THE WHITE HOUSE

WASHINGTON

June 27, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: **HEATHER HOWARD**

CC: **MELANNE VERVEER**
LISSA MUSCATINE
ANN O'LEARY

SUBJECT: **UPDATE ON EFFORTS TO IMPROVE THE TREATMENT OF CHILDREN WITH EMOTIONAL AND BEHAVIORAL CONDITIONS**

Before your interview with the Medical Editor of CBS, I wanted to briefly update you on what has happened since your event in March announcing new Federal efforts to improve the diagnosis and treatment of children with emotional and behavioral conditions.

- **New guidelines for the diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) from the American Academy of Pediatrics**. At your Roosevelt Room event, you announced that the Academy was developing new guidelines for the diagnosis and treatment of ADHD. In May, the Academy released the new treatment guidelines to their 55,000 members. The new guidelines require that ADHD symptoms be present in two or more of a child's settings, and that the symptoms adversely affect the child's academic or social functioning for at least six months. The new guidelines recommend that the assessment of ADHD include information obtained directly from parents or caregivers, as well as a classroom teacher or other school professional, regarding the core symptoms of ADHD in various settings. They also recommend that evaluation include assessment for co-existing conditions, such as learning and language problems, aggression, disruptive behavior, depression or anxiety. The Academy is currently developing the new ADHD treatment guidelines, which are expected to be released this fall.

- **NIMH research.** NIMH is in the process of funding a $5 million multi-site trial on the use of Ritalin to treat ADHD in preschoolers.

- **FDA efforts.** Due in large part to the attention you have focused on this issue, the FDA is now working to develop the science base necessary to create protocols for developing new labeling information for pediatric dosages. In September, the FDA's Pediatric Advisory Subcommittee will be meeting to discuss the ethical issues surrounding studying children, and in October, the FDA and NIMH are holding a joint meeting entitled "Psychopharmacology for Young Children: Clinical Needs and Research Opportunities."

- **Planning for the Fall Surgeon General's Conference on the Treatment of Children with Behavioral and Mental Disorders**. Planning for the conference, scheduled for September 17th and 18th, 2000, is ongoing. On Monday, June 26, 2000, the Surgeon General held a "listening session," to which he invited 50 groups representing healthcare providers, educators, parents, and consumers. Representatives from NIMH, the FDA, SAMSA, and the Center for Mental Health Services also participated. The meeting, which I attended, solicited input on four key questions:

  - What are the key barriers to identifying, recognizing or referring children with mental health needs (e.g., definitional, systems, training, assessment issues, costs, etc.)?
  - What are the major challenges to using evidence-based strategies to identify and treat children with mental health problems?
  - What are the major service obstacles to delivering mental health care to children and families?
  - What are the key research and service priorities in children's mental health?

  The overarching themes in the comments were:

  - The importance of coordination between the different providers in children's lives, including those in the health care, education, and child care systems.
  - The need for better training for health providers and educators, to help them assess children's behavioral and mental problems.
  - The critical importance of proper assessment, which everyone agreed cannot happen during a ten-minute doctor's visit.
  - The importance of involving families in all aspects of treatment, including diagnoses, service design and delivery.
  - The need for research on the zero to five population.
  - The difficulties in translating research into practice.

  As you mentioned in your speech at the March event, pharmaceutical companies and health insurers need to be included in this discussion. The Surgeon General's office has assured me that they will be included in the fall conference.

MEMORANDUM

TO: **HRC**
FROM: **Erika Batcheller**
RE: **CBS Interview on Ritalin/Psychotropic drugs**
DATE: **June 27, 2000**

You are scheduled for a 5-minute interview Wednesday morning with CBS television for an upcoming segment on ADHD. The segment will focus on the dramatic increase in the number of children diagnosed with ADHD and the use of psychotropic drugs. CBS is principally interested in talking to you about your initiatives to encourage the safe use of medication for children with emotional and behavioral conditions.

The interviewer will be Matt Mulchaey, a reporter for WTVH, the local CBS affiliate. CBS has arranged to have him pose questions to you immediately following your interview with him around 8:15 a.m.

The segment on ADHD will run in the next couple of weeks on CBS *This Morning*. A re-packaged piece with excerpts from your interview will be used later for CBS *Evening News with Dan Rather*.

Background follows, including:

1) An update on efforts since March 20 White House event on Ritalin/Psychotropic drugs;
2) Background material from March 20 event, including the briefing memo, press paper and your remarks; and
3) Information on the CBS segment.

Thanks

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March 17, 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 – 10:45 AM
Location:	
From:	Ann O'Leary, Heather Howard and Ruby Shamir

I. PURPOSE

To demonstrate your commitment to children's health by gathering health and education experts to discuss the appropriate treatment of young children with emotional and behavioral conditions.

II. BACKGROUND

Overview

This event focuses on the controversy surrounding the recent increase in the prescription of stimulants and antidepressants to preschoolers despite the 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, pharmacalogical, 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 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. *NIMH 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 members –*will we know if this is the case on Sunday?*].

2. *Announcement of Federal Conference on the Treatment of Children with Behavioral and Mental Disorders*: The Surgeon General will coordinate a conference with HHS, 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. *Attach the abstract?* 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, as opposed to less than X percent of children in urban areas [*get NIMH cite from Devorah]*. 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 pyschological or social damage may stem from an on-going cycle of punishment and ostracism for behaviors that the child cannot control without help. Children with these types of problems are at significantly higher risk for anti-social activities later on than those without behavioral problems. 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 there 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 etc.

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

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

March 20, 2000

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HILLARY ROHDAM CLINTON'S LONGSTANDING COMMITMENT TO CHILDREN. For over 25 years, Hillary Clinton has fought to raise awareness and support policies that protect children. She was a strong advocate for: the passage of the Children's Health Insurance Program, the Family and Medical Leave Act; new regulatory and statutory authority for pediatric labeling; administration efforts to improve child care. The new pediatric labeling regulations and the FDA Modernization Act enacted by the Clinton Administration have improved the information available to both parents and physicians about the appropriate use of medications for children. In the 18 months

since these initiatives have been implemented, research has been completed on 19 drugs, resulting in new safety information being added to six drugs with changes expected for the other 13. Studies of an additional 125 drugs are already underway.

Launch of New Public-Private Effort to Improve the Diagnosis and Treatment of Children with Emotional and Behavioral Conditions

Remarks by First Lady Hillary Rodham Clinton
Roosevelt Room
March 20, 2000

Thank you all for joining us here this morning. I want to thank Secretary Shalala for her leadership, and I'm also pleased she refuses to sit still. Because whenever our children's health is at stake, she's out there working very hard to make sure we all pay attention.

Also, I'm pleased to be joined not only by Secretary Shalala, but by Surgeon General David Satcher, and FDA Director Jane Henney, and NMIH Commissioner Dr. Steve Hyman, and Dr. Judith Heumann, and representatives from many of the groups who are on the frontlines working on behalf of all of our children, particularly children with behavioral and emotional challenges.

We just came from a meeting where we talked about what more we can do to ensure that children with emotional and behavioral problems get the diagnosis and treatment they need, and when they need it. Today's meeting and the announcements around it are important steps, but they are certainly not the last step we need to take in ensuring that all of our children get the health and support and treatment that they deserve.

You know, when a child comes to us who is hurt or sick, there is nothing more terrifying for any of us, especially parents, when we don't know how to make it better. If they have a broken arm, we want to fix it; if they have a deadly disease, we want to do everything we possibly can to cure it. And it's no different if the problem they bring to us lies in their head or their heart.

Thanks in large part to the leadership of Tipper Gore, the President's mental health adviser, we've come a long way in our battle to bring mental illness out of the shadows and make sure it is treated just as seriously as physical illness. More and more often, those treatments include drugs, even for young children. That is the issue we're here today to discuss.

As many of you know, the Journal of the American Medical Association recently reported that the number of preschoolers who are taking psychotropic drugs increased dramatically from 1991 to 1995. We know that the increase for Ritalin alone was 150 percent, and the use of anti-depressants increased over 200 percent. Now I am no doctor, as is obvious, but I am a parent and I have been a longtime children's advocate. And these findings concern me. I know they concern Dr. Hyman, Secretary Shalala and countless other experts.

But let me be very clear: We are not here to bash the use of these medications. They have literally been a Godsend for countless adults and young people with behavioral and emotional problems. We know that when children with such problems are left untreated, they

may fail to reach their God-given potential later in their lives. That's why we are here. We want the best information for every parent, every doctor, every teacher—every single person who cares for our children.

But we do have to ask some serious questions about the use of prescription drugs in all children. We have to ask, for example, how are we diagnosing, treating and caring for children with behavioral and emotional conditions? Do we have the best tools to make the most accurate diagnoses? When it comes to drug treatments for children, why are we seeing such great variations by community and race? And what effects do overuse and underuse of these medications have on our children?

We need to ask also, why aren't we doing a better job of combining drugs, when necessary, with family therapy and other behavior modifications? And what about the effects on our very youngest children who haven't been tested for these prescription drugs and whose brains are in their most critical stage of development?

These are tough questions, and none of us have all of the answers. But as we made clear in the meeting this morning, we are building on a record, not starting from scratch. We have already taken critical steps over the past few years to ensure that drugs are being tested and labeled specifically for children. Some of you may remember that was a long, drawn out struggle, that we were finally able to make progress and we were able to make an announcement at the White House last year. In so doing, we have learned that finding the right prescription for a child is not always just a matter of decreasing the dosage.

You know, I think it's important that all of us adults recognize that children are not just miniature adults; that their systems, their developmental needs, are different from that of an adult. We also learned quite a bit from the first ever Surgeon General's report on mental illness, which came out in December. It grew out of the White House Conference on Mental Illness, led by Tipper Gore. It taught us that the stigma of mental illness is worse for children; that too many health care professionals lack training in the area of children's mental, emotional and behavioral needs; and that we have a long way to go to increase awareness about children's mental health.

So clearly, we must do more. We know that the questions being raised are very difficult and they cannot be answered overnight. And they certainly won't be answered by the government, or health care professionals or educators or parents acting alone. Every single person with a stake in our children's health has an important role to play.

So I'm very pleased today to announce some of the immediate steps we are taking to make sure that children with mental illness, with behavioral and emotional problems, get the right care at the right time.

As our meeting made clear, we already know a lot about the proper diagnosis and treatment of emotional and behavioral problems in children. But that critical information has not reached many of the people who need it most—many of the parents, many of the teachers,

many of the school nurses, many of the school social workers, many of the family physicians, many of the pediatricians—so there are a few things we are going to try to do to change that.

Today, the NMIH is releasing a new, easy to understand fact sheet that parents can use to make the right decisions about their children's treatment for these conditions. The Education Department will soon release an information kit to help parents and teachers better care for children with ADHD. And I want to thank both the American Academy of Pediatrics and the American Academy of Family Physicians for all they are doing on this issue. This spring and fall, the American Academy of Pediatrics will give all of their 55,000 members up-to-date guidelines for diagnosing and treating children with emotional and behavioral problems. And as part of their yearlong focus on mental health, the American Academy of Family Physicians is sponsoring continuing education courses about these conditions for their 90,000 members.

But now we also have to admit, honestly, that there are some areas where we still just don't know enough, and that's especially true when it comes to giving prescription drugs to our very youngest children. I am pleased that NIMH will dedicate over $5 million to conduct a landmark study examining ADHD and Ritalin use in preschoolers. This study will look at the gap between what we are finding out in the science labs and what is happening in clinical practice, so we can ensure that our children get the care they need. In addition, the FDA will look at some common psychotropic drugs and begin a process to find out what dosage levels are appropriate for very young children. This information will then be included on the labels of these medications, and the studies on them will address the obvious ethical issues that arise when you examine the use of prescription drugs in such a vulnerable group.

Finally, I'm delighted that this fall, the office of the Surgeon General will coordinate a national conference on the treatment of children with behavioral and mental disorders. It will bring together experts from the administration, parents, advocates, educators, researchers, healthcare professionals and consumers. It will look at the challenges we are all still facing in caring for children with mental illnesses. It will help us develop long term strategies that each of us can use to help young people get the childhood and chance in life that we all deserve.

I remember, as we were talking today, that I was fortunate, more than 30 years ago, to work at the Yale Child Study Center, one of the premier research institutions in our country when it comes to treating our young children. And I was exposed to some of the greatest minds and experts in the country about how to treat very young children. And there was nothing more challenging and, in many ways, heartbreaking, than a preschooler with obvious mental, emotional and behavioral problems. That child cannot speak for him or herself. So it's often difficult to find out what kind of conditions in the child's life led to—if there is a cause and effect—the kind of behavior that is being observed. So I know firsthand—from 30 years of work on my own behalf, and watching experts who are really on the frontlines of this—that this is a very big challenge we are taking on today.

But I am also concerned that we are seeing increasing numbers of children who are both being diagnosed with certain disorders and whose behaviors are crying out for helpful intervention. We spoke earlier today in our meeting about the increasing number of very young

children in foster care. The fastest growing group of children being put into foster care are children under 5. They come into foster care because of abuse or neglect and they therefore have more than the kinds of problems that one would expect in the population at large. We talked about the increasing numbers of children who are in the juvenile justice and criminal justice systems. We are not doing what we need to do to help intervene and treat those children, just as we are not providing adequate medical and mental health services in our adult prisons. These are problems that affect all of society, not just the individual with the specific problem or that individual's family or those teachers and others that come into contact with that young person. This has ramifications for all of us.

All we need to do is look back a few weeks and think about the 6-year-old that brought the gun to school to kill the other 6-year-old. That is a problem that did not just occur the morning the child picked that gun up off of the bed in that terrible condition in which he was living. So all of us have a stake in the research, the diagnosis and the treatment. And I would also add that we need some other people at the table, and we're going to try to do that through Dr. Satcher's efforts and the efforts of the associations represented here. We need to be sure that the insurance industry, the HMO industry, the pharmaceutical industry—as well as decision-makers at all levels of government—are also at the table. We do have a lot of information about what works, but we need more. And that's what this meeting and these announcements are about. But we should at least be trying to implement what we do know works while we look for more answers, and follow up on the efforts that will be underway.

You know, when a child is sad or misbehaving, it is never easy for even the most well-intentioned, best-meaning parent to figure out what is happening. Anyone who has ever had a child who is pre-verbal with any kind of illness, or a toddler, or a preschooler, knows how difficult it is. Some of these young people have problems that are symptoms of nothing more than childhood or adolescence. Some of them need a parent to love them, or a person simply to listen to them talk about their pain. And yet some do have severe emotional and mental problems that can be greatly helped by prescription drugs. These children are waiting for our help—every one of them—and today we are taking important steps to provide it.

It is my great hope that this meeting will move us closer to the day that we will be able, number one, to remove the stigma from these problems so that no parent or no community has to wonder whether this is something that should be talked about, or help should be sought for. And number two, that we will treat the problems of the body and the mind the very same.

I hope that all of us will see this as a beginning and that we will be even more committed to doing whatever it takes to make sure that our children get the help, support and love that they need to have.

Thank you all very much.

TREATMENT OF YOUNG CHILDREN WITH MENTAL CONDITIONS
When to Get Help • People to Talk To • Learning About Medications

A NOTE TO PARENTS

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

Although progress has been made in diagnosing the mental illnesses that begin in childhood, children's brains are in a state of rapid change and growth, and diagnosis and treatment of mental disorders must be viewed with this in mind. While some problems are short lived, others are persistent and very serious, and parents should seek help for their children. Treatment decisions should be weighed for risks and benefits, and each child should be viewed individually.

WHEN TO GET HELP

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

PEOPLE TO TALK TO IF YOU ARE CONCERNED ABOUT YOUR CHILD

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

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

LEARNING ABOUT MEDICATIONS

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

anti-depressants, anti-anxiety agents, anti-psychotics, and mood stabilizers.

Stimulants

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

Brand Name	Generic Name	Approved Age
Adderal	amphetamines	3 and older
Cyclert	pemoline	6 and older
Dexedrine	dextro-amphetamine	3 and older
Ritalin	methylphenidate	6 and older

Anti-Depressant and Anti-Anxiety Medications

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

Brand Name	clomipramine	8 and older (OCD)
Anafranil	fluovoxamine	12 and older
Luvox	doxepin	6 and older (bedwetting)
Sinequan	imipramine	6 and older (OCD)
Tofranil	sertranline	
Zoloft	Approved Age	
Generic Name	10 and older (OCD)	

Other medications that are used to treat these disorders in children include Effexor (venlafaxine), Paxil (paroxetine), Prozac (fluoxetine), Serzone (nefazodone), and Wellbutrin (bupropion). They are not labeled for pediatric use.

Anti Psychotics

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

Brand Name	Generic Name	Approved Age
Haldol	Haloperiodol	3 and older
generic only	Thioridazine	2 and older
Orap	Pimozide	12 and older

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

Mood Stabilizers

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

Brand Name	Depakote	Lamictal
Cibalith-S	Eskalith	Lithobid

Neurontin	lamotrigine	2 and older (for seizures)
Tegretol	lithium carbonate	12 and older
Generic Name	gabapentin	16 and older (for seizures)
lithium citrate	carbamazepine	12 and older
divalproex sodium	Approved Age	12 and older (for seizures)
lithium carbonate	12 and older	any age (for seizures)

Research on the effectiveness of these and other medications in children and adolescents with bipolar disorder are ongoing. In addition, studies are investigating various forms of psychotherapy, including cognitive-behavioral therapy, to complement medication treatment for this illness in young people.

FOR MORE INFORMATION ON MENTAL DISORDERS IN CHILDREN
CONTACT THE NATIONAL INSTITUTES OF MENTAL HEALTH 301 443 4513 / www.nimh.nih.gov

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S

TO: Lissa Muscatine
First Lady's Press Office
The White House

FM: Frederick J. Balboni, Jr.

RE: CBS request for Hillary Rodham Clinton

DA: May 23, 2000

As per my conversation with you late yesterday afternoon, please expedite the following media request.

The CBS Medical Unit would like to put together a segment within the next two-three weeks for *CBS This Morning* dealing with ADHD and featuring Mrs. Clinton as an in-studio guest. A re-packaged piece with interview excerpts will be used later for the *CBS Evening News with Dan Rather*. Mrs. Clinton will be asked to speak about her initiatives aimed at reducing the number of children in the U.S. that are currently on Ritalin and other psychotropic drugs.

Over the last ten years there has been a 700 percent increase in the use of potent psycho-stimulants among young children meant to treat various behavioral disorders such as Attention Deficit Hyperactivity Disorder (ADHD). Many continue to debate the use of Ritalin and other therapeutic pharmaceuticals as therapies for these neurological abnormalities. Currently, no objective, biologically based diagnostic test exists for ADHD, which leaves decisions about Ritalin use to educated guesswork.

As part of Mrs. Clinton's segment, CBS is considering including Russell Barkley, Ph.D., a world- renowned author and expert on ADHD, who, in conjunction with Boston Life Sciences, Inc., is currently involved in extensive research on a first-ever biologically based diagnostic for ADHD. Dr. Barkley will speak about the complexities of diagnosing and treating ADHD along with his current research with Altropane™. If an objective diagnostic were available, healthcare providers could accurately identify the presence or absence of ADHD, and bring new confidence and certainty to diagnosis and treatment.

HRC to be interviewed by medical editor.

ABOUT ALTROPANE™

Abnormalities in several dopamine receptor genes and the dopamine transporter gene have been linked to ADHD. The response of patients to medications that block dopamine transporter molecules (DAT), such as Ritalin, implicate a DAT abnormality as a primary biological cause of ADHD.

Researchers at Boston Life Sciences, Inc. in Boston have developed Altropane™, a radio-pharmaceutical imaging agent that binds with high specificity to DAT in the brain. A recent study published in *The Lancet* using Altropane™ in conjunction with SPECT imaging demonstrated that there is an abnormal elevation of DAT in the striatum of subjects with clinically diagnosed ADHD[1]. These results suggest that high striatal DAT may be a biological marker for ADHD.

Currently, Altropane™ is in Phase II clinical trials on a "fast track" designation for use as an ADHD diagnostic. Altropane also recently completed Phase III clinical trials for the early diagnosis of Parkinson's Disease, for which there is presently no objective test.

ABOUT BLSI:

Boston Life Sciences, Inc (NASDAQ: BLSI) is a development stage biotechnology company engaged in the research and development of novel therapeutic and diagnostic products to treat chronic debilitating diseases, such as cancer and central nervous system disorders. Marc Lanser, M.D. founded Boston Life Sciences in 1992 while a faculty member at Harvard Medical School.

Accompanying this fax is Dr. Barkley's Bio and two recent press articles on the ADHD that reference Altropane™.

Thanks you in advance for your assistance.

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[1] Fishman, Alan J. Dopamine Transporter Density is Elevated in Patients with Attention Deficit Disorder. *The Lancet.* December 18, 1998.

MEMORANDUM

TO: **HRC**
FROM: **Erika Batcheller**
RE: **CBS Interview on Ritalin/Psychotropic drugs**
DATE: **June 27, 2000**

You are scheduled for a 5-minute interview Wednesday morning with CBS television for an upcoming segment on ADHD. The segment will focus on the dramatic increase in the number of children diagnosed with ADHD and the use of psychotropic drugs. CBS is principally interested in talking to you about your initiatives to encourage the safe use of medication for children with emotional and behavioral conditions.

The interviewer will be Matt Mulchaey, a reporter for WTVH, the local CBS affiliate. CBS has arranged to have him pose questions to you immediately following your interview with him around 8:15 a.m.

The segment on ADHD will run in the next couple of weeks on CBS *This Morning*. A re-packaged piece with excerpts from your interview will be used later for CBS *Evening News with Dan Rather*.

Background follows, including:

1) An update on efforts since March 20 White House event on Ritalin/Psychotropic drugs;
2) Background material from March 20 event, including the briefing memo, press paper and your remarks; and
3) Information on the CBS segment.

Thanks

THE WHITE HOUSE

WASHINGTON

June 27, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: HEATHER HOWARD

CC: MELANNE VERVEER
LISSA MUSCATINE
ANN O'LEARY

SUBJECT: UPDATE ON EFFORTS TO IMPROVE THE TREATMENT OF CHILDREN WITH EMOTIONAL AND BEHAVIORAL CONDITIONS

Before your interview with the Medical Editor of CBS, I wanted to briefly update you on what has happened since your event in March announcing new Federal efforts to improve the diagnosis and treatment of children with emotional and behavioral conditions.

- **New guidelines for the diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) from the American Academy of Pediatrics**. At your Roosevelt Room event, you announced that the Academy was developing new guidelines for the diagnosis and treatment of ADHD. In May, the Academy released the new treatment guidelines to their 55,000 members. The new guidelines require that ADHD symptoms be present in two or more of a child's settings, and that the symptoms adversely affect the child's academic or social functioning for at least six months. The new guidelines recommend that the assessment of ADHD include information obtained directly from parents or caregivers, as well as a classroom teacher or other school professional, regarding the core symptoms of ADHD in various settings. They also recommend that evaluation include assessment for co-existing conditions, such as learning and language problems, aggression, disruptive behavior, depression or anxiety. The Academy is currently developing the new ADHD treatment guidelines, which are expected to be released this fall.

- **NIMH research.** NIMH is in the process of funding a $5 million multi-site trial on the use of Ritalin to treat ADHD in preschoolers.

- **FDA efforts.** Due in large part to the attention you have focused on this issue, the FDA is now working to develop the science base necessary to create protocols for developing new labeling information for pediatric dosages. In September, the FDA's Pediatric Advisory Subcommittee will be meeting to discuss the ethical issues surrounding studying children, and in October, the FDA and NIMH are holding a joint meeting entitled "Psychopharmacology for Young Children: Clinical Needs and Research Opportunities."

- **Planning for the Fall Surgeon General's Conference on the Treatment of Children with Behavioral and Mental Disorders**. Planning for the conference, scheduled for September 17th and 18th, 2000, is ongoing. On Monday, June 26, 2000, the Surgeon General held a "listening session," to which he invited 50 groups representing healthcare providers, educators, parents, and consumers. Representatives from NIMH, the FDA, SAMSA, and the Center for Mental Health Services also participated. The meeting, which I attended, solicited input on four key questions:

  - What are the key barriers to identifying, recognizing or referring children with mental health needs (e.g., definitional, systems, training, assessment issues, costs, etc.)?
  - What are the major challenges to using evidence-based strategies to identify and treat children with mental health problems?
  - What are the major service obstacles to delivering mental health care to children and families?
  - What are the key research and service priorities in children's mental health?

  The overarching themes in the comments were:

  - The importance of coordination between the different providers in children's lives, including those in the health care, education, and child care systems.
  - The need for better training for health providers and educators, to help them assess children's behavioral and mental problems.
  - The critical importance of proper assessment, which everyone agreed cannot happen during a ten-minute doctor's visit.
  - The importance of involving families in all aspects of treatment, including diagnoses, service design and delivery.
  - The need for research on the zero to five population.
  - The difficulties in translating research into practice.

  As you mentioned in your speech at the March event, pharmaceutical companies and health insurers need to be included in this discussion. The Surgeon General's office has assured me that they will be included in the fall conference.

March 17, 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 – 10:45 AM
Location:
From: Ann O'Leary, Heather Howard and Ruby Shamir

I. PURPOSE

To demonstrate your commitment to children's health by gathering health and education experts to discuss the appropriate treatment of young children with emotional and behavioral conditions.

II. BACKGROUND

Overview

This event focuses on the controversy surrounding the recent increase in the prescription of stimulants and antidepressants to preschoolers despite the 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, pharmacalogical, 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 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. *NIMH 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 members *–will we know if this is the case on Sunday?*].

2. *Announcement of Federal Conference on the Treatment of Children with Behavioral and Mental Disorders*: The Surgeon General will coordinate a conference with HHS, 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. *Attach the abstract?* 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, as opposed to less than X percent of children in urban areas [*get NIMH cite from Devorah]*. 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 pyschological or social damage may stem from an on-going cycle of punishment and ostracism for behaviors that the child cannot control without help. Children with these types of problems are at significantly higher risk for anti-social activities later on than those without behavioral problems. 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 there 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 etc.

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

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

March 20, 2000

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HILLARY ROHDAM CLINTON'S LONGSTANDING COMMITMENT TO CHILDREN. For over 25 years, Hillary Clinton has fought to raise awareness and support policies that protect children. She was a strong advocate for: the passage of the Children's Health Insurance Program, the Family and Medical Leave Act; new regulatory and statutory authority for pediatric labeling; administration efforts to improve child care. The new pediatric labeling regulations and the FDA Modernization Act enacted by the Clinton Administration have improved the information available to both parents and physicians about the appropriate use of medications for children. In the 18 months

since these initiatives have been implemented, research has been completed on 19 drugs, resulting in new safety information being added to six drugs with changes expected for the other 13. Studies of an additional 125 drugs are already underway.

Launch of New Public-Private Effort to Improve the Diagnosis and Treatment of Children with Emotional and Behavioral Conditions

Remarks by First Lady Hillary Rodham Clinton
Roosevelt Room
March 20, 2000

Thank you all for joining us here this morning. I want to thank Secretary Shalala for her leadership, and I'm also pleased she refuses to sit still. Because whenever our children's health is at stake, she's out there working very hard to make sure we all pay attention.

Also, I'm pleased to be joined not only by Secretary Shalala, but by Surgeon General David Satcher, and FDA Director Jane Henney, and NMIH Commissioner Dr. Steve Hyman, and Dr. Judith Heumann, and representatives from many of the groups who are on the frontlines working on behalf of all of our children, particularly children with behavioral and emotional challenges.

We just came from a meeting where we talked about what more we can do to ensure that children with emotional and behavioral problems get the diagnosis and treatment they need, and when they need it. Today's meeting and the announcements around it are important steps, but they are certainly not the last step we need to take in ensuring that all of our children get the health and support and treatment that they deserve.

You know, when a child comes to us who is hurt or sick, there is nothing more terrifying for any of us, especially parents, when we don't know how to make it better. If they have a broken arm, we want to fix it; if they have a deadly disease, we want to do everything we possibly can to cure it. And it's no different if the problem they bring to us lies in their head or their heart.

Thanks in large part to the leadership of Tipper Gore, the President's mental health adviser, we've come a long way in our battle to bring mental illness out of the shadows and make sure it is treated just as seriously as physical illness. More and more often, those treatments include drugs, even for young children. That is the issue we're here today to discuss.

As many of you know, the Journal of the American Medical Association recently reported that the number of preschoolers who are taking psychotropic drugs increased dramatically from 1991 to 1995. We know that the increase for Ritalin alone was 150 percent, and the use of anti-depressants increased over 200 percent. Now I am no doctor, as is obvious, but I am a parent and I have been a longtime children's advocate. And these findings concern me. I know they concern Dr. Hyman, Secretary Shalala and countless other experts.

But let me be very clear: We are not here to bash the use of these medications. They have literally been a Godsend for countless adults and young people with behavioral and emotional problems. We know that when children with such problems are left untreated, they

may fail to reach their God-given potential later in their lives. That's why we are here. We want the best information for every parent, every doctor, every teacher—every single person who cares for our children.

But we do have to ask some serious questions about the use of prescription drugs in all children. We have to ask, for example, how are we diagnosing, treating and caring for children with behavioral and emotional conditions? Do we have the best tools to make the most accurate diagnoses? When it comes to drug treatments for children, why are we seeing such great variations by community and race? And what effects do overuse and underuse of these medications have on our children?

We need to ask also, why aren't we doing a better job of combining drugs, when necessary, with family therapy and other behavior modifications? And what about the effects on our very youngest children who haven't been tested for these prescription drugs and whose brains are in their most critical stage of development?

These are tough questions, and none of us have all of the answers. But as we made clear in the meeting this morning, we are building on a record, not starting from scratch. We have already taken critical steps over the past few years to ensure that drugs are being tested and labeled specifically for children. Some of you may remember that was a long, drawn out struggle, that we were finally able to make progress and we were able to make an announcement at the White House last year. In so doing, we have learned that finding the right prescription for a child is not always just a matter of decreasing the dosage.

You know, I think it's important that all of us adults recognize that children are not just miniature adults; that their systems, their developmental needs, are different from that of an adult. We also learned quite a bit from the first ever Surgeon General's report on mental illness, which came out in December. It grew out of the White House Conference on Mental Illness, led by Tipper Gore. It taught us that the stigma of mental illness is worse for children; that too many health care professionals lack training in the area of children's mental, emotional and behavioral needs; and that we have a long way to go to increase awareness about children's mental health.

So clearly, we must do more. We know that the questions being raised are very difficult and they cannot be answered overnight. And they certainly won't be answered by the government, or health care professionals or educators or parents acting alone. Every single person with a stake in our children's health has an important role to play.

So I'm very pleased today to announce some of the immediate steps we are taking to make sure that children with mental illness, with behavioral and emotional problems, get the right care at the right time.

As our meeting made clear, we already know a lot about the proper diagnosis and treatment of emotional and behavioral problems in children. But that critical information has not reached many of the people who need it most—many of the parents, many of the teachers,

many of the school nurses, many of the school social workers, many of the family physicians, many of the pediatricians—so there are a few things we are going to try to do to change that.

Today, the NMIH is releasing a new, easy to understand fact sheet that parents can use to make the right decisions about their children's treatment for these conditions. The Education Department will soon release an information kit to help parents and teachers better care for children with ADHD. And I want to thank both the American Academy of Pediatrics and the American Academy of Family Physicians for all they are doing on this issue. This spring and fall, the American Academy of Pediatrics will give all of their 55,000 members up-to-date guidelines for diagnosing and treating children with emotional and behavioral problems. And as part of their yearlong focus on mental health, the American Academy of Family Physicians is sponsoring continuing education courses about these conditions for their 90,000 members.

But now we also have to admit, honestly, that there are some areas where we still just don't know enough, and that's especially true when it comes to giving prescription drugs to our very youngest children. I am pleased that NIMH will dedicate over $5 million to conduct a landmark study examining ADHD and Ritalin use in preschoolers. This study will look at the gap between what we are finding out in the science labs and what is happening in clinical practice, so we can ensure that our children get the care they need. In addition, the FDA will look at some common psychotropic drugs and begin a process to find out what dosage levels are appropriate for very young children. This information will then be included on the labels of these medications, and the studies on them will address the obvious ethical issues that arise when you examine the use of prescription drugs in such a vulnerable group.

Finally, I'm delighted that this fall, the office of the Surgeon General will coordinate a national conference on the treatment of children with behavioral and mental disorders. It will bring together experts from the administration, parents, advocates, educators, researchers, healthcare professionals and consumers. It will look at the challenges we are all still facing in caring for children with mental illnesses. It will help us develop long term strategies that each of us can use to help young people get the childhood and chance in life that we all deserve.

I remember, as we were talking today, that I was fortunate, more than 30 years ago, to work at the Yale Child Study Center, one of the premier research institutions in our country when it comes to treating our young children. And I was exposed to some of the greatest minds and experts in the country about how to treat very young children. And there was nothing more challenging and, in many ways, heartbreaking, than a preschooler with obvious mental, emotional and behavioral problems. That child cannot speak for him or herself. So it's often difficult to find out what kind of conditions in the child's life led to—if there is a cause and effect—the kind of behavior that is being observed. So I know firsthand—from 30 years of work on my own behalf, and watching experts who are really on the frontlines of this—that this is a very big challenge we are taking on today.

But I am also concerned that we are seeing increasing numbers of children who are both being diagnosed with certain disorders and whose behaviors are crying out for helpful intervention. We spoke earlier today in our meeting about the increasing number of very young

children in foster care. The fastest growing group of children being put into foster care are children under 5. They come into foster care because of abuse or neglect and they therefore have more than the kinds of problems that one would expect in the population at large. We talked about the increasing numbers of children who are in the juvenile justice and criminal justice systems. We are not doing what we need to do to help intervene and treat those children, just as we are not providing adequate medical and mental health services in our adult prisons. These are problems that affect all of society, not just the individual with the specific problem or that individual's family or those teachers and others that come into contact with that young person. This has ramifications for all of us.

All we need to do is look back a few weeks and think about the 6-year-old that brought the gun to school to kill the other 6-year-old. That is a problem that did not just occur the morning the child picked that gun up off of the bed in that terrible condition in which he was living. So all of us have a stake in the research, the diagnosis and the treatment. And I would also add that we need some other people at the table, and we're going to try to do that through Dr. Satcher's efforts and the efforts of the associations represented here. We need to be sure that the insurance industry, the HMO industry, the pharmaceutical industry—as well as decision-makers at all levels of government—are also at the table. We do have a lot of information about what works, but we need more. And that's what this meeting and these announcements are about. But we should at least be trying to implement what we do know works while we look for more answers, and follow up on the efforts that will be underway.

You know, when a child is sad or misbehaving, it is never easy for even the most well-intentioned, best-meaning parent to figure out what is happening. Anyone who has ever had a child who is pre-verbal with any kind of illness, or a toddler, or a preschooler, knows how difficult it is. Some of these young people have problems that are symptoms of nothing more than childhood or adolescence. Some of them need a parent to love them, or a person simply to listen to them talk about their pain. And yet some do have severe emotional and mental problems that can be greatly helped by prescription drugs. These children are waiting for our help—every one of them—and today we are taking important steps to provide it.

It is my great hope that this meeting will move us closer to the day that we will be able, number one, to remove the stigma from these problems so that no parent or no community has to wonder whether this is something that should be talked about, or help should be sought for. And number two, that we will treat the problems of the body and the mind the very same.

I hope that all of us will see this as a beginning and that we will be even more committed to doing whatever it takes to make sure that our children get the help, support and love that they need to have.

Thank you all very much.

TREATMENT OF YOUNG CHILDREN WITH MENTAL CONDITIONS

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

A NOTE TO PARENTS

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

Although progress has been made in diagnosing the mental illnesses that begin in childhood, children's brains are in a state of rapid change and growth, and diagnosis and treatment of mental disorders must be viewed with this in mind. While some problems are short lived, others are persistent and very serious, and parents should seek help for their children. Treatment decisions should be weighed for risks and benefits, and each child should be viewed individually.

WHEN TO GET HELP

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

PEOPLE TO TALK TO IF YOU ARE CONCERNED ABOUT YOUR CHILD

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

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

LEARNING ABOUT MEDICATIONS

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

anti-depressants, anti-anxiety agents, anti-psychotics, and mood stabilizers.

Stimulants

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

Brand Name	Generic Name	Approved Age
Adderal	amphetamines	3 and older
Cyclert	pemoline	6 and older
Dexedrine	dextro-amphetamine	3 and older
Ritalin	methylphenidate	6 and older

Anti-Depressant and Anti-Anxiety Medications

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

Brand Name	clomipramine	8 and older (OCD)
Anafranil	fluovoxamine	12 and older
Luvox	doxepin	6 and older (bedwetting)
Sinequan	imipramine	6 and older (OCD)
Tofranil	sertranline	
Zoloft	Approved Age	
Generic Name	10 and older (OCD)	

Other medications that are used to treat these disorders in children include Effexor (venlafaxine), Paxil (paroxetine), Prozac (fluoxetine), Serzone (nefazodone), and Wellbutrin (bupropion). They are not labeled for pediatric use.

Anti Psychotics

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

Brand Name	Generic Name	Approved Age
Haldol	Haloperiodol	3 and older
generic only	Thioridazine	2 and older
Orap	Pimozide	12 and older

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

Mood Stabilizers

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

Brand Name	Depakote	Lamictal
Cibalith-S	Eskalith	Lithobid

Neurontin	lamotrigine	2 and older (for seizures)
Tegretol	lithium carbonate	12 and older
Generic Name	gabapentin	16 and older (for seizures)
lithium citrate	carbamazepine	12 and older
divalproex sodium	Approved Age	12 and older (for seizures)
lithium carbonate	12 and older	any age (for seizures)

Research on the effectiveness of these and other medications in children and adolescents with bipolar disorder are ongoing. In addition, studies are investigating various forms of psychotherapy, including cognitive-behavioral therapy, to complement medication treatment for this illness in young people.

FOR MORE INFORMATION ON MENTAL DISORDERS IN CHILDREN
CONTACT THE NATIONAL INSTITUTES OF MENTAL HEALTH 301 443 4513 / www.nimh.nih.gov

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TO: Lissa Muscatine
First Lady's Press Office
The White House

FM: Frederick J. Balboni, Jr.

RE: **CBS** request for Hillary Rodham Clinton

DA: May 23, 2000

As per my conversation with you late yesterday afternoon, please expedite the following media request.

The CBS Medical Unit would like to put together a segment within the next two-three weeks for *CBS This Morning* dealing with ADHD and featuring Mrs. Clinton as an in-studio guest. A re-packaged piece with interview excerpts will be used later for the *CBS Evening News with Dan Rather*. Mrs. Clinton will be asked to speak about her initiatives aimed at reducing the number of children in the U.S. that are currently on Ritalin and other psychotropic drugs.

Over the last ten years there has been a 700 percent increase in the use of potent psycho-stimulants among young children meant to treat various behavioral disorders such as Attention Deficit Hyperactivity Disorder (ADHD). Many continue to debate the use of Ritalin and other therapeutic pharmaceuticals as therapies for these neurological abnormalities. Currently, no objective, biologically based diagnostic test exists for ADHD, which leaves decisions about Ritalin use to educated guesswork.

As part of Mrs. Clinton's segment, CBS is considering including Russell Barkley, Ph.D., a world- renowned author and expert on ADHD, who, in conjunction with Boston Life Sciences, Inc., is currently involved in extensive research on a first-ever biologically based diagnostic for ADHD. Dr. Barkley will speak about the complexities of diagnosing and treating ADHD along with his current research with Altropane™. If an objective diagnostic were available, healthcare providers could accurately identify the presence or absence of ADHD, and bring new confidence and certainty to diagnosis and treatment.

HRC to be interviewed by medical editor.

ABOUT ALTROPANE™

Abnormalities in several dopamine receptor genes and the dopamine transporter gene have been linked to ADHD. The response of patients to medications that block dopamine transporter molecules (DAT), such as Ritalin, implicate a DAT abnormality as a primary biological cause of ADHD.

Researchers at Boston Life Sciences, Inc. in Boston have developed Altropane™, a radio-pharmaceutical imaging agent that binds with high specificity to DAT in the brain. A recent study published in *The Lancet* using Altropane™ in conjunction with SPECT imaging demonstrated that there is an abnormal elevation of DAT in the striatum of subjects with clinically diagnosed ADHD[1]. These results suggest that high striatal DAT may be a biological marker for ADHD.

Currently, Altropane™ is in Phase II clinical trials on a "fast track" designation for use as an ADHD diagnostic. Altropane also recently completed Phase III clinical trials for the early diagnosis of Parkinson's Disease, for which there is presently no objective test.

ABOUT BLSI:

Boston Life Sciences, Inc (NASDAQ: BLSI) is a development stage biotechnology company engaged in the research and development of novel therapeutic and diagnostic products to treat chronic debilitating diseases, such as cancer and central nervous system disorders. Marc Lanser, M.D. founded Boston Life Sciences in 1992 while a faculty member at Harvard Medical School.

Accompanying this fax is Dr. Barkley's Bio and two recent press articles on the ADHD that reference Altropane™.

Thanks you in advance for your assistance.

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[1] Fishman, Alan J. Dopamine Transporter Density is Elevated in Patients with Attention Deficit Disorder. *The Lancet.* December 18, 1998.

Launch of New Public-Private Effort to Improve the Diagnosis and Treatment of Children with Emotional and Behavioral Conditions

Remarks by First Lady Hillary Rodham Clinton
Roosevelt Room
March 20, 2000

Thank you all for joining us here this morning. I want to thank Secretary Shalala for her leadership, and I'm also pleased she refuses to sit still. Because whenever our children's health is at stake, she's out there working very hard to make sure we all pay attention.

Also, I'm pleased to be joined not only by Secretary Shalala, but by Surgeon General David Satcher, and FDA Director Jane Henney, and NMIH Commissioner Dr. Steve Hyman, and Dr. Judith Heumann, and representatives from many of the groups who are on the frontlines working on behalf of all of our children, particularly children with behavioral and emotional challenges.

We just came from a meeting where we talked about what more we can do to ensure that children with emotional and behavioral problems get the diagnosis and treatment they need, and when they need it. Today's meeting and the announcements around it are important steps, but they are certainly not the last step we need to take in ensuring that all of our children get the health and support and treatment that they deserve.

You know, when a child comes to us who is hurt or sick, there is nothing more terrifying for any of us, especially parents, when we don't know how to make it better. If they have a broken arm, we want to fix it; if they have a deadly disease, we want to do everything we possibly can to cure it. And it's no different if the problem they bring to us lies in their head or their heart.

Thanks in large part to the leadership of Tipper Gore, the President's mental health adviser, we've come a long way in our battle to bring mental illness out of the shadows and make sure it is treated just as seriously as physical illness. More and more often, those treatments include drugs, even for young children. That is the issue we're here today to discuss.

As many of you know, the Journal of the American Medical Association recently reported that the number of preschoolers who are taking psychotropic drugs increased dramatically from 1991 to 1995. We know that the increase for Ritalin alone was 150 percent, and the use of anti-depressants increased over 200 percent. Now I am no doctor, as is obvious, but I am a parent and I have been a longtime children's advocate. And these findings concern me. I know they concern Dr. Hyman, Secretary Shalala and countless other experts.

But let me be very clear: We are not here to bash the use of these medications. They have literally been a Godsend for countless adults and young people with behavioral and emotional problems. We know that when children with such problems are left untreated, they may fail to reach their God-given potential later in their lives. That's why we are here. We want

the best information for every parent, every doctor, every teacher—every single person who cares for our children.

But we do have to ask some serious questions about the use of prescription drugs in all children. We have to ask, for example, how are we diagnosing, treating and caring for children with behavioral and emotional conditions? Do we have the best tools to make the most accurate diagnoses? When it comes to drug treatments for children, why are we seeing such great variations by community and race? And what effects do overuse and underuse of these medications have on our children?

We need to ask also, why aren't we doing a better job of combining drugs, when necessary, with family therapy and other behavior modifications? And what about the effects on our very youngest children who haven't been tested for these prescription drugs and whose brains are in their most critical stage of development?

These are tough questions, and none of us have all of the answers. But as we made clear in the meeting this morning, we are building on a record, not starting from scratch. We have already taken critical steps over the past few years to ensure that drugs are being tested and labeled specifically for children. Some of you may remember that was a long, drawn out struggle, that we were finally able to make progress and we were able to make an announcement at the White House last year. In so doing, we have learned that finding the right prescription for a child is not always just a matter of decreasing the dosage.

You know, I think it's important that all of us adults recognize that children are not just miniature adults; that their systems, their developmental needs, are different from that of an adult. We also learned quite a bit from the first ever Surgeon General's report on mental illness, which came out in December. It grew out of the White House Conference on Mental Illness, led by Tipper Gore. It taught us that the stigma of mental illness is worse for children; that too many health care professionals lack training in the area of children's mental, emotional and behavioral needs; and that we have a long way to go to increase awareness about children's mental health.

So clearly, we must do more. We know that the questions being raised are very difficult and they cannot be answered overnight. And they certainly won't be answered by the government, or health care professionals or educators or parents acting alone. Every single person with a stake in our children's health has an important role to play.

So I'm very pleased today to announce some of the immediate steps we are taking to make sure that children with mental illness, with behavioral and emotional problems, get the right care at the right time.

As our meeting made clear, we already know a lot about the proper diagnosis and treatment of emotional and behavioral problems in children. But that critical information has not reached many of the people who need it most—many of the parents, many of the teachers, many of the school nurses, many of the school social workers, many of the family physicians, many of the pediatricians—so there are a few things we are going to try to do to change that.

Today, the NMIH is releasing a new, easy to understand fact sheet that parents can use to make the right decisions about their children's treatment for these conditions. The Education Department will soon release an information kit to help parents and teachers better care for children with ADHD. And I want to thank both the American Academy of Pediatrics and the American Academy of Family Physicians for all they are doing on this issue. This spring and fall, the American Academy of Pediatrics will give all of their 55,000 members up-to-date guidelines for diagnosing and treating children with emotional and behavioral problems. And as part of their yearlong focus on mental health, the American Academy of Family Physicians is sponsoring continuing education courses about these conditions for their 90,000 members.

But now we also have to admit, honestly, that there are some areas where we still just don't know enough, and that's especially true when it comes to giving prescription drugs to our very youngest children. I am pleased that NIMH will dedicate over $5 million to conduct a landmark study examining ADHD and Ritalin use in preschoolers. This study will look at the gap between what we are finding out in the science labs and what is happening in clinical practice, so we can ensure that our children get the care they need. In addition, the FDA will look at some common psychotropic drugs and begin a process to find out what dosage levels are appropriate for very young children. This information will then be included on the labels of these medications, and the studies on them will address the obvious ethical issues that arise when you examine the use of prescription drugs in such a vulnerable group.

Finally, I'm delighted that this fall, the office of the Surgeon General will coordinate a national conference on the treatment of children with behavioral and mental disorders. It will bring together experts from the administration, parents, advocates, educators, researchers, healthcare professionals and consumers. It will look at the challenges we are all still facing in caring for children with mental illnesses. It will help us develop long term strategies that each of us can use to help young people get the childhood and chance in life that we all deserve.

I remember, as we were talking today, that I was fortunate, more than 30 years ago, to work at the Yale Child Study Center, one of the premier research institutions in our country when it comes to treating our young children. And I was exposed to some of the greatest minds and experts in the country about how to treat very young children. And there was nothing more challenging and, in many ways, heartbreaking, than a preschooler with obvious mental, emotional and behavioral problems. That child cannot speak for him or herself. So it's often difficult to find out what kind of conditions in the child's life led to—if there is a cause and effect—the kind of behavior that is being observed. So I know firsthand—from 30 years of work on my own behalf, and watching experts who are really on the frontlines of this—that this is a very big challenge we are taking on today.

But I am also concerned that we are seeing increasing numbers of children who are both being diagnosed with certain disorders and whose behaviors are crying out for helpful intervention. We spoke earlier today in our meeting about the increasing number of very young children in foster care. The fastest growing group of children being put into foster care are children under 5. They come into foster care because of abuse or neglect and they therefore have more than the kinds of problems that one would expect in the population at large. We talked about the increasing numbers of children who are in the juvenile justice and criminal justice

systems. We are not doing what we need to do to help intervene and treat those children, just as we are not providing adequate medical and mental health services in our adult prisons. These are problems that affect all of society, not just the individual with the specific problem or that individual's family or those teachers and others that come into contact with that young person. This has ramifications for all of us.

All we need to do is look back a few weeks and think about the 6-year-old that brought the gun to school to kill the other 6-year-old. That is a problem that did not just occur the morning the child picked that gun up off of the bed in that terrible condition in which he was living. So all of us have a stake in the research, the diagnosis and the treatment. And I would also add that we need some other people at the table, and we're going to try to do that through Dr. Satcher's efforts and the efforts of the associations represented here. We need to be sure that the insurance industry, the HMO industry, the pharmaceutical industry—as well as decision-makers at all levels of government—are also at the table. We do have a lot of information about what works, but we need more. And that's what this meeting and these announcements are about. But we should at least be trying to implement what we do know works while we look for more answers, and follow up on the efforts that will be underway.

You know, when a child is sad or misbehaving, it is never easy for even the most well-intentioned, best-meaning parent to figure out what is happening. Anyone who has ever had a child who is pre-verbal with any kind of illness, or a toddler, or a preschooler, knows how difficult it is. Some of these young people have problems that are symptoms of nothing more than childhood or adolescence. Some of them need a parent to love them, or a person simply to listen to them talk about their pain. And yet some do have severe emotional and mental problems that can be greatly helped by prescription drugs. These children are waiting for our help—every one of them—and today we are taking important steps to provide it.

It is my great hope that this meeting will move us closer to the day that we will be able, number one, to remove the stigma from these problems so that no parent or no community has to wonder whether this is something that should be talked about, or help should be sought for. And number two, that we will treat the problems of the body and the mind the very same.

I hope that all of us will see this as a beginning and that we will be even more committed to doing whatever it takes to make sure that our children get the help, support and love that they need to have.

Thank you all very much.