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The Scary Truth About Stock Options

U.S.News & WORLD REPORT

MARCH 6, 2000

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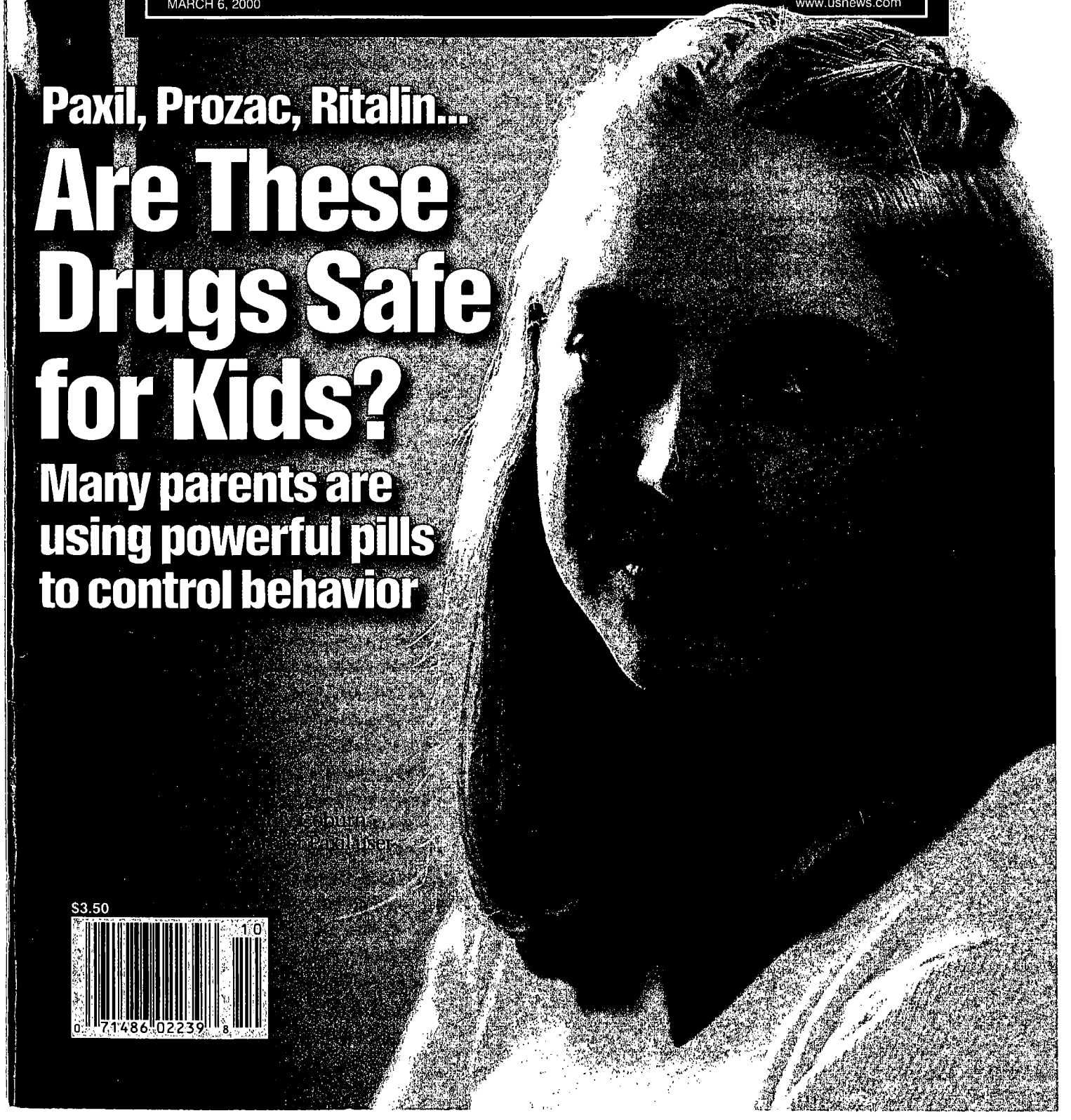

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A Weak Case, but a Brave Prosecution

By Stephen Gillers

Those who wanted a conviction of the four police officers in the Amadou Diallo case are now looking for someone to blame for the acquittals. It can't be the jury, which had four black members and conscientiously deliberated for 14 hours across three days. It can't be the judge, who by all accounts ran a fair courtroom. So that leaves the prosecution. Finger pointing and second guessing have already begun.

But it is wrong to blame the Bronx district attorney, Robert T. Johnson.

The state faced an enormous burden: not only did the prosecution have to prove guilt beyond a reasonable doubt, but it also had to disprove the justification defense by convincing the jury that the officers had no reason to fear danger.

With the only witnesses to the event the officers themselves and a neighbor who heard the word "gun," that challenge was formidable. And the charge that the prosecutors erred in not humanizing Mr. Diallo fails to grasp that this evidence would have been irrelevant. The state's accusation did not depend on whether Mr. Diallo was a saint or a sinner. He was entitled to the protection of the law regardless of his character.

Indeed, the idea that the prosecution should have been more aggressive begs the question — aggressive with what? It had little direct evidence, and the four officers were consistent in their testimony and credible in their demeanor.

> Criticisms after the Diallo verdict are unfounded.

If Mr. Johnson had a difficult case — as he surely knew he did — then why go to trial at all? A courtroom loss, even if predictable, does not mean the case should not have been brought. And it does not mean the trial will have no value.

To be sure, it would have been improper for the prosecutor to seek an indictment if he lacked evidence to convict or believed that the defendants were innocent. But once Mr. Johnson concluded (as he could have) that the facts could support conviction, he was free to weigh other interests in deciding whether to indict — like the public benefit of airing the facts in open court.

Too often that opportunity is lost. The ritual is familiar. A police officer shoots someone. He claims that the victim seemed dangerous or that he appeared to have a weapon. The victim's friends and family challenge the officer's story. The community calls for justice. The district attorney, pledging a full and fair investigation, appeals for calm. Some months later, a press release reports that the case was presented to a grand jury, which refused to indict.

We saw this happen in November in the case of Gidone Busch, the Brooklyn man killed by police bullets while allegedly wielding a hammer. Two years ago, a Queens grand jury refused to indict a federal marshal who shot a teenager after mistaking a foil-wrapped candy bar for a gun.

What did the grand jury process in these two cases tell us about our criminal justice system? Practically nothing. The identities of the grand jurors were secret. The evidence they heard was secret. The prosecutors' arguments to the grand jurors were secret. Did they imply that they would be happy for the cases to go away? We will never know.

Mr. Johnson did not follow this script in the Diallo case. Because we had a trial, and because the trial was televised, the public could see the evidence firsthand and watch how its criminal justice system performed. Mr. Johnson lost, but the beauty of a public trial is that it educates us, whatever the result.

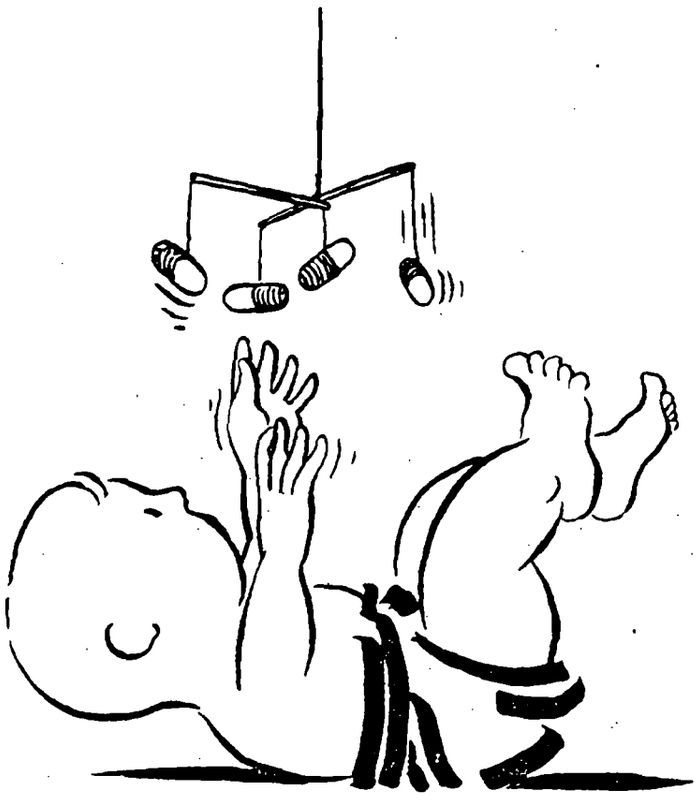
In the Diallo case, we learned that the Police Department appears to have mismanaged its responsibility to New Yorkers, to Mr. Diallo and perhaps even to the four defendants. Why were officers without much experience working together assigned to the same street crimes unit? Why did the unit's senior member have only several months of experience? And most important, why didn't the department teach its officers how to handle suspicious situations without resorting so rapidly and irrevocably to the use of deadly force?

These questions lack satisfactory answers even after the verdict, but Mr. Johnson's willingness to bring and lose a hard case guaranteed that they would at least be debated. Those who are now quick to criticize should think again about how their words may deter other prosecutors from taking the same chance. □

The New York Times
WEDNESDAY, MARCH 1, 2000

The Role For Pills in Preschool

By Harold S. Koplewicz



Matthew Martin

The outcry over a recent report showing a dramatic increase in the use of medications like Ritalin for preschoolers reminded me of a patient of mine named Christopher.

In the early 1980's, when I was researching the efficacy of Ritalin in young children, Christopher was 3½. He still slept in a crib to discourage his getting up in the middle of the night and wandering around the house. It didn't work: he often escaped, going to the kitchen and playing with the stove. Babysitters came only once. Nursery schools kept him for just a few days.

We observed Christopher and his mother in our clinic. She kept running after him to catch his attention; he played with 61 toys in one five-minute span. Then we put Christopher on Ritalin. In his mother's words: "He became a different child. He will sit and let me read a book to him. I can take him to a puppet show. We now can enjoy each other."

Christopher is now 20, a high school graduate who describes himself as well adjusted and happy. He also still takes Ritalin twice a day.

I guess I shouldn't be surprised that attention deficit hyperactivity disorder is still so frequently dismissed as childhood exuberance or "just a phase." Most adults do not realize how it differs from behavior that is simply on the active end of normal. Children with the disorder are 10 times as likely as the average child to drop out of high school. They have a higher incidence of drug abuse. This is a real psychiatric disorder and requires treatment.

The latest study, published in the Journal of the American Medical Association, found that between 1991 and 1995, there was a twofold to threefold increase in the use of Ritalin and similar drugs in children aged 2 to 4. About 1 in 100 children received Ritalin in 1995. Is 1 percent of children taking such medications too high?

Unfortunately, we have no information about the percentage of very young children who meet the criteria for an accurate diagnosis of A.D.H.D. For those who do, medications like Ritalin are the best treatment we have.

When a diagnosis calls for it, Ritalin can be a godsend.

Understandably, there is concern that medications may affect brain development. Encouragingly, the evidence we have, although limited and crude, does not suggest that development is compromised by Ritalin.

Critics are also concerned that some medications for psychiatric illness are prescribed for preschoolers without approval by the Food and Drug Administration for use in that age group. But this practice holds true in other areas of medical care. One asthma medication, for example, is frequently given to young kids even though the F.D.A. has not approved it for children. There is ample evidence of Ritalin's effectiveness for school-aged children with A.D.H.D., and some evidence that it helps younger children.

What should be at issue is not the clinical wisdom of giving Ritalin to young children, but who gives it and how the decision is made. Unfortunately, pediatricians and general practitioners are usually not trained to undertake the necessary clinical evaluations to make psychiatric diagnoses and monitor treatment.

Increasing use of Ritalin is not necessarily cause for alarm. The real outrage is that an estimated 20 percent of the nearly 10 million American children and teenagers who suffer from diagnosable psychiatric illnesses ever receive help. □

Harold S. Koplewicz, a physician, is the author of "It's Nobody's Fault: New Hope and Help for Difficult Children and Their Parents."

The New York Times
WEDNESDAY, MARCH 1, 2000

March 18, 2000

MEETING ON THE SAFE USE OF MEDICATION FOR YOUNG CHILDREN WITH EMOTIONAL AND BEHAVIORAL CONDITIONS

Date:	**Monday, March 20, 2000**
Time:	**10:00 AM – 11:00 AM**
Location:	**Map Room, Roosevelt Room**
From:	**Ann O'Leary, Heather Howard and Ruby Shamir**

I. PURPOSE

To demonstrate your commitment to children's health by convening health and education experts to discuss the appropriate treatment of young children with emotional and behavioral conditions with a particular focus on the use of medication in treatment.

II. BACKGROUND

Overview

This event focuses on the controversy surrounding the recent increase in the prescription of stimulants and antidepressants to preschoolers despite a lack of information about the safety and efficacy of these drugs for young children.

While progress has been made in diagnosing and treating children with emotional and behavioral conditions, justifiable concerns have been raised about the inappropriate over- and under-utilization of medications such as Ritalin, clonidine, and antidepressants in the very young. Just as important, there is a lack of understanding among parents, teachers and health professionals about the best diagnostic, pharmacological, and behavioral interventions now available.

Several themes have emerged from our discussions with health professionals: 1) parents need more information on how to deal with children who are experiencing behavior changes – signs to look for, how to get help, when and what medication is appropriate; 2) the importance of proper diagnosis, and the collaboration between parents, educators, and mental health professionals that is necessary for such a diagnosis; 3) when psychotropic drugs may be appropriate, in combination with other therapies, and 4) the importance of careful monitoring and management of treatment.

At the event, along with Secretary Shalala and representatives of parents and a broad range of health and education professionals, you will announce a public-private effort to develop strategies to ensure that children with emotional and behavioral conditions are appropriately diagnosed, treated, monitored, and managed by qualified professionals.

Policy Deliverables

1. *Information for Parents*: One major theme of the event will be the importance of giving parents the information they need to help insure their children receive appropriate care. To that end, NIMH has developed an easy to understand Q&A fact sheet on treating children with mental and behavioral conditions. This fact sheet will be available on the Internet, and the groups participating in the event have agreed to distribute the fact sheet through their membership. In addition, the Department of Education will commit to distributing an information kit to parents and teachers on strategies for the many things that can do to help children with ADHD.

2. *Announcement of Federal Conference on the Treatment of Children with Behavioral and Mental Disorders*: The Surgeon General will coordinate a conference with HHS, FDA, the Department of Education and representatives of the provider, research, consumer advocacy, and education communities. Topics of discussion will include: developing a research strategy 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.

3. *NIMH Research*: NIMH will announce that it is dedicating $X 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.

4. *Additional Pediatric Labeling Efforts*: 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 (generic name for Ritalin), clonidine, and other drugs commonly used in children. These studies will be designed to address the ethical issues associated with the study of these drugs in this vulnerable population.

5. *Private Sector Efforts*: You will praise private sector efforts to improve diagnosis and treatment protocols for young children under the age of six.

JAMA Report

On February 23, 2000, JAMA published a report, "Trends in the Prescribing of Psychotropic Medications to Preschoolers," which found that the prescription of psychotropic medications for preschoolers increased dramatically between 1991 and 1995. Attached please find the abstract from this report. There were numerous press reports on this issue in response to the study; several are attached.

The studies published in JAMA, 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 to treat attention deficit disorders, and the number of these children increased 169 percent over the five-year period.

- In this five-year period, the number of children under the age of five on clonidine, which is used to treat insomnia in children with attention deficit disorders, tripled.
- *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. Other research indicates racial variations as well: a study of one Maryland HMO indicated that African-Americans children were 2.5 times less likely to receive Ritalin as white children. This wide variation in treatment patterns supports the need for more research to determine appropriate treatment protocols for children with behavioral disorders.
- *Failure to treat emotional and behavioral disorders has severe life-long consequences.* Studies suggest that many children with untreated emotional and behavioral disorders fail to reach their full potential. Brain damage causing lifelong psychological 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 in their life than those without behavioral problems. Accurate, early diagnosis, with education, support, and if necessary and appropriate, medication, can overcome many early problems and help prevent long-term negative behavior.
- *More research is necessary to ensure informed treatment decisions.* Many drugs of the being prescribed to 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.

In December, the Surgeon General published the first-ever Surgeon General's Report on Mental Health, stemming from the White House Conference on Mental Health led last June by Tipper Gore. Several important messages on children and mental health came out of the conference and subsequent report: 1) children are not just small adults – their brains are very different and are continually developing, and thus what we know about the impact of medication on adults does not necessarily translate to children; 2) there is a lack of training among pediatricians and family practitioners about how to handle mental health issues in children; 3) the stigma of mental illness is often worse for children than adults; and 4) it is important to raise public awareness of the mental health problems children face.

Success of Pediatric Labeling Efforts

In 1997, you led efforts to improve the safety of pediatric drugs, championing the passage of the Better Pharmaceuticals for Children Act, enacted as part of the FDA Modernization Act. The new law provides financial incentives for pharmaceutical companies to conduct studies on the effects of their medications on children. The new financial incentives for companies, as well as new regulatory authority for pediatric labeling, 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, 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. In contrast, in the five years preceding the legislation, only 11 studies to gather additional safety information about drugs already on the market were conducted. Of course, much more still needs to be learned about young children with emotional and behavioral disorders.

III. PARTICIPANTS

Open Press Session
Secretary Shalala
Surgeon General Satcher
NIMH Director Dr. Steve Hyman
FDA Commissioner Dr. Jane Henney

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

IV. SEQUENCE OF EVENTS

The event will have two parts: closed strategy meeting in the Map Room, and then press announcement in the Roosevelt Room.

9:30- 10:30 am	**STRATEGY MEETING** Map Room
10:00am	**THE FIRST LADY** will arrive in the Map Room
10:02- 10:20am	Each group will have 2 minutes to present their accomplishments
10:20- 10:35am	**THE FIRST LADY** will do a photo receiving line with group leaders.

10:35am	Group leaders will be escorted to the Roosevelt Room
10:37am	**THE FIRST LADY** proceeds to the Roosevelt Room joined by Shalala
10:40-10:57am	**ANNOUNCEMENTS** • Secretary Shalala will introduce the issue and you, highlighting your leadership. • You will speak for approximately five minutes.
10:58am	**THE FIRST LADY** departs

V. PRESS PLAN

- Open Press for the opening session, closed for strategy session.

VI. REMARKS

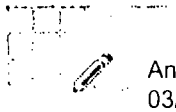
- Provided by Laura Schiller

ATTACHMENTS

- Press articles
- JAMA abstracts

To be provided with talking points:

- Press paper and NIMH Fact Sheet/Q&As for parents



Ann O'Leary
03/18/2000 08:26:37 AM

Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP

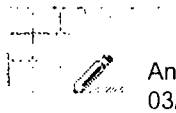
cc: Ruby Shamir/OPD/EOP@EOP, Heather H. Howard/OPD/EOP@EOP
Subject: Re:

Devorah -

I'm sorry for my disorganization. My parents flew in from Maine yesterday and it has been a bit hectic. I have serveral more suggestions below in red. Could you please page me when you have a final draft and also let me know when we are getting to the press? Thanks much.

-Ann

---------- Forwarded by Ann O'Leary/OPD/EOP on 03/18/2000 08:14 AM ----------



Ann O'Leary
03/17/2000 06:29:01 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: Ruby Shamir/OPD/EOP@EOP
bcc: Records Management@EOP
Subject: Re:

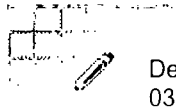
Devorah -

See comments in **BOLD** throughout.

Page me if you need me. I'll send you more info. shortly.

-Ann

Devorah R. Adler



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

Record Type: Record

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

cc:
Subject:

DRAFT: FIRST LADY HILLARY RODHAM CLINTON LAUNCHES NEW FEDERAL EFFORT TO ENSURE [THE APPROPRIATE TREATMENT OF CHILDREN WITH EMOTIONAL AND BEHAVIORAL DIFFICULTIES] ~~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 and educationprofessionals, launched ~~an unprecedented~~ **(GIVEN MEG'S EFFORTS I WOULD CUT -- which we should praise upfront)** 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, **caregivers,** providers,**and** ~~teachers~~ **educators,** 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), **and the U.S. Department of Education** on Treatment of Children with Behavioral and Mental Disorders to take place this fall**; and a pledge from the U.S. Department of Education to distribute information kits to parents and teachers on Attention Deficit Hyperacivity Disoder (ADHA)**. She will also praise private sector efforts to improve diagnosis and treatment protocols for young children under the age of six **(do we have any specifics?)**.

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 **(spell out)**, 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, 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 **(is this problem widespread -- I'm afraid it could scare people)**.

- **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.

(I THINK IT IS IMPORTANT TO ADD THAT MEDICATION CAN HELP CHILDREN WITH SEVERE EMOTIONAL AND BEHAVIORAL DISORDERS)

- **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 [WITH BEHAVORIAL AND EMOTIONAL PROBLEMS]. 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 **[WILL GROUPS DISTRIBUTE??]**. In addition, the Department of Education will soon release a research based information kit on the many things for parents and teachers can do to help children with ADHD.

- **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 **very young**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~~ will** 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; presenting research based strategies for parents and teachers of children with behavioral and emotional difficulties; 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.

- ~~**Information for parents and teachers on ADHD. (NEED TO ADD INFO)**~~ **instead move up to section with NIMH**

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.

First Lady Hillary Rodham Clinton

Meeting on the Safe Use of Medications for Young

Children with Emotional and Behavioral Conditions

March 20, 2000

List of Attendees

MaryLee Allen, Director, Child Welfare & Mental Health Division, Children's Defense Fund

Lanny R. Copeland, MD, Chairman of the Board, American Academy of Family Physicians

Gail Daniels, President, Board of Directors, Federation of Families for Children's Mental Health

Kevin P. Dwyer, MA, NCSP, President, National Association of School Psychologists

Michael M. Faenza, MSSW, President & CEO, National Mental Health Association

Randy A. Fisher, President, School Social Work Association of America

Mary E. Foley, MS, RN, President, American Nurses Association

Gregory A. Humphrey, Special Assistant to the President, American Federation of Teachers

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Trends in the Prescribing of Psychotropic Medications to Preschoolers

Julie Magno Zito, PhD; Daniel J. Safer, MD; Susan dosReis, PhD; James F. Gardner, ScM; Myde Boles, PhD; Frances Lynch, PhD

Context Recent reports on the use of psychotropic medications for preschool-aged children with behavioral and emotional disorders warrant further examination of trends in the type and extent of drug therapy and sociodemographic correlates.

Objectives To determine the prevalence of psychotropic medication use in preschool-aged youths and to show utilization trends across a 5-year span.

Design Ambulatory care prescription records from 2 state Medicaid programs and a salaried group-model health maintenance organization (HMO) were used to perform a population-based analysis of three 1-year cross-sectional data sets (for the years 1991, 1993, and 1995).

Setting and Participants From 1991 to 1995, the number of enrollees aged 2 through 4 years in a Midwestern state Medicaid (MWM) program ranged from 146,369 to 158,060; in a mid-Atlantic state Medicaid (MAM) program, from 34,842 to 54,237; and in an HMO setting in the Northwest, from 19,107 to 19,322.

Main Outcome Measures Total, age-specific, and gender-specific utilization prevalences per 1000 enrollees for 3 major psychotropic drug classes (stimulants, antidepressants, and neuroleptics) and 2 leading psychotherapeutic medications (methylphenidate and clonidine); rates of increased use of these drugs from 1991 to 1995, compared across the 3 sites.

Results The 1995 rank order of total prevalence in preschoolers (per 1000) in the MWM program was: stimulants (12.3), 90% of which represents methylphenidate (11.1); antidepressants (3.2); clonidine (2.3); and neuroleptics (0.9). A similar rank order was observed for the MAM program, while the HMO had nearly 3 times more clonidine than antidepressant use (1.9 vs 0.7). Sizable increases in prevalence were noted between 1991 and 1995 across the 3 sites for clonidine, stimulants, and antidepressants, while neuroleptic use increased only slightly. Methylphenidate prevalence in 2 through 4-year-olds increased at each site: MWM, 3-fold; MAM, 1.7-fold; and HMO, 3.1-fold. Decreases occurred in the relative proportions of previously dominant psychotherapeutic agents in the stimulant and antidepressant classes, while increases occurred for newer, less established agents.

Conclusions In all 3 data sources, psychotropic medications prescribed for preschoolers increased dramatically between 1991 and 1995. The predominance of medications with off-label

(unlabeled) indications calls for prospective community-based, multidimensional outcome studies.

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The prevalence of psychotropic medication treatment for children and adolescents with emotional and behavioral disorders has significantly increased in the United States during the last few decades, particularly in the last 15 years. Specifically, the 5 through 14-year-old age group has experienced a great increase in stimulant treatment for attention-deficit/hyperactivity disorder (ADHD), and the 15 through 19-year-old age group has had sizable increases in the use of antidepressant medications.[1,2]

Approved and unapproved indications for psychotropic medications in young children are not extensive. These include: short-term use of analgesics and sedatives/hypnotics for pain relief; hydroxyzine for situational anxiety associated with medical, presurgical, and dental procedures; tricyclic antidepressants for nocturnal enuresis (6-year-olds and older); and amphetamines for ADHD in those 3 years old and older.[3] Accordingly, the prevalence of psychotropic medication treatment for children younger than 5 years old has not received much professional attention until recently.[4-6]

Concern about this age group relates to off-label (unlabeled) use, ie, for treatment indications with little or no proven efficacy and lacking product package insert labeling information approved by the US Food and Drug Administration (FDA).[7] One psychiatric newsletter, citing FDA-compiled marketing data, reported that 3000 prescriptions for fluoxetine hydrochloride were written for children aged younger than 1 year in 1994.[8] In a 1998 professional meeting report,[5] pediatric researchers noted that 57% of 223 Michigan Medicaid enrollees aged younger than 4 years with a diagnosis of ADHD received at least 1 psychotropic medication to treat this condition during a 15-month period in 1995-1996. Of the treatments, methylphenidate and clonidine were prescribed most often.

Although the use of psychotropic medication in preschool-aged children compared with older youths is relatively small, the reports cited argue for additional assessment to more systematically estimate its use. Consequently, 3 large, computerized data sources were used to estimate total, age-specific, and gender-specific psychotropic medication prevalence for 2 through 4-year-olds; to compare prevalence in the youngest age group with that in older children and adolescents; and to show utilization trends in the 5-year span from 1991-1995.

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Data Sources

Three large data sets were assembled from 2 types of health care systems. The first 2 are outpatient data sets from 2 geographically distinct Medicaid populations, 1 in a Midwestern state and 1 in a mid-Atlantic state. The third set of data comes from a group-model health maintenance organization (HMO) serving a predominantly employed population in the northwest region of the United States

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employed population in the northwest region of the United States. The total enrollments for those younger than age 20 years in 1991 and 1995, respectively, are as follows: Midwestern Medicaid (MWM), 669,164 and 687,722; mid-Atlantic Medicaid (MAM), 165,502 and 248,466; and group-model HMO (HMO), 131,038 and 131,860. These populations included both continuous and noncontinuous enrollees for each study year. The Medicaid youth populations were almost entirely eligible under Aid to Families with Dependent Children, and a small proportion qualified because of disability status (Supplemental Security Income) or foster care status. Nonwhites were overrepresented in the Medicaid populations and were underrepresented among HMO enrollees according to general statistical profiles of the settings.[9]

Study Measures

Psychotropic medication prevalence was defined for each study year as the frequency of persons with 1 or more HMO pharmacy records or Medicaid prescription claims for a psychotropic medication class, subclass, or specific medication per 1000 enrolled youths. Time trends were assessed across the 5-year span with data from 3 cross-sectional annual analyses (1991, 1993, and 1995).

For age-specific prevalence, children were grouped into 4 age strata (aged 2-4, 5-9, 10-14, and 15-19 years) according to US census categories. Data analyses focused on children aged 2 through 4 years. We were unable to investigate psychotropic medication use in infants 1 year old or younger in the 2 Medicaid populations because year of birth is recorded in a 2-digit field. Thus, "95" could refer to someone born in 1895 or 1995. We were unable, therefore, to distinguish those 1 year old and younger from 100- and 101-year-olds. We do present data on methylphenidate use in infants 1 year old or younger from the HMO program, as 4-digit years of birth were available. From 1991-1995, the number of enrollees aged 2 through 4 years ranged from 146,369 to 158,060 in the MWM program; from 34,842 to 54,237 in the MAM program, and from 19,107 to 19,322 in the HMO.

A separate analysis was performed to examine medication use among preschool-aged children by year of age. Gender-specific prevalence provided separate prevalence rates for boys and for girls.

Psychotropic Medications

Three psychotropic medication classes were examined: stimulants (methylphenidate, other stimulants), antidepressants (selective serotonin reuptake inhibitors [SSRIs], tricyclic antidepressants [TCAs], and other antidepressants), and neuroleptics. Selection was based on the frequent use of stimulants and antidepressants and the public health significance of the use of neuroleptics in the very young. In addition, 2 specific medications (methylphenidate and clonidine) were examined because their use alone or as a combined treatment has increased substantially since the early 1990s. All the drugs were identified using a data dictionary encompassing the national drug codes for each of the 3 study years. The study was given an exempt classification by the institutional review board–expedited review.

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Total Psychotropic Medication Prevalence

The rank order of psychotropic medication prevalence in 1995 for the MWM program shows that, per 1000 enrollees, stimulants (12.3) were the leading treatment among those 2 through 4 years old, followed by antidepressants (3.2), clonidine (2.3), and neuroleptics (0.9) (Table 1). Within classes, methylphenidate prevalence (11.1 per 1000 enrollees) represented 90% of the stimulant treatment, while TCA prevalence (2.4 per 1000 enrollees) led the antidepressant class. A similar ranking of medication prevalence in 1995 was observed for the MAM program, while preschool-aged children in the HMO had nearly 3 times more clonidine use than antidepressant use (Table 1).

Pronounced differences in psychotropic prevalence across the 3 sites are apparent from Table 1. Stimulant and antidepressant use in 1995 was considerably less among preschoolers in the MAM program and HMO than among those in the MWM program. Enrollees in the MWM program and in the HMO led in the use of clonidine, whereas its use in the MAM program was one-half to two-thirds that of the other sites. Neuroleptic use per 1000 enrollees in either Medicaid program (0.9 in the MWM program, and 0.5 in the MAM program) was more common than in the HMO (0.2).

Time Trends in Psychotropic Medication Prevalence Across a 5-Year Span

The rate of psychotropic medication prescribed for preschoolers in the MWM program increased substantially from 1991-1995. The increase was greatest for clonidine (28.2-fold), stimulants (3.0-fold), and antidepressants (2.2-fold). By contrast, neuroleptic use did not increase substantially during this time. Comparisons of psychotropic medication between sites showed that trends were similar in all 3 sites, with minor deviations for neuroleptics and antidepressants in the population enrolled in the HMO (Table 1). Specifically, the methylphenidate prevalence increase by site was: MWM, 3-fold; MAM, 1.7-fold; and HMO, 3.1-fold. Increases were more dramatic when the base prevalence was low. For example, methylphenidate use in the HMO was the lowest of the 3 sites, but its rise from 1.3 per 1000 enrollees in 1991 to 4.0 per 1000 in 1995 represented the largest methylphenidate increase (3.1-fold) across the 3 sites (Table 1).

Age-Specific Methylphenidate Medication Prevalence

Methylphenidate use according to age group in children and adolescents in the MWM program was most prominent for those aged 5 through 14 years (Figure 1). By comparison, children 2 through 4 years old were treated at approximately one tenth the rate of their 5 through 14-year-old counterparts. The time trend analysis revealed that those in all 4 age groups experienced increases in the use of methylphenidate during the 5-year period. The largest methylphenidate increase (311%) was among 15 through 19-year-olds, whereas the 2 through 4-year-olds, like the 5- through 14-year-olds, had a smaller but still substantial increase (169% to 176%). The increase in prevalence within the preschool-aged group was greater for older children in the MWM program (from 6.9 to 20.8 per 1000 4-year-olds vs 1.1 to 3.5 per 1000 2-year-olds). The age-specific trends by year of age for those in the MAM program and HMO were consistent with those in the MWM program (Figure

1). There was no methylphenidate use in infants 1 year old or younger in the HMO population.

Gender-Specific Methylphenidate Medication Prevalence

There was a greater proportional increase in preschool-aged girls receiving methylphenidate from 1991 through 1995; in the HMO, the male-to-female ratio decreased from 7:1 to 4:1 during this time. A similar but less dramatic trend was evident in the MAM program (4:1 in 1991 to 3:1 in 1995). By contrast, the gender ratio for methylphenidate treatment in the MWM program was stable over these years (3:1 in 1991 and in 1995).

Changes in Drug Utilization and Off-Label Use

Changes in the use of older agents with a well-established efficacy profile were observed. For example, despite a general increase in total stimulant use, methylphenidate use in the MAM program decreased proportionally by 7% from 1991 to 1995, while the use of other stimulant medications rose from 15% to 27% of total stimulant use among preschoolers. In all 3 sites, TCAs were the mainstay of the antidepressant category in 1991, and their prevalence remained relatively stable through 1995. By contrast, the use of SSRI antidepressants increased dramatically at the Medicaid sites, although by 1995 these drugs comprised only a small proportion of antidepressants used in the HMO (Figure 2). Thus, antidepressant use increased, particularly through off-label use, in the preschool-aged group.

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Several prominent trends characterized the use of psychotropic medications in preschoolers during the early to mid 1990s. Overall, there were large increases for all study medications (except the neuroleptics) and considerable variation according to gender, age, geographic region, and health care system. These findings are remarkable in light of the limited knowledge base that underlies psychotropic medication use in very young children.[10] Controlled clinical studies to evaluate the efficacy and safety of psychotropic medications for preschoolers are rare.[3] Efficacy data are essentially lacking for clonidine and the SSRIs and methylphenidate's adverse effects for preschool children are more pronounced than for older youths.[11] Consequently, the vast majority of psychotropic medications prescribed for preschoolers are being used off-label.[7] Specific study findings are discussed below according to 3 major outcomes: prevalence findings for specific medications; age- and gender-specific data; and geographic and health care system variations.

Prevalence Findings

Stimulant treatment in preschoolers increased approximately 3-fold during the early 1990s. The prominence of stimulant and clonidine use is consistent with Michigan Medicaid use patterns for children younger than 4 years with an ADHD diagnosis.[5] The data show greater US methylphenidate prevalence for children younger than age 5 years than was reported in a prevalence study in Western

Australia (0.26% to 0.64% vs approximately 0.1%).[1c] Hypothesized reasons for the overall increased stimulant use include: (1) a larger pool of eligible youths because of expanded diagnostic criteria for ADHD since 1980[13]; (2) more girls being treated for ADHD as evidenced by the narrowing of the gender ratio even among preschoolers; (3) greater acceptance of biological treatments for a behavioral disorder; and (4) the expanded role of school and preschool health personnel in identifying medical needs.[14]

Methylphenidate accounted for the vast majority of stimulant use (eg, 90% of the 1995 stimulant use in the MWM program). There was a modest but consistent decrease in the proportion of methylphenidate use relative to other stimulants across the 3 time periods. Generalizing from the efficacy and adverse effect experience of stimulants in older youths to preschoolers is often not valid,[11] at least partly because of preschoolers' developmental immaturity.

Clonidine had the most dramatic increases, although its use in 1995 was only 15% to 35% of the prevalence rate of stimulants. Clonidine use is particularly notable because its increased prescribing is occurring without the benefit of rigorous data to support it as a safe and effective treatment for attentional disorders. Cardiovascular adverse effects including bradycardia, atrioventricular block, and syncope with exercise have been reported in children treated with clonidine in combination with other medications for the treatment of ADHD and its comorbidities.[15, 16] Problems with abrupt withdrawal producing noradrenergic overdrive have been reported. Its use to combat the insomnia associated either with ADHD itself or secondary to the stimulant treatment of ADHD is new and largely uncharted,[17, 18] and its increased use for ADHD since 1991 helps explain the increased clonidine poisonings in children taking either their own medications or that of siblings.[19, 20]

The combined use of clonidine and methylphenidate has been associated with questions of safety[16, 21] and has been debated.[22] Unfortunately, the present data do not distinguish single vs concomitant medication use, information vital to understanding how these agents are being used in children. Such an analysis is better undertaken in a continuously enrolled cohort so that censored data do not create artifactual findings. We are currently conducting a continuously enrolled retrospective cohort study.

Antidepressants were the second most commonly prescribed psychotropic class of drugs for preschoolers, and their use increased substantially from 1991-1995. Tricyclic antidepressants still represent the bulk of early childhood antidepressant use, although the growth in use of SSRIs was strong in those enrolled in both Medicaid programs but very modest in those in the HMO. The proportional decrease in use of TCAs was largely explained by the recent increase in use of SSRIs, a trend we have previously shown for older youths[2] and one that has been documented in adults.[23] The use of TCAs for enuresis is common among 5 through 13-year-olds,[24] but its use in the preschool group is puzzling. It is also likely that some use of imipramine and desipramine was related to the treatment of ADHD in preschoolers.[25]

Neuroleptic use was infrequent and relatively stable across the study period. The neuroleptic prevalence rate in this preschool data showed rates one-tenth to one-half the annual prevalence among 5 through 19-year-olds in Rome from 1986 through 1991.[26] Both the neuroleptic and antidepressant findings bring new information on

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population-based prevalence and provide some benchmarks to chart the use of these agents in ambulatory settings. Additional clinical interpretation, however, awaits prospective outcome studies.

Age- and Gender-Specific Prevalence Findings

Preschoolers' use of methylphenidate showed increases similar to those of 5 through 14-year-olds, suggesting that the expanded use of this medication for attentional disorders in US youths extends even to the very young. It is notable that the largest gains in use occurred among high school–aged students (15 through 19-year-olds), a trend that has been documented from county school survey data.[13]

Geographic and Health Care System Variations

Disparities in psychotropic medication prevalence data between the 2 state Medicaid program populations are provocative and suggest numerous hypotheses. These include differences between the states in (1) policies for eligibility or access to continuing care; (2) the proportion of individuals with emotional or mental disorders that may be related to the proportion of youths receiving Supplemental Security Income and foster care in each state; (3) preschool health assessment and referral programs; (4) physician specialty training, particularly among psychiatrists and primary care providers, with resultant referral or practice differences; (5) the cultural values that underlie families' decisions to accept or reject medication for behavioral or mental disorders; and (6) racial/ethnic population differences that may affect cultural orientations and beliefs. Also notable is the finding that the HMO prevalence rates, collectively, were substantially lower than those of the Medicaid programs. In this instance, geography and clinical population factors confound the prevalence findings related to HMO vs Medicaid systems. The presence of less severely disabled youths in the HMO population is likely to explain a large part of the differences, but geographic and patient cultural factors need to be considered as well. Also, the rapid expansion of Supplemental Security Income benefits since 1990 resulted in more youths with ADHD being eligible for Medicaid coverage than in previous years.[27]

Limitations

The study is limited in several ways. First, the findings may be generalizable to comparable Medicaid programs and to group-model HMO enrollees, but the extent to which they may apply to other treatment settings is unknown. Second, the cross-sectional nature of the data from the 3 study years do not permit a follow-up of the natural course of treatment. Until a continuously enrolled cohort is assembled, descriptive data on the natural course of treatment and prescription changes over time cannot be adequately assessed. However, noncontinuously enrolled individuals make up the bulk of the Medicaid membership. Thus, capturing these annual data snapshots of both noncontinuous and continuous enrollees is useful for clinical description. Third, no diagnostic codes were linked to the medications in this analysis, thus limiting information about why certain medications were selected. Fourth, computerized data sources use a limited number of variables to describe the clinical patterns in the usual practice settings. However, they have the advantage of describing the usual practice setting without the artificiality and the interference that prospective studies impose on physicians' decisions about medication and patients' decisions about treatment. Compared with data from specialty clinic samples, data from community treatment settings provide a far more accurate

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from community treatment settings provide a far more accurate assessment of medication practices, therapy variations, and treatment. Adding outcome assessments would allow the effectiveness of the treatments to be evaluated.

Clinical Research Recommendations

Because children's responses to medications are not necessarily similar to those of adults, systematic and careful outcome research specifically needs to be done for them.[7] Two types of studies would help provide more systematic information on psychotropic drug therapy in children. First, epidemiologic (naturalistic) studies could describe youth treatment in major medical settings (eg, traditional preferred provider organizations, Medicaid, salaried medical group-model HMOs, and other managed care organizations) to document types of treatments, diagnosis, severity, and time in treatment and to evaluate clinical outcomes. Outcome measures could include symptom control; social, day care, and preschool functioning; parent satisfaction; reasons for initiation and discontinuation; and adverse drug events.[28] Second, randomized, double-blind, controlled clinical trials are needed for off-label indications to evaluate dosages, efficacy, and safety of single and multiple agents shown to be commonly used or widely recommended. For disorders that occur very infrequently or questionable combinations of drug therapy with unknown risks, a case registry approach may be useful.

Future studies using large databases for clinical descriptive information should require that the year of birth be stored as a 4-digit number to avoid misclassification of elders as youths. Finally, youths in Medicaid programs should be subdivided by type of eligibility (eg, low income [formerly Aid to Families with Dependent Children, now called Temporary Assistance for Needy Families], Supplemental Security Income, or foster care) so that the total treatment prevalence, which includes children with known disabilities and major social stressors, will not be unfairly compared with that of less impaired youths in non-Medicaid populations.[27]

Unresolved questions involve the long-term safety of psychotropic medications, particularly in light of earlier ages of initiation and longer durations of treatment. While it is reassuring that anecdotal reports have rarely documented these problems, the possibility of adverse effects on the developing brain cannot be ruled out.[29] Active surveillance mechanisms for ascertaining subtle changes that the developing personality may undergo as a result of a psychotropic drug's impact on brain neurotransmitters should be developed.

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REFERENCES

1.
Safer DJ, Zito JM, Fine EM.
Increased methylphenidate usage for attention deficit disorder in the 1990s.
Pediatrics.
1996;98(6 pt 1):1084-1088.
MEDLINE

2.
Zito JM, dosReis S, Safer DJ, Gardner J.
Trends in psychotropic prescriptions for youths with Medicaid insurance from a midwestern state: 1987-1995.
Paper presented at: New Clinical Drug Evaluation Unit Meeting; June 1998; Boca Raton, Fla.

3.
Greenhill LL.
The use of psychotropic medication in preschoolers: indications, safety, and efficacy.
Can J Psychiatry.
1998;43:576-581.
MEDLINE

4.
Minde K.
The use of psychotropic medication in preschoolers: some recent developments.
Can J Psychiatry.
1998;43:571-575.
MEDLINE

5.
Rappley MD, Gardiner JC, Mullan PB, Wang J, Alvarez FJ.
Psychotropic medications in children ages 1 to 3 with ADHD.
Paper presented at: Pediatric Academic Societies Meeting (Joint Specialties and Themes: Behavioral Pediatrics); May 4, 1998; New Orleans, La.

6.
Pathiyal A, Miwa LJ, Sverdiov LS, Gardner E, Jones JK.
Patterns of methylphenidate use.
Paper presented at: American Society for Clinical Pharmacology and

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Therapeutics; March 31, 1998; New Orleans, La.

7.
Vitiello B, Jensen PS.
Medication development and testing in children and adolescents: current problems, future directions.
Arch Gen Psychiatry.
1997;54:871-876.
MEDLINE

8.
Grinfeld MJ.
Psychoactive medications and kids: new initiatives launched.
Psychiatric Times.
1998;15:69.

9.
Zito JM, Safer DJ, Riddle MA, Johnson RE, Speedie SM, Fox M.
Prevalence variations in psychotropic treatment of children.
J Child Adolesc Psychopharmacol.
1998;8:99-105.
MEDLINE

10.
Jensen PS, Vitiello B, Leonard H, Laughren TP.
Child and adolescent psychopharmacology: expanding the research base.
Psychopharmacol Bull.
1994;30:3-8.
MEDLINE

11.
Firestone P, Musten LM, Pisterman S, Mercer J, Bennett S.
Short-term side effects of stimulant medication are increased in preschool children with attention-deficit/hyperactivity disorder: a double-blind placebo-controlled study.
J Child Adolesc Psychopharmacol.
1998;8:13-25.
MEDLINE

12.
Valentine J, Zubrick S, Sly P.
National trends in the use of stimulant medication for attention deficit hyperactivity disorder.
J Paediatr Child Health.
1996;32:223-227.
MEDLINE

13.
Safer DJ, Zito JM.
Pharmacoepidemiology of methylphenidate and other stimulants for the treatment of ADHD.
In: Greenhill LL, Osman BB, eds. *Ritalin: Theory and Practice.* 2nd ed. Larchmont, NY: MA Liebert Publishers; 2000:7-26.

14.
Davilla RR, Williams ML, MacDonald JT.
Clarification of policy to address the needs of children with attention deficit hyperactivity disorders within general and/or special education.
Memorandum from: US Dept of Education. Washington, DC: US Dept of Education, Office of Special Education; September 16, 1991.

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15.
Cantwell DP, Swanson J, Connor DF.
Case study: adverse response to clonidine.
J Am Acad Child Adolesc Psychiatry.
1997;36:539-544.
MEDLINE

16.
Swanson JM, Flockhart DA, Udrea D, Cantwell DP, Connor DF, Williams L.
Clonidine in the treatment of ADHD: questions about safety and efficacy [letter].
J Child Adolesc Psychopharmacol.
1995;5:301-304.

17.
Prince JB, Wilens TE, Biederman J, Spencer TJ, Wozniak JR.
Clonidine for sleep disturbances associated with attention-deficit hyperactivity disorder: a systematic chart review of 62 cases.
J Am Acad Child Adolesc Psychiatry.
1996;35:599-605.
MEDLINE

18.
Ahmann PA, Waltonen SJ, Olson KA, Theye FW, Van Erem AJ, LaPlant RJ.
Placebo-controlled evaluation of Ritalin side effects.
Pediatrics.
1993;91:1101-1106.
MEDLINE

19.
Erickson SJ, Duncan A.
Clonidine poisoning—an emerging problem: epidemiology, clinical features, management and preventive strategies.
J Paediatr Child Health.
1998;34:280-282.
MEDLINE

20.
Kappagoda C, Schell DN, Hanson RM, Hutchins P.
Clonidine overdose in childhood: implications of increased prescribing.
J Paediatr Child Health.
1998;34:508-512.
MEDLINE

21.
Popper CW.
Combining methylphenidate and clonidine: pharmacologic questions and news reports about sudden death.
J Child Adolesc Psychopharmacol.
1995;5:157-166.

22.
Wilens TE, Spencer TJ, Swanson JM, Connor DF, Cantwell D.
Combining methylphenidate and clonidine: a clinically sound medication option vs. ill-advised.
J Am Acad Child Adolesc Psychiatry.
1999;38:614-619.
MEDLINE

23.
Pinous HA, Tanielian TL, Marcus SC, et al

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Pincus HA, Tanielian TL, Marcus SC, et al.
Prescribing trends in psychotropic medications: primary care, psychiatry, and other medical specialties.
JAMA.
1998;279:526-531.
MEDLINE

24.
Foxman B, Valdez RB, Brook RH.
Childhood enuresis: prevalence, perceived impact, and prescribed treatments.
Pediatrics.
1986;77:482-487.
MEDLINE

25.
Geller B, Reising D, Leonard HL, Riddle MA, Walsh BT.
Critical review of tricyclic antidepressant use in children and adolescents.
J Am Acad Child Adolesc Psychiatry.
1999;38:513-516.
MEDLINE

26.
Traversa G, Spila-Alegiani S, Arpino C, Ferrara M.
Prescription of neuroleptics for children and adults in Italy.
J Child Adolesc Psychopharmacol.
1998;8:175-180.
MEDLINE

27.
Perrin JM, Kuhlthau K, McLaughlin TJ, Ettner SL, Gortmaker SL.
Changing patterns of conditions among children receiving Supplemental Security Income disability benefits.
Arch Pediatr Adolesc Med.
1999;153:80-84.
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28.
Hoagwood K, Jensen PS, Petti T, Burns BJ.
Outcomes of mental health care for children and adolescents, I: a comprehensive conceptual model.
J Am Acad Child Adolesc Psychiatry.
1996;35:1055-1063.
MEDLINE

29.
Vitiello B.
Pediatric psychopharmacology and the interaction between drugs and the developing brain.
Can J Psychiatry.
1998;43:582-584.
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Design Ambulatory care prescription records from 2 state Medicaid programs and a salaried group-model health maintenance organization (HMO) were used to perform a population-based analysis of three 1-year cross-sectional data sets (for the years 1991, 1993, and 1995).

Setting and Participants From 1991 to 1995, the number of enrollees aged 2 through 4 years in a Midwestern state Medicaid (MWM) program ranged from 146,369 to 158,060; in a mid-Atlantic state Medicaid (MAM) program, from 34,842 to 54,237; and in an HMO setting in the Northwest, from 19,107 to 19,322.

Main Outcome Measures Total, age-specific, and gender-specific utilization prevalences per 1000 enrollees for 3 major psychotropic drug classes (stimulants, antidepressants, and neuroleptics) and 2 leading psychotherapeutic medications (methylphenidate and clonidine); rates of increased use of these drugs from 1991 to 1995, compared across the 3 sites.

Results The 1995 rank order of total prevalence in preschoolers (per 1000) in the MWM program was: stimulants (12.3), 90% of which represents methylphenidate (11.1); antidepressants (3.2); clonidine (2.3); and neuroleptics (0.9). A similar rank order was observed for the MAM program, while the HMO had nearly 3 times more clonidine than antidepressant use (1.9 vs 0.7). Sizable increases in prevalence were noted between 1991 and 1995 across the 3 sites for clonidine, stimulants, and antidepressants, while neuroleptic use increased only slightly. Methylphenidate prevalence in 2 through 4-year-olds increased at each site: MWM, 3-fold; MAM, 1.7-fold; and HMO, 3.1-fold. Decreases occurred in the relative proportions of previously dominant psychotherapeutic agents in the stimulant and antidepressant classes, while increases occurred for newer, less established agents.

Conclusions In all 3 data sources, psychotropic medications prescribed for preschoolers increased dramatically between 1991 and 1995. The predominance of medications with off-label

(unlabeled) indications calls for prospective community-based, multidimensional outcome studies.

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1. How can I be sure that my child is accurately diagnosed? Isn't it difficult to diagnose a mental disorder in very young children?

2. What criteria or methodology are used to make these diagnoses in very young children?

3. What types of providers should I take my child to?

4. Won't my child just grow out of this?

5. Are there types of ~~normal~~ typical behavior in children under the age of 7 that are sometimes misinterpreted to be abnormal? Is this different for girls? For boys?

6. What are the consequences of not treating my child for their disorder?

QUESTIONS ON MEDICATIONS

1. How do I know if my child needs medication?

2. What happens if my child is overmedicated?

3. What happens if my child is undermedicated?

4. When appropriately prescribed, what are the common dosage levels by age groups?

5. Should my child take medication only when she is in school? Or should she take it for all waking hours?

6. Is it a good idea to give my child a break from their medication every once in a while?

7. Even when appropriately prescribed, are there any health risks associated with the use of psychotropic drugs in children?

8. Does it make a difference if a medication is specifically approved for use in children? Does that increase the risks associated with the use of the drug?

9. Is there anything my child shouldn't do while he is on this type of medication?

QUESTIONS ON TREATMENT

1. What are examples of non-medical interventions that help children?

2. Do therapies or other types of treatments work? How effective are they as compared to medications?

3. Are these therapies ever used by themselves? Do they always have to be used together with medications?

4. What types of providers specialize in these therapies and treatments?

5. What does a behavioral therapist do?

6. What does a family counselor do?

7. What does a social worker do?

HRC – Outline of Remarks

- Have fought hard to ensure that any prescription drug used by children is appropriately tested and labeled – in 1997, the Administration won the first part of this battle when FDA put forward a regulation requiring manufactures to do studies on pediatric populations for prescription drugs to ensure that they are adequately tested for the unique needs of children and that they are properly labeled for use by children
- In the past several weeks, the Journal of the American Medical Association reported that the number of 2-4 year old children on Ritalin, antidepressants and other psychotropic drugs increased dramatically from 1991-1995 and that there was a lack of information about the use of these drugs in very young children
- This report spurred a flurry of articles about the overall use of psychiatric drugs in children of all ages
- I am here today with Secretary Shalala, Surgeon General Satcher, Director of FDA Jane Haney, Director of NIMH Dr. Steve Hyman, and representatives from the Education Department to begin to lay out a strategy for further examining the use of psychiatric drugs in young children and a strategy for making sure parents, teachers, pediatricians, and family practitioners have good information on the overall treatment of children with mental disorders, and specifically information on the appropriate use of psychiatric drugs for children
- Also in the audience – [need list of groups]
- In December, the Surgeon General came out with the first-ever Surgeon General's Report on Mental Illness stemming from the White House Conference on Mental Illness led by Tipper Gore, the President's Mental Health Advisor
- Several important messages on children and mental health came out of the conference and the subsequent report – (1) kids are not little adults – their brains are very different and are continually developing (2) lack of training of pediatricians and family practitioners about mental health issues for children (3) not dedicating nearly enough funding for the research of child mental health (4) stigma is often worse for children (5) the importance of raising public awareness
- SG will be exploring this issue further and is expected to come out with a supplemental report on children and mental illness in the future
- Today, I am pleased to announce that I have gathered this group together to take immediate action and hold a strategy session on next steps
- NIMH

Andy Rotherham
03/09/2000 09:38:34 AM

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Subject: fyi on kids and meds

from Salon.com

Kids on drugs

A behavioral pediatrician questions the wisdom of medicating our children.

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BY LAWRENCE H. DILLER, M.D.

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 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 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.

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 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.

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.

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 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 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.
salon.com | March 9, 2000

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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."

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SHOW: WORLD NEWS TONIGHT (6:30 PM ET)

February 22, 2000, Tuesday

TYPE: Profile

LENGTH: 450 words

HEADLINE: MORE RITALIN PRESCRIBED TO CHILDREN AGED TWO TO FOUR

ANCHORS: PETER JENNINGS

REPORTERS: JOHN McKENZIE

PETER JENNINGS, anchor:

There is a study in tomorrow's issue of the Journal of the American Medical Association which finds a significant rise in the use of prescription stimulants and anti-depressants among the young. With the growing aware of mental illness that shouldn't come as a great surprise, until you hear that these new users are approximately ages two through four. The biggest increase is in the use of Ritalin. Here is ABC's John McKenzie.

JOHN McKENZIE reporting:

(VO) Ritalin is used to treat attention deficit hyperactivity disorder. The study found that between 1991 and 1995, Ritalin prescriptions for preschoolers jumped by as much as 300 percent, to as many as one out of every 100 children between the ages of two and four.

Dr. JOSEPH COYLE (Harvard Medical School): The use of medications in this age group clearly appears to be inappropriate when used at--on such a widespread basis.

McKENZIE: (VO) Dr. Joseph Coyle, head of the Harvard psychiatry department, says there are extreme cases where Ritalin is appropriate for preschoolers. But he says this rapid increase in the number of prescriptions raises a number of troubling questions. For example, are these children getting proper diagnosis? The typical symptoms of attention deficit hyperactivity can easily be misleading in preschoolers.

Dr. LAWRENCE GREENHILL (Columbia University): High levels of impulsivity, hyperactivity and inattention can be found from time to time in normal three-year-olds. And this makes it more difficult.

McKENZIE: (VO) Even if the diagnosis is correct, is Ritalin the proper treatment? Many doctors are enthusiastic about Ritalin because it can be so effective in treating older children. But in younger children, there have been only a few studies with mixed results. While it is not illegal to prescribe Ritalin to preschoolers, the warning label clearly states, " Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established" and safety is of particular concern. From birth to four years of age, the brain is undergoing dynamic, unparalleled development. And no one knows the long-term impact of starting on Ritalin this early.

Dr. GREENHILL: The earlier you introduce these psychiatric drugs, in the treatment of a very young child, the more you may influence the development of motor skills, language skills and personality.

McKENZIE: Some researchers say this study is further evidence that when it comes to very young children and psychiatric disorders, many doctors may be too quick to diagnose, and too willing to prescribe medications. John McKenzie, ABC News, New York.

February 23, 2000, Wednesday, CITY EDITION

SECTION: FRONT, Pg. 1A

LENGTH: 836 words

HEADLINE: Prescriptions for Prozac, Ritalin rising sharply for preschoolers; study finds doctors are giving the drugs despite little knowledge of the effects on children so young.

BYLINE: SUSAN OKIE The Washington Post

Doctors are prescribing stimulants like Ritalin and antidepressants like Prozac for preschoolers at rates that are rising rapidly, according to a new study released Tuesday.

The study, which examined the use of such medicines in children between ages of 2 and 4 in three large health systems in different parts of the United States, found the use of such drugs had doubled or even tripled between 1991 and 1995.

The rapid increase in the use of these drugs in such young children occurred despite the fact that none of the most-commonly used drugs has been approved for children under 6 and little research has been done on the medicines' effects on children so young.

"The knowledge base that we have to support the effectiveness and safety of these medicines in preschool-age children is certainly insufficient," said Julie Magno Zito of the University of Maryland School of Pharmacy, the study's principal author. "There's no dosing information for these children. . . . Are we satisfied that it's appropriate?"

Although previous studies have documented a rapid increase in Ritalin among older children in recent years, the new study is the most comprehensive effort so far to examine the use of such drugs in preschoolers. Experts said Tuesday that they believe the findings -- published in today's issue of the Journal of the American Medical Association -- reflect a national trend.

The study analyzed data from two state Medicaid programs and a health maintenance organization and found that as many as 1.5 percent of children between 2 and 4 years old were receiving stimulants, antidepressants or anti-psychotic drugs -- a group that includes "major tranquilizers" such as thorazine. The findings suggest that, nationally, as many as 150,000 children in this age group were taking such medicines in 1995, up from about 100,000 in 1990, said Zito.

The study does not describe what conditions the children were being treated for, nor whether the drugs were prescribed by pediatricians, family practitioners or sychiatrists.

Zito and other experts said, however, that the growing use of stimulants and antidepressants in preschoolers is undoubtedly related to a recent national increase in the use of such drugs to treat attention deficit hyperactivity disorder (ADHD) in older children. As many as 2 million elementary schoolchildren in the United States are thought to have ADHD, and during the 1990s the number receiving Ritalin, amphetamines and other stimulants has almost tripled.

Doctors' increasing use of stimulants and antidepressants in very young children may also reflect the inadequacy of mental health services available to many children with severe psychiatric or developmental problems, several experts said Tuesday.

"Many insurance companies will not pay for a physician and a psychologist on the same day," said Marsha D. Rappley of Michigan State University's College of Human Medicine. "As a profession, we need to do more about finding better ways to help these families."

The study examined data on more than 200,000 children between the ages of 2 and 4 who were enrolled in one of three health care systems -- a Medicaid program in a mid-Atlantic state, a Medicaid program in the Midwest, and an HMO in the Pacific Northwest. It found that between 1991 and 1995, the use of stimulants, antidepressants and clonidine in this age group increased substantially, while the use of major tranquilizers increased only slightly.

Stimulants (primarily Ritalin) were the category of drugs most commonly prescribed, but there was considerable geographic variation. For instance, in 1995, about 11 of every 1,000 children between 2 and 4 years old in the Midwestern Medicaid program received Ritalin, vs. about four of every 1,000 in the HMO. When antidepressants were used, an older family of drugs called tricyclic antidepressants was most often chosen, but use of the newer class that includes Prozac increased dramatically between 1991 and 1995 at the two Medicaid programs.

In an editorial accompanying the study, Joseph T. Coyle of the Harvard Medical School in Boston sharply criticized the growing use of stimulant and antidepressant drugs in preschool-age children.

This age "is a time of extraordinary, unprecedented changes in the brain," Coyle said in a telephone interview. "We have very little information about the long-term impact of treatment with these drugs early in development."

Stimulants such as Ritalin have been tested in preschoolers and are considered safe, but they don't work as well in this age group as in older children and are also more likely to produce side effects such as sleeplessness and loss of appetite, said Judith Rapoport of the National Institute of Mental Health. She said antidepressants such as Prozac have not been studied in preschoolers.

Rappley expressed concern about the use of clonidine, a blood pressure medicine with sedative effects that some doctors have prescribed for ADHD in older children.

AP Source: Journal of the American Medical Association DRUGGING TH;

YOUNG A study found that the number of 2- to 4-year-olds on psychiatric drugs, including stimulants such as Ritalin and anti-depressants such as Prozac, jumped between 1991 and 1995.; 14 per 1,000 preschoolers; 1991; 1993; 1995 Total stimulants; Ritalin Total anti-depressants;

Note: Results shown are for 151,675 preschoolers in one Midwestern Medicaid group.; (Figures in chart were imprecise, SEE microfilm for graphic.)

February 24, 2000

SECTION: Guardian Home Pages; Pg. 3

LENGTH: 754 words

HEADLINE: The pre-school pill poppers

BYLINE: Julian Borger in Washington

Julian Borger in Washington

Americans are renowned for their pill-popping tendencies, but a study suggests the habit has even spread to the kindergarten. Toddlers between the age of two and four are being prescribed stimulants, anti-depressants and other drugs in dramatically increasing numbers for perceived psychiatric problems.

The use of stimulants such as Ritalin to treat hyperactivity is increasingly common in the United States among school-age children. The study discovered a three-fold rise in prescriptions of medical drugs for children under five.

Paedriatricians expressed shock yesterday that the drug-dependent culture was afflicting pre-school children before any conclusive research had been carried out on the effect of psychiatric drugs on brain development. Nor are there clear guidelines on how to tell whether a two-year-old has attention deficit disorder or is just a lively toddler.

The study, published in Jama, the Journal of the American Medical Association, analysed prescriptions to 200,000 toddlers under the national Medicaid and private health systems. Doctors' prescriptions of stimulants (mainly Ritalin) increased from 4.1 to 12.3 per 1;000 pre-school children between 1991 and 1995. The use of anti-depressants increased from 1.4 to 3.2 toddlers per 1,000.

Although psychiatric drugs of all kinds were prescribed to only 1.5% of the toddlers in the study, the trend was sharply upwards and the Jama researchers said they suspected it had continued on its steep trajectory in the five years since the study was conducted.

The recent explosion in the use of 'lifestyle' drugs such as the anti-depressant Prozac has generated fears that a significant part of the population is becoming dependent on prescription medicines to solve its problems. Increasingly drugs such as Ritalin have been used to address the problems of 'difficult' children.

Nearly 3% of all Americans between the ages of five and 18 are on Ritalin - almost 3m children. The Jama study confirms evidence that surfaced in a smaller survey in Michigan in 1998, that children were being put on medication for supposed psychiatric problems even before they were old enough to go to school.

US experts have suggested that the growing trend towards treating 'problem' children with drugs may be a consequence of a health system in which both wholly private and subsidised systems are reluctant to pay for counselling or other non-drug treatments, which are harder to quantify. Paediatricians also point to growing pressure from parents and schools to diagnose troublesome children as having medical problems such as attention deficit disorder.

Steven Hyman, director of the US national institute of mental health, told the New York Times he was 'more than shocked' by the findings, adding that the use of psychiatric drugs in young children was 'an area of enormous concern'.

Reasons given by American doctors for prescribing these medicines include pain relief (analgesics and sedatives/hypnotics), anxiety associated with medical or dental procedures (hydroxyine), bed- wetting in children

over six years old (tricyclic antidepressants), and attention deficit hyperactivity disorder in children of three years and older, for which they are given a variety of drugs. There are concerns that some drugs may affect children's growth.

Few of the psychiatric drugs mentioned in the Jama study are approved for treating children of preschool age, and packets of methylphenidate (the generic name for Ritalin) carry warnings against prescribing the drug to children under six.

Most psychiatric drugs work by neutralising or enhancing chemicals in the brain, but animal studies suggest that those chemicals play a critical role in the growth of nerve cells in the brain.

Joseph Coyle, chairman of psychiatry at Harvard Medical School, said: 'These interventions are occurring at a critical time in brain development and we don't know what the consequences are.'

He argued that the normal behaviour of many two- or three-year-olds is hard to distinguish from hyperactivity.

Julie Zito, an associate professor of pharmacy and medicine at the University of Maryland and the study's lead author, said: 'It is not really clear that children this young could meet the diagnostic criteria for either attention deficit hyperactivity disorder or depression.'

Ritalin, being given to more and more hyperactive children, has caused enormous controversy in the US and now the UK.

 THE INDIANAPOLIS STAR

February 23, 2000, Wednesday , CITY FINAL EDITION

SECTION: NEWS; Pg. A10

LENGTH: 340 words

HEADLINE: Physician urges time, not medicine, for tots' behavioral problems

BYLINE: KATHLEEN SCHUCKEL; STAFF WRITER

Preschoolers are receiving anti-depressants and other psychiatric drugs at skyrocketing rates to substitute for the lack of time and care that parents, doctors, educators and others have for them, say two Indianapolis doctors.

Psychiatric drugs should not be used with preschoolers, because studies haven't proven them safe for young children, said Dr. Morris Green, the Perry W. Lesh professor of pediatrics at the Indiana University School of Medicine.

Even so, Green said he has no doubt the drugs are being used widely in the United States -- including in Indiana.

In 1994, Indiana had the fifth-highest level of Ritalin use in the country, according to the federal Drug Enforcement Administration. Ritalin is mostly prescribed to children to help stem hyperactivity or attention problems.

In the past decade, Green, the former chief physician at Riley Hospital for Children, said he has seen an increasing number of out-of-control toddlers: They bite, hit, scream, destroy things and don't sleep much.

These children can, and should, be treated with behavioral methods, Green said. But it takes an investment of time on the part of the physician, who often isn't paid by insurance for the time needed to help the child, he said.

Dr. Shardha K. Sabesan, a psychiatrist who treats children and adolescents at Midtown Community Mental Health Center, turns to drugs for children as young as 4 or 5 as a last resort, because few other supports exist.

There are many ill-prepared teen-age parents and too few community programs to rely on behavioral methods alone, she said.

Sabesan said psychotropic medicines have become safer with fewer side effects in recent years, making them an option for some emotionally disturbed children.

Green isn't swayed. He thinks most parents can help their child's behavior by providing structure, predictability and time.

He urges parents and others in the community to come together to meet children's needs. "This is not just a medical or psychiatric problem. It's a community problem."

February 23, 2000, Wednesday

SECTION: WIRE; Pg. A03

LENGTH: 772 words

HEADLINE: Troubling trend: tots on Ritalin

BYLINE: Associated Press

CHICAGO -- The number of 2- to 4-year-olds taking psychiatric drugs like Ritalin and Prozac soared 50 percent between 1991 and 1995, according to a new study that experts said reveals a troubling and growing trend.

Doctors said the effects of such drugs are largely unknown in children so young, and they worry the drugs could affect the development of young minds. More than 200,000 preschool-aged children around the country were studied for the report in Wednesday's Journal of the American Medical Association.

"These are substantial increases with little or no data supporting their use. I think that's the message that should go out," said Julie Magno Zito, lead author and assistant professor of pharmacy and medicine at the University of Maryland.

The researchers suggest the increase is due to a growing acceptance of such drugs and because more and more children are attending day-care and are being pressured to conform to school standards of good behavior.

Michele Barker, a Hot Springs, Ark., mother of three, learned firsthand about psychiatric drug use in small children before her son, Heath, started kindergarten.

Nicknamed "the red tornado" for his auburn hair and wild ways, Heath's penchant for tearing things up and plunging off furniture worried his parents, so they had him tested. A pediatrician diagnosed an attention deficit disorder and prescribed the stimulant Ritalin in the 1990s. Heath was 4 years old.

Heath's mother has anecdotal evidence suggesting -- as the authors do – that the increases are continuing. Through her involvement in several Web support groups for parents of children with behavior problems, she said she's hearing of "more and more 3- and 4-year-olds" being put on drugs like Prozac.

"It's become a quick fix," said Barker, 39.

Dr. Joseph Coyle of Harvard Medical School's psychiatry department said the study reveals a troubling trend. He said "there is no empirical evidence to support psychotropic drug treatment in very young children" -- and there are valid concerns that such treatment could harm brain development.

"These disturbing prescription practices suggest a growing crisis in mental health services to children and demand more thorough investigation," Coyle wrote in a JAMA editorial.

The authors reviewed Medicaid prescription records from 1991, 1993 and 1995 for preschoolers from a midwestern state and a mid-Atlantic state; and for those in an HMO in the Northwest. The states were not identified.

Use of stimulants, anti-depressants, anti-psychotics and clonidine -- a drug used in adults to treat high blood pressure and increasingly for insomnia in hyperactive children -- were examined. Substantial increases were seen in every category except anti-psychotics, though in some cases the actual number of prescriptions was quite small.

The number of children getting any of the drugs totaled about 100,000 in 1991

and jumped to 150,000 in 1995. That year, 60 percent of the youngsters on drugs were age 4, 30 percent were 3 and 10 percent were 2-year-olds.

The use of clonidine skyrocketed in all three groups. Although the numbers were small, the researchers said the clonidine increases were particularly remarkable because its use for attention disorders is "new and largely uncharted." They noted that slowed heart beat and fainting have been reported in children who use clonidine with other medications for attention disorders.

Dr. David Fassler, chairman of the American Psychiatric Association's council on adolescents and their families, said the medications studied "can be extremely helpful for some children, even quite young children. " But he said they should be prescribed only after a comprehensive evaluation and in conjunction with other therapy.

Their use is increasing in part because doctors are getting better at diagnosing behavior disorders at an early age, Fassler said.

However, because their effects on younger children and their development aren't known, Fassler said, the Food and Drug Administration has recently instructed pharmaceutical companies to study the connection.

Barker said Ritalin calmed her son and helped him do well in school. But it also stole his bubbly personality, so she took him off it after four years.

"He started becoming the so-called zombie," she said. The family altered his diet and tried nutritional supplements instead.

Now almost 12 and drug-free for nearly four years, Heath is repeating fifth grade and has some learning difficulties. But his mother said he seems happier, and so is she.

"I don't care if he's not an honor roll student," she said, "because he's healthy."

The Associated Press State & Local Wire

January 9, 2000, Sunday, PM cycle

SECTION: State and Regional

LENGTH: 170 words

HEADLINE: Ritalin manufacturer sued over death of Canton couple's daughter

DATELINE: CANTON, Ohio

A couple is seeking more than $50,000 from the makers of Ritalin, claiming the drug caused their daughter's death of a rapid heartbeat.

Janet and Michael Hall filed the suit against Novartis Pharmaceuticals Corp. in Stark County Common Pleas Court on Thursday.

The couple's 11-year-old daughter, Stephanie Marie Hall, took Ritalin to treat an attention-deficit hyperactivity disorder.

She died in January 1996, a day after her physician doubled her Ritalin dosage, said Steven Okey, the Halls' attorney.

The lawsuit accuses the East Hanover, N.J., company of producing a defective product and concealing adverse reactions and Ritalin -related deaths.

Novartis officials said they could not comment on the lawsuit, but they did issue a statement that said Ritalin is a safe and effective therapy for attention-deficit hyperactivity disorder.

About 2 million to 3 million patients in the United States take Ritalin or its generic equivalent to help treat the disorder, according to the company.

January 2, 2000, Sunday ALL EDITIONS

HEADLINE: Daydreaming of everyone on Ritalin; Don't hook your kids on drugs

BYLINE: LAWRENCE DILLER

Pippi Longstocking just left my office on Ritalin. Of course, that's not her real name. Her name could be Kayley, Anna, Natalie or that of a half-dozen other girls I see in a week at my behavioral pediatrics practice in an affluent suburb east of San Francisco.

Eleven-year-old Pippi was not performing "up to her potential" at her private school, according to her teacher. She daydreamed and, when called upon, was often not prepared to answer. She could be silly in the classroom. This girl in my office demonstrated academic skills two grade levels above average. She spoke to me cogently and thoughtfully about her life. She dreamed about living on a ranch with many animals. She did act a bit nervous and giggly with her parents and more serious younger brother. But she did not seem to me like a serious case of attention deficit hyperactivity disorder, or ADHD, and I told her parents so.

I didn't think she needed medication at this time. I suggested that we work on making consequences more immediate for Pippi at home and at school, and if she still was struggling a few months from now, perhaps Ritalin could be tried then.

Pippi's mom asked me if there was really anything bad about taking Ritalin and if not, why not do it now so that Pippi could do better in school immediately. I said that most children and adults have little problem taking Ritalin and that it was probably pretty safe. It works, ADHD or not, to improve focus and attention on tasks found boring or difficult. Pippi's dad, uneasy about using a drug that also had abuse potential, thought they should wait.

The family came back to see me a week later. Dad had changed his mind. Another doctor felt Pippi had mild ADHD and gave them a prescription. Pippi apparently felt OK about taking it. The prescribing doctor had only left the instructions on the bottle, "1 to 3 tablets per day." They asked me to tell them more about using the medication. I internally shrugged and started to tell them how to determine the optimal dose and frequency using a teacher-feedback sheet. They left happy. I felt strange.

I find myself evaluating and prescribing medication for more and more Pippis and Tom Sawyers. These seemingly normal children are inattentive or disinterested in school and a bit slow to finish their chores at home. Concerned and loving parents bring them in because the children aren't performing "up to their potential" or are disruptive in their classrooms.

Ritalin production is up 700 percent this decade. Production of Dexedrine and Adderall, the other two stimulants used for ADHD, has tripled in the past three years. America uses 85 percent of the world's Ritalin. While school-age boys remain the largest users of Ritalin, girls and adults are the most rapidly increasing groups taking the drug.

In some rural areas, virtually no children get Ritalin. Yet in Virginia Beach, one in five white fifth-grade boys receives Ritalin at school.

I wish to offer a Swiftian "Modest Proposal" of my own. With classroom sizes now averaging 30 kids per class and about 4 million children taking Ritalin, I propose that we increase the number of children taking Ritalin to 7 million. We then could probably increase class size to 45 children and save a lot of money.

Ritalin "works," but I don't see it as the moral equivalent or substitute for better parenting and schools. Currently, our country has an intolerance for temperamental diversity in our children. I worry about an America where there's no place for an unmedicated Pippi Longstocking.

Lawrence Diller, who practices in Walnut Creek, Calif., is the author of "Running on Ritalin: a Physician Reflects on Children, Society and Performance in a Pill."