes in adults. Research on the effectiveness of these and other medications in children and adolescents with bipolar disorder is ongoing. In addition, studies are investigating various forms of psychotherapy, including cognitive-behavioral therapy, to complement medication treatment for this illness in young people.

Effective treatment depends on appropriate diagnosis of bipolar disorder in children and adolescents. There is some evidence that using antidepressant medication to treat depression in a person who has bipolar disorder may induce manic symptoms if it is taken without a mood stabilizer. In addition, using stimulant medications to treat co-occurring ADHD or ADHD-like symptoms in a child with bipolar disorder may worsen manic symptoms. While it can be hard to determine which young patients will become manic, there is a greater likelihood among children and adolescents who have a family history of bipolar disorder. If manic symptoms develop or markedly worsen during antidepressant or stimulant use, a physician should be consulted immediately, and diagnosis and treatment for bipolar disorder should be considered.

# DRAFT FOR PARENTS

## Mood Stabilizing Medications

Brand Name	Generic Name	Approved Age (children)
Cibalith-S	lithium citrate	12 and older
Depakote	divalproex sodium	2 and older (for seizures)
Eskalith	lithium carbonate	12 and older
Lamictal*	lamotrigine	16 and older (for seizures)
Lithobid	lithium carbonate	12 and older
Neurontin*	gabapentin	12 and older (for seizures)
Tegretol	carbamazepine	any age (for seizures)

\* Putative mood stabilizers

### References

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