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

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

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

March 20, 2000

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

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

- **Failure to treat emotional and behavioral disorders can have severe life-long consequences.** Studies suggest that many children with untreated emotional and behavioral conditions fail to reach their full potential. Untreated mental illness has a negative impact on the developing brain, causing lifelong emotional and social damage. Children with these types of problems are at significantly higher risk for anti-social activities later on than those without behavioral problems. It is evident that an accurate early diagnosis, education, support, and medication, if necessary, can overcome many early problems and help prevent long-term negative behavior.

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

- **The number of children under the age of five on clonidine increased exponentially.** The 28-fold increase in children using clonidine, used in children with attention deficit disorders or children exhibiting disruptive behaviors, is notable, as the increase in its use occurred without research ensuring that it is safe and effective. Adverse effects, including rapid or irregular heartbeat and fainting, have been reported in children using the drug with other medications for attention-deficit disorder.

- **The number of children aged two through four taking stimulants such as Ritalin more than doubled.** The vast majority of preschoolers taking stimulants were on Ritalin to treat attention deficit disorders – as many as ninety percent in one study – and the number of these children increased by 150 percent over a five year period. Although there are a disproportionate number of boys taking medication for attention deficit disorders as opposed to girls (a ratio of 4:1), the number of girls being diagnosed and treated with attention deficit disorders increased over this time period; in one study, the proportion of girls taking stimulants increased by 60 percent.

- **Many children are inappropriately diagnosed and treated.** Studies indicate wide geographic and ethnic variation in the numbers of children receiving psychotropic drugs such as Ritalin. In one study, the percentage of children receiving Ritalin was as high as 10 percent – 2 to 3 times as high as the expected rate of attention deficit disorder. The percentage of boys receiving medication for attention deficit disorder in the fifth grade was as high as 20 percent. Other research indicates racial variations as well; a study of one Maryland HMO indicated that African-Americans children were 2.5 times less likely to receive Ritalin as white children. This wide variation in treatment patterns supports the need for more research to determine appropriate treatment protocols for children with emotional and behavioral disorders. Although little is known about the effects of over medication on children, unnecessary use of these medications can have adverse effects on the developing brain and the emotional and social development of young children.

- **More research is necessary to ensure informed treatment decisions.** Many of the drugs being prescribed for very young children have not been tested in children under the age of 16; few have been tested for children under the age of six. More research is necessary to ensure that providers and parents have necessary information, especially about the impact of medication on brain development, to make appropriate treatment decisions.

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

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

Lisa Ferdinando
03/21/2000 09:39:09 AM

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Subject: FOX Special Report, March 20, 2000

FOX SPECIAL REPORT WITH BRIT HUME
March 20, 2000

BRIT HUME, HOST: Welcome to Washington. I'm Brit Hume.

After an exhilarating experience on the campaign trail and a vacation in Bora-Bora, John McCain came back to the place that Pat Buchanan once called, quote, ``that soul-stifling institution on Jenkins Hill.'' Jenkins Hill is what Capitol Hill was called before they built the building, and it is to there that the senator has returned.

Correspondent Brian Wilson reports.

(BEGIN VIDEOTAPE)

BRIAN WILSON, FOX NEWS (voice-over): There were no wildly enthusiastic crowds, no buses filled with reporters, no confetti for John McCain and he quietly slipped into a side entrance of the Russell Senate Office Building. Though he lost his bid for the Republican nomination, John McCain returns to the Senate having won at least the grudging respect of his peers. His insurgent high-profile campaign made him a player on the national stage, his ability to energize a base of independent and first-time voters duly noted by GOP party bosses.

He emerged from meetings with his staff to say he will remain loyal to the party, support the nominee, but he is not walking away from campaign finance reform.

SEN. JOHN MCCAIN (R-AZ), FORMER PRESIDENTIAL CANDIDATE: I also will not abandon my reform agenda and those millions of people who are relying on me to pursue it.

WILSON: And how will that go over this time around?

MARK PRESTON, ``ROLL CALL'': ... that his message is going to resonate back into the -- into the halls of Congress. Now, is the leadership going to be happy about that? No.

WILSON: Senate leaders will reach to to McCain, witness the majority leader of the Senate, Trent Lott, last week during a press conference with presumptive nominee George W. Bush.

SEN. TRENT LOTT (R-MS), MAJORITY LEADER: We're going to welcome him back, like the Senate always does. You know, the Senate is not a place just of regional or ideological or partisan passions. We're also personal friends, and some time we fight like tigers. And when you fight with John McCain, you got to prepare to fight like a tiger.

WILSON: The Senate's most ardent foe of campaign finance reform, Kentucky's Mitch McConnell, has even scheduled hearings on the topic for Wednesday. Still, passing campaign finance reform this year is expected to be an uphill battle, and some believe that's the way John McCain likes it.

PRESTON: His personality, you know, his whole life story, has -- has seemed to be ``Come and get me.'' You know, ``Come and get me. And if I fall, so be it. But -- but I'm not backing down.''

(END VIDEOTAPE)

WILSON: McCain also has plans to form a PAC, a political action committee, to fund his crusade. Ironically, that's one of the things that he was going to outlaw in an earlier version of campaign finance reform -- Brit.

HUME: Well, Brian, tomorrow's the day they have the big policy lunches. The

Democrats get together, Republicans get together with -- among their own members. What kind of -- what exactly is going to happen there? What are they going to say? What's going to happen with McCain?

WILSON: Well, you know, basically, the Senate is one of the only places where you address your political enemies by the title of ``distinguished gentleman,'' so they'll be very nice. But there's some wariness here because, remember, John McCain was out there beating up on their guy and beating up on the institution of Congress. And John McCain remembers that some members of Congress were beating up on him when he was on the campaign trail. They'll be civil, but they'll be wary.

HUME: All right, we'll be watching, Brian. Brian Wilson, thanks very much.

Pat Buchanan, believing he's certain to be the nominee of the Reform Party, believes that nomination alone should qualify him for inclusion in this year's presidential debates, right up there with Al Gore and George W. Bush. He says the fact that he will receiving federal matching funds for his campaign is proof he's qualified. Receipt of federal money may seem an unusual standard for a conservative to use, but Buchanan is planning to take his case to court if he has to. He outlined his first step at a Washington news conference.

Steve Centanni has the story.

(BEGIN VIDEOTAPE)

STEVE CENTANNI, FOX NEWS (voice-over): Pat Buchanan let it be known in no uncertain terms if the Reform Party candidate is shut out of the presidential debates, he says it'll be unfair, unjust, anti-democratic and un-American.

PAT BUCHANAN (REF), PRESIDENTIAL CANDIDATE: It is, if you will, a conspiracy by the two parties to keep third parties out of the presidential debates and therefore to maintain a hammerlock on the presidency of the United States, the most powerful office in the world.

CENTANNI: The Commission on Presidential Debates decided this year's three debates are open only to candidates who rank 15 percent or higher in the national polls, but Buchanan, who's in single digits in the polls, claims that's an arbitrary and unfair standard, and he argues that debates can be all-important. He says JFK won the 1960 election based on his debate performance. In 1988, Dukakis looked cold and calculating when asked about the death penalty, and Ross Perot gained ground in the 1992 debates.

BUCHANAN: Ross Perot went into the election -- went into the debates at 7 percent and emerged at 19 percent, 12 percent increase. That's equal to a shift of 12 million votes.

CENTANNI: But others say the presidential debates should only include those who have a realistic chance at becoming president.

STEPHEN HESS, BROOKINGS INSTITUTION: This is not primarily an educational experience. This is an experience for the American people to have the last shot at deciding which serious candidate they want to be the next president of the United States. And I think they deserve that opportunity without distraction.

CENTANNI: Buchanan wants the major candidates to push for inclusion of the Reform Party in the debates. Vice President Al Gore would only say that he's focused on debating George W. Bush, and Governor Bush has pretty much the same position.

GOV. GEORGE W. BUSH (R-TX), PRESIDENTIAL CANDIDATE: I look forward to debating Vice President Gore head on head.

CENTANNI (on-camera): The debate commission turned down our request for an interview, but said their criteria are fair and clear. Buchanan's filing a complaint with the Federal Elections Commission, and if they turn him down, he says he'll go to federal court.

In Washington, Steve Centanni, FOX NEWS.

(END VIDEOTAPE)

HUME: And coming up next, we'll tell you why Hillary Rodham Clinton decided not to accompany the president overseas.

Stay with us.

(COMMERCIAL BREAK)

HUME: Campaign themes of the first lady's New York Senate race include child welfare, health and education. Now Hillary Rodham Clinton has found an issue that combines all three, the growing use of Ritalin and other drugs to medicate young children. She has announced a new plan

aimed at curbing that trend. Mrs. Clinton's aides insist she's doing this as first lady, not as candidate.

After all, as Rita Cosby reports, the event was held at the White House.

(BEGIN VIDEOTAPE)

RITA COSBY, FOX NEWS (voice-over): The first lady was flanked by health care leaders as she announced new federal studies into the escalating use of controversial drugs such as Ritalin for children who have attention deficit disorders.

HILLARY RODHAM CLINTON (D), NEW YORK SENATE CANDIDATE: We have to ask, for example, how are we diagnosing, treating and caring for children with behavioral and emotional conditions?

COSBY: As she was leaving, Mrs. Clinton used the opportunity to address another social problem, children and guns, a politically sensitive issue that resonates with New York voters.

CLINTON: Certainly, the easy, ready access to guns makes emotional and behavioral problems that might have been fought out on a playground or been, you know, manifest by verbal arguments much more deadly and dangerous.

COSBY: Critics say Mrs. Clinton is only talking politics, knowing children's health care and youth violence are important issues, especially for women voters. Some question why she's pushing a topic that could remind the public of her failed health care initiatives. Republicans also say Mrs. Clinton is trying to have it both ways.

PATRICIA HARRISON, REPUBLICAN NATIONAL COMMITTEE CO-CHAIR: What we are seeing here is a first lady who wants to be a candidate for the Senate of New York not really doing too well right now. So now she has resurfaced as first lady, and it looks a little bit like a candidate desperately seeking an issue.

COSBY: The first lady didn't join the president on this week's trip to Southeast Asia because, he aides say, she's busy campaigning for the Senate seat. But her staff says the event at the White House was strictly done in her role as first lady. Her office said, quote, ``Mrs. Clinton's interest in children's health and issues such as this pre-date her Senate campaign by about three decades."

Democrats say the criticism of the first lady is unfair.

JULIAN EPSTEIN, HOUSE JUDICIARY COMMITTEE MINORITY COUNSEL: That is a somewhat absurd criticism that she can't exist in this dual capacity, as a first lady and as a senatorial candidate. It probably means she gets a little bit less sleep at night, but people like and I think admire the hard work that she puts on it.

(END VIDEOTAPE)

COSBY: And Mrs. Clinton's promotion of this latest health care issue isn't going away any time soon. A conference on psychiatric drugs and also children is expected to take place at the White House this fall, right around election time -- Brit.

HUME: Rita, has the first lady commented yet on that police shooting over the weekend in New York that has stirred such a controversy?

COSBY: Brit, she has not yet. And in that case, a Hispanic police officer shot an unarmed black man. But she did talk about her overall gun policy. She's calling for a sweeping licensing system of gun owners and also mandatory trigger locks, very similar to her rival, Rudolph Giuliani.

HUME: All right, Rita Cosby, thanks very much.

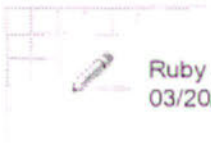
The latest Zogby America poll shows that nearly 64 percent of Americans agree with President Clinton's position that Congress should strengthen gun control legislation with trigger locks and waiting periods for gun show sales. Only 27 percent agreed with the NRA official Wayne LaPierre's statement that the president is willing to accept an increased level of violence so he can promote an anti-gun agenda. Eighty-two percent of Democrats and two thirds of independents agreed with the president. Republicans were more divided, 46 percent for LaPierre, 41 percent for Mr. Clinton.

Another death of an unarmed man, as we mentioned, at the hands of the New York City police department is more political trouble for Mayor Rudy Giuliani. Throughout the Amadou Diallo and Abner Louima cases, the mayor supported the NYPD. Now Giuliani is under fire again from black activists who call Thursday's shooting the latest example of what they're calling police brutality.

FOX NEWS's David Lee Miller reports.

(BEGIN VIDEOTAPE)

DAVID LEE MILLER, FOX NEWS (voice-over): New York City Civil Rights leaders



Ruby Shamir
03/20/2000 08:18:19 AM

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Devorah R. Adler
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cc:
Subject: here are the q&a for this morning -- can you send to your press office

Q: Aren't you politicizing an issue to benefit the First Lady in her Senate race?

A: Absolutely not. The First Lady's history and support for children's health issues is well known and documented. She, like many other parents and children's advocates, have been concerned about the potential inappropriate use of medications, particularly in preschoolers. She feels that the recent medical journal articles on this issue need to be highlighted further, but more importantly, addressed, and has been working with the Administration to see what interventions could be considered. She hopes, as does the rest of the Administration, that the information we are providing to parents, the diagnostic and treatment protocols that the AAP is announcing it will release, and our ongoing pediatric research and labeling initiatives, will make significant headway in this regard.

Q: What has Hillary Clinton's involvement been in the past on this issue?

A: Throughout her professional lifetime, the First Lady has been involved in children's issues. In 1997, she was a strong advocate within the Administration for the development and release of regulations as well as subsequent legislation to significantly increase pediatric labeling information developed by FDA for physicians and parents.

The First Lady's record on children's health care, child care, and education, speaks for itself. She was a strong advocate for: the passage of the Children's Health Insurance Program, the Family and Medical Leave Act; new regulatory and statutory authority for pediatric labeling; administration efforts to improve child care.

Q: Is Tipper Gore part of this announcement? Is she supportive of this?

A: Tipper Gore is pleased to see attention focused on this important issue. She has played an unprecedented leadership role on mental health issues and has encouraged this next step focusing on mental health issues and children. As the First Lady's remarks point out, Tipper Gore's leadership on this issue is unparallelled. All of the actions being taken today build on the landmark work resulting from the first ever White House Conference on Mental Health and the release of the unprecedented Surgeon General's Report on Mental Health last year, both of which were spearheaded by Tipper Gore in her role as the President's Mental Health Advisor.

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- **Failure to treat emotional and behavioral disorders can have severe life-long consequences.** Studies suggest that many children with untreated emotional and behavioral conditions fail to reach their full potential. Untreated mental illness has a negative impact on the developing brain, causing lifelong emotional and social damage. Children with these types of problems are at significantly higher risk for anti-social activities later on than those without behavioral problems. It is evident that an accurate early diagnosis, education, support, and medication, if necessary, can overcome many early problems and help prevent long-term negative behavior.

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- **Announcement that NIMH will dedicate more than $5 million to research on attention deficit disorder and Ritalin use in preschoolers.** Today, the National Institute of Mental Health announced that it plans to invest more than $5 million in research on the use of medication to treat attention deficit disorder in preschool children. This research will assemble the latest information on the use of these drugs and identify discrepancies between clinical practice and current scientific evidence.

- **New efforts to provide parents with up-to-date information on the appropriate diagnosis and treatment of children with emotional and behavioral conditions.** This week, NIMH will release a new fact sheet to help parents of children with behavioral and emotional conditions understand the treatment options available and guide them in their decision-making process. This fact sheet includes easy to understand information on when to include medication in an overall treatment plan; how to help determine if a child's problems are serious; and when and how to get help. The Department of Education will also release an information kit on ways for teachers and parents of children with attention deficit disorders.

- **A national Conference on the Diagnosis and Treatment of Children with Behavioral and Mental Disorders.** This fall, the Office of the Surgeon General, together with NIMH and FDA, will coordinate a Conference on Treatment of Children with Behavioral and Mental Conditions. This national conference, which will build on the success of the recent White House Conference on Mental Health chaired by Tipper Gore, and the Surgeon General's Report on Mental Health, will include representatives of provider, consumer advocacy, and education communities. Topics of discussion include: developing research on treatments and services that can be used by providers nationwide; how best to determine the efficacy and safety of medications in young children; and ways to address the difficulty of accurate diagnosis in preschoolers. The Surgeon General will also release a report on children's mental health by the end of the year.

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

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

THE WHITE HOUSE

WASHINGTON

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

The Scary Truth About Stock Options

U.S.News & WORLD REPORT

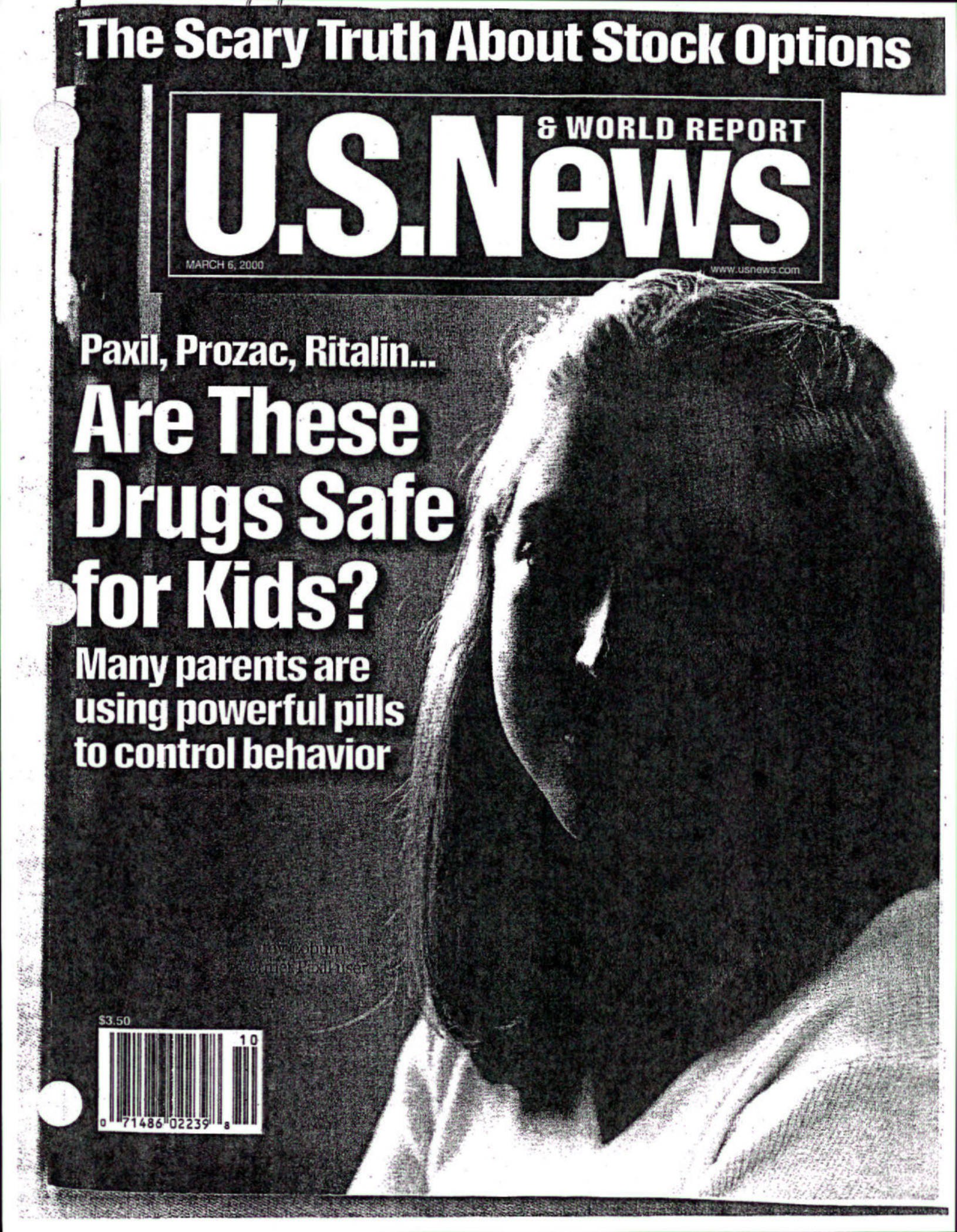
MARCH 6, 2000

www.usnews.com

Paxil, Prozac, Ritalin...

Are These Drugs Safe for Kids?

Many parents are using powerful pills to control behavior



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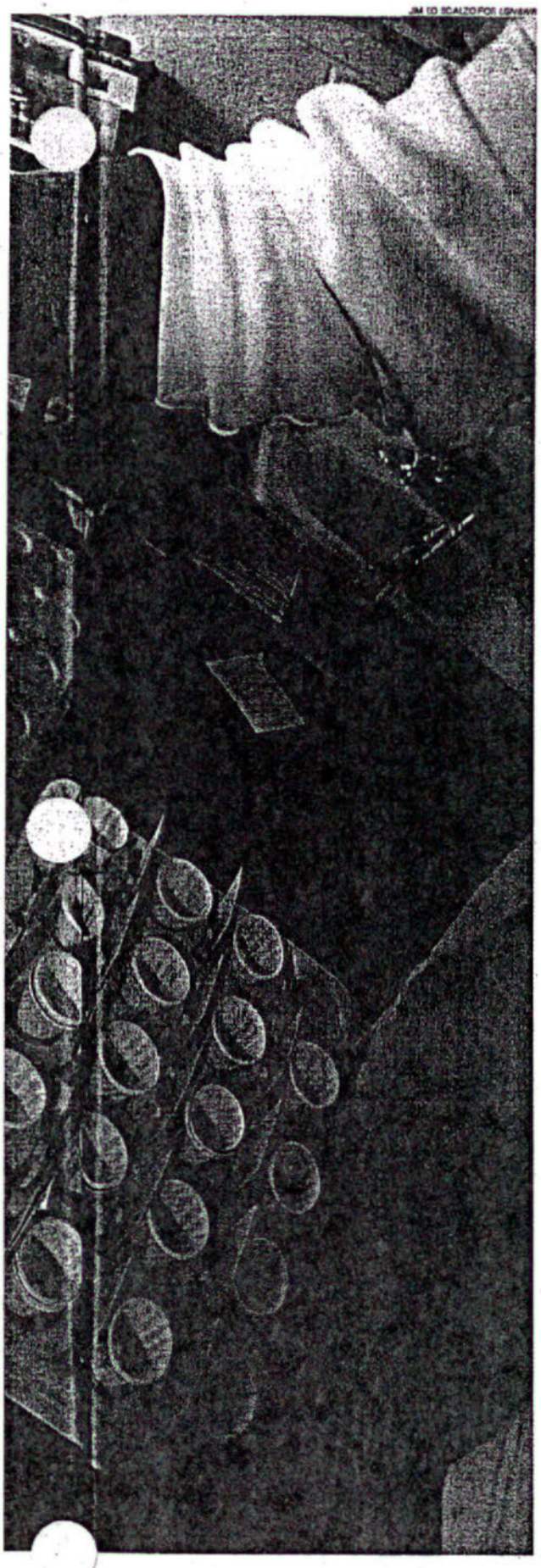

The Perils Of Pills

The psychiatric medication of children is dangerously haphazard

BY NANCY SHUTE, TONI LOCY, AND DOUGLAS PASTERNAK

Before Joshua Andrews turned 1 year old, he was leaping out of his crib and tearing through the house. By 2, he was darting out the front door and bolting straight into traffic. By 3, he was endangering the life of the family hamster with well-aimed pencil pokes through the cage wires. He'd kick his friends, say he was sorry, then kick them again. He'd cuddle in his mother's arms for a moment, then elbow her aside to dart around wildly. By the age of 4, he had been asked to leave his Norwood, Mass., preschool, told never to return to summer camp, and sent to a special residential school three times—each time for about a month—for impulsive, aggressive behavior. "That was my little son," Joshua's mother, Susan, recalls. "Dr. Jekyll and Mr. Hyde."

About nine months ago, Susan and Joshua's psychiatrist decided to treat the boy with Wellbutrin, an antidepressant, to calm him down and help him focus. "At first I was afraid. I didn't want to medicate him," Susan recalls. "But I was at my wit's end."

A nurse dispenses medications to students at a middle school.

● *"How are these children qualifying for the use of these medications?"*

Although most people picture the toddler years as a time of peekaboo and *Pat the Bunny*, more and more preschoolers like Joshua are being treated with powerful psychiatric drugs. Last week, researchers reported in the *Journal of the American Medical Association* that the number of 2-to-4-year-old children on Ritalin, antidepressants, and other psychoactive drugs increased dramatically from 1991 through 1995. Startling as it is, the news about toddlers merely underscores the rise in the use of powerful psychiatric drugs in kids of all ages—despite the fact that these drugs are largely untested for use in the young. According to the surgeon general, almost 21 percent of children age 9 and up have a mental disorder, including depression, attention deficit hyperactivity disorder, and bipolar disorder.

A little knowledge. But the treatment children get is often dangerously haphazard. Some are heedlessly medicated, with no follow-up; other children don't get the treatment they desperately need to be able to play and learn and grow. The problem is exacerbated by the fact that the majority of psychiatric prescriptions written for children and adolescents are handled by general practitioners and pediatricians who lack mental health training. Of nearly 600 family physicians and pediatricians who responded to a 1999 University of North Carolina survey, 72

MICHELE MCDONALD FOR USN&WR

percent said they had prescribed antidepressants to children under 18. But only 16 percent of the doctors said they felt "comfortable" doing so, and just 8 percent said they have adequate training to treat childhood depression. Peter Jensen, a professor of child psychiatry at Columbia University, says bluntly: "Pediatricians and family practitioners should not be prescribing these drugs for children under 18.

Susan Andrews gives Joshua, 4, his medication in their Norwood, Mass., home.

● *He was "Dr. Jekyll and Mr. Hyde."*

They don't have the time or the skills. This is a complicated area of medicine."

Kathy Hale of Lexington, Ky., knows this scenario all too well. When her daughter Katie saw the pediatrician at age 7, the doctor quickly diagnosed ADHD and prescribed Ritalin. But Katie's temper and aggression only intensified. The grade schooler pulled a butcher knife on her older sister and gave her stepfather a black eye. Kathy called the pediatrician several times and begged to have her daughter sent to a hospital, but he refused. Last October, Kathy decided to take Katie, now 13, to a psychiatrist at the University of Kentucky, who diagnosed bipolar disorder. Katie is

Behavior in a pill

These are some of the most common psychiatric medications.

NAME OF DRUG	USED TO TREAT	TOTAL PRESCRIPTIONS IN 1999 (ALL AGES)	INTENDED EFFECT	SIDE EFFECTS
Methylphenidate (Ritalin)	Attention deficit hyperactivity disorder	11.4 million	Mildly stimulate the central nervous system	Addiction, nervousness, insomnia, loss of appetite
Amphetamines (Dexedrine, Biphetamine, Desoxyn)	Hyperactivity in children, narcolepsy, obesity	6.5 million	Stimulate the central nervous system	Addiction, nervousness, insomnia, loss of appetite
Tricyclic antidepressants (Tofranil, Norpramin, Aventyl)	Major depression. In children, Tofranil is used to treat bed-wetting	31.5 million	Restore the brain's normal level of neurotransmitters	Dry mouth, constipation, blurry vision, difficulty urinating
SSRI antidepressants (Prozac, Zoloft, Paxil)	All types of depression and several anxiety disorders	84.0 million	Influence the brain chemical serotonin	Insomnia, nausea, diarrhea, headache, nervousness

now on lithium and Risperdal, and her mother says she's on the right track.

Psychiatric drugs can help youngsters, but they have not been tested even in older children, and most are not approved by the Food and Drug Administration for pediatric use. Almost nothing is known about how antidepressants and other psychoactive drugs affect a child's developing brain.

The increased use of psychiatric drugs in children also raises larger questions on how our society deals with difficult behavior. Last week, a United Nations panel lambasted the United States for overprescribing psychiatric drugs, particularly stimulants; according to the panel, the United States consumes 80 percent of the world's methylphenidate (the generic name for Ritalin). Are American youngsters indeed suffering more behavioral illnesses, or have we as a society become less tolerant of disruptive behavior? Mental health officials say they don't know. Much of the official psychiatric diagnostic manual's entry on ADHD reads like a catalog of a typical young child's behavior: "squirms in seat"; "is often 'on the go' "; "interrupts or intrudes on others." Child psychiatrists uniformly report that diagnosing mental disorders in children is a difficult, delicate task—and the younger the child, the tougher the call. "How are these children qualifying for the use of these medications?" asks Julie Magno Zito, an associate professor of pharmacy and medicine at the University of Maryland–Baltimore and lead author of the *JAMA* study. "The fact that there are such dramatic increases means that something's changing. Why?"

Raising questions. Zito's report is the first large-scale look at psychiatric drug use among the very young. The data show that the use of Ritalin and other stimulants, which are used to treat attention disorders, increased almost threefold in the early 1990s. By 1995, 12 of every 1,000 children in the Midwestern Medicaid group were on a stimulant. The children's use of antidepressants doubled, to 3 out of every 1,000 at Midwestern Medicaid. In other research, Zito has found increased medication use among older children, too.

Given that 3 percent to 5 percent of school-age children are affected by ADHD and 2.5 percent by depression (the number rises to 8 percent in teens), psychiatrists say it's not surprising to see 1.2 percent of children being treated for ADHD and 0.3 percent for depression. What does upset the doctors is the paucity of research on how the drugs work in children and how the drugs affect future growth and development.

Until very recently, the FDA didn't require drug companies to test the safety and effectiveness of drugs on children, because of ethical and safety concerns. Prozac is not FDA approved for children under 18; Ritalin, which has been much more extensively studied in children than the antidepressants, is not approved for children under 6. But doctors can still legally prescribe those drugs to children, and frequently do, for whatever therapeutic use they decide is appropriate. The situation is changing; the FDA has made testing of drugs intended for children mandatory starting in December. But for now, doctors have almost no data to turn to in deciding how to use psychiatric drugs on kids.

Children are not miniature adults. Their bodies metabolize medications differently. Their brains are in the midst of rapid development. Animal studies suggest that the brain's developing neurotransmitter system can be exquisitely sensitive to drugs, leading to permanent changes in adult life. Thus doctors who prescribe psychiatric drugs to children, even with the best intentions, are experimenting on their patients. Says Robert Johnson, director of adolescent medicine for the University of Medicine and Dentistry of New Jersey: "We know more about the effects of marijuana on kids than Prozac."

For their part, practitioners say that they're often pressured by managed-care companies and insurers to avoid referring their patients to mental health specialists and to reduce the time they spend with families. Time is money in health care today, and it takes a lot of time to properly assess a child's behavior, emotions, and family situation. "You need at least four 45-minute sessions, observing the

CHERYL HIMMELSTEIN FOR USN&WR

Amy Coburn, 16, plays outside her Perry, Utah, home with nephews and a niece.
● *On Paxil, "I thought the world was watching me. There were cameras everywhere."*

JIM LO SCALZO FOR USNEWS

Eydie Alguadich continues to give 8-year-old Danielle extra tutoring and help.
● *"She wasn't learning in class."*

child, with the family, taking a family history," says Stanley Greenspan, a child psychiatrist in Bethesda, Md., and author of *Building Healthy Minds*. "But in many situations a child is being prescribed and diagnosed in one half-hour meeting. Insurance coverage doesn't support the kind of assessment you need."

Two wrongs. The push to diagnose quickly and simply creates a paradoxical result: Children are both undermedicated and overmedicated. "Twenty percent or less of kids with major depression get treatment," says Neal Ryan, a professor of child psychiatry at the University of Pittsburgh. Many of the children who are diagnosed are massively undertreated, Ryan says, in part because of parents' fears of stigmatizing their children.

Martin Teicher, an associate professor of psychiatry at Harvard Medical School, estimates that as many as half of the children diagnosed with depression actually have bipolar disorder and that many are mistakenly placed on antidepressants or ulants. "That is a bad cocktail," he says. elly Bagwell of Silver Creek, Miss., saw ner 2-year-old daughter, Tori, flail and thrash for hours, uncontrollably, after her pediatrician put her on Ritalin. After Tori tried to jump out a second-story window, the Bagwells took her off the medication. It took four more years before Tori was diagnosed with bipolar disorder. Tori is now doing well on Zyprexa, an antipsychotic, and Topamax and Depakote, mood stabilizers. "Without this diagnosis, she'd be in an institution," her mother says.

Because there are no treatment guidelines and dosage standards, the prevalence of psychotropic drugs for children varies wildly, from doctor to doctor, school to school, and county to county. Ritalin use, for instance, ranges from 7 percent among children in inner-city Baltimore to 1 percent in Salt Lake City. Psychiatrists were particularly alarmed at the evidence in last week's *JAMA* study that doctors are increasingly prescribing tricyclic antidepressants for children, as well as more clonidine. Tricyclics such as Elavil have never been proven to work in children, and they can cause fatal overdoses, unlike newer antidepressants such as Prozac and Paxil. Clonidine, a blood-pressure medication prescribed for children as a tranquilizer, also has dangerous side effects. "There's all risk and very little benefit for these two drugs," says Steven Hyman, director of the National Institute of Mental Health.

All too often, children get drugs with none of the behavior modification, counseling, and long-term follow-up that mental health experts say are essential. "The quickest and easiest thing is to write a pre-

WHAT TO ASK

Queries for a doctor or a therapist:

● **How will you make a diagnosis?** At a minimum, the provider should interview you for at least an hour about the child's medical and family history, observe the child for a similar amount of time, and talk to teachers or baby sitters.

● **If medication is called for, how long should my child take it to know if it works?** Since psychotropic medications are untested on children, it will be a process of trial and error. If a drug causes any troubling side effect, talk to your doctor immediately about stopping it.

scription," says Paul Lipkin, a pediatrician and head of clinical programs at the Kennedy Krieger Institute in Baltimore. "It's harder to convince parents to go in for weeks of psychotherapy." A cost-conscious health care environment encourages the use of medication—about $20 a week for selective serotonin reuptake inhibitor (SSRI) antidepressants like Prozac—over therapy, which runs $150 for a 45-minute session. But even the pharmaceutical companies say it is inappropriate to prescribe antidepressants for children without exploring other methods of treatment, particularly behavioral therapy. Rajinder Judge, director of neuroscience at Eli Lilly, the maker of Prozac, says these antidepressants should not be used as "the first line of treatment."

Judy Coburn has seen a system where psychotropic medications were handed out to children indiscriminately. Three years ago, a few months after Judy's husband committed suicide, her 13-year-old daughter, Amy, was admitted to a hospital near their Perry, Utah, home. She was contemplating suicide. When her mother picked her up a week later, the discharge nurse said that Amy had been placed on 20 mg a day of Paxil, an SSRI antidepressant—the same drug her father had been taking when he killed himself. He had been taking just 10 mg a day. "I remember I asked the counselor at the hospital, 'Am I supposed to bring her back for a follow-up?' " recalls Judy. "And he said, 'No, the medication will keep her calmed down.' And he did not say anything about any side effects at all." The drug insert for Paxil lists paranoid reactions, antisocial behavior, trouble concentrating, and hostility as some of the rare, but serious, behavioral side effects of the drug. Amy experienced all of these reactions. She stopped taking Paxil because of the side effects, and counseling helped her deal with the grief over her father's death. Today Amy, 16, is a girl with a broad smile who enjoys acting in school plays.

Many parents say that without medication, their children would not have been able to learn in school, play with friends, and do all the little things that are essential to the business of growing up. Eydie Alguadich will never forget the day her 5-year-old daughter, Danielle, started to say, "Mommy, I wish I was dead." It went on for two years. "I had a major, major prejudice against using drugs on children," says Alguadich, an interior designer and stay-at-home mom in Herndon, Va. When a pediatrician recommended that her older daughter, Samanthe, take Ritalin at age 2, Alguadich enrolled her in a gym class instead. But as she watched Danielle founder despite intensive tutoring from her mother, she decided it was time to seek help and brought her in for an assessment by psychologists and pediatricians. Danielle, 8, now takes Ritalin, as do her two older sisters. Their mother says they're no longer struggling in school, and the drug appears to have no side effects. "Kids know when there's something wrong," Alguadich says. "It's the parents who are the last to know."

JIM WEST—IMPACT VISUALS FOR USN&WR

Haley Francis, 4, is being treated for bipolar disorder.
● *"It's no different than cancer or diabetes."*

National experiment. The vast pharmacological experiment on America's children raises larger questions of whether behavior is a medical or social issue. Two hundred years ago, the mentally ill were considered cursed or evil. Only in this cen-

A PARENT'S GUIDE

Tools to treat a troubled child

When a child under age 5 is constantly fighting, flitting, running, biting, bouncing off the walls, and otherwise annoying grown-ups, he or she could have a serious behavioral problem. Or maybe the kid's just a typical toddler. Prescribing drugs for these children is the final treatment tool, child psychiatrists stress, and should come only after child and family have been evaluated and other approaches have been tried.

Behavioral therapy can help when a child, even a preschooler, has attention deficit hyperactivity disorder, says Enrico Mezzacappa, child psychiatrist at Children's Hospital in Boston. The therapy is a consistent system of rewards and consequences. "You catch them being good, you praise them and give lots of rewards," said Bruce Black, a child psychiatrist in Wellesley, Mass. If they're bad, a parent gives them a timeout or takes away a toy.

Children with obsessive-compulsive disorder can benefit from behavioral therapy as well as exposure therapy. If a girl feels a need to constantly wash after touching a toy that she fears is dirty, or just plain yucky, she might be led to touch the toy and taught relaxation techniques to ease anxiety.

When such therapies fail to provide relief, they may begin to work with medication. Parents should be advised that little is known about immediate or long-term effects of psychotropic drugs; virtually all are untested on children younger than 6.

Severe depression in a very young child is almost always caused by a major upheaval. "In kids under 5, it's marital discord, divorce, witnessing violence," says Glen Elliott, director of child and adolescent psychiatry at the University of California–San Francisco. A pill won't help. The daunting solution is to change family life or move from a dangerous neighborhood. *–Susan Brink*

tury have doctors come to understand that depression, schizophrenia, and other disorders arise from the genes and cells, not from the Devil. Even 20 years ago, children were thought to be incapable of becoming depressed, a holdover from the Freudian belief that it took an adult superego to suffer angst. By recognizing the biological basis of mental disorders, medicine has offered millions of people the possibility of a real life. But in elevating the biological causes of mental disorders, society risks ignoring other key factors: family, environment, culture. If a child behaves badly because the parents' marriage is in turmoil, is the problem with the child or with the family? Are today's parents too busy to give difficult children the one-on-one attention and patience they need? Do teachers demand that children be drugged rather than accept a rambunctious classroom?

Lawrence Diller, a behavioral pediatrician in Walnut Creek, Calif., and author of *Running on Ritalin*, says that society's increased demands on children make it harder for them to cope and force teachers and parents to consider drugs for troubled children. "The expectations of children are going down in age and up in standards. More and more is asked of kids, with less and less support." ●

With Susan Brink, Mary Lord, John S. MacNeil, Mark E. Madden, Stacey Schultz, and Rachel Sobel

CAUSE AND EFFECT

Can drugs spark acts of violence?

By any measure, Jarred Viktor was a troubled kid. The 16-year-old was experimenting with illegal drugs, drinking heavily, and talking about suicide. In 1995, Brenda Viktor brought her son to their family physician, David Borecky, near the Viktors' Escondido, Calif., home. After a brief visit, Borecky handed Jarred a three-week supply of the antidepressant Paxil. He said the drug would take time to kick in and told Jarred that he wouldn't need to see him for two to three weeks. Ten days later, Jarred stabbed his grandmother 61 times. He was convicted of first-degree murder and is doing life without parole.

No one will ever know what role Paxil played in Jarred's actions. Borecky believes it played none and that his treatment of Jarred was appropriate. In 1991 the Food and Drug Administration found no link between Prozac, a cousin to Paxil, and suicide or violence in adults. But the FDA has not examined the drug's effect on kids. And none of this class of drugs is approved for use in kids with depression.

Doctors are divided on the issue of antidepressants and violence. Many experts say it's impossible to know whether violent acts are linked to the drug or to the disease itself. But others find the anecdotal evidence convincing. "What jumped out at me," says psychiatrist Alan Abrams, who testified for the defense at Jarred's trial, "was this very withdrawn kid who started acting as though he was primed to explode" days after he started taking Paxil. Abrams believes the drug caused Jarred to become violent.

COURTESY OF VIKTOR FAMILY

Jarred Viktor, 17, at graduation with his parents, Brenda and Jurgen, following his murder conviction. Below, Matt Miller. ● *"There was a pill that we were told could fix Matt."*

Known risks. SmithKline Beecham, the maker of Paxil, and other drug companies say their medications play no role in violent behavior or suicide. Still, the companies do warn in package inserts that a small number of patients, fewer than 1 percent, may experience side effects, including abnormal dreams, agitation, hostility, suicidal thoughts, and delusions. But with an estimated 1.5 million young-

COURTESY OF MILLER FAMILY

sters receiving these antidepressants in 1996 alone, that's about 15,000 who could be vulnerable.

Matt Miller's parents believe their child was among the vulnerable. Miller, a 13-year-old from Overland Park, Kan., was given free samples of Zoloft in 1997 by his psychiatrist. There was no printed information; the Millers say they were told Matt might get a bellyache and have trouble sleeping. "We were ecstatic that there was a pill that we were told could fix Matt," his father says. Seven days later, Matt's mother went to collect laundry from her son's room and found him hanging inside his closet. The Millers have filed suit against Pfizer, the manufacturer of Zoloft. The company believes the drug is not linked to violence.

Even experts who believe these drugs can cause violent behavior blame not the drugs themselves but the way in which physicians diagnose and monitor their patients. Psychiatrist Frederick Goodwin, a former head of the National Institute of Mental Health, contends that kids who get violent may have been misdiagnosed and placed on the wrong drug in the first place. That is why it is critical to see a doctor with expertise in mental health care, experts say. Unless things change, says Goodwin, "then the likelihood of these negative events happening goes way up." *–D.P. and T.L.*

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."

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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;

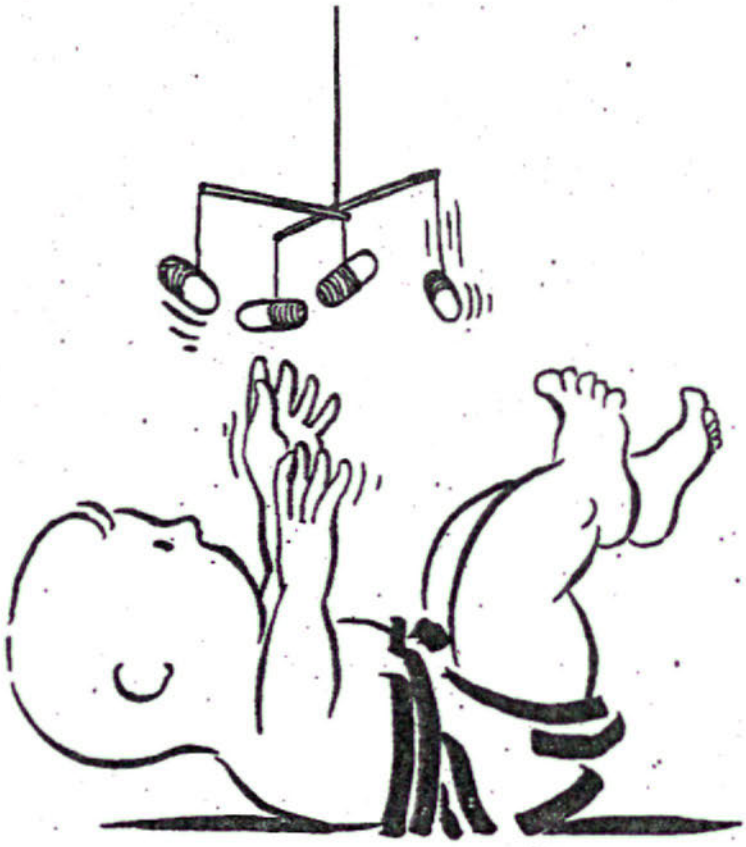
YOUNG A study found that the number of 2- to 4-year-olds on psychiatric drugs, including stimulants such as Ritalin and anti-depressants such as Prozac, jumped between 1991 and 1995.; 14 per 1,000 preschoolers; 1991; 1993; 1995 Total stimulants; Ritalin Total anti-depressants;

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

NY Times
3/1/00

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."

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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.

JAMA. 2000;283:1025-1030

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.

METHODS

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

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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.

COMMENT

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

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Australia (0.26% to 0.64% vs approximately 0.1%).[14] 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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ABSTRACT
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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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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

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

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Lissa –

FYI. Here's some background info on HRC's past work with children + health issues. (To answer questions about whether HRC is just doing the children + medication event to further herself politically.)

Ruby says these are in draft form, so use cautiously (i.e. don't fax to press).

Jen

To: Lissa & Jenn

Fr. Ruby

67805

Draft THE FIRST LADY Draft

February, 2000

The First Lady has fought for policies that help parents balance work and family, strengthen America's public schools, and provide greater opportunities to children and youth of all backgrounds, particularly those who are most vulnerable. She has sought to expand access to quality health care for all Americans, and to increase the economic security of working families.

SUPPORTING WORKING PARENTS AND THEIR FAMILIES

"Today... more of America's parents are working, by choice or by necessity. More than ever, parents rely on child care and after-school programs to care for their children for part of the day. We all have a stake in making sure that every child in care is safe and nurtured. This is part of America's unfinished business..." [The First Lady, 1/7/98]

Promoting Child Care and Early Learning. The First Lady has worked tirelessly to make child care better, safer, and more affordable for America's working families and to ensure that children enter school ready to learn. She chaired the White House conferences on child care and early childhood brain development, which led to the Administration's proposal for substantial new investments in child care, Head Start and other programs serving young children.

Supporting A Family-Friendly Workplace. The First Lady supported the Family and Medical Leave Act of 1993, which has enabled millions of Americans to take job-protected leave following the birth or adoption of child, or for the care of a sick relative, and continues to promote the expansion of the FMLA to millions more American workers.

Helping Families Meet Their Responsibilities. Recognizing that many Americans find themselves responsible for the care of their elderly or disabled relatives, The First Lady has worked on behalf of initiatives to meet the long-term care needs of families including the Administration's proposed $3,000 tax credit.

Giving Parents the Tools They Need To Protect Their Children. The First Lady has long believed that parents should have control over their children's exposure to media. She hosted a White House convening on children's television, advocated for increased educational programming for children, led a round-table discussion with the President and Vice President on the V-Chip, and strongly advocates the establishment of a voluntary uniform ratings system for all forms of media.

INCREASING OPPORTUNITY FOR AMERICA'S CHILDREN

"I don't think there are any more important missions that we can undertake...than to be sure we raise the next generation of learners." [The First Lady, 3/18/99]

Expanding School Choice. The First Lady has long encouraged the establishment of public charter schools to give parents more choice in schooling, has and worked to secure funding for charter schools in Washington DC.

Improving Schools for Our Children. The First Lady has encouraged education reform initiatives designed to improve the quality of the public education our children receive, by fighting for high academic standards and strong accountability. She has been a strong advocate for policies that turn around failing schools, reduce class size, and improve teacher quality, and has led efforts – such as the Prescription for Reading literacy initiative -- to ensure that children are mastering the basics.

Working to Reduce Youth Violence. The First Lady has championed significant new investments in programs to prevent violence. She fought for the Administration's most recent proposal to invest $1 billion in the 21st Century Community Learning Centers program to give children most in need a safe place to learn during the after school and summertime hours. The First Lady has urged Congress to pass legislation to keep guns out of the hands of children, co-chaired the White House Conference on School Safety and spurred the creation of the National Campaign Against Youth Violence.

Assisting the Neediest of Children. As the Administration's most prominent advocate on foster care and adoption, The First Lady has worked on behalf of the over 500,000 children who live in foster care because of abuse or neglect. She has promoted the adoption of children living in foster care and worked for passage of the Adoption and Safe Families Act of 1997, and the Foster Care Independence Act of 1999, two pieces of landmark legislation which reformed our nation's child welfare system by putting considerations of children's health and safety first.

WORKING TO IMPROVE HEALTH CARE FOR ALL AMERICANS

The health of our citizens should not be a partisan issue...Americans deserve quality care.... This country is capable of

THE FIRST LADY

DRAFT Promoting Financial Security and Economic Growth DRAFT
February, 2000

Working to Save Social Security. The First Lady has advocated for the Administration's policies of fiscal discipline which will extend the program's solvency to 2050 by paying down the national debt and dedicating the interest savings to Social Security -- a down payment on truly strengthening Social Security. She has also worked to ensure that the Administration's reform proposals incorporate the particular concerns women face with Social Security.

Promoting Economic Development. The First Lady has long believed that a key component to growth of poor communities is extending access to capital and training to non-traditional, underserved borrowers. For over 15 years, she has worked to develop community lending institutions and the innovative policies to support them in the U.S. and abroad. Over the course of this Administration, she has:

- developed a Presidential awards program to honor excellence in microenterprise development, and coordinated all microenterprise programs within the U.S. government;
- laid the groundwork for the creation of the Community Development Financial Institution Fund which Fund increases the availability of credit, investment capital, financial services, and other development services in distressed communities;
- joined Senators Kennedy and Domenici for the launch of the PRIME Act – a program to provide grants to organizations that provide planning, marketing and financial management training to microentrepeneurs;
- worked with USAID to launch a new international Microenterprise Development Initiative and visited countless international micro-lending efforts in poor communities worldwide.

The First Lady strongly supports the Administration's New Markets Investment Initiative which seeks to spur new capital investment in businesses in economically distressed areas through a package of tax credits and loan guarantees, as well as efforts to bridge the "digital divide" – unequal access to technology by income, education level, race, and geography – and continues to fight for the expansion of the Administration's microenterprise initiatives.

Advancing Women's Economic Security and Empowerment. The First Lady has worked hard to ensure that the Administration's economic policies include a focus on women. She has advocated for the Administration's policy on ensuring equal pay for women and supports the newest $27 million budget proposal, has worked to ensure that bankruptcy reform does not adversely impact women and families, particularly in terms of child support collection, and in the Social Security debate she has focused her attention on ensuring that the features of Social Security that are important to women are preserved and strengthened.

Making Welfare Reform Work. The First Lady was a strong supporter of welfare reform, and now the number of Americans on welfare is at its lowest level since 1969 – 30 years ago – as millions of people move from welfare to work. She also knows how important it is to support working families as they transition from welfare to work, which is why she has actively sought to increase access to affordable, safe, high quality child care, has to expand health care coverage, and raise the minimum wage.

Supporting an Increase in the Minimum Wage. The First Lady believes that parents who work hard and play by the rules should not have to raise their children in poverty, and that's why she has advocated the Administration's proposal to increase the minimum wage one dollar over the next two years, which would mean an additional $2,000 each year for families struggling to make ends meet.

Fighting for Targeted Tax Relief.. The First Lady has always supported efforts to provide targeted tax relief to the hard-pressed Americans and as well as middle class Americans. She has fought for efforts to expand the Earned Income Tax Credit, and strongly supports the Administration's current expansion proposal which would deliver tax relief for 6.8 million families. The First Lady has also been the Administration's foremost

advocate for targeted tax relief for middle-income Americans such as a new proposal to help make college affordable for millions of American families.

THE FIRST LADY

DRAFT Working to Improve Health Care for All Americans DRAFT
February, 2000

Working to Expand Access to Health Care. The First Lady has long championed a broad array of health initiatives, from reform of our health care delivery system to prevention programs that help Americans lead longer, healthier lives. In 1993, she traveled the country to listen to Americans talk about their health care concerns and testified before five Congressional committees on health reform. While she now works to expand access to health insurance through smaller steps, she continues to believe that we must make progress to ensure that every American has access to quality, affordable health care.

Working to Improve, Strengthen and Modernize Medicare. The First Lady has been a strong supporter of the Administration's comprehensive plan to reform and modernize Medicare by making the program more efficient and competitive, extending the solvency of the Health Insurance trust fund, and modernizing benefits -- including adding a long overdue, voluntary prescription drug benefit. Additionally, with The First Lady's strong leadership, the Administration proposed and Congress adopted, the expansion of Medicare coverage to help pay for annual mammogram screenings for all Medicare beneficiaries age 40 and over, screening tests for both colorectal and cervical cancer, and a diabetes self-management benefit.

Meeting Prescription Drug Needs of Patients. The First Lady strongly supports the Administration's proposed prescription drug benefit under Medicare which would be voluntary, available and affordable to all beneficiaries, including those with low-incomes who would pay low to no costs for coverage.

Addressing Children's Health Care Needs. The First Lady has been a longtime champion of meeting the special health needs of children:

- The First Lady helped to create and promote the Children's Health Insurance Program – the single largest investment in health care for children since 1965 – which now provides health insurance for two million low income children who would otherwise be uninsured. The five year, $24 billion State Children's Health Insurance Program (SCHIP) will provide health care coverage for up to five million children.
- The First Lady launched the Childhood Immunization Initiative and helped secure passage of the Vaccines for Children program.
- The First Lady has fought hard to support children's hospitals. She secured funding in last year's budget to support graduate medical education at free-standing children's hospitals, a move much hailed by advocates, and worked to double the funding for this program in the Administration's proposed FY 2001 budget.
- The First Lady has promoted research and funding of specific health problems such as juvenile diabetes and epilepsy. Last year, she launched the Administration's comprehensive childhood asthma initiative and helped secure funding for the Environmental Protection Agency to study the causes of asthma, and promote awareness. She also inaugurated a public outreach campaign for Pediatric AIDS at the White House and received an award from the Pediatric AIDS Foundation for her commitment to the issue.

Fighting for Women's Health Care Needs. The First Lady has helped bring women's health needs to the forefront of Administration's health care efforts:

- The First Lady has always fought for comprehensive reproductive health services for women, working to protect a woman's right to choose and to promote safe reproductive health services for women in the U.S. and around the world.
- The First Lady has championed budget increases for the National Cancer Institute and other agencies to support research on breast cancer detection, treatment, and cures; she launched the Medicare Mammography Campaign to urge older women to get mammograms and to promote the use of Medicare coverage for mammography, implemented by this Administration; she helped develop and implement the National Action Plan on Breast Cancer, a public-private partnership coordinated at the Department of Health and Human Services; and advocated for legislation pending before the Congress to ensure that women who have mastectomies are entitled to sufficient hospital stays from their HMOs.

HILLARY RODHAM CLINTON: A CHAMPION OF BREAST CANCER RESEARCH AND DETECTION, PREVENTION AND AWARENESS

SUPPORTING BREAST CANCER RESEARCH. Hillary Clinton has been a champion of significant budget increases for the National Cancer Institute and other agencies to support research on breast cancer detection, treatment, and to seek a cure for the disease. Investment in research has led to historic advances, including the identification of new breast cancer genes and promising new treatments. In October of 1998, Mrs. Clinton hosted an event at the White House to announce budget increases in breast cancer research and new initiatives supported by the research. From fiscal years 1993 to 1999, discretionary funding for breast cancer research, prevention and treatment at the Department of Health and Human services has more than doubled – from $283 million to $599 million.

PROMOTING THE APPLICATION OF THE LATEST IN DEFENSE AND SPACE TECHNOLOGY TO BETTER DETECT CANCEROUS TISSUE AND DEVELOP LESS INSTRUSIVE SURGERY METHODS FOR PATIENTS. Hillary Clinton championed budget investments to enable the Department of Defense, the Center Intelligence Agency, NASA, and other public and private entities to explore ways in which imaging technologies from other fields can be applied to the early detection of breast cancer. In particular, the computer technologies that have been used to improve imaging satellites have been used to improve breast cancer detection, as well. And, imaging technologies from the defense community – originally used for missile guidance and target recognition – is also being used to better detect breast cancer.

CHAIRING MEDICARE MAMMOGRAPHY CAMPAIGN TO URGE OLDER WOMEN TO GET MAMMOGRAPHY SCREENING. Early detection of breast cancer is crucial for successful treatment. In 1995, Hillary Clinton launched the Medicare Mammography Campaign to urge older women to get mammograms and to promote the use of Medicare coverage for mammography. Mrs. Clinton efforts have included:

- Travelling the country listening to seniors and raising awareness of the importance of mammography screening;
- Taping Public Service Announcements encouraging older women to get mammography screening; and
- Convening business leaders at the White House to build a public-private partnership to promote mammography. Private sector partners have included American Greetings, which included in its Mother's Day greeting cards an insert urging women to get mammograms and directing them to a toll-free number for more information.

With Hillary Clinton's strong leadership, the President proposed and Congress adopted, the expansion of Medicare coverage to help pay for annual mammogram screenings for all Medicare beneficiaries age 40 and over. Under this new benefit, which became available January of 1998, Medicare will waive the Part B deductible for screening mammograms.

PROMOTING BREAST CANCER AWARENESS. Hillary Clinton has been a chief advocate in the Administration for raising awareness of breast cancer issues and putting them at the top of the Administration's agenda. Mrs. Clinton's activities have included:

- Receiving at the White House in 1993 the National Breast Cancer Coalition petition with recommendations on breast cancer policy and awareness;

- Helping to develop and implement the National Action Plan on Breast Cancer, a public-private partnership coordinated at the Department of Health and Human Services;
- Supporting the National Action Plan on Breast Cancer web site to serve as a gateway to information on breast cancer research, treatment, and prevention (http://www.napbc.org);
- Hosting White House events to mark October as Breast Cancer Awareness Month;
- Dedicating "Talking it Over," Mrs. Clinton's syndicated column, to breast cancer issues (10/95, 12/95, 9/96, 7/98); and
- Unveiling at the White House the official breast cancer awareness stamp, which helps to fund breast cancer research.

CHAMPIONED PENDING LEGISLATION TO SUPPORT PATIENTS WITH BREAST CANCER AND OTHER DISEASES. Mrs. Clinton has been a strong advocate for legislation pending before the Congress to ensure that women who have mastectomies are entitled to sufficient hospital stays from their HMOs. And, Mrs. Clinton has fought for a strong Patients Bill of Rights to ensure that cancer patients have the right to see a specialist, are not forced to change doctors in the middle of a cancer treatment if an employer changes health care providers, and have an independent appeals process if critical treatment is delayed or denied. In addition, Mrs. Clinton has strongly supported legislation which would outlaw discrimination based on the results of genetic screening.

PROMOTING AWARENESS OF OTHER CANCERS. Hillary Clinton has been a champion of increased awareness of colorectal cancer, prostate cancer, and ovarian cancer by advocating successfully for Medicare preventive benefits such as annual screenings. Mrs. Clinton has hosted events at the White House to raise awareness of the importance of screenings for these diseases and to urge research to improve detection and treatment.