Surgeon General's Conference on
Children's Mental Health: Developing a National Action Agenda

Working Agenda
8/10/00

September 18, 2000

8:00 – 8:30 Welcome
David Satcher, M.D., Ph.D.
Surgeon General
Steven Hyman, M.D.
Director, National Institute of Mental Health
Bernie Arons, M.D.
Director, Center for Mental Health Services

8:30– 10:30
Panel 1: Identifying, recognizing and referring children with mental health needs.

Chair:, Mary Jane England, M.D., Washington Business Group on Health

Identification of mental health needs 20 + 10 min

(Content: Broad picture of unmet needs, health disparities and policy implications. Discrepancy between need and availability of mental health and substance abuse services. Integrate all systems involved (e.g., juvenile system, child welfare, substance abuse, special health care, etc.). Pros and cons of labeling, diagnosis vs. functional impairments, based on a developmental perspective)
Dan Offord, M.D., McMaster University (to be confirmed)
Senora Simpson, Ph.D., Family Member

(Content for the three sections below: Focus on national data: How are mental health needs identified or recognized in various systems and what are the barriers to recognition? How well do these systems identify and refer children with recognized mental health needs? What linkages do or do not exist among these systems? Speakers will provide national data on identification/recognition/referral within these systems and identify, where appropriate, federal or state policies that address recognition, linkage, and treatment services (e.g., EPDST for primary care, IDEA for education)

Primary care and identification of mental health needs 15 min
Kelly Kelleher, M.D., Western Psychiatric Institute

Schools and identification of mental health needs 15 min
Steve Forness, Ph.D., UCLA

Preschool and identification of mental health needs 10 min
Neal Halfon, M.D., UCLA (to be confirmed)

Child Welfare and identification of mental health needs 10 min
John Landsverk, Ph.D., Children's Hospital, San Diego

Juvenile Justice and identification of mental health needs 10 min
Linda Teplin, Ph.D., Northwestern University

Discussants 30 min
Donna Gore Olsen (Family Member)
James Comer, MD, Yale Child Study Center (To be confirmed)
Jane Knitzer, Ed.D., Columbia University
Glorisa Canino, Ph.D.; University of Puerto Rico

10:30 – 10:45 BREAK

10:45 - 12:30
Panel 2: Health Service Disparities: Access, Quality and Diversity.

Chair: Spero Manson, Ph.D., University of Colorado

Access, barriers, and quality. 15+15 +15 min

Content: Pathways into, through, and out of service systems. Adequacy or appropriateness of care. Impact of stigma, cultural attitudes, beliefs and practices. Availability of services in non-traditional settings (e.g., church, boys/girls clubs) and gate-keeper settings (e.g., schools, primary care, childcare, homes). Problems with coordination and disparities in access or use of services.

David Takeuchi, Ph.D., Indiana University
Margaret Alegria, Ph.D., University of Puerto Rico
Ken Wells, Ph.D., The RAND Corporation

Reaching Out to and Engaging Families 10 +10+10 min

(Content: To address stigma and mental health. What creates stigma, how has it changed? How does it affect families' willingness to access MH services, providers, and services delivered? How can we better engage families in evidence-based services and treatments?)

Barbara Friesen, Ph.D., Portland State University
C. Veree Jenkins (Family Member)
Lynn Pedraza (Family Member)

Discussants: 30 min

Laurie Flynn, NAMI (Family Member)
Carl Bell, M.D., Community Mental Health Council, Chicago
Michael Faenza, President & CEO, NMHA
Vera Piña (Family Member)

12:30 LUNCH PICK-UP

12:30 - 2:30 Working lunch and break out discussion groups

Break out discussion groups (Facilitators and rapporteurs to be identified from the guest list) Suggested groupings: 10 groups of about 30 persons each

2:30 – 2:45 BREAK

2:45 – 5:30
Panel 3: State of the evidence on treatments, services, systems of care and financing.

Chaired by Chris Koyanagi, J.D., Bazelon Center for Mental Health

Prevention, Early Intervention and Community-based Services 15 + 10 min

(Content: State of the evidence on effectiveness of these services for children with a range of disorders, including respite care, wrap-around services, school-based treatments, etc. Where is the evidence strongest? Where is it weakest?)

Barbara Burns, Ph.D., Duke University
Tim Lewis, Ph.D., University of Missouri

State of the evidence on treatments for children with specifiable mental disorders
10 +15 + 10 min

(Content: Synthesis of the evidence on behavioral, pharmacological and combination treatments.)

Thomas Laughren, M.D., FDA
Peter Jensen, M.D., Columbia University
Evelyn Green, Family Member

Research to Practice Gap: Why the Gap and What to Do 15 min

(Content: The gap in various settings/systems. What is known about evidence-based treatments? Why is knowledge not used? How can knowledge be made more relevant? How can practice be changed?

John Weisz, Ph.D. UCLA

Systems of Care: Financing and organizing service systems 15+15+10 min

(Content: Structure of reimbursement systems and impact on access and use of MH services. Public-private partnerships. Key elements in implementing effective services in the community. Consumer perspective.)

Richard Frank, Ph.D., Harvard University (to be confirmed)
Robert Friedman, Ph.D., University of South Florida
Angelique Harris (Youth)

Discussants 30 min

Barbara Huff, Federation of Families (Family Member)
Larke Huang, Ph.D., George Mason University
Phillipa Hambrick, Dallas Independent School District
Michael Dennis, Ph.D., Chestnut Health Systems

5:30 - 6:30 General discussion

September 19, 2000

8:00 – 10:00 Breakout session: Facilitated as before (10 groups, 30 per group)

10:00 – 10:15 BREAK

10:15-12:15 Breakout session: Facilitated as before – wrap up recommendations.

12:15-1:45 LUNCH
Reporters synthesize recommendations from breakout groups

1:45-3:00 Reporters report back to Dr. Satcher.

3:00 – 4:30 General Discussion

4:30 – 5:30 *Final session: Summary of Findings*
Facilitated by Dr. Satcher (?)

Note: 300 invitees from professional associations, family advocacy associations, the scientific community, and industry will attend. The final session will identify areas of consensus and recommendations from attendees for policy reforms to improve identification, recognition, treatment, and service delivery for children with mental disorders, based on the best available evidence. The Surgeon General will issue a national action agenda based on the recommendations that come from this conference and

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.

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

The Washington Times

September 07, 2000, Thursday, Final Edition

SECTION: PART A; COMMENTARY; Pg. A17

LENGTH: 860 words

HEADLINE: Can courts decree drugs for children?

BYLINE: Phyllis Schlafly

BODY:

Can a judge constitutionally order a controversial drug to be given to a child over the opposition of his parents? Such action by a Family Court judge in Albany, N.Y., has touched off a national debate pitting public schools and the courts against parental rights.

Seven-year-old Kyle Carroll of Berne, N.Y., was diagnosed by a psychologist as having ADHD (attention deficit/hyperactivity disorder), and a physician prescribed the psychotropic drug **Ritalin.** The boy soon exhibited two of the drug's common side effects, sleeplessness and appetite loss.

When Kyle's parents told school officials they wanted to temporarily discontinue the medication, they got a visit from the Albany County Child Protective Services and a petition to appear in court. The school district accused the Carrolls of "educational neglect," and they received what amounted to an order from Judge Gerard E. Maney to start using **Ritalin** again.

Under what was described as "at least the theoretical threat of having their child removed from their custody," the Carrolls agreed to "an adjournment in contemplation of dismissal ACOD ." There was no fact-finding hearing before Judge Maney, no testimony taken and no written decision rendered.

According to law guardian Pamela J. Joern of Albany, who supported the school's position, "The consent ACOD directed the parents to comply with the doctor's treatment regimen, which was a prescription for **Ritalin.** They could get a second opinion, but they couldn't ignore the problem."

This case underscores the need for better medical privacy protection in order to safeguard against government intervention in personal medical decisions. A family's decision whether to use **Ritalin** is not the government's business.

In order to avoid a prolonged court battle, the Carrolls compromised, which is usually what happens when parents are subjected to intimidation by state child protection agencies. The injustice of Judge Maney's decision will go unreviewed by higher courts, but the Kyle Carroll case has kicked up a storm of protest on the Internet.

This case is a good example of judicial activism that would never be known outside the local community if it were not for the free flow of news and information on the Internet. Hundreds of criticisms of this decision appeared on Internet message boards within days.

In traditional channels of communication, many disputes degenerate into both sides reciting hearsay and bogus facts, with no hope of resolution. On the Internet, it is so easy to include checkable hard facts in the discussion, and one side can actually persuade the other.

A quick search on Yahoo yields a variety of sites that are critical of **Ritalin,** including support groups, pharmacies and alternative medications. The case against Napster, soon to be heard by the U.S. 9th Circuit Court of Appeals, has ominous implications for this exchange of information about **Ritalin** on the Internet.

The same reasoning behind the injunction recently issued against Napster would chill or even require shutting down Web sites that provide medical information to Internet users. Since "**Ritalin**" is a registered trademark, and some of the official information on it and ADHD is copyrighted, the arguments behind the anti-Napster injunction could enable the owner of **Ritalin** to demand that Yahoo provide only authorized links about **Ritalin.**

Ritalin does not treat an objective physical illness as, for example, insulin treats diabetes. **Ritalin** is a serious drug used to control behavior problems and is very attractive to the schools because it makes the child more likely to shut up, sit down and do what he is told.

There are some 3.8 million schoolchildren, mostly boys, who are said to have ADHD, according to the American Academy of Pediatrics. Estimates are that most of them are on **Ritalin** or similar psychotropic drugs.

The number of children labeled ADHD and taking **Ritalin** has greatly increased since 1991 when ADHD was covered under the Individuals with Disabilities Education Act, a federal program that brings more funding to public schools in order to provide extra services.

Under IDEA, the school is required to craft an Individualized Education Plan to accommodate each child, which may include drugs prescribed by a medical doctor, and that's how Kyle happened to be given **Ritalin.**

In May, the Dallas law firm Waters and Kraus filed a **class action** suit alleging fraud and conspiracy against the Swiss-owned manufacturer of **Ritalin,** Novartis, as well as the private ADHD support group Children and Adults With Attention Deficit/Hyperactivity Disorder and the American Psychiatric Association. The suit charges the three defendants committed fraud in conspiring to overpromote the diagnosis of ADHD and its treatment with the stimulant drug methylphenidate (**Ritalin**).

Information about **Ritalin's** side effects, withdrawal symptoms, manufacturer warnings and interactions with other drugs is now very accessible on the Internet. The public needs the Internet to sort out the facts about **Ritalin,** ADHD and medical privacy rights.

Phyllis Schlafly is a nationally syndicated columnist.

LANGUAGE: ENGLISH

LOAD-DATE: September 7, 2000

National Partnership for Women & Families

CHALLENGE 2·0·0·0

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The New York Times

View Related Topics

September 14, 2000, Thursday, Late Edition - Final

SECTION: Section A; Page 16; Column 1; National Desk

LENGTH: 452 words

HEADLINE: Suits Charge Conspiracy by Maker and Doctors' Group to Expand **Ritalin** Use

BYLINE: By BARRY MEIER

BODY:

Lawyers involved in **class-action** lawsuits against the tobacco industry, gun makers and health maintenance organizations filed two lawsuits yesterday against another target, the widely used drug **Ritalin.**

The lawsuits, filed in federal courts in California and New Jersey, say the Novartis Pharmaceuticals Corporation, the drug's manufacturer, and the American Psychiatric Association, a professional group, conspired to create a market for **Ritalin** and expand its use.

For more than a decade, **Ritalin** has been increasingly prescribed for children in whom attention deficit disorder or attention deficit hyperactivity disorder has been diagnosed. That has prompted debate among scientists, psychiatrists and government officials over whether children are receiving too much medication or their behavioral disorders are being diagnosed incorrectly.

Officials of Novartis Pharmaceuticals, a unit of Novartis AG, and the American Psychiatric Association said they could not comment on the lawsuits because they had not seen them.

But representatives of each group said the accusations in the new lawsuits sounded similar to those in a **class-action** lawsuit brought against them earlier this year in Texas.

At that time, Novartis said **Ritalin,** which is also known by its chemical name methylphenidate, had been used safely and effectively in thousands of children for more than 40 years and that it was the most studied drug used for attention deficit hyperactive disorder.

The psychiatric association called the accusations in the Texas suit "groundless" and an "opportunistic attack on the scientific process that underlies this effort."

The new lawsuits seek to halt what they call unlawful practices and ask that profits from sales of the drug be returned to consumers.

One of those bringing the latest lawsuits is Richard Scruggs, a lawyer from Pascagoula, Miss., who represented dozens of states in actions brought in recent years against cigarette makers. Earlier this year, Mr. Scruggs also filed lawsuits against several health maintenance organizations charging that they had defrauded consumers by failing to provide them with treatments.

John Coale, a Washington lawyer who is also involved in the **Ritalin** lawsuits, said the litigation was brought because Novartis and the psychiatric group promoted the idea that many children had attention deficit order and attention deficit hyperactivity disorder as a way of expanding the market for the drug.

"They were giving this stuff away like candy," Mr. Coale said.

In March, the White House announced an effort to reverse a sharp increase in the number of preschool children using **Ritalin,** Prozac and other psychiatric drugs.

http://www.nytimes.com

LANGUAGE: ENGLISH

LOAD-DATE: September 14, 2000

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General News;ritalin and class action

The Associated Press State & Local Wire

View Related Topics

September 9, 2000, Saturday, BC cycle

SECTION: State and Regional

LENGTH: 1287 words

HEADLINE: Family court decision sparks debate on behavior-modifying drugs

BYLINE: By LYNN BREZOSKY, Associated Press Writer

DATELINE: BERNE, N.Y.

BODY:

Kyle Carroll was past his twos and still not talking. Or rather, he was speaking, but in a language that seemed all his own. It was the first hint Jill and Michael Carroll had that something was different about their son.

In kindergarten, it became clear Kyle wasn't about to focus in the classroom. A pediatrician diagnosed Kyle with Attention Deficit Hyperactivity Disorder and prescribed a trial run of **Ritalin.**

That trial has lasted three years now, in the Carroll's view long enough. But at the end of a torturous yearlong battle with the Berne-Knox-Westerlo school district, they learned they don't have the choice of stopping it, despite their arguments the drug is wiping out sectors of their son's personality and turning him into a sickly, staring, insomniac.

Under a consent order signed by Albany County Family Court Judge Gerald Maney in May, the couple must continue administering medications prescribed by a physician meeting court approval. That means unless they find a doctor who recommends taking their child off medication, and they haven't yet, they must continue giving Kyle **Ritalin** or risk losing him on grounds of neglect.

What makes the order landmark is that **Ritalin** is a different kind of medicine, part of an emerging class of pills that treat behavior rather than disease. The Carroll's case is believed to be the first in which the state has mandated a chemical change in personality in a child who's not deemed homicidal or suicidal. It raises a national question - whose decision is it to administer behavior-modifying drugs?

To Dr. Peter Breggin, consultant in a **class-action** suit accusing the American Psychiatric Association (APA) of conspiring with Novartis (the pharmaceutical company that makes **Ritalin)** to sell as much of the drug as possible - the ruling speaks of the loss of the most basic of constitutional rights, of mind control, of Big Brother. Only now, he says, Big Brother is Big Business. And by introducing youths to the notion there are biological defects in their brains and capitalizing on the idea of a quick-fix cure, Breggin says, the drug companies are no better than the cigarette manufacturers now paying out millions for encouraging addiction to their product.

On the flip side is the possibility raised by **Ritalin's** many defendants - that millions of children are part of the first generation of humans to have a medicine that allows them to focus and succeed, both in the classroom and the schoolyard, the microcosms of the professional world

and society. Stimulant medications can then seem as progressive as insulin or penicillin.

Yet even the staunchest proponents of stimulant medications such as **Ritalin,** the APA is one proponent, express surprise at Maney's ruling.

"It's an unusual case up there," said Dr. Richard Harding, professor of clinical sociology and pediatrics at the University of South Carolina and president-elect of the APA. Ideally, Harding said, the decision will be made jointly between parents and doctors, never forced.

Breggin, author of several books on the subject, crusades against psychotropic drugs as a whole, and calls Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder "a fabrication."

"The diagnosis is if the kid squirms in his chair, interrupts, is sloppy - a list of things that annoy teachers and make it hard to teach," he said. There's no real diagnostic evidence of ADD, he says, none of the different colored brain clusters one sees in cases of Alzheimer's Disease or strokes.

Jeffrey Schaler, a psychologist who teaches at American University's School of Public Affairs, agrees.

"There's no deficiency that **Ritalin** is fixing," he says, "what it's doing is changing a behavior so the child complies with expectations and behaviors expected of him. You drug the child and get him to comply by drugging."

Albany County Family Court, Schaler says, has invaded the Carroll's privacy.

Beyond that, he sees the decision as a fearsome precedent, an entry into a new gray area socially, with consequences no one can even guess at.

"Psychologists and psychiatrists are going back over history saying just about every great person, every person who had some great contribution to society had some sort of mental problem. If you gave all those people drugs would that have stopped?" Shaler asks.

Schaler, however, thinks it's wrong to blame the companies, who are simply making a product, rather than the mindset of "thou shalt not have any difficulty in your life."

"The bottom line is studying's hard work," he says. "The bottom line is you just have to focus and discipline yourself."

It's an argument Jordan Lippman, a 22-year-old student at Union College in Schenectady, has grown tired of.

Until 11th grade, when he was diagnosed with dyslexia and ADD and prescribed a cocktail of the stimulant Adderall and the anti-depressant Welbutrin, Lippman was miserable.

"I always knew I was different because I was always in detention for forgetting my pens, forgetting my assignments," he says. "I knew I was intelligent, yet it didn't correspond to anything. I knew the material but I couldn't make it translate into anything like good grades."

Lippman's parents were well-off enough to send him to a private high school near their home in Tenafly, N.J., where he received plenty of one-on-one attention.

On the strength of a personal interview and an award-winning senior year project on Attention Deficit Disorder (the success he says started his momentum), he was accepted to Union College, a highly selective private college in Schenectady.

When a test was pulled away from him before he could finish it, Lippman realized he wasn't cutting it. He has since built a support group for students with ADD and ADHD, and lobbied deans and the college president. In effect, he has changed the campus climate for those with ADD.

His peers have been the hardest to convince. In a written debate with Lippman that played out in the campus newspaper, Concordiensis, a former suite mate wrote "one of the aspects of Union that makes it a desirable college, is that not everyone can attend here. If a student cannot keep up with his or her peers in the classroom, perhaps Union is not the ideal college for him or her."

Lippman replied in part, "you know that I work just as hard, and three to four times as long as most other students here at Union. My strengths are abstract verbal reasoning, but it is extremely difficult for me to do the initial processing of written language."

He says ADD is misnamed because it's not an attention disorder but rather a control disorder, in which the part of the brain that organizes and plans isn't working. He says his medication combined with self-awareness and awareness on the part of the college has helped him succeed.

Lippman is now completing an internship with the New York City-based International Dyslexic Association, boasting a 3.676 finish for the last term, and meeting with editors from the Princeton Review to modify listings of services for the disabled listed by colleges.

He's impressed faculty and developed mentors, including Dr. Rudy Nydegger, a clinical psychologist who teaches management and psychology at the college.

In his own practice, Nydegger advocates a therapy that frequently includes writing prescriptions for stimulant medications.

"I don't look at solving problems by throwing drugs at them, but if we can get those kids calmed down and focused then we can help them learn techniques for managing their behavior," he says.

And he for one is convinced ADD and ADHD have long existed.

"We called it other things," he says. "We called kids stupid, underachievers."

GRAPHIC: With AP Photo

LANGUAGE: ENGLISH

LOAD-DATE: September 10, 2000

General News;ritalin and class action

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

'00 CV 1839 E (CGA)

TODD D. VESS, a Minor, by DEBORAH VESS, his Guardian ad Litem, individually, on behalf of those Similarly Situated and on behalf of the General Public of the State of California,

Plaintiffs,

v.

CIBA-GEIGY CORP. USA; NOVARTIS PHARMACEUTICALS CORP.; CHILDREN AND ADULTS WITH ATTENTION-DEFICIT/ HYPERACTIVITY DISORDER (CHADD); AMERICAN PSYCHIATRIC ASSOCIATION, and DOES 1 through 100, inclusive,

Defendants.

CASE NO.

CLASS ACTION COMPLAINT FOR VIOLATION OF THE CONSUMER LEGAL REMEDIES ACT [CALIFORNIA CIVIL CODE §1760 et seq.];

and

COMPLAINT FOR RESTITUTION AND INJUNCTIVE RELIEF UNDER CALIFORNIA BUSINESS AND PROFESSIONS CODE §17200 AND §17500

and

DEMAND FOR JURY TRIAL

Individual and representative Plaintiff TODD D. VESS, by and through DEBORAH VESS as his Guardian ad Litem ("Plaintiff"), on behalf of the general public on behalf of those similarly situated,

alleges on personal knowledge those facts which pertain to the named Plaintiff or to his attorneys and further allege on information and belief as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because the amount in controversy exceeds Seventy-Five Thousand dollars ($75,000.00) and because there is complete diversity of citizenship between plaintiff and all defendants.

2. Venue is appropriate pursuant to 28 U.S.C. §1391.

3. At all relevant times, Defendants have done and continue to do business in the State of California and County of San Diego. They have made contracts to be performed in whole or in part in California. Defendants' products have been manufactured, tested, sold, offered for sale, supplied or placed in the stream of commerce in California. In the course of business, Defendants have materially participated with other Defendants in performing the acts described above, while knowing that Ritalin was dangerous and substantially certain to cause injury to Plaintiff and others similarly situated. They have received and continue to receive substantial compensation and profits from the sale of Ritalin in California and San Diego County. Defendants have made material omissions and misrepresentations in California. The wrongful acts and conduct, in furtherance of a conspiracy, are the basis of the claims that have occurred and continue to occur in California and San Diego County.

PARTIES

A. **Plaintiff (and Those Similarly Situated)**

4. TODD D. VESS, individually, through his Guardian ad Litem, DEBORAH VESS, is a minor who resides in the State of California, County of San Diego and County, and appears individually with respect to all causes of action, and also appears on behalf of those individuals similarly situated with respect to the First Cause of Action.

B. **Plaintiff (and the General Public)**

5. With respect to the Second and Third Causes of Action, plaintiff, a resident of the State of California, brings this action pursuant to California Business and Professions Code §17204, individually and as a private attorney-general on behalf of the members of the general public of California.

6. Plaintiff was prescribed, and purchased and ingested, the drug Ritalin in June, 1994, when he was nine years of age.

C. Defendants.

7. Defendant CIBA-GEIGY CORP. USA is a corporation with its principal place of business in New Jersey and its corporate headquarters in the State of New York. It may be served through its registered agent in the state of California. The Prentice-Hall Corporation System, Inc., 2730 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. This defendant has, at all times material hereto, transacted substantial and continuous business in the State of California.

8. Defendant NOVARTIS PHARMACEUTICALS CORP. is a corporation with its principal place of business and corporate headquarters in New Jersey. It may be served through its registered agent in the State of California. Corporation Service Company, 2730 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. This defendant has, at all times material hereto, transacted substantial and continuous business in the State of California.

9. Defendant CHILDREN AND ADULTS WITH ATTENTION-DEFICIT / HYPERACTIVITY DISORDER (CHADD) is an unincorporated association with its principal office in Maryland. It may be served by serving its registered agent in California. Larry Komar, 1104 East Walnut Creek, Covina, California 91724. This defendant has, at all times material hereto, transacted substantial and continuous business in the State of California.

10. Defendant AMERICAN PSYCHIATRIC ASSOCIATION is a nonprofit corporation with its principal place of business in Washington, D.C. It may be served by serving its registered agent in California. Paracorp Incorporated, 1130 K Street, Suite LL60, Sacramento, California 95814. This defendant has, at all times material hereto, transacted substantial and continuous business in the State of California.

11. Plaintiff is informed and believes and thereon alleges that at all times herein mentioned, the true names and capacities, whether individual, corporate, associate or otherwise of defendants DOES 1 through 100, inclusive, are unknown at this time to plaintiff who therefore sues said defendants by such fictitious names. Plaintiff is informed and believes and thereon alleges that each of the defendants designated herein by such fictitious names were involved in the distribution,

manufacturing, promotion and/or sale of Ritalin, and were in some way legally responsible for the events and happenings herein referred to which were a legal cause and substantial factor in bringing about injuries and damages to plaintiff as alleged. Plaintiff will amend this complaint to allege the true names and capacities of the DOE defendants when ascertained.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

12. Ritalin is a psycho stimulant drug. It is the trade name for a pharmacological substance known as methylphenidate. Methylphenidate, and therefore Ritalin, are "Class II" or "Schedule II" controlled substances under the Controlled Substance Act. See 21 U.S.C. §812; 21 C.F.R. §1308.12.

13. From approximately 1955 through 1995, the exclusive or primary manufacturer and supplier of Ritalin in this country was defendant Ciba-Geigy Corp., USA ("Ciba"). In 1996, Ciba merged with Sandoz Pharmaceuticals Corp. to become defendant Novartis Pharmaceutical Corp. ("Novartis"). Upon information and belief, Novartis is presently, and has been since 1996, the sole or primary manufacturer and supplier of Ritalin in the United States. Ciba, however, continues as a separate corporate entity. For ease of reference, defendants Ciba and Novartis are sometimes referred to in this complaint as "Ciba/Novartis."

14. Ciba/Novartis has manufactured, marketed and sold Ritalin since approximately 1955. The product was promoted, beginning in the 1960's, by Ciba as an antidepressant "which brightens moods and improves performance." Defendant also claimed effectiveness for depression, chronic fatigue and psychoneurosis. From 1955 until the late 1970's, Ciba aggressively sought applications and markets for Ritalin in an effort to boost sales and profits.

15. Ciba/Novartis, in combination with the defendant doctors and the American Psychiatric Association (APA), planned, conspired, and colluded to create, develop, promote, and confirm the diagnoses of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) in a highly successful effort to increase the market for its product Ritalin. Due to the concerted efforts of these parties, Attention Deficit Disorder was first listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM) in 1980. The DSM recognized ADHD as "diagnosis" in 1987.

16. The DSM is a widely used and disseminated compendium of psychiatric diagnoses. Listing of a "diagnosis" in the DSM provides an official-seeming, medical imprimatur to a particular set of symptoms or behaviors that may, in fact, be entirely normal. A new official "diagnosis" in the DSM, however, generates vast numbers of new prescriptions, increased insurance coverage, and great public attention.

17. In addition to its actions and involvement with the creation of the ADD and ADHD diagnoses, Ciba/Novartis took steps to promote and dramatically increase the sales of Ritalin by way of the following:

a. Actively promoting and supporting the concept that a significant percentage of children suffer from a "disease" which required narcotic treatment/therapy;

b. Actively promoting Ritalin as the "drug of choice" to treat children diagnosed with ADD and ADHD;

c. Actively supporting groups such as Defendant CHADD, both financially and with other means, so that such organizations would promote and support (as a supposed neutral party) the ever-increasing implementation of the ADD/ADHD diagnosis as well as directly increasing Ritalin sales;

d. Distributing misleading sales and promotional literature to parents, schools, and other interested persons in a successful effort to further increase the number of diagnoses and the number of persons prescribed Ritalin.

18. Ciba/Novartis deliberately, willfully, intentionally, and negligently promoted the diagnosis of ADD/ADHD and sales of Ritalin through its promotional literature and through its training of sales representatives. In so doing, despite knowledge of such problems and/or adverse reactions, Defendants willfully failed to address or provide adequate information to consumers, doctors, and/or schools concerning the many significant hazards of methylphenidate use and prescription, including, but not limited to, the following:

a. Cardiovascular problems, including palpitations, tachycardia, hypertension, arrhythmias, chest pain and cardiac arrest;

b. Central nervous system problems, including psychosis with hallucinations,

excessive brain stimulation (convulsions), drowsiness, confusion, insomnia, agitation, anxiety, irritability, nervousness, dysphoria, impaired cognitive test performance, dyskinesia, depression, and zombie-like constriction of affect and spontaneity;

c. Gastrointestinal problems, including anorexia, nausea, vomiting, stomach ailments, dry mouth, and constipation;

d. Pituitary dysfunction, including growth hormone and prolactin disruption, weight loss, growth suppression, growth retardation, anemia, exfoliate dermatitis, leukopenia, etc.

19. Despite information in the medical and scientific literature concerning these side effects of Ritalin use, Defendants failed in all respects to advise potential consumers, doctors, and/or schools, teachers or other interested parties of the nature and extent of such side effects. Furthermore, Defendant CHADD similarly failed to provide adequate information to interested parties concerning the nature and extent of potential side effects.

20. In addition, Ciba/Novartis continuously misrepresented to the consuming public, physicians and other interested parties, the efficacy of the drug Ritalin, without ever advising such persons that Ritalin usage would not improve academic performance and/or have any long term effect on the symptoms associated with ADD and/or ADHD.

21. Defendant American Psychiatric Association ("APA") conspired, colluded and cooperated with the other Defendants to facilitate and encourage the development and acceptance of diagnosis of ADD (1980) and ADHD (1987). While so doing, the APA received and accepted financial contributions from Ciba as well as other members of the pharmaceutical industry, which donations and contributions directly effected and caused APA to make every effort possible to support and confirm a new medical "diagnosis" for which a stated treatment would be methylphenidate, i.e., Ritalin. In so doing, Defendant APA aided, abetted and promoted the concept of Ritalin therapy for treatment of the vast numbers of children who began to be diagnosed with ADD and ADHD, pursuant to the APA's recommendations and support for the diagnosis.

22. The interrelationship between the drug industry and the APA caused and contributed

to the APA's assistance, support, aid and collusion with Ciba/Novartis in creating a novel medical "diagnosis" that could be, and ultimately was, applied to a large percentage of children in the United States, and for which the APA, in combination with other defendants, continued and presently continue to promote the prescription, use, and sale of Ritalin.

23. Defendant CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder) is an unincorporated association dedicated and promoted to the principle that significant numbers of persons suffer from a "disease" that did not exist until 1980. CHADD works closely with Ciba/Novartis and the American Psychiatric Association.

24. Based on information and belief, CHADD has been a recipient of financial donations and contributions from Defendants Ciba/Novartis for many years. CHADD received $748,000 from Ciba/Novartis in the period 1991 to 1994 alone. During the periods when CHADD received funding from Ciba/Novartis, CHADD deliberately made efforts to increase the sales of Ritalin, and to increase the supply of methylphenidate available in the United States, and to reduce or eliminate laws and restrictions concerning the use of Ritalin and methylphenidate in the United States, all at the request, and to the financial benefit, of Ciba/Novartis.

25. Ciba/Novartis made such financial contributions with the purpose of advertising and promoting sales of Ritalin - an internationally controlled substance. Ciba/Novartis has thus repeatedly violated Article 10 of the United Nations Convention on Psychotropic Substances, 1019 U.N.T.S. 175 (1971).

26. CHADD's activities nationwide have led to a significant increase in the amount of Ritalin taken by school children and have directly resulted in enormous profits to Ciba/Novartis. so doing, CHADD has promoted the concept of a diagnosis of "disease" or "brain damage" as well as promoting and supporting the concept that appropriate therapy for such a diagnosis is a prescription for Ritalin. In so doing, CHADD has acted as an agent of, and/or has aided and abetted Ciba/Novartis in its efforts to increase sales and earn additional profits from the sale of Ritalin.

CO-CONSPIRATORS

27. Each Defendant is sued individually as a primary violator and as a co-conspirator. The liability of each Defendant arises from each Defendant's agreement to commit unlawful acts and the

performance of those acts, in concert, to further the agreement. The conspiracy began as early as the 1950s and continues to the present. Defendants and each of them knowingly and willfully entered into and pursued a common course of conduct, by agreement with the other Defendants and third parties, to commit all or part of the unlawful acts alleged herein. Such unlawful acts were committed intentionally, knowingly, maliciously and without legal justification or excuse.

28. All Defendants conspired, combined and colluded to promote and dramatically increase the sales of Ritalin by way of the following:

a. Actively promoting and supporting the concept that a significant percentage of children suffer from a "disease" which required narcotic treatment/therapy;

b. Actively promoting Ritalin as the "drug of choice" to treat children diagnosed with ADD and ADHD;

c. Distributing misleading sales and promotional literature to parents, schools and other interested persons in a successful effort to further increase the number of diagnoses and the number of persons prescribed Ritalin;

d. Deliberately neglecting to address or provide adequate information to consumers, doctors, and/or schools concerning the many significant hazards of methylphenidate use and prescription, including, but not limited to, the following:

i. Cardiovascular problems, including palpitations, tachycardia, hypertension, arrhythmias, chest pain and cardiac arrest;

ii. Central nervous system problems, including psychosis with hallucinations, excessive brain stimulation (convulsions), drowsiness, confusion, insomnia, agitation, anxiety, irritability, nervousness, dysphoria, impaired cognitive test performance, dyskinesia, depression, and zombie-like constriction of affect and spontaneity;

iii. Gastrointestinal problems, including anorexia, nausea, vomiting, stomach ailments, dry mouth, and constipation;

iv. Pituitary dysfunction, including growth hormone and prolactin

disruption, weight loss, growth suppression, growth retardation, anemia, exfoliate dermatitis, leukopenia, etc.

e. Misrepresenting to the consuming public, physicians and other interested parties, the efficacy of the drug Ritalin, without ever advising such persons that Ritalin usage would not stimulate or improve academic performance and/or have any long term effect on the symptoms associated with ADD and/or ADHD.

f. Facilitating the creation of a new diagnoses in the DSM.

29. Despite information in the medical and scientific literature concerning these side effects of Ritalin use, Defendants failed in all respects to advise potential consumers, doctors, and/or schools, teachers or other interested parties of the nature and extent of such side effects. Furthermore, Defendant CHADD similarly failed to provide adequate information to interested parties concerning the nature and extent of potential side effects.

30. The interrelationship between Ciba/Novartis, the drug industry as a whole, and the APA caused and contributed to the APA's assistance, support, aid, and collusion with Ciba/Novartis in creating a novel medical "diagnosis" that could be, and ultimately was, applied to a large percentage of children in the United States, and for which the APA, in combination with other defendants, continued and presently continue to promote the prescription, use and sale of Ritalin.

CLASS ACTION ALLEGATIONS
By Plaintiff on Behalf of All Others Similarly Situated
(Relating to Count One - Violation of California Civil Code § 1750 *et seq.*)

31. Plaintiff brings this Class action, individually and on behalf of others similarly situated, as a Class action pursuant to Federal Rule of Civil Procedure, Rule 23 and Section 1781 of the California Civil Code. The Class which Plaintiffs seek to represent is:

The class shall be composed of all California residents who purchased and/or ingested the drug Ritalin.

32. Specifically excluded from the Plaintiff Class are Defendants herein, any entity in which any of the Defendants has a controlling interest, any officers, directors or employees of any of the Defendants and legal representatives, heirs, successors, and assignees of any of the Defendants. Also excluded are any federal, state or local entities.

33. This action is brought and may properly be maintained as a Class action pursuant to Federal Rule of Civil Procedure 23. The community of interest in the litigation is well defined and the proposed Class is easily ascertainable. This action satisfies the numerosity, commonality, typicality, adequacy, predominance and superiority requirements of this provision. In addition this action may be brought under California Civil Code § 1781.

34. Numerosity of the Class. The Class is so numerous that the individual joinder of all Members is impractical under the circumstances of this case. While the exact number of Class Members is unknown to Plaintiff at this time, Plaintiff believes that at a minimum, there are thousands of Class Members located throughout the State of California.

35. Common Questions Predominate. Common questions of law and fact exist as to all Members of the Class and predominate over any questions affecting only individual Members of the Class. These common legal and factual questions arise from various issues, which do not vary among Class Members:

(a) All Defendants conspired, combined and colluded to promote and dramatically increase the sales of Ritalin by way of the following:

i. Actively promoting and supporting the concept that a significant percentage of children suffer from a "disease" which required narcotic treatment/therapy;

ii. Actively promoting Ritalin as the "drug of choice" to treat children diagnosed with ADD and ADHD;

iii. Distributing misleading sales and promotional literature to parents, schools and other interested persons in a successful effort to further increase the number of diagnoses and the number of persons prescribed Ritalin;

iv. Deliberately neglecting to address or provide adequate information to consumers, doctors, and/or schools concerning the many significant hazards of methylphenidate use and prescription, including, but not limited to, the following:

(A) Cardiovascular problems, including palpitations, tachycardia, hypertension, arrhythmias, chest pain and cardiac arrest;

(B) Central nervous system problems, including psychosis with hallucinations, excessive brain stimulation (convulsions), drowsiness, confusion, insomnia, agitation, anxiety, irritability, nervousness, dysphoria, impaired cognitive test performance, dyskinesia, depression, and zombie-like constriction of affect and spontaneity;

(C) Gastrointestinal problems, including anorexia, nausea, vomiting, stomach ailments, dry mouth, and constipation;

(D) Pituitary dysfunction, including growth hormone and prolactin disruption, weight loss, growth suppression, growth retardation, anemia, exfoliate dermatitis, leukopenia, etc.

v. Misrepresenting to the consuming public, physicians and other interested parties, the efficacy of the drug Ritalin, without ever advising such persons that Ritalin usage would not stimulate or improve academic performance and/or have any long term effect on the symptoms associated with ADD and/or ADHD.

vi. Facilitating the creation of a new diagnoses in the DSM.

(b) Despite information in the medical and scientific literature concerning these side effects of Ritalin use, Defendants failed in all respects to advise potential consumers, doctors, and/or schools, teachers or other interested parties of the nature and extent of such side effects. Furthermore, Defendant CHADD similarly failed to provide adequate information to interested parties concerning the nature and extent of potential side effects.

36. Typicality of Claims. Plaintiff's claims are typical of the claims of Members of the Class, all of whom have purchased and/or ingested the Ritalin manufactured, distributed, and marketed by Defendants. Plaintiff and all Class Members have sustained, and will continue to sustain damages, injuries and irreparable harm arising out of Defendants' common course of conduct.

37. Adequacy of Representation. Plaintiff, by Deborah Vess, his Guardian ad Litem, will fairly and adequately protect the interest of Members of the Plaintiff Class. Plaintiff resides in California and purchased and/or ingested Defendants' products in California during the Class period.

Plaintiff is representative Members of the Class, are united by a common interest, and are adequate representatives since they have no interests that are adverse to the interests of absent Class Members. Plaintiff has retained counsel who are both competent and experienced in the prosecution of complex consumer fraud, mass tort and class actions. Plaintiff and his counsel intend to prosecute this action vigorously for the benefit of the Class. Plaintiff and his counsel will fairly and adequately protect the interests of the Members of the Class.

38. Superiority and Substantial Benefit. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of Class Members' claims is impractical. Even if all Class Members could afford individual litigation, the court system could not. It would be unduly burdensome for the courts to adjudicate identical legal and factual issues in hundreds of thousands of cases. Individual litigation increases delay and expense to all parties, and especially the court system, associated with the resolution of the complex legal and factual issues of the case. The prosecution of separate actions by the individual Members of the Class would create a risk of inconsistent adjudications with respect to individual Class Members, thus establishing incompatible standards of conduct for Defendants. The prosecution of separate actions would create a risk of adjudications that would be dispositive of the interests of the other Class Members who are not parties to such adjudications, thus substantially impairing the ability of such non-party Class Members to protect their interests. Individual litigation of this case presents a great potential for inconsistent or contradictory judgments.

39. Class action treatment is a superior method of adjudication and provides a substantial benefit to the litigants and the courts since it presents far fewer management difficulties and provides the benefits of a single adjudication and comprehensive supervision by a single court. Furthermore, as the damages suffered by each individual Member of the Class may be relatively small, the expenses and burden of individual litigation would make it difficult or impossible for individual Members of the Class to redress the wrongs done to them. An important public interest will be served by addressing the matter as a class action. Notice of the pendency and of any resolution of this class action can be provided to Class Members by publication and broadcast.

40. Furthermore, Plaintiff's claims are certifiable as a Class action because Defendants

have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

41. Plaintiff, by Deborah Vess, his Guardian ad Litem, is unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action. Accordingly, the proposed Class fulfills the certification criteria of California law and certification of the above-defined Class is appropriate under one or more of the provisions of California law.

FIRST CAUSE OF ACTION

CLASS ACTION FOR VIOLATION OF THE CONSUMER LEGAL REMEDIES ACT
[California Civil Code §1750, et seq.]
(By All Plaintiffs Against All Defendants)

42. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

43. California Civil Code §1770 provides, in relevant part:

> The following unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer are unlawful: . . .
>
> (2) Misrepresenting the source, sponsorship, approval or certification of goods or services;
>
> (3) Misrepresenting the affiliation, connection or association with, or certification by, another;
>
> . . .
>
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have.
>
> . . .
>
> (7) Representing that goods or services are of a particular

standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

44. Defendants have committed, and continue to commit, an unlawful method of competition, and unfair and deceptive acts in violation of Civil Code § 1770 by their commission of deceptive acts which have deceived and continue to deceive the consuming public, including Plaintiff. In particular, Defendants affirmatively misrepresented material facts and failed to disclose material facts to the Plaintiff, including but not limited to the following:

a. Actively promoting and supporting the concept that a significant percentage of children suffer from a "disease" which required narcotic treatment/ therapy;

b. Actively promoting Ritalin as the "drug of choice" to treat children diagnosed with ADD and ADHD;

c. Distributing misleading sales and promotional literature to parents, schools and other interested persons in a successful effort to further increase the number of diagnoses and the number of persons prescribed Ritalin;

d. Deliberately neglecting to address or provide adequate information to consumers, doctors, and/or schools concerning the many significant hazards of methylphenidate use and prescription, including, but not limited to, the following:

i. Cardiovascular problems, including palpitations, tachycardia, hypertension, arrhythmias, chest pain and cardiac arrest;

ii. Central nervous system problems, including psychosis with hallucinations, excessive brain stimulation (convulsions), drowsiness, confusion, insomnia, agitation, anxiety, irritability, nervousness, dysphoria, impaired cognitive test performance, dyskinesia, depression, and zombie-like constriction of affect and spontaneity;

iii. Gastrointestinal problems, including anorexia, nausea, vomiting, stomach ailments, dry mouth, and constipation;

iv. Pituitary dysfunction, including growth hormone and prolactin

disruption, weight loss, growth suppression, growth retardation, anemia, exfoliate dermatitis, leukopenia, etc.

e. Misrepresenting to the consuming public, physicians and other interested parties, the efficacy of the drug Ritalin, without ever advising such persons that Ritalin usage would not stimulate or improve academic performance and/or have any long term effect on the symptoms associated with ADD and/or ADHD.

f. Facilitating the creation of a new diagnoses in the DSM.

45. Plaintiff, pursuant to California Civil Code §1780, seeks an order of this court enjoining such methods, acts and practices and an order requiring the Defendants to undertake the following:

a. Disgorge all revenues and profits acquired as a result of the unlawful methods, acts and practices;

b. Provide restitution resulting from the unlawful method, acts and practices of defendants;

c. Pay exemplary damages; and

d. Any other relief this Court deems proper.

SECOND CAUSE OF ACTION

UNFAIR COMPETITION UNDER CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTION 17200 (Against All Named Defendants)

46. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

47. Plaintiff hereby brings this action individually and on behalf of the general public pursuant to Section 17200 et seq. of the Business and Professions Code of the State of California, the "Unfair Competition Act."

48. The acts complained of in each of the preceding paragraphs of this complaint, and each of them, constitute unfair and/or unlawful acts in competition in violation of Section 17200 of the California Business and Professions Code. Such acts and violations have not abated and will continue to occur unless enjoined.

49. These violations have injured Plaintiff, the General Public, and fair and lawful competition. These violations have coextensively unjustly enriched the defendants. Plaintiff and the general public are entitled to injunctive, disgorgement/restitution, and other equitable relief.

THIRD CAUSE OF ACTION

INDUCEMENT THROUGH FALSE AND MISLEADING STATEMENT UNDER BUSINESS AND PROFESSIONS CODE SECTION 17500 (Against All Defendants)

50. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs as though fully set forth herein.

51. Plaintiff hereby brings this action individually and on behalf of the general public pursuant to Section 17500 et seq. of the Business and Professions Code of the State of California, the "Unfair Competition Act."

52. Notwithstanding their knowledge of the increased threat cardiovascular problems, central nervous system problems, gastrointestinal problems, and pituitary dysfunction, among other adverse consequences connected to the use of Ritalin, as described above, defendants, and each of them, continued to market, advertise and sell Ritalin to physicians, health care personnel and teachers, and to the General Public.

53. The acts of untrue and misleading advertising by defendants, and each of them, as described above presents a continuing threat to members of the general public of California in that their prescription and use of the drug methylphenidate presents the serious threat of hazards such as cardiovascular, central nervous system and gastrointestinal problems, as well as pituitary dysfunction.

54. The general public of the state of California have no other adequate remedy of law in that individual lawsuits would prove too time consuming and burdensome and would not properly address the monetary damage and equitable relief requested herein.

55. As a direct and proximate result of the aforementioned acts, Defendants received and continue to receive in excess of a billion dollars in sales from the sale of Ritalin to members of the General Public of California who were prescribed and ingested Ritalin, to their detriment.

56. These violations have injured the General Public and fair and lawful competition. These violations have coextensively unjustly enriched defendants, and each of them. The General

Public is entitled to disgorgement of profits, restitution and other equitable relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants, jointly and severally, as follows:

For the First Cause of Action:

1. Plaintiff prays for injunctive and declaratory relief as a result of Defendants' violation of California Civil Code §1750 *et seq*, as follows:

(a) Injunctive relief to halt unlawful methods, acts and practices engaged in by defendants;

(b) Requiring Defendants to disgorge all revenues and profits acquired as a result of their unlawful methods, acts and practices;

(c) Requiring Defendants to provide restitution resulting from unlawful methods, acts and practices of defendants;

(d) Requiring Defendants to pay exemplary damages; and

(e) Any further relief this Court deems proper;

For the Second and Third Causes of Action:

1. Plaintiff prays for equitable relief for violations of Section 17200 and Section 17500 of the Business and Professions Code as hereinabove alleged. Such relief includes:

(a) Injunctive relief to halt prior violations of law and to assure fair and lawful competition, including court orders regulating advertising, marketing, and production practices;

(b) Restitution to plaintiff and the general public who have been injured or otherwise disadvantaged by defendants' unfair and unlawful acts in competition;

(c) Restitution sufficient to fully disgorge the revenues obtained from plaintiff and the general public for unfair and unlawful acts in competition;

(d) For attorneys' fees as provided by statute and/or pursuant to the "common fund" doctrine and/or pursuant to equitable principles of contribution.

For All Causes of Action:

1. For Plaintiff's reasonable attorneys' fees and costs.

2. For prejudgment interest as provided by law.

3. For costs of suit incurred herein.

4. For such other and further relief as this Court deems equitable, just and proper.

JURY DEMAND

Plaintiff herein demands a trial by jury.

DATED: September 13, 2000

DOUGHERTY, HILDRE, DUDEK & HAKLAR

By: _____

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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.

file: Ritalin

Subcommittee on Children and Families
Committee on Labor and Human Resources
Senator Christopher J. Dodd
Ranking Member

FACSIMILE TRANSMITTAL FORM

Phone: (202)224-5630
Fax: (202)224-7475

DATE: 3/28/00 TIME: _____ A.M. P.M.

TO: Ann O'Leary

of _____

FAX # ( ) 4562878

PHONE # ( ) _____

FROM:

- ____ Brooke Byers
- ____ Suzanne Day
- ____ Jim Fenton
- X Jeanne Ireland
- ____ Other: _____

NUMBER OF PAGES, including this form: 10

COMMENTS / MESSAGE: As discussed

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3/28/00 draft

DRAFT

106TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To protect and improve research efforts concerning the health and welfare of children.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Children's Research Protection Act".

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Children are the future of the Nation and the preservation and improvement of child health is in the national interest.

(2) The preservation and improvement of child health may require the use of pharmaceutical products.

(3) While currently only 4 out of 5 drugs on the market in the United States have been approved for use by children, The enactment of the Better Pharmaceuticals for Children provisions of the Food and Drug Administration Modernization Act (Public law 105-115) is expected to increase the pediatric testing of pharmaceuticals and thus to increase the numbers of children involved in research.

(4) Children are a vulnerable population and thus need additional protections for their involvement in research relative to adults. Yet, current Federal guidelines for the protection of children involved in research have not been updated since ____ and only are required for research supported by the Department of Health and Human Services.

(5) Currently, in the United States, there is a shortage of pharmacologists trained to address the special needs of children. There are fewer than 200 academic-based clinical pharmacologists in the United States, of which only ____ are pediatric pharmacologists. Currently, only 20 physicians complete clinical pharmacology specialty training pro-

grams each year, and of these, only ____ specialize in pediatric pharmacology.

(b) PURPOSES.—It is the purpose of this Act to—

(1) ensure the adequate and appropriate protection of children involved in research by reviewing and updating as needed the Federal regulations for the protection of human subjects contained in subpart A of part 45 of title 46, Code of Federal Regulations (referred to as the "Common Rule") and by making subpart D of part 45 of title 46, Code of Federal Regulations (Additional Protections for Children Involved as Subjects in Research) mandatory for all Federal research involving children in research; and

(2) ensure that an adequate number of pediatric pharmacologists are trained and retained, in order to meet the increased demand for expertise in this area created by the better pharmaceuticals for children provisions of the Food and Drug Administration Modernization Act (Public law 105-115), so that all children have access to medications that have been adequately and properly tested on children.

SEC. 3. REVIEW OF REGULATIONS.

(a) REVIEW.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall conduct a review of the regulations under subparts A and D of part 45 of title 46, Code of Federal Regulations, as such regulations relate to children, and consider any modifications that may be necessary to ensure the safety of children participating in research.

(b) AREAS OF REVIEW.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall focus on—

(1) the definition of "minimal risk", including the level of risk that a healthy child can be subjected to in research (such as whether research may be conducted that involves greater than minimal risk if it has benefits for children generally rather than only for the particular child involved in the research);

(2) the definitions of "informed consent" and "assent" for child clinical research participants and their parents or guardians;

(3) the definition of "adequate provisions" for soliciting participants for research;

(4) the definition of "direct benefit to the individual subjects";

(5) the definition of "generalizable knowledge about the subject's disorder or condition";

(6) whether or not payment (financial or other) is provided to a child or his or her parent or guardian for the participation of the child in research, and if so, the amount and type given;

(7) the long-term follow-up done with respect to children involved in medical clinical research trials;

(8) the expectations of child research participants for the direct therapeutic benefits of their research involvement;

(9) safeguards for research conducted in emergency situations with a waiver of informed consent;

(10) parent and child notification in instances in which research rules have been violated;

(11) whether or not regulations have been complied with and the manner in which such compliance takes place;

(12) the manner in which compliance with the regulations is investigated; and

(13) the manner in which the regulations might differ based on a child's age.

(c) CONSULTATION.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall consult broadly with experts in the field, includ-

ing pediatric pharmacologists, pediatricians, and bioethics experts.

(d) CONSIDERATION OF ADDITIONAL PROVISIONS.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall consider—

(1) whether a new subpart should be added to part 45 of title 46, Code of Federal Regulations, that provides guidelines for conducting research with other vulnerable populations, including physically or mentally disabled, cognitively impaired, and economically or educationally disadvantaged individuals; and

(2) whether the Secretary should establish a national data safety and monitoring board to review adverse events associated with research involving children.

(e) REQUIREMENT.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall require that all research involving children that is conducted by, using amounts made available through, or regulated by the Department of Health and Human Services or the Food and Drug Administration be in compliance with subpart D of part 45 of title 46, Code of Federal Regulations.

SEC. 4. GRANTS FOR PEDIATRIC PHARMACOLOGY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall award grants to the Pediatric Pharmacology Research Units of the National Institute of Child Health and Human Development to enable such units to provide post-residency fellowship training awards to pediatricians in order to ensure the specialized training of doctors in pediatric pharmacology.

(b) AMOUNT OF GRANT.—In awarding grants under subsection (a), the Secretary of Health and Human Services shall ensure that each of the 13 Pediatric Pharmacology Research Units receive adequate amount under the grant to enable the Unit to fund at least 1 fellow each year for a 3-year period, at a total of $75,000 per fellowship per year.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $975,000 to carry out this section.

SEC. 5. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

Part G of title IV of the Public Health Service Act is amended by inserting after section 487E (42 U.S.C. 288–5) the following:

"SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING PEDIATRIC PHARMACOLOGY.

"(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, shall establish a program to enter into contracts with qualified physicians under which such physicians agree to undergo training in, and practice, pediatric pharmacology, in consideration of the Federal Government agreeing to repay, for each year of service as a pediatric pharmacologist, not more than $35,000 of the principal and interest of the educational loans of such physicians.

"(b) APPLICATION OF PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established under subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

"(c) FUNDING.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

"(2) AVAILABILITY.—Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning

after the fiscal year for which the amounts were made available.".