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COLLECTION:
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FOLDER TITLE:
Children's Mental Health [2]

2013-0436-S
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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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

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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, antianxiety 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.

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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)

▪ *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.

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

Coyle JT, 2000. Psychotropic drug use in very young children [editorial]. *Journal of the American Medical Association, 283*: 1059-1060.

Physician's Desk Reference (PDR), 1999. Medical Economics Company, Montvale, NJ.

Zito JM, et al., 2000. Trends in the prescribing of psychotropic medications to preschoolers. *Journal of the American Medical Association, 283*: 1025-1030.

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

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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."

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Antipsychotic Medications

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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.

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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.

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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 stablizers

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Warlick, Kenneth

From: Warlick, Kenneth
Sent: Friday, March 17, 2000 2:33 PM
To: Guard, Patty
Subject: ADHD

Q: How should I work with my child's school to ensure that the teacher and other staff understand the importance of my child's treatment?

A: First you should meet and share information about your child and his/her needs with a professional staff member with whom you feel comfortable talking. This may be the principal, your child's teacher, the school nurse, a guidance counselor, social worker or school psychologist.

Each child's needs are different. The person you talk with should be able to tell you which other people in the school need to be informed and can help to arrange a meeting with those individuals if needed. In most cases the child's teacher, principal, and school nurse need to be informed. However, children who are eligible for services under IDEA or 504 should have a plan developed by their individual education program (IEP) team or 504 team.

If your child is receiving medication, be sure to ask for any policies or rules your school or district has about either the use of medication or who can administer medication.

Be sure to ask questions about how your school will monitor the effects of your child's treatment and/or medication on school performance and how they will provide you and your child's doctor information (feedback) on those effects.

Ann-

FYI

Here is a Q+A. I thought one question would cover it.

Also attached is an updated "commitment list". I have sent it to Diane Rossi to see if there is anything else she wants added.

Judy would like the NICHY phone # on any fact sheet the First Lady may hand out (see attached info on NICHY).

Patty 205-5507

Department of Education Response to ADHD/Ritalin Initiative

1. **The Department is disseminating a document for parents of children with ADHD developed recently by one of our grantees, the National Information Center for Children and Youth with Disabilities. The document is available by calling 1-800-695-0285 or accessing the NICHY web site at www.nichcy.org**

2. **The Department will update and disseminate a research based ADHD information kit for parents and teachers. We will collaborate with our partners in other agencies to incorporate relevant information from their work. We will collaborate with parent, teacher and advocacy organizations in the design of the materials to ensure that the materials will be in a usable format.**

3. **We would like to collaborate with NIMH on research that incorporates behavioral interventions as part of a comprehensive treatment approach.**

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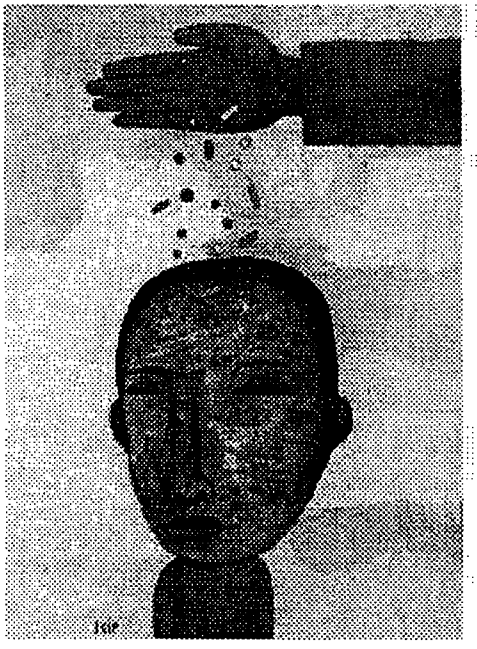

Kids on drugs

A behavioral pediatrician questions the wisdom of medicating our children.

By Lawrence H. Diller, M.D.

March 9, 2000 | I've practiced behavioral pediatrics since 1978 in Walnut Creek, Calif., an affluent suburb of San Francisco. I have evaluated and treated more than 2,000 children who struggle with behavior and performance at home or at school. Last year alone, I wrote more than 700 prescriptions for Ritalin or a similar stimulant. I am not against prescribing psychiatric medication to children.

But I've become increasingly uneasy with the role I play and the readiness of families and doctors to medicate children.

I recently obtained some information from the National Disease and Therapeutic Index of IMS Health that adds to my uneasiness about the number of children taking psychiatric drugs in the United States.

IMS Health is to drug companies what the A.C. Nielsen company is to television networks. The pharmaceutical industry relies on it to report on the latest trends in medication usage. The company recently surveyed changes in doctors' use of psychiatric drugs on children between 1995 and 1999 and found stimulant drug use is up 23 percent; the use of Prozac-like drugs for children under 18 is up 74 percent; in the 7-12 age group it's up 151 percent; for kids 6

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percent; in the 7-12 age group it's up 151 percent; for kids 6 and under it's up a surprising 580 percent. For children under 18, the use of mood stabilizers other than lithium is up 40-fold, or 4,000 percent and the use of new antipsychotic medications such as Risperdal has grown nearly 300 percent.

Approximately 5 million American children take a psychiatric drug today. Based on production/use quotas maintained by the Drug Enforcement Administration and national physician practice surveys, it's possible to say with confidence that nearly 4 million children took the stimulant drug Ritalin, or its equivalent, in 1998.

Stimulants such as Ritalin have been used for more than 60 years to treat hyperactivity and inattentiveness in children. Over the past 10 years, however, psychiatric drug use for children has broadened considerably. There are more drugs and they are being used for more purposes. Ritalin is now prescribed for children as young as 2 and 3. A recent Michigan survey of Medicaid children found a few hundred toddlers taking stimulants and other psychiatric drugs. A study released two weeks ago in the Journal of the American Medical Association confirmed this trend in children of privately insured families.

Medicines originally developed and tested to treat depression in adults, such as the well-known Prozac (now in liquid form for easy pediatric administration), Paxil and Zoloft, but also Wellbutrin, Effexor and Serzone, are now being employed for a wide range of children's behavioral problems. Medications originally developed to treat blood pressure, such as clonidine (Catapress) and its longer-acting relative, Tenex, are also being used for behavioral management.

Pierre, 8-year-old Bobby's father, pleaded with me to evaluate his son. Bobby was on three different psychiatric medications. Pierre and Bobby's mother, Carol, had bitterly divorced and had been fighting since Bobby was 2. Bobby had had problems at school since kindergarten. Teachers described him as distractible, hyperactive, slow to learn and with few friends.

But his behavior at home, especially with his mother, posed the biggest headaches. He defied Carol and flew into violent rages, hitting and trying to bite her. Time outs were ineffective because he would either escape from his room or completely trash it.

Pierre admitted that he had seen this kind of behavior from Bobby only three or four times over the past three years. But

Bobby only three or four times over the past three years. But at Carol's, Bobby had major temper tantrums at least weekly. Carol took Bobby to a child therapist when he was 4. The therapist thought Bobby might have "ADD" -- attention deficit disorder or, properly, ADHD (H for hyperactivity). She also thought he was depressed because of the divorce. Weekly play-therapy sessions for Bobby continued for three years and Carol sometimes got advice from the therapist on how to handle Bobby.

Pierre only met the therapist once. He acknowledged he'd never been a big fan of therapy and questioned its value. Carol had been a psychiatric patient for much of their 17-year marriage. She suffered from serious bouts of depression and took Prozac, the well-known antidepressant, and Ativan, a medication for anxiety much like Valium.

Bobby's pediatrician started him at age 5 on Ritalin, the best-known stimulant for ADHD, because the boy kept getting up from circle time and twice ran out of the classroom at school. Later he was switched to a very similar stimulant medication, Dexedrine. Bobby's acting out and impulsiveness continued, so Carol took him to a child psychiatrist who added the drug Wellbutrin to his regimen, thinking that Bobby's irritability might be a sign of depression. (Wellbutrin has been used primarily to treat depression in adults, but has also been employed for a variety of other problems from anorexia nervosa to stopping smoking.) The Wellbutrin did not make much of a difference and after two months was stopped.

Bobby's problem persisted. At Carol's his bedtime would begin at 8:30 and at 11 Bobby was still up, getting out of bed, pestering his mother for water or food and driving her "crazy." Another medication, Anafranil, was prescribed to help him fall asleep. (Anafranil was originally used in adult depression and obsessive-compulsive disorder, a condition of unwanted recurrent thoughts and compulsive behaviors like repetitive hand washing. But it often was too sedating for most people to tolerate.) Bobby fell asleep faster when he took this pill. Pierre, who in general had fewer problems with Bobby, only occasionally gave him this medication.

Bobby was 7 when Carol took him to a private psychiatric clinic well known for its controversial use of brain scans for psychiatric diagnosis and its liberal use of psychoactive medications. Bobby, now getting bigger, had stabbed another child with a pencil. No brain scan was done but the psychiatrist said that Bobby suffered from bipolar disorder, the current name for manic depression, and should take yet

another drug. This fifth medication, Neurontin, originally approved as an anticonvulsant, more recently had been categorized felicitously as a "mood stabilizer." The psychiatrist said this medication would help Bobby control his episodes of rage and prevent a further worsening of his symptoms.

When I first met Bobby he took Dexedrine in the morning, Neurontin three times a day and Anafranil at night only before bedtime. He took 12 pills a day when he stayed with his mother. At his father's, he usually skipped the Dexedrine and Anafranil, especially on weekends. Pierre was afraid to stop the Neurontin because he had been told that Bobby might experience headache and irritability if that medication were abruptly discontinued.

Bobby was a very unhappy, angry boy caught in a web of strained emotions and loyalties between his parents. He was not an easy child to raise, especially for his mother, who had her own problems with depression. Bobby's story is disturbing not for its uniqueness but for how it represents a growing trend in the U.S. -- young children are being given essentially untested and potentially dangerous psychotropic drugs alone and in combination in greater volume than ever before.

Diagnosing bipolar disorder in children as young as 3 has become the latest rage. It justifies using a host of meds to treat very difficult-to-manage, unhappy children. The old-line drug, lithium, has been replaced by newer, untested (in children) mood stabilizers like Neurontin or Depakote as a first-choice intervention for pediatric "manic depression." Finally, a new class of anti-psychotic medications -- the most popular these days is Risperdal -- is heralded as the ultimately effective treatment for a number of diagnoses whose common features are not hallucinations or psychosis, but severe acting-out behaviors.

No one knows precisely how many children are taking these non-stimulant medications. The most recent survey of physicians' practices had 1.5 million children taking an anti-depressant in 1996. Most were teenagers (girls are the majority), but more than 200,000 children under 12 are also prescribed an antidepressant. Other data tells us that rates of antidepressant use since 1996 continue to rise. For example, 150,000 prescriptions for clonidine were written for children in 1996. More than 100,000 children take "mood-stabilizing" drugs for purported bipolar disorder. Again, most are teens (here boys predominate) but it's being advised that children as young as 3 take these drugs. More than 200,000 children

receive anti-psychotic medications, mostly to control unruly behavior rather than to treat hallucinations or other symptoms of schizophrenia.

The number of children combining two or more psychoactive drugs is unknown. Combined pharmacotherapy (known pejoratively as polypharmacy) has been strongly endorsed by leading research groups as the sensible approach to treating the co-morbid, or multiple occurring, diagnoses common in "high problem resistant behavior" children. Some doctors call it prescribing by "symptom chasing."

No other society prescribes psychoactive medications to children the way we do. We use 80 percent of the world's stimulants such as Ritalin. Only Canada comes close to our rates, using half, per capita, the amounts we do. Europe and industrialized Asia use one-10th of what we do. Psychiatrists in those countries are perplexed and worried about trends in America. The use of psychoactive drugs other than Ritalin for preteen children is virtually unheard of outside this country.

Next page | Instead of blaming Johnny's mother, now we blame his brain and genes

Illustration by Jordin Isip

Kids on drugs | page 1, 2, 3

In my practice of behavioral pediatrics I regularly meet children under 13 on two psychiatric medications. A 5-year-old girl troubled by fears had tried eight different psychoactive drugs over the year before she saw me. I met the mother of a 29-month-old boy who wanted me to prescribe medication. I didn't, but later I learned the boy was getting lithium, Zoloft and Risperdal from another doctor.

Is this cutting-edge treatment or an outrage? I'm not sure. But with three or four exceptions, none of these drugs, alone or in combination, has been shown to be effective for a specific psychiatric condition in children. Outside of the stimulants and old-line anti-psychotic group, only two of the most frequently prescribed medications, Luvox and Zoloft, have been studied sufficiently to obtain the Food and Drug Administration's approval for psychiatric use in children. Only a handful more have been examined systematically to eliminate the placebo effect, which has a particularly powerful influence in psychiatric conditions and in children. None of the newer medications has been studied beyond a few months for efficacy or side effects, and no one has looked at their effects on children's growth and development.

Until recently the recondite and rarified worlds of academic child psychiatry and psychology have largely supported the increased use of these medications. Joseph Biederman, chief of Harvard's pediatric psychopharmacology clinic, hails the increased use of psychiatric drugs in children as evidence "that child psychiatry is finally catching up to adult psychiatry" in psychopharmacological practice.

Other leaders in the field of child psychiatry are not as sanguine. Michael Jellinek, who as the head of child psychiatry at Harvard is effectively Biederman's boss, and Peter Jensen, who recently stepped down as director of child and adolescent research of the National Institutes of Mental Health, have both publicly worried whether physicians' prescribing practices for children have outstripped their

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prescribing practices for children have outstripped their scientific substantiation. They are also concerned that not enough is being done about the world these troubled children live in.

It's Johnny's Brain: The Triumph of Biological Psychiatry in America

What makes America so different from the rest of the world in how it views and treats children's emotional and behavioral problems? Perhaps no other profession fell so completely under the sway of Freudian ideas as American psychiatry and psychology did in the first 60 years of the 20th century. Yet by the late 1960s critics both within and outside of American psychiatry had doubts about psychoanalysis as a science and as an effective treatment. In the 1950s drugs like lithium, Thorazine and Elavil, found to be useful in alleviating psychiatric symptoms, further challenged the Freudian hegemony on psychiatric thinking and practice in this country.

By the 1970s research and academic psychiatrists fomented an internal revolution culminating in 1980 with the publication of the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III). The DSM III replaced the old Freudian diagnoses, which were based on traumatic childhood experience, with etiologically neutral lists of symptoms collected into supposedly definable syndromes. DSM III was meant only to be descriptive and used primarily for research. Few outside of an inner circle of research psychiatrists knew of a paragraph in the introduction, deleted at the last moment (ostensibly to maintain etiological neutrality), that said the presumptive cause of most of the disorders listed was biological, that is, the result of heredity or a chemical imbalance.

It really didn't matter what was written, because over the next 10 years American academic psychiatry shifted 180 degrees from blaming Johnny's mother for all his problems to blaming Johnny's brain and genes.

The introduction of Prozac in the late 1980s cemented America's belief in the biological basis for abnormal behavior. Prozac was no more effective than earlier antidepressants but had less severe side effects, which allowed greater numbers of less severely disabled people to continue to take the drug. A logic developed that if a drug improved behavior, the problems must be biologically based. No one speaks of headache as an "aspirin deficiency" even though the drug relieves the symptoms. Nevertheless terms like "chemical imbalance" became increasingly fashionable in explaining problem behavior.

problem behavior.

Media exaggeration of scientific findings contributed to the revolution. The acceptance of Prozac made taking a psychotropic drug no longer taboo; it became the topic of dinner-party conversation. Nearly one in 10 Americans has taken Prozac or one of its close drug relatives. With so many adults taking a drug for mood, it didn't take long for the primary drug for children's behavior, Ritalin, to zoom in use.

Ritalin production and use for the treatment of ADHD rose by more than 700 percent between 1991 and 1998. Amphetamine production also used for ADHD initially lagged but has tripled in use since 1996. Trade amphetamine (primarily Adderall) surpassed trade Ritalin prescriptions in 1998, a testament primarily to the marketing success of the manufacturers of Adderall.

As Prozac opened the door for Ritalin use in children, Ritalin itself ushered in a new "better children through chemistry" age in our country. At least Ritalin had been the most studied of pediatric drugs, though only a handful of the thousands of studies look at patients other than boys or monitor the children beyond a couple of weeks. Meanwhile research on other psychotropic drugs for use in children has been limited. Until recently, funding for studies of psychiatric medication in children was meager by adult comparisons. Questions about children's rights and consent to participate in studies raised thorny ethical issues, and the pharmaceutical industry did not believe there was much of a market for these drugs in children and so it did not fund studies.

Ironically, the new belief in a robust market for psychotropics in children has fueled a host of pending studies of different drugs for different child psychiatric conditions.

The community of pediatric psychopharmacology researchers is rather small; Biederman's Harvard program has been arguably the most productive and influential. His work stands as prototypic of children's psychiatric research under the DSM (now in its fourth edition) and demonstrates how a drug becomes established in the pediatric psychiatric pharmacopea. His research has won awards and his professional publications are prolific.

Biederman's group demonstrated in the late 1980s that the tricyclic antidepressants (their chemical structure contains three "rings") imipramine and desipramine, abandoned as a treatment for childhood depression because studies had shown them to be ineffective, could be used in high doses to

successfully treat children with ADHD who had failed to respond to stimulants. In 1996, the Harvard clinic published a paper that said that 23 percent of their ADHD children also "had" bipolar disorder. (Most child psychiatrists believed manic depression to be a rare disorder in children.)

The Harvard group had always found higher rates of co-occurrence or "co-morbidity" of other disorders in their ADHD patients, but this rate of bipolar disease in children astonished the world of academic child psychiatry.

Biederman further claimed he could diagnose manic depression in children as young as 3. Few of these children demonstrated the classic signs of mania, euphoria or grandiosity. They did not have distinct periods of several weeks or months between their highs and lows. These children could cycle on a daily basis. They were very angry, very irritable kids.

Few of these kids were crazy. They could distinguish reality as long as they weren't enraged. They were very unhappy and very difficult to control. But Biederman felt that children diagnosed as bipolar could be saved from a lifetime of antisocial behavior and substance abuse by aggressively treating them with medication.

The presumed hereditary and biochemical nature of bipolar disorder would justify the use of a new class of drugs known as mood stabilizers: lithium, Depakote, Neurontin -- all drugs with far more serious short- and long-term side effects than Ritalin.

The response from other academic researchers was mixed. Debate goes on in the professional journals over the definition and frequency of bipolar disorder in children. One psychiatrist commented cynically that "Ritalin is for irritable and irritating children while lithium is for very irritable and very irritating children." The practical effect, though, of the announcement of this new interpretation of pediatric bipolar disorder, was that these medications began to be used in very young children without even short-term evidence of their effectiveness and safety.

Of late, the new anti-psychotic drug, Risperdal, has been touted by the Biederman group as more effective than mood stabilizers in controlling the symptoms of bipolar children. Risperdal's ascendancy as the drug of choice has not been slowed by a different set of more serious disabling side effects.

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How should drugs properly be studied for use in children? Only two of the newer psychotropic drugs have been approved by the FDA for the treatment of a psychiatric condition in children. Paxil and Luvox, both variations of Prozac, have proved effective in clinical trials required by the FDA for the treatment of pediatric obsessive compulsive disorder (OCD). No other medication, as yet, has met FDA approval. Several drug trials in children, actively supported by the pharmaceutical industry, are under way.

Once a drug is approved for use by the FDA for the treatment of a specific medical condition, a doctor can legally prescribed it "off label" for any purpose. Virtually every other med used to treat children's behavior is prescribed this way. Off-label use of medicines in pediatrics is common, but nowhere more so than in psychiatric medications. Physicians are constrained only by their own judgment and ethics. Local hospital and medical boards usually do little to interfere with doctors' preferences for treatment.

Most of the drugs used to treat children's emotional problems first became available after they met the FDA's standards for approval in psychiatric clinical trials in adults. A few were initially approved for use in adults for other medical conditions: Depakote and Neurontin for control of seizures, clonidine for blood pressure.

The typical path to the widespread use of any of these drugs for children begins with a report of a single child's response to a drug, usually as a letter in one of the professional journals. Journal editors explicitly state their openness to these kinds of "case" reports and more critical peer review scrutiny is omitted. The report will generate other letters until a series of cases are reported in which everyone -- the kids, parents and doctors -- knows what drug the child is taking.

Such studies are notorious for creating expectations of both positive and unwanted placebo effects. In the only study

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positive and unwanted placebo effects. In the only study demonstrating the effectiveness of Prozac in children when the patients and doctors didn't know which pill was taken, 60 percent of the improvement in depressive symptoms was attributed to the placebo effect.

The Super Bowl of drug testing, which supposedly can distinguish between the actual effects of the active ingredients of a medication and placebo, is called the double-blind randomized control study (DBRCS). In a DBRCS neither the family nor doctor knows whether the child is getting the medication or an identical capsule filled with an inert ingredient. Only the pharmacist who prepares the medication knows which capsule contains the drug to be tested.

Patients are carefully screened for the psychiatric condition to be treated and then are randomly selected to receive either the real drug or the placebo. The children are monitored by their parents and doctors for improvements and side effects; along with benefits coming from placebo, many children complain of unwanted effects like headache and stomachache while taking placebos. After a pre-determined period it is revealed who took the drug and who took the the placebo. Only then does one learn the "real" vs. "believed" effects of the drug.

Such DBRCS are expensive; until recently, pediatric psychopharmacology researchers have been limited by low funds for their studies. Those few DBRCSs that had been run usually included only enough children, usually fewer than 100, to generate the likelihood of a statistically significant difference between drug and placebo required for scientific journal publication, but not enough for FDA approval.

But with only scores of children assessed, drugs like Prozac, imipramine, clonidine and Wellbutrin have come to be prescribed for hundreds of thousands of children. Research with imipramine demonstrated that adult drug studies do not necessarily correspond to effects in children. Nonetheless, adult medication trials are regularly invoked to justify the use of those same agents in children.

Calls for increased funding for pediatric psychopharmacology research are ubiquitous within the child mental-health community. The pharmaceutical industry, which now sees a children's market large enough to justify the expense, is funding several large studies, hoping to obtain FDA approval for the tested drugs.

On the other hand, studies on psychosocial interventions provide no similar profit-driven initiative for investigation. The much lower funding for this kind of research comes

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The much lower funding for this kind of research comes primarily from government. However, with the profit-motive incentive to develop new drugs and the real-life pressures to medicate children these days, there is ever-increasing pressure to medicate.

When all you've got is a hammer, everything starts to look like a nail.

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Tomorrow: A view from the front lines and Bobby's story, continued

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About the writer

Dr. Lawrence H. Diller practices behavioral pediatrics in Walnut Creek, Calif. He is the author of "Running on Ritalin: A Physician Reflects on Children, Society, and Performance in a Pill."

Sound off

Send us a Letter to the Editor

Send e-mail to Lawrence H. Diller, MD

Ann,

Here is a bullet on our piece.

- Announced that the Department of Education has information for parents and teachers. There are many things parents and teachers can do to help children with ADHD. The National Information Center for Children and Youth with Disabilities, funded by the Department of Education, recently developed a fact sheet on ADHD. It includes tips for parents and teachers who work with children with ADHD. The fact sheet is available by calling 1-800-695-0285 or by accessing the web at www.nichcy.org. Information on positive behavioral supports for educators and parents of children with ADHD and other behavior and emotional problems is available at http://www.ed.gov/offices/OSERS/OSEP/links.html.

  The Department of Education will update and widely disseminate an information kit for parents and teachers with the most current research based information this Fall.

The other comments we had on the document are attached. If you want to discuss with Judy, she can be reached at home this week-end at (202) 332-5497.

Hope this helps.

Patty

IDEAs that Work
U.S. Office of Special Education Programs

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U.S. DEPARTMENT OF EDUCATION
OFFICE OF SPECIAL EDUCATION AND REHABILITATIVE SERVICES
OFFICE OF SPECIAL EDUCATION PROGRAMS
OFFICE OF THE DIRECTOR

TELEPHONE NO : (202) 205-5507 Switzer Building - Room 3086
FAX NO : (202) 260-0416 Switzer Building - Room 3090

DATE:

TO
Ann O'Leary - FAX 456-2878
1st Set 1 thru 9 then Note to Ann 10 more Total 19

FROM
Patty Guard

ED/OSEP Revisions to NIH Q&A 3/16/00

A Note to Parents

A child's aggressive or antisocial behavior can be a real concern to parents. All children act out at times, as a part of typical development. Some children, however, experience more significant behavioral problems that stand out and which may be an indicator of a more serious ~~behavioral or emotional disturbance~~ problem. A variety of treatments exist for children with mental disorders.

There has been recent public concern over reports that very young children are being prescribed psychotropic medications. Some parents are criticized for giving these 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 and teacher or caretaker.

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

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Children's Mental Health [2]

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Betty Currie

ZT-3071

Sonia G. Chessen
03/16/2000 02:04:33 PM

Record Type: Record

To: Ann O'Leary/OPD/EOP@EOP

cc:
Subject:

I just read the Parents Q and A thing quickly. My first two comments are

1. The audience - this is always a difficult line to walk, but this plays to a pretty sophisticated reader. It possibly can't be dummied down, but just a question.

2. The whole area of HOW to determine the right specialist. Pediatricians are willing to prescribe Ritalin relatively easily based on a little parent and teacher input. What the teachers are mostly commenting on is behavior. If a parent is concerned about the diagnostic end of things, where do they go? (b)(6) [redacted] So there are some clear questions about How to get a sound diagnosis, and How to know what specialist to go to and finally, How to get referred to that specialist. If you describe it well enough the pediatrician will prescribe the meds on the spot.

C0017

TREATMENT OF YOUNG CHILDREN WITH MENTAL DISORDERS

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

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. 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 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. Treatment decisions should be weighed for risks and benefits, and each child should be viewed individually.

WHEN TO GET HELP

It's important to recognize behavior changes, but also to differentiate them from signs of more serious problems. ~~Sometimes, changes in behavior that you find worrisome may be a normal~~ part of your child's development, and do not need medical attention. 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

~~If you are concerned about your child's behavior, talk to your doctor.~~ Ask questions ~~and find out everything you can about the behavior or symptoms that worry you.~~ 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. Be sure to tell your doctor about extreme symptoms, such as self-injury, impulsive or aggressive behavior, persistent sadness, 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, and behavioral therapists, 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.

Brand Name	Generic Name	Approved Age
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.

Brand Name	Generic Name	Approved Age
Anafranil	clomipramine	10 and older (OCD)
Luvox	fluovoxamine	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 children with schizophrenia, bipolar disorder, autism, Tourette's syndrome, and severe conduct disorders.

Brand Name	Generic Name	Approved Age
Haldol	Haloperiodol	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).

Brand Name	Generic Name	Approved Age
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 another 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

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.

Treatment

: What should I do if my child is diagnosed with a mental disorder
t at effects his/her early development or education?

: Children with mental disorders may be eligible for services and/or accommodations under one of two federal laws, the Individuals with Disabilities Education Act (IDEA) and Section 504 of the Rehabilitation Act. If you believe that your child has a disability, and the school district believes that your child may need special education or related services, the school district must evaluate your child. If the school district does not evaluate a child, it must notify the parents of their due process rights. According to federal law, a school is responsible for providing an educational diagnosis of a child. To determine a child's level of disability and best treatment, a multi-disciplinary team is formed that includes teachers, parents, and someone with training in child psychopathology (usually the school psychologist or school social worker).

: Which mental disorders are seen in hildren?

: Mental disorders with possible onset in hildhood include: anxiety disorders; 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.

(reordered)

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 are some strategies for treating my child's emotional or behavioral disorder, such as ADHD?

A: Children with emotional or behavioral disorders such as ADHD can learn to control some aspects of their behavior and to succeed in school and at home. When parents establish and enforce a few rules and maintain a system of rewards, children incorporate such rules into their daily routine. Remember that every child, with or without ADHD, has individual strengths and weaknesses. Once you identify your child's strengths, you can use them to build your child's self-esteem and help to provide the confidence your child needs to tackle whatever he or she finds difficult.

- Discipline can best be maintained by establishing a few consistent rules with immediate consequences whenever each rule is broken. Rules should be phrased positively in terms of what your child should do.
- Another effective strategy is to provide a specified time-out location for your child to go when he or she is out of control. This should not be seen as a place of punishment, but as a place the child uses to calm down. Younger children may need to be told to go the time-out location, but older children should learn to sense when they need to calm down and go on their own.

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.

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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. Still 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, antianxiety 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.

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

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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)

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• *Antipsychotic Medications:* These medications are used to treat children with schizophrenia, bipolar disorder, autism, Tourett'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.

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Mood Stabilizing Medications

Brand Name	Generic Name	Approved Age (children)
Citralith-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

Coyle JT. 2000. Psychotropic drug use in very young children [editorial]. *Journal of the American Medical Association, 283*: 1059-1060.

Physician's Desk Reference (PDR). 1999. Medical Economics Company. Montvale, NJ.

Zito JM, et al., 2000. Trends in the prescribing of psychotropic medications to preschoolers. *Journal of the American Medical Association, 283*: 1025-1030.

For More Information on Mental Disorders in Children, Contact:

Office of Communications and Public Liaison, NIMH
Information Resources and Inquiries Branch
6001 Executive Blvd., Room 8184, MSC 9663
Bethesda, MD 20892-9663
Phone: 301-443-4513
TTY: 301-443-8431
FAX: 301-443-4279
Mental Health FAX 4U: 301-443-5158
E-mail: nimhinfo@nih.gov
NIMH home page address: www.nimh.nih.gov

ANN,

You may also find this document helpful! It was designed for parents. It is written at a fairly low literacy level. It is also a recent publication.

We fund this center.

Lou DANIELSON

National Information Center for Children and Youth with Disabilities

NICHCY

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Washington, DC 20013
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Attention-Deficit/Hyperactivity Disorder (AD/HD)

✧ Mario's Story ✧

Mario is 10 years old. When he was 7, his family learned he had AD/HD. At the time, he was driving everyone crazy. At school, he couldn't stay in his seat or keep quiet. At home, he didn't finish his homework or his chores. He did scary things, too, like climb out of his window onto the roof and run across the street without looking.

Things are much better now. Mario was tested by a trained professional to find out what he does well and what gives him trouble. His parents and teachers came up with ways to help him at school. Mario has trouble sitting still, so now he does some of his work standing up. He's also the student who tidies up the room and washes the chalkboard. His teachers break down his lessons into several parts. Then they have him do each part one at a time. This helps Mario keep his attention on his work.

At home, things have changed, too. Now his parents know why he's so active. They are careful to praise him when he does something well. They even have a reward program to encourage good behavior. He earns "good job points" which they post on a wall chart. After earning 10 points he gets to choose something fun he'd like to do. Having a child with AD/HD is still a challenge, but things are looking better.

✧ What is AD/HD? ✧

Attention-Deficit/Hyperactivity Disorder (AD/HD) is a condition that can make it hard for a person to sit still, control behavior, and pay attention. These difficulties usually begin before the person is 7 years old. However, these behaviors may not be noticed until the child is older.

Doctors do not know just what causes AD/HD. However, researchers who study the brain are coming closer to understanding what may cause AD/HD. They believe that some people with AD/HD do not have enough of certain chemicals (called *neurotransmitters*) in their brain. These chemicals help the brain control behavior.

Parents and teachers do not cause AD/HD. Still, there are many things that both parents and teachers can do to help a child with AD/HD.

✧ How Common is AD/HD? ✧

As many as 5 out of every 100 children in school may have AD/HD. Boys are three times more likely than girls to have AD/HD.

✧ What Are the Signs of AD/HD? ✧

There are three main signs, or symptoms, of AD/HD. These are:

- problems with paying attention,
- being very active (called *hyperactivity*), and
- acting before thinking (called *impulsivity*).

More information about these symptoms is listed in a book called the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), which is published by the American Psychiatric Association (1994). Based on these symptoms, three types of AD/HD have been found:

- *inattentive* type, where the person can't seem to get focused or stay focused on a task or activity;
- *hyperactive-impulsive* type, where the person is very active and often acts without thinking; and
- *combined* type, where the person is inattentive, impulsive, and too active.

Inattentive type. Many children with AD/HD have problems paying attention. Children with the inattentive type of AD/HD often:

- do not pay close attention to details;
- can't stay focused on play or school work;

- don't follow through on instructions or finish school work or chores;
- can't seem to organize tasks and activities;
- get distracted easily; and
- lose things such as toys, school work and books. (APA, 1994, pp. 83-84)

Hyperactive-impulsive type. Being too active is probably the most visible sign of AD/HD. The hyperactive child is "always on the go." (As he or she gets older, the level of activity may go down.) These children also act before thinking (called *impulsivity*). For example, they may run across the road without looking or climb to the top of very tall trees. They may be surprised to find themselves in a dangerous situation. They may have no idea of how to get out of the situation.

Hyperactivity and impulsivity tend to go together. Children with the hyperactive-impulsive type of AD/HD often may:

- fidget and squirm;
- get out of their chairs when they're not supposed to;
- run around or climb constantly;
- have trouble playing quietly;
- talk too much;
- blurt out answers before questions have been completed;
- have trouble waiting their turn;
- interrupt others when they're talking; and
- butt in on the games others are playing (APA, 1994, p. 84)

Combined type. Children with the combined type of AD/HD have symptoms of both of the types described above. They have problems with paying attention, with hyperactivity, and with controlling their impulses.

Of course, from time to time, all children are inattentive, impulsive, and too active. With children who have AD/HD, *these behaviors are the rule, not the exception.*

These behaviors can cause a child to have real problems at home, at school, and with friends. As a result, many children with AD/HD will feel anxious, unsure of themselves, and depressed. These feelings are not symptoms of AD/HD. They come from having problems again and again at home and in school.

✧ How Do You Know ✧ If a Child Has AD/HD?

When a child shows signs of AD/HD, he or she needs to be evaluated by a trained professional. This person may work for the school system or may be a professional in private practice. A complete evaluation is the only way to know for sure if the child has AD/HD. It is also important to:

- rule out other reasons for the child's behavior, and
- find out if the child has other disabilities along with AD/HD.

✧ What About Treatment? ✧

There is no quick treatment for AD/HD. However, the symptoms of AD/HD can be managed. It's important that the child's family and teachers:

- find out more about AD/HD;
- learn how to help the child manage his or her behavior;
- create an educational program that fits the child's individual needs; and
- provide medication, if parents and the doctor feel this would help the child.

✧ What About School? ✧

School can be hard for children with AD/HD. Success in school often means being able to pay attention and control behavior and impulse. These are the areas where children with AD/HD have trouble.

There are many ways the school can help students with AD/HD. Some students may be eligible to receive special education services under the Individuals with Disabilities Education Act (IDEA). Under the newest amendments to IDEA, passed in 1997, AD/HD is specifically mentioned

continued on page 4

Tips for Parents

- ☐ Learn about AD/HD. The more you know, the more you can help yourself and your child. See the list of resources and organizations at the end of this publication.
- ☐ Praise your child when he or she does well. Build your child's abilities. Talk about and encourage his or her strengths and talents.
- ☐ Be clear, be consistent, be positive. Set clear rules for your child. Tell your child what he or she *should* do, not just what he shouldn't do. Be clear about what will happen if your child does not follow the rules. Have a reward program for good behavior. Praise your child when he or she shows the behaviors you like.
- ☐ Learn about strategies for managing your child's behavior. These include valuable techniques such as: charting, having a reward program, ignoring behaviors, natural consequences, logical consequences, and time-out. Using these strategies will lead to more positive behaviors and cut down on problem behaviors. You can read about these techniques in many books. See "Resources" on page 4 of this publication.
- ☐ Talk with your doctor about whether medication will help your child.
- ☐ Pay attention to your child's mental health (and your own!). Be open to counseling. It can help you deal with the challenges of raising a child with AD/HD. It can help your child deal with frustration, feel better about himself or herself, and learn more about social skills.
- ☐ Talk to other parents whose children have AD/HD. Parents can share practical advice and emotional support. Call NICHCY to find out how to find parent groups near you.
- ☐ Meet with the school and develop an educational plan to address your child's needs. Both you and your child's teachers should get a written copy of this plan.
- ☐ Keep in touch with your child's teacher. Tell the teacher how your child is doing at home. Ask how your child is doing in school. Offer support.

Tips for Teachers

- ☐ Learn more about AD/HD. The resources and organizations at the end of this publication will help you identify behavior support strategies and effective ways to support the student educationally. We've listed some strategies below.
- ☐ Figure out what specific things are hard for the student. For example, one student with AD/HD may have trouble starting a task, while another may have trouble ending one task and starting the next. Each student needs different help.
- ☐ Post rules, schedules, and assignments. Clear rules and routines will help a student with AD/HD. Have set times for specific tasks. Call attention to changes in the schedule.
- ☐ Show the student how to use an assignment book and a daily schedule. Also teach study skills and learning strategies, and reinforce these regularly.
- ☐ Help the student channel his or her physical activity (e.g., let the student do some work standing up or at the board). Provide regularly scheduled breaks.
- ☐ Make sure directions are given step by step, and that the student is following the directions. Give directions both verbally and in writing. Many students with AD/HD also benefit from doing the steps as separate tasks.
- ☐ Let the student do work on a computer.
- ☐ Work together with the student's parents to create and implement an educational plan tailored to meet the student's needs. Regularly share information about how the student is doing at home and at school.
- ☐ Have high expectations for the student, but be willing to try new ways of doing things. Be patient. Maximize the student's chances for success.

under the category of "Other Health Impairment" (OHI). We've included the IDEA's definition of OHI in the box to the right. Other students will not be eligible for services under IDEA. However, they may be eligible for services under a different law, Section 504 of the Rehabilitation Act of 1973. In both cases, the school and the child's parents need to meet and talk about what special help the student needs.

Most students with AD/HD are helped by supports or changes in the classroom (called *adaptations*). Some common changes that help students with AD/HD are listed in the "Tips for Teachers" box on page 3. More information about helpful strategies can be found in NICHCY's publication called *Attention-Deficit/Hyperactivity Disorder*. The resources listed below will also help families and teachers learn more about ways to help children with AD/HD.

IDEA's Definition of "Other Health Impairment"

Many students with ADHD now may qualify for special education services under the "Other Health Impairment" category within the Individuals with Disabilities Education Act (IDEA). IDEA defines "other health impairment" as...

"...having limited strength, vitality or alertness, including a heightened alertness to environmental stimuli, that results in limited alertness with respect to the educational environment, that is due to chronic or acute health problems such as asthma, attention deficit disorder or attention deficit hyperactivity disorder, diabetes, epilepsy, a heart condition, hemophilia, lead poisoning, leukemia, nephritis, rheumatic fever, and sickle cell anemia; and adversely affects a child's educational performance."

34 *Code of Federal Regulations* §300.7(c)(9)

✧ Resources ✧

Alexander-Roberts, C. (1994). *ADHD parenting handbook: Practical advice for parents from parents: Proven techniques for raising a hyperactive child without losing your temper.* Dallas, TX: Taylor Publishing. [Telephone: 1-800-677-2800.]

Barkley, R. (1995). *Taking charge of AD/HD.* New York: Guilford Press. [Telephone: 1-800-365-7006.]

Dendy, S.A. Z. (1995). *Teenagers with ADD: A parents' guide.* Bethesda, MD: Woodbine House. [Telephone: 1-800-843-7323.]

Fowler, M. (1994). Attention-deficit/hyperactivity disorder. *NICHCY Briefing Paper,* 1-16. [Telephone: 1-800-695-0285. Also available on NICHCY's Web site: www.nichcy.org]

Fowler, M. (1999). *Maybe you know my kid: A parent's guide to identifying, understanding, and helping your child with ADHD* (3rd ed.). New York: Birch Lane Press. [Telephone: 1-800-447-2665.]

Fowler, M. (1992). *CH.A.D.D. educators manual: An in-depth look at attention deficit disorders from an educational perspective.* Plantation, FL: CH.A.D.D. [Telephone: 1-800-233-4050.]

Wodrich, D.L. (1994). *Attention deficit hyperactivity disorder: What every parent wants to know.* Baltimore, MD: Paul H. Brookes. [Telephone: 1-800-638-3775.]

✧ Organizations ✧

CH.A.D.D. (Children and Adults with Attention-Deficit/Hyperactivity Disorder)
8181 Professional Place, Suite 201
Landover, MD 20785
(301) 306-7070
(800) 233-4050
E-mail: national@chadd.org
Web: www.chadd.org

National Attention Deficit Disorder Association
P.O. Box 1303
Northbrook, IL 60065-1303
E-Mail: mail@add.org
Web: www.add.org

FS19, August 1999

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HILLARY CLINTON

On Your Side: Working Hard for Available and Affordable Prescription Drugs
February, 2000

Fighting the Pharmaceutical Industry for Fairness in Drug Pricing. Hillary Clinton has a long history of fighting for available and affordable prescription drugs both to prevent diseases and to ensure the best treatment for illnesses. Over the past seven years, Hillary Clinton has continually pushed pharmaceutical companies to lower drug prices for all and fought hardest for those most in need – women, children, and seniors. Hillary Clinton is continuing her work today by fighting for lower-priced prescription drugs for seniors.

Meeting the Needs of Children. As a part of her work fighting for quality, affordable health care for children, Hillary Clinton secured funding to provide vaccines for uninsured and under-insured children and won pediatric labeling on prescription drugs.

- **Worked to Raise Child Immunization Rates to All Time High.** Hillary Clinton has worked hard to address the need for affordability and available children's vaccines. Once, during her travels throughout the country, Hillary met a woman from Vermont who ran a dairy farm with her husband who was required by law to immunize her cattle against disease, but could not afford to give her pre-school children inoculations as well. Struck by this example and many others, Hillary Clinton launched the Childhood Immunization Initiative and helped secure passage of the Vaccines for Children program designed to provide free vaccine to uninsured and under-insured children, starting in October 1994. Today, the Vaccines for Children program is going strong, with all 50 states participating in the program. Enrollment of private providers into the Vaccines for Children Program has almost doubled since the beginning of the program in October 1994. Over 31,000 private provider sites (which may include multiple providers per site) and approximately 12,000 public clinics are enrolled in the program. Additionally, childhood immunization coverage rates in 1998 were the highest ever recorded. 90 percent of toddlers in 1996, 1997 and 1998 received the most critical doses of each of the routinely recommended vaccines, surpassing the Administration's 1993 goal.

- **Promoting Regulation that Drug Companies Provide Adequate Testing for Children.** Hillary Clinton has long recognized the difficulties many parents face providing the right drugs, and the right dosage, to their children. She knew that most drugs – even those commonly used by children – had not been widely tested on pediatric populations, and that drugs are likely to have a different impact on children. In 1992, Hillary Clinton met Elizabeth Glaser and heard of her struggle with AIDS and her child's struggle with the same deadly disease. Hillary was struck by Elizabeth Glaser's story – that while she could receive appropriate prescription drugs, her child was not able to receive the same benefits. Prescription drugs were not being tested on children and the FDA had no way of knowing which prescription drugs were most effective for kids and in which dosages. With this story and may others, Hillary Clinton began to fight for appropriate testing and labeling of prescription and over-the-counter drugs for children. In early 1997, Hillary sat down with head of the Food and Drug Administration, David Kessler, to develop a strategy for making this happen. As a result, in 1997 the President directed an important Food and Drug Administration regulation requiring manufacturers to do studies on pediatric populations for new prescription drugs – and those currently on the market – to ensure that prescription drugs are adequately tested for the unique needs of children. This regulation also requires proper labeling of drugs for use by children.

TO: Judy & Patty

-PM86-

260-0416

Devorah R. Adler
03/17/2000 11:11:17 AM

Record Type: Record

To: Ann O'Leary/OPD/EOP@EOP

cc:

Subject:

Please give me comments.

DRAFT: FIRST LADY HILLARY RODHAM CLINTON LAUNCHES NEW FEDERAL EFFORT TO ENSURE SAFE USE OF PSYCHOTROPIC MEDICATION IN CHILDREN
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 that children with emotional and behavioral conditions are appropriately diagnosed, treated, monitored, and managed by qualified professionals. 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 psychotropic 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, pharmacalogical, and behavioral interventions now available.

In order to provide the information necessary to improve diagnosis, treatment, and management practices to both parents and providers, the First Lady will announce new Federal action, including: the release of a new, easy to understand fact sheet about treatment of children with mental disorders for parents; a new 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; the initiation of a process at FDA to improve pediatric labeling information for children under the age of seven; and a national conference hosted by the Surgeon General, NIMH, and the Food and Drug Administration (FDA) on Treatment of Children with Behavioral and Mental Disorders to take place this fall. She will also praise private sector efforts to improve diagnosis and treatment protocols for young children under the age of six.

IMPROVING TREATMENT THERAPIES FOR YOUNG CHILDREN WITH BEHAVIORAL AND MENTAL DISORDERS. New regulatory authority for pediatric labeling as well as new financial incentives included in PDUFA have significantly 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,

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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. However, recent research indicates that more needs to be learned about young children with emotional and behavioral disorders. Recent studies published in the *Journal of the American Medical Association* reviewing selected provider data found that:

- **The number of children aged two through four taking stimulants such as Ritalin more than doubled.** Ninety percent of preschoolers on medication were on Ritalin or a similar stimulant in order to treat attention deficit disorders, and the number of these children increased 169 percent over a five year period. Although there is a 4:1 ratio in the number of boys to girls taking medications for ADHD, 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 Ritalin or a similar stimulant increased by 60 percent.

- **The number of children under the age of five on clonidine tripled.** The increase in children using clonidine, used to treat insomnia in children with attention deficit disorders, is notable as the increase in its use has occurred without research to ensure that it is a safe and effective treatment. Adverse effects, including rapid or irregular heartbeat and fainting, have been reported in children using the drug together with other medications for attention-deficit disorder. The increased use of the drug since 1991 helps explain the increase in clonidine poisoning in children.

- **Many children are inappropriately treated.** Studies indicate wide geographic variation in the numbers of children receiving psychotropic drugs such as Ritalin. One study indicated that in some suburban areas, as many as 40 percent of children were on Ritalin, as opposed to less than X percent of children in urban areas. *[need NIMH cite].* Other research indicates racial variations as well; a study of one Maryland HMO indicated that as 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.

- **Failure to treat emotional and behavioral disorders has severe life-long consequences.** Studies suggest that that many children with untreated emotional and behavioral disorders fail to reach their full potential. Brain damage causing lifelong psychologic or social damage may stem from an on-going cycle of punishment and ostracism for behaviors that the child cannot control without help. 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.

- **More research is necessary to ensure informed treatment decisions.** Many of the drugs being used by very young children have not been tested in children under the age of 16; none have been tested for children under the age of six. More research is necessary to ensure

that providers and parents have the information they need, especially information about the impact of medication on brain development, to make appropriate treatment decisions.

NEW FEDERAL EFFORT TO ENSURE THE SAFE AND EFFECTIVE USE OF PSYCHOTROPIC DRUGS IN YOUNG CHILDREN. Today, First Lady Hillary Rodham Clinton launched a new Federal effort to ensure that providers and parents have the information they need to make appropriate treatment decisions for children with behavioral and mental disorders. This multi-faceted effort includes:

- **New efforts to provide parents with up-to-date information on the appropriate treatment of children with mental disorders.** This week, the National Institute of Mental Health will release a new fact sheet to help parents of children with mental disorders make the right decisions about their child's treatment. This fact sheet includes easy to understand information on the inclusion of medication in an overall treatment plan; how to help determine if a child's problems are serious; and how to get help. Upon release, this fact sheet will be distributed to X providers nationwide.

- **Initiate a process for the development of additional pediatric labeling requirements for psychotropic drugs used in children.** Today, FDA will announce that it will work with its Pediatric Advisory Commission 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 commonly used in children. These studies, which will be based on national research goals, will be designed to address the ethical issues associated with the study of these drugs in this vulnerable population.

- **Announced that NIMH will dedicate $X million in a landmark study to determine the impact of the use of medication for behavioral and emotional conditions in young children.** Today, the National Institute of Mental Health announced that within the next X months, it would invest $X million in research to determine the efficacy of medications used to treat behavioral and emotional conditions in very young children. This research, conducted in concert with FDA, will assemble the latest information on the use of these drugs, determine safety and efficacy, and identify discrepancies between clinical practice and scientific evidence.

- **A national Conference on the Treatment of Children with Behavioral and Mental Disorders.** This summer, the Office of the Surgeon General will coordinate a Federal Conference on Treatment of Children with Behavioral and Mental Disorders. This national conference, which will build on the success of the recent White House Conference on Mental Health hosted by Tipper Gore, will include representatives of the provider, research, consumer advocacy, and education communities. Topics of discussion include: developing a research strategy that can be used to develop interventions that can be used by providers nationwide; how best to ethically determine the efficacy and safety of medications in young children; and

strategies to address the difficulty of accurate diagnosis in preschoolers.

NEW PRIVATE SECTOR COMMITMENT TO ENSURING APPROPRIATE DIAGNOSIS OF EMOTIONAL AND BEHAVIORAL DISORDERS IN YOUNG CHILDREN. Today, the First Lady will praise the American Academy of Pediatrics (AAP) for their new commitment to release diagnosis and treatment protocols that focus on children under the age of six with emotional and behavioral disorders. Upon their completion in *[insert date]* this important information will be distributed to all X members of the AAP.

FIRST LADY HILLARY ROHDAM CLINTON'S LONGSTANDING COMMITMENT TO CHILDREN. In 1997, the First Lady was a strong advocate for appropriate pediatric labeling for parents and health care professionals. In addition, the First Lady championed the passage of the Better Pharmaceuticals for Children Act, enacted in 1997 as part of the FDA Modernization Act, that provides additional financial incentives for companies to conduct these studies. The number of studies to determine the safety of specific drugs in children conducted in 18 months since the passage of this legislation is ten times higher than the number of studies conducted in the five years before the Act's passage.

Saturday, Mar. 18 - Sunday, Mar. 26	Travel to India, Bangladesh, and Pakistan
Saturday, Mar. 25	Radio Address (taped on Fri. 3/24) Topic: TBD
Monday, Mar. 27	No Message Event
Tuesday, Mar. 28	Press Conference with President Mubarak
Wednesday, Mar. 29	Possible Digital Divide Event Location: TBD
Thursday, Mar. 30	Message Opportunity, Possible Topic: Hate Crimes Location: TBD, New York
Friday, Mar. 31	No Message Event
Saturday, Apr. 1	Radio Address (taped Fri. 3/31)

IDEAs that Work
U.S. Office of Special Education Programs

FAX

U.S. DEPARTMENT OF EDUCATION
OFFICE OF SPECIAL EDUCATION AND REHABILITATIVE SERVICES
OFFICE OF SPECIAL EDUCATION PROGRAMS
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DATE:

TO
Ann O'Leary - FAX 456-2878

FROM
Patty Guard

PHOTOCOPY PRESERVATION

Department of Education Response to ADHD/Ritalin Initiative

1. **The Department will update and disseminate a research based ADHD information kit for parents and teachers. We will collaborate with our partners in other agencies to incorporate relevant information from their work. We will collaborate with parent, teacher and advocacy organizations in the design of the materials to ensure that the materials will be in a usable format.**

2. **We would like to collaborate with NIMH on research that incorporates behavioral interventions as part of a comprehensive treatment approach.**