

**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.

# 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	sertranline	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)**