



Overload: Regulating the Sources of Information about Attention-Deficit/Hyperactivity Disorder

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**Overload:
Regulating the Sources of Information
about Attention-Deficit/Hyperactivity Disorder**

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Abstract

Information relating to attention-deficit/hyperactivity disorder (AD/HD) has flooded the consumer and medical markets in recent years. Information “overload” is often problematic, but it is especially the case with AD/HD. Those afflicted with the disorder are uniquely unsuited to make sense of the mass of information that is presented to them. The purpose of this article, therefore, is to examine whether any legal controls exist to regulate the flow of information on AD/HD. The author looks at three of the most important sources of information on the disorder—the schools, the media, and doctors—and discusses the possibility of regulation in each area. With regard to the AD/HD information emanating from the schools, he notes that Congress has already attempted regulation with the proposed Child Medication Safety Act of 2003. Although the bill did not ultimately become law, its mere existence shows the understanding of many legislators that regulatory control of AD/HD information is important. As to the media, the author writes that regulation in this area is desperately needed. However, as a result of certain constitutional and statutory limitations, he believes that such regulation is not likely to be forthcoming anytime soon. Finally, the author describes several attempts that have been made to regulate doctors and the way in which they receive and dispense information about AD/HD. After noting how these attempts have generally failed to produce results, he goes on to state his belief that substantive and effective regulation in this area is a task that is easily achievable.

I.

Meet Frank Alexander. Frank is a first-year student at Harvard Law School, and at the moment, he is sitting in one of his required courses, Civil Procedure. The professor, wearing a three-piece suit and large spectacles, is walking up and down the aisles of the lecture hall, reciting the facts of the landmark case, *Pennoyer v. Neff*.¹ Frank, however, is not listening. He is looking out the window, where he sees a groundskeeper mowing the lawn. He watches the man and follows him as he pushes the mower. The groundskeeper, however, soon moves out of sight, and Frank begins to fidget in his seat—that is, until he looks out the window again and catches sight of an attractive young lady walking by. He follows her gait along the nearby path until, suddenly, he notices the professor standing ominously over him, asking, “Mr. Alexander? Are you with us?”

¹*Pennoyer v. Neff*, 95 U.S. 714 (1877).

Will you please answer my question?" Frank, having been distracted by the people outside, does not know what the professor is talking about and stares back blankly. Frustrated by his student's inattentiveness, the professor glares at Frank for a moment and then turns to Frank's neighbor, Sylvia Davis. "Ms. Davis," he says, "Perhaps you can help out Mr. Alexander and answer my question. Mr. Alexander does not seem to care about his legal education." Sylvia, who has already made it clear to everyone in the class that she intends to make law review, answers the question with alacrity, and as she does so, Frank slides down in his chair, embarrassed about being the center of this kind of attention. These sorts of things seem to happen all the time to him, and he has developed quite a reputation among his fellow students. What Frank does not realize, though, is that he may be suffering from attention-deficit/ hyperactivity disorder, or AD/HD.²

AD/HD is a condition characterized by one or more of the following symptoms: inattention, hyperactivity, and impulsivity. The most common attribute of people with the disorder is the inability to focus. Like Frank, AD/HD sufferers find that their minds wander, and they are typically disorganized and forgetful. They do not finish assignments, whether at school or at work. In those rare instances when they do manage to finish, the work is usually filled with mistakes. Also, many of those with AD/HD are isolated in their daily lives and have problems in social settings because of a failure to understand the rules that govern interpersonal relationships.³ Although the common nature of these symptoms makes difficult any estimation of the actual number of people suffering from the disorder, most well-informed observers agree that approximately one to two percent of the child population, as well as two to four percent of adults, suffer from AD/HD.⁴

²This introduction is modeled on excerpts from two different sources: Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?" 57 Food Drug L.J. 247 (2002); Ken Livingston, "Ritalin: Miracle Drug or Cop-Out?" *The Public Interest*, No. 127 (Spring 1997), pp. 3-18, online at <http://www.pbs.org/wgbh/pages/frontline/shows/medicating/readings/publicinterest.html>. Frank Alexander is a fictional character, as is Sylvia Davis.

³Livingston, *supra* note 2.

⁴Although the disorder was long thought to affect only children, doctors now know that it can affect adults as well. Ilina

In recent years, AD/HD has become extremely controversial. Some researchers believe that the disorder is biologically-based and that the inattention, hyperactivity, and impulsivity characteristic of the condition are attributable to problems with a person's brain chemistry. As such, those adhering to this view argue that medication with psychostimulant drugs is the best, and sometimes only, treatment for the disorder. Others, however, believe that AD/HD is a man-made construct and that prescription of psychostimulant medication is a reprehensible practice, especially when children are involved. Advocates of this position claim that psychostimulants are dangerous and addicting substances that serve only to enrich psychiatrists and pharmaceutical companies and argue that there is nothing physically wrong with people who think they have AD/HD.⁵ Improvements in parenting, teaching, and the environment are all that are needed to solve the problems of these individuals.⁶

Each side in this debate has put forth an overwhelming amount of information to support its position. Articles supporting these different views of AD/HD appear constantly in books, newspapers, and magazines, as well as on the Internet. Physicians, school teachers, psychologists, and a variety of self-help groups also contribute to the body of material about the disorder. Academic research on AD/HD continues at a frenzied pace, and new studies relating to the condition are released almost every week.⁷

Singh, *A Crutch, A Tool: How Mothers and Fathers of Boys with AD/HD Experience and Understand the Work of Ritalin*. Harvard University Graduate School of Education Ed.D. Dissertation (2000), p. 8. The official psychiatric view is that three to five percent of children suffer from AD/HD, but this figure is considered by many experts to be inflated. Statement of William Carey, M.D., Director of Behavioral Pediatrics, Children's Hospital of Philadelphia, in *Protecting Children: The Use of Medication in Our Nation's Schools and H.R. 1170, Child Medication Safety Act of 2003*. Hearing Before the Subcommittee on Education Reform of the Committee on Education and the Workforce, United States House of Representatives, 108th Congress, May 6, 2003 (Washington, D.C.: U.S. Government Printing Office, 2003), online at <http://www.house.gov>; Lisa Belkin, "Office Messes," *The New York Times Magazine*, July 18, 2004, p. 26.

⁵Singh 18.

⁶As Lawrence Diller explains, these two positions represent the familiar "nature versus nurture" argument. Lawrence Diller, *Running on Ritalin* (New York: Bantam Books, 1998), p. 10.

⁷Statement of Lance Clawson, in *Protecting Children*, *supra* note 4.

More often than not, those who produce all this information believe that they are serving an important public purpose—to educate others about AD/HD. What they fail to understand, however, is that too much information in the public arena can undermine their efforts. These days, anyone who engages all the different authorities on AD/HD in an attempt to learn about the disorder is confronted with so many different facts—many of which directly contradict one another—that he or she is likely to walk away confused, rather than well informed. There is no clarity in the debate about AD/HD, and it is never clear what facts are valid and what facts are not. Evidence can be found to support almost any position.⁸ Needless to say, this is extremely frustrating for those who may be afflicted with the disorder.⁹ It also poses problems for doctors, mental health workers, law enforcement officials, teachers, school administrators, and policy makers who seek out information about AD/HD because they have to deal with it on a daily basis.

To be sure, information “overload” is not unique to AD/HD. A number of factors, however, combine to make the problem particularly acute in the case of the disorder. First, AD/HD, in a variety of forms, has been around for a long time, so a lot of information about it has been produced over the years. Second, it is a disorder in which the diagnostic process is particularly elastic. There is no objective, scientific test for AD/HD, and doctors disagree about the best methods of evaluation and diagnosis. Each physician seems to follow a different procedure when confronted with AD/HD-type symptoms. With such confusion in the

⁸Diller 314.

⁹The drafters of the 1998 National Institutes of Health AD/HD Consensus Conference Statement recognized these problems. They wrote: “Families of children impaired by the symptoms of AD/HD are in a very difficult position. An already painful decision-making process is often made substantially worse by the media war between those who overstate the benefits of treatment and those who overstate the dangers of treatment.” Cited in testimony of Bob Seay before the Arkansas House of Representatives, House Interim Committee on Public Health, Welfare, and Labor, May 3, 2000, included in *Ritalin Use Among Youth: Examining the Issues and Concerns*. Hearing before the Subcommittee on Early Childhood, Youth and Families of the Committee on Education and the Workforce, United States House of Representatives, 106th Congress, May 16, 2000 (Washington, D.C.: U.S. Government Printing Office, 2000), p. 143.

medical community, the ready availability of information on the disorder is dangerous, because it makes the manipulation of fact a particularly easy task. Third, because psychostimulants—drugs that can affect the very essence of our humanity—are used for treating the disorder, the controversy over AD/HD has aroused extreme passions.¹⁰ It is a fight that is bitter and contentious, and adherents of the different views on AD/HD release information constantly in an attempt to get the better of their opponents. Fourth, and most importantly, those with AD/HD—due to the nature of the condition and the way in which it prevents people from focusing on a task for any extended period of time—are uniquely unsuited to make sense of all the information that is presented to them.

The purpose of this article is to examine whether there are any legal controls that exist to regulate the flow of information about AD/HD. As might be imagined, this is a difficult subject. AD/HD is a disorder that has many interested parties—parents, children, teachers, doctors, employers, pharmaceutical companies, and federal and state governments, to name just a few. Understanding how information flows among these groups is an extremely complicated endeavor. It is a web that is not easily untangled. Within the legal realm, the subject lies at the intersection of First Amendment law and food and drug law. And within food and drug law, one comes up against many of the most difficult and divisive issues of the day—issues such as off-label prescribing, direct-to-consumer marketing, and regulation of the pharmaceutical industry.

Despite these difficulties, this is an issue that must be addressed. There are a number of reasons for its importance. First, there are ethical concerns relating to informed consent. When individuals are seeking

¹⁰Singh 205.

information about AD/HD, they should be made aware of the controversy surrounding the disorder. They should know about the potential side effects of the medications used to treat the condition. They should be told of studies showing a correlation between psychostimulant use and later drug use. They should also know that use of certain AD/HD medications could bar a person from military service.¹¹ When children are involved, these facts must be communicated all the more clearly to parents, because children do not make the decision themselves about taking medication. Without a clear and accurate presentation of all these issues, people cannot make informed and educated decisions about what is best for them and the members of their family.

Second, despite the massive body of literature that has sprung up around AD/HD, there are still people who are not receiving any information about the disorder. There are many concerns about those individuals who suffer from AD/HD, but who have not been diagnosed and who are not receiving the help they need.¹² Researchers have studied this problem in depth.¹³ For example, in one notable study, they performed evaluations of 1285 children in four communities—Atlanta, Georgia; New Haven, Connecticut; Westchester County, New York; and San Juan, Puerto Rico. It turned out that 5.1% of children and adolescents between the ages of nine and seventeen had AD/HD, yet only 12.1% of these children were being treated with medication. Results such as these suggest that a great many people with the disorder are not receiving

¹¹These concerns were articulated by Patricia Weathers, President, Parents for Label and Drug Free Education. See Statement of Patricia Weathers in *Attention-Deficit/Hyperactivity Disorder—Are We Overmedicating Our Children?* Hearing before the Committee on Government Reform, United States House of Representatives, 107th Congress, September 26, 2002 (Washington, D.C.: U.S. Government Printing Office, 2003), online at <http://frwebgate.access.gpo.gov>.

¹²American Academy of Child and Adolescent Psychiatry (AACAP), *Practice Parameters for the Assessment and Treatment of Children, Adolescents, and Adults With Attention-Deficit/Hyperactivity Disorder*, cited in Clawson, *supra* note 7. According to the American Medical Association (AMA), many AD/HD children go undiagnosed and untreated as a result of misinformation about the disorder.

¹³Dr. Peter Jensen is the Ruane Professor of Child Psychiatry at Columbia University. He was formerly the Associate Director for Child and Adolescent Research at the National Institute of Mental Health (NIMH).

appropriate treatment.¹⁴ Also, significant geographic differences in the prescription of psychostimulant medication make one suspect that there are problems with information flow. There are tremendous variations from community to community. In certain Virginia school districts, one out of every six white males in the fifth grade uses a psychostimulant drug.¹⁵ Yet, in other counties throughout the United States, not a single person receives psychostimulant medication.¹⁶ If these disparities are indeed the result of a system-wide failure to get people the information they need, steps must be taken to improve this situation.¹⁷

Third, and more generally, we aim, as a society, for an economically efficient allocation of resources—in other words, resources should be put to their most productive uses. Under the practices currently used to diagnose and treat AD/HD, however, the allocation of resources is extremely unproductive. This is evident when looking, for example, at the phenomenon of direct-to-consumer advertising. Various advertisements for new AD/HD drugs and treatment modalities have flooded the media in recent years. One can hardly turn on the television or read a newspaper and not see an advertisement for an AD/HD medication. Although these

¹⁴AACAP Practice Parameters, *supra* note 12. See Peter Jensen, et al., “Are Stimulants Overprescribed? Treatment of AD/HD in Four U.S. Communities,” *Journal of the American Academy of Child and Adolescent Psychiatry* 38:7 (July 1999); Peter Jensen, “Is AD/HD Overdiagnosed and Overtreated? A Review of the Epidemiological Evidence,” *Report on Emotional and Behavioral Disorders in Youth* 2:4 (Fall 2003).

¹⁵Statement of Lawrence Diller, in *Ritalin Use Among Youth*, *supra* note 9.

¹⁶Problems with geographic distribution are evident from a variety of sources. The Drug Enforcement Administration (DEA) has a system known as ARCOS (Automation of Reports and Consolidated Orders System) that tracks certain controlled substances from point of manufacture to the location where the drugs are distributed to consumers. ARCOS data shows that there is wide variability in the use of certain psychostimulants from one state to another and from one community to another within states. Also, reporters from *The Cleveland Plain Dealer* studied for one full year the actual prescriptions written in every county in the nation. Some counties had 20% of school-age boys on psychostimulant medication while other counties had practically no one receiving stimulant medication. See Sabrina Eaton and Elizabeth Marchak, “Ritalin Prescribed Unevenly in U.S.,” *The Cleveland Plain Dealer*, May 6, 2001, p. 1A. Finally, in the February 2003 issue of *Pediatrics*, the professional journal of the American Academy of Pediatrics (AAP), researchers documented the significant “geographical variation in the prevalence of stimulant medication use.” Emily R. Cox, et al., “Geographic Variation in the Prevalence of Stimulant Medication Use Among Children 5 to 14 Years Old: Results from a Commercially Insured U.S. Sample,” *Pediatrics* 111: 237-243 (February 2003).

¹⁷That people are not being treated may not be the result of information failures, but rather of conscious rejection of the information once it is presented. The condition already has become trivialized by the growing numbers of cases being diagnosed. As a result, people may simply dismiss the information once they receive it. Also, certain racial and ethnic groups look down upon the mental health system in general and the AD/HD diagnosis in particular. For example, many African-Americans do not go to medical specialists for behavior and performance problems because they fear doctors’ use of drugs. Crack cocaine has been so injurious to the black community that many blacks are apprehensive about using any kind of stimulant. Similarly, many Asian immigrants living in the United States are not comfortable using the mental health system to solve their problems. Such cultural differences are understandable. As Lawrence Diller relates, “Cultures differ in the degree to which their members accept emotional distress or tolerate underperformance. They also vary in how people feel about seeking professional assistance for emotional problems and in their acceptance or disapproval of drugs to relieve distress or improve performance.” Diller 316.

advertisements do serve many valuable purposes, they also make it more likely that scarce medical resources are devoted to issues that may not actually be urgent. There is abundant evidence that in the few minutes that a patient usually spends with his doctor, he spends much of the time talking about what he has seen in these advertisements.¹⁸ Similarly, a diagnosis of AD/HD often provides access to certain specialized medical and educational resources. However, the use of these resources by people who are given an AD/HD diagnosis when it is not warranted limits the resources available for those who are truly disabled. Information controls can go a long way toward ensuring that resources are being allocated in ways that provide the maximum benefit.¹⁹

To explore these issues, Part II of this article will take a closer look at AD/HD, its history, and the way it has been treated over the years. I will then examine in detail three of the most important vehicles for information about the disorder. Part III will explore the school system in general and the role of teachers in particular. Part IV will focus on the media, looking at two specific areas: the Internet and direct-to-consumer advertising. Part V will examine the role of physicians in the AD/HD diagnostic and treatment process. Finally, Part VI will provide conclusions and discuss ways to improve the flow of information about the disorder.

II. AD/HD, its history, and methods of treatment

¹⁸Stephen J. Ceccoli, *Pill Politics: Drugs and the FDA* (Boulder: Lynne Rienner Publishers, 2004), pp. 156-157.

¹⁹It should be noted that the presentation of so much information about AD/HD—much of which is devoted to the use of medication for treatment of the disorder—also has the potential to undermine the nation’s war on drugs. A television advertisement warning children about the dangers of drugs may very well be followed by one pushing a psychostimulant or other drug. As Ken Livingston has written, “There is something odd, if not downright ironic, about the picture of millions of American school children filing out of ‘drug-awareness’ classes to line up in the school nurse’s office for their midday dose of amphetamine.” Livingston, *supra* note 2. Mary Eberstadt has stated the problem differently: “How has it come to pass that in *fin-de-siècle* America, where every child from preschool onward can recite the ‘anti-drug’ catechism by heart, millions of middle- and upper-middle class children are being legally drugged with a substance so similar to cocaine that, as one journalist accurately summarized the science, ‘it takes a chemist to tell the difference’?” Mary Eberstadt, “Why Ritalin Rules,” *Policy Review* 94 (April & May 1999), online at <http://www.policyreview.org/apr99/eberstadt.html>.

There are certain individuals who simply cannot focus on a task for an appropriate period of time.²⁰ This is more than the typical inattention and restlessness that plagues us all occasionally; the lack of focus in people with AD/HD is constant and pervasive. Because most people do not understand the debilitating nature of the disorder, those suffering from AD/HD and others familiar with the condition often use a number of colorful analogies to describe what the AD/HD-afflicted experience on a daily basis. “AD/HD is like having thirty televisions on at one time, and the medicine turns off twenty-nine so you can concentrate on the one,” says Kerri Houston, national field director for the American Conservative Union and the mother of two AD/HD children.²¹ Dr. Andrew P. Levin, clinical director of the outpatient mental health service of the Westchester division of the St. Vincent’s Catholic Medical Center of New York, uses a different analogy. “Trying to function with untreated [AD/HD] is like driving through the rain without windshield wipers,” he says.²² And Robert Tudisco, a lawyer with AD/HD who also represents clients with the disorder, opts for yet another approach: “As I sit here and talk to you in a relatively calm conversation, there’s an amusement park going on in my head.”²³

As suggested above, these problems come with tremendous consequences. AD/HD can lead to disorganization, forgetfulness, school failure, poor social relationships, underperformance at work, chronic drug use, and brushes with the law. A never-ending cycle of employment and unemployment is also common.²⁴ Some AD/HD sufferers, however, are more likely than others to experience these problems. This is because there are three distinct subtypes of the disorder—an inattentive subtype, a hyperactive-impulsive subtype, and

²⁰Statement of Richard K. Nakamura, Acting Director, NIMH, in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11.

²¹Michael Fumento, “Trick Question,” *The New Republic*, February 3, 2003, p. 18.

²²“Attention Deficit: Not Kids Only!” *The New York Times Magazine*, October 29, 2000, p. 46.

²³Belkin 27.

²⁴“International Consensus Statement on AD/HD,” in *Clinical Child and Family Psychology Review* 5:2 (June 2002), p. 92.

a combined subtype. According to the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), the official handbook of psychiatric illness, the inattentive subtype exists when people exhibit at least six of nine inattention symptoms listed in the DSM and no more than five hyperactive-impulsive behaviors. The hyperactive-impulsive subtype is seen in those people who display at least six of nine hyperactive-impulsive symptoms but less than six inattention symptoms. And the combined subtype is found in people who exhibit at least six inattention and at least six hyperactive-impulsive symptoms.²⁵ Whether a person with the disorder experiences social isolation or problems at work depends in large part on what kind of AD/HD he has.

In an attempt to explain such phenomena, researchers have looked into the biological causes of AD/HD. The disorder has been linked to several specific brain regions, especially the frontal lobe, the basal ganglia, and the cerebellum. Those with AD/HD usually have less electrical activity and less reactivity to stimulation in these areas of the brain.²⁶ There are also volumetric differences and differences in metabolic activity in the brains of those with AD/HD.²⁷ Relying heavily on such research, the U.S. Surgeon General, the American Medical Association, the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, and the American Academy of Pediatrics

²⁵George J. DuPaul and Gary Stoner, *AD/HD in the Schools* (New York: The Guilford Press, 2003), p. 26. Whatever subtype is at issue, doctors require that other criteria be met as well. For example, symptoms of the disorder must have begun prior to age seven; the child or adult must demonstrate the problem behaviors in at least two situations (school, home, or work); the behaviors must cause significant distress or impairment in functioning; and the behaviors cannot be better explained by other diagnostic conditions. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV-TR) (Washington, D.C.: American Psychiatric Association, 2000), pp. 83-85; Diller 56.

²⁶“International Consensus Statement on AD/HD,” *supra* note 24. See, e.g., R.A. Barkley, et al., “Frontal lobe functions in attention deficit disorder with and without hyperactivity: A review and research report,” *Journal of Abnormal Child Psychology* 20 (1992), pp. 163-188; M. Teicher, et al., “Functional deficits in basal ganglia of children with attention-deficit/hyperactivity disorder shown with functional magnetic resonance imaging relaxometry,” *Nature Medicine* 6 (2000), pp. 470-473.

²⁷AD/HD brains are generally smaller. Research using magnetic resonance imaging (MRI) and positron emission tomography (PET) found that total brain size in subjects with AD/HD is approximately three to five percent smaller than in age- and gender-matched control subjects. Belkin 27.

have all recognized AD/HD as a legitimate disorder.²⁸ Also, in 2002, an international group of scientists released a statement supporting the AD/HD diagnosis.²⁹

If an individual suspects that he has AD/HD, a comprehensive evaluation by a specially trained professional is essential.³⁰ This is easier said than done, however. For a number of reasons, AD/HD is not an easy diagnosis for doctors to make.³¹ First, as was mentioned above, there is no confirmatory test for the disorder. Second, with AD/HD, there is a high degree of co-morbidity, which means that many people with the disorder also experience other psychiatric problems.³² It is often difficult for doctors to distinguish these problems from AD/HD. Third, the diagnostic criteria for AD/HD are in many ways a collection of common behaviors. Many people fidget with their hands, are inattentive, and avoid boring tasks. Therefore, it is up to the doctor to evaluate the frequency, intensity, and degree of impairment in a patient.³³ But this, in turn, is an impressionistic and subjective process. Results are very much open to interpretation.³⁴

Should a doctor actually diagnose an individual with AD/HD, the National Institute of Mental Health (NIMH) gives doctors advice on how to treat the disorder. NIMH guidelines prescribe what has come to be known as “multimodal” treatment. This includes behavioral therapy, counseling, special education interventions, and potential medication use. Multimodal treatment, however, is labor-intensive and expensive.³⁵ As a result, although such efforts may be recommended as part of a treatment plan and although many doctors

²⁸“International Consensus Statement on AD/HD,” *supra* note 24.

²⁹*Id.*; Statement of Richard K. Nakamura, *supra* note 20.

³⁰Statement of Richard K. Nakamura, *supra* note 20.

³¹AACAP Practice Parameters, *supra* note 12.

³²A study conducted by the NIMH showed that 69% of children with AD/HD have co-occurring disorders. In other words, only 31 percent of children with AD/HD have AD/HD alone with no other disorder. The study found that 40 percent of children with AD/HD had oppositional defiant disorder, 34 percent had anxiety disorder, 14 percent had conduct disorder, and four percent had a mood disorder. Children with auditory or visual problems can also exhibit AD/HD symptoms.

³³Diller 58.

³⁴Statement of William Carey, *supra* note 4; Diller 61-62. As the author Lisa Belkin relates, to many, the disorder is “little more than spaciness redefined as a disease.” This is because the symptoms look suspiciously like bad habits. Belkin 26-27.

³⁵Diller 45.

ascribe to multimodal treatment in theory, in practice the NIMH guidelines are rarely followed.³⁶

Psychostimulant therapy is usually the only treatment provided.³⁷ Psychostimulant medication increases the availability of neurotransmitters such as dopamine and norepinephrine in certain parts of the brain. This speeds up the activity of neurons and results in a greater arousal of the central nervous system. This, in turn, provides better executive function and increased attention and behavior control.³⁸ The most commonly employed psychostimulants are methylphenidate hydrochloride (hereinafter, methylphenidate), dextroamphetamine, and mixed amphetamine.³⁹ Methylphenidate, however, is used most widely. Over 80% of children treated with psychostimulants use some form of the drug on a daily basis.⁴⁰

Side effects of the psychostimulants can include sleeplessness, weight loss, growth retardation, heart damage, and psychosis. There has also been concern that these drugs impact cognitive processes. AD/HD expert Lawrence Diller writes, “Both parents and researchers have at times noticed that children taking psychostimulants sometimes answer questions in ways that seem overly compliant or narrow, suggesting that the drug

³⁶*Id.*

³⁷Approximately 1.5 million children in the United States are treated with psychostimulant medications. Daniel Safer and Julie Magno Zito, “Pharmacoepidemiology of methylphenidate and other stimulants for the treatment of AD/HD,” in Laurence L. Greenhill and Betty B. Osman, eds. *Ritalin: Theory and Practice* (Larchmont: Liebert, 2000), pp. 7-26. Data on physician prescribing practices suggest that few general practitioners or pediatricians provide treatment other than pharmacotherapy with psychostimulants. Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration (DEA), United States Department of Justice, “Methylphenidate: A Background Paper,” October 1995, online at [http://ablechild.org/dea%20report %2010-1-95.htm](http://ablechild.org/dea%20report%2010-1-95.htm).

³⁸Executive function includes short-term memory, as well as the ability to plan and stay focused on a task without being distracted by emotional impulses. See Dr. Thomas E. Brown, ed., *Attention-Deficit Disorders and Comorbidities in Children, Adolescents, and Adults* (Washington, D.C.: American Psychiatric Press, 2000).

³⁹Other examples of psychostimulants include caffeine and cocaine.

⁴⁰DuPaul and Stoner 191; Safer and Zito, *supra* note 37. Methylphenidate is sold as the brand-name medications “Concerta” and “Ritalin.” Dextroamphetamine goes by the trade name “Dexedrine,” and mixed amphetamine is sold most commonly as “Adderall.”

might restrict creative thinking.”⁴¹ Partly as a response to these side effects, pharmaceutical companies have worked in recent years to develop nonstimulant medications to treat AD/HD. At the end of 2002, the U.S. Food and Drug Administration (FDA) approved atomoxetine, better known by its trade name “Strattera,” a nonstimulant sold by Eli Lilly and Company.⁴² Strattera allows people to take on certain jobs—for example, machine operation or airline piloting—that would be dangerous under the influence of psychostimulants.⁴³ It is also the first medication specifically designed for AD/HD in adults.⁴⁴ The drug, however, has not been extensively studied, and debate continues about its effectiveness.

The earliest report we have of individuals who would fit the modern AD/HD diagnosis dates back to 1902. Lecturing before the Royal Academy of Physicians in London, doctor George Still described a certain group of children as “aggressive,” “defiant,” “resistant to discipline,” “excessively emotional,” and “passionate.” He also noted how these children manifested little “inhibitory volition.”⁴⁵ We do not hear much more about this collection of symptoms until 1917-1918, when an outbreak of encephalitis, a viral infection of the brain, piqued the interest of researchers. Doctors examined children who experienced behavioral and cognitive problems after their illness, and they found pervasive evidence of inattention, hyperactivity, and impulsivity. Over the course of the next decade, researchers studied these symptoms sporadically, and by the 1930s, they had come up with names such as “organic drivenness” and “restlessness syndrome” for this set of problems.⁴⁶

⁴¹Diller 26.

⁴²Strattera prevents the reuptake of norepinephrine, a neurotransmitter believed to be important in regulating attention, impulsivity, and activity levels. The reuptake inhibition mechanism keeps more norepinephrine at work in the synapses. Demian Faunt, “Attention to details: intensified promotion of Strattera to physicians emphasizes nonstimulant and noncontrolled status, which translates into a strong sales start,” *Med Ad News*, October 1, 2003, p. 38.

⁴³Belkin 29.

⁴⁴DuPaul and Stoner 194.

⁴⁵G.F. Still, “Some abnormal psychical conditions in children.” *Lancet* 1: 1008-12, 1077-82, 1163-68 (1902); Diller 51.

⁴⁶Diller 51-52.

It was, however, only in the early 1940s that the condition began to be studied in depth. Doctors focused in on a specific group—children who, because of a presumed problem with their nervous systems, had learning disabilities. Although no evidence of damage to the brain could be found in most of these children, it was believed that they did have brain damage because they experienced the same learning problems as individuals who were known to have suffered brain injury (e.g., after trauma). In these subjects, however, doctors believed that the brain injury was so small that it was undetectable. Therefore, they introduced the term “minimal brain damage” (MBD) to describe the cause of these children’s deficits.⁴⁷ Over the years, MBD came to be a broad diagnosis and included a number of behaviors that resemble the symptoms of modern AD/HD, including hyperactivity, distractibility, and impulsivity.⁴⁸ However, some medical providers—particularly those who remained faithful to the art of psychoanalysis—did not use the MBD terminology and instead opted for the more ambiguous diagnosis of “emotional disturbance” to describe the AD/HD-like symptoms they came across.

Throughout the 1950s, psychoanalysts and psychiatrists cooperated in what was seen as a common effort to help those suffering from behavioral and emotional problems. By the end of the decade, however, this cooperation had largely come to an end. Many psychiatrists were frustrated with psychoanalysis and its lack of tangible results in treating MBD/emotional disturbance, and they decided to emphasize the organic nature of the disorder. They were aided by two developments. First, in 1957, Maurice Laufer coined a new name—“hyperkinetic disorder of childhood”—to describe the constellation of symptoms that characterized MBD/emotional disturbance. Laufer, writing in the *Journal of Pediatrics*, discussed MBD’s “organic components,” narrowed its symptoms to one in particular (hyperactivity), and recommended amphetamine

⁴⁷Statement of David Fassler, in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11.

⁴⁸Other behaviors included “excessive restlessness, poor ability to sustain interest in activities, aimless wandering, and excessive appetite.” Diller 52. By the 1950s, MBD was changed to “minimal brain dysfunction.”

for treatment.⁴⁹ After publication of this article, doctors began to urge their colleagues to compensate for their prior neglect of biology.⁵⁰ In journals and other trade publications, they encouraged “the consideration of organic factors when diagnosing children’s behavior because the psychogenic factors have so often been exclusively emphasized.”⁵¹ They also told their colleagues to look “as carefully among the myriad of possibilities of organic causation as [they did] in the past among the interpersonal, deprivation and stress factors.”⁵²

The second important development during this period was the appearance of Ritalin, a new psychostimulant marketed by Ciba Pharmaceuticals.⁵³ Ritalin was not initially intended as a treatment for hyperkinetic disorder of childhood. Rather, it was designed for mild depression and narcolepsy. The appearance of Ritalin, however, was important because by this time, there were many studies that established that psychostimulants lessened hyperactivity, and doctors understood how these medications worked (see below).⁵⁴ Furthermore, with Laufer’s new biological paradigm, there was a clear role for the psychostimulants. Doctors therefore prescribed Ritalin “off-label.”⁵⁵ As use of the drug became more popular, researchers began to change how they studied hyperkinetic disorder. Lawrence Diller writes, “This was the start of a trend away from attempts to identify the source of the problems—which was proving so difficult—and toward a more pragmatic approach: simply sorting out and describing symptoms in detail, and learning what did or did not lead to improvement.”⁵⁶

⁴⁹Maurice Laufer and Eric Denhoff, “Hyperkinetic behavior syndrome in children,” *Journal of Pediatrics* 50: 463-474 (1957).

⁵⁰Singh 93-94.

⁵¹*Id.*; M. Knobel, et al., “Hyperkinesia and organicity in children,” *Archives of General Psychiatry* 1: 310-321 (1959), p. 319.

⁵²Singh 93-94; Sam D. Clements and John E. Peters, “Minimal brain dysfunction in the school-aged child: diagnosis and treatment,” *Archives of General Psychiatry* 6: 185-97 (1962), p. 197.

⁵³Ritalin is a brand-name version of methylphenidate.

⁵⁴Diller 52.

⁵⁵“Off-label” prescribing is discussed below in Part V.

⁵⁶Diller 52.

It should be noted, however, that the new emphasis on biology, hyperactivity, and medication was not all-consuming during this period. Despite many doctors advocating a wholesale change in approach, psychoanalytic methods were still used by medical providers in treating the symptoms of hyperkinetic disorder. In the early 1960s, for example, it was still commonly believed that the most effective treatment for the disorder combined psychotherapy, parental counseling, and psychostimulant medication.

The year 1972, however, marked a key moment in the history of the disorder. In that year, Virginia Douglas, head of a research team at McGill University in Montreal, delivered a paper to the Canadian Psychological Association about a group of children that she had been studying. These were children who had been diagnosed with hyperkinetic disorder, but their problems centered less on hyperactivity and more on inattention and impulsivity. In fact, many of the kids showed no sign of hyperactivity at all. Douglas therefore believed that the emphasis on hyperactivity in the diagnosis and treatment of hyperkinetic disorder was incorrect.⁵⁷ Instead, she favored an approach whereby hyperactivity was placed on an equal footing with inattentiveness and impulsivity. In other words, she sought to reverse the earlier emphasis on hyperactivity initiated by Laufer.

This new approach was supported by other research, and there was soon born a new name for the condition—attention-deficit disorder, or ADD. This new terminology reflected the belief among diagnosticians that

⁵⁷*Id.* at 53.

attention, and not hyperactivity, was the key problem.⁵⁸ Official acceptance of this view came in 1980 with the introduction of ADD in the DSM-III (the third edition of the DSM). The DSM-III definition of ADD, however, was written in such a way that it encompassed millions of people—namely those individuals with problems of inattention and/or impulsivity without any hyperactivity.⁵⁹ The text made a clear distinction between ADD with hyperactivity (ADD/H) and without (ADD/WO).⁶⁰

After the DSM revisions in 1980, debate continued to rage among mental health professionals about the importance of hyperactivity in the ADD diagnosis. As the decade progressed, there were increasing concerns that it had been deemphasized too much. The 1987 revision of the DSM, the DSM-III-R, therefore replaced “attention-deficit disorder” (ADD) with “attention-deficit/hyperactivity disorder” (AD/HD).⁶¹ This change, however, was made somewhat prematurely. By the time of the 1994 publication of the DSM-IV, diagnosticians believed that the earlier DSM-III distinctions had been more accurate, and they changed the criteria once again, implementing the current classification system with its three subtypes (with inattention only, with hyperactivity-impulsivity only, and the combined form).⁶²

Throughout much of the history of AD/HD, psychostimulant medications have provided the main form of treatment for the disorder, and these drugs have a long and complex history of their own. Their power was discovered accidentally in the mid-1930s by Charles Bradley, a pediatrician who served as the director of

⁵⁸Singh 11.

⁵⁹Diller 32, 53.

⁶⁰Livingston, *supra* note 2; American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, Third Edition (DSM-III) (Washington, D.C.: American Psychiatric Association, 1980).

⁶¹Diller 54. The term “ADD” no longer exists officially. Most people, however, continue to use the acronym. Lawrence Diller says the reason for this is not clear: “[P]erhaps [it] is because it is simply easier to say, or perhaps because it more accurately reflects the growing number of children and adults who demonstrate problems only with attention.” *Id.*

⁶²Livingston, *supra* note 2.

the Emma Pendleton Bradley Home in East Providence, Rhode Island, the nation's first psychiatric hospital devoted to children.⁶³ Bradley worked with kids under fourteen who were of normal intelligence but who demonstrated a variety of neurological and behavioral disorders.⁶⁴ Bradley's discovery was made when he gave benzedrine, a mixture of two types of amphetamine, to children who had undergone a spinal tap in an attempt to cure the headaches common after such a procedure. Although the headaches did not disappear, this experimental treatment regimen decreased the activity level of many of the children and also increased their compliance and academic performance.⁶⁵

Bradley first published his findings in 1937 in *The American Journal of Psychiatry*.⁶⁶ He noted the children's newfound motivation and their enhanced ability to read, comprehend, and do arithmetic. He also stated that half of the children became "more placid and easy-going."⁶⁷ He wrote, "It appears paradoxical that a drug known to be a stimulant should produce subdued behavior." Bradley's observation of "subdued behavior," however, was in actuality the children's intensified focus.⁶⁸ Over the years, he and his colleagues continued their experiments with psychostimulants and published their results in the leading professional journals of the day.

⁶³The Emma Pendleton Bradley Home opened its doors in 1931 and was equipped mainly for the care of children with neurologic and behavior disorders. In using benzedrine to cure headaches, Bradley was likely experimenting with different methods of treatment. Iina Singh writes, "The 1930s was an era of radical experimentation with drug therapies, often based on a hit or miss premise rather than on theoretical foundations. The drug companies were glad to support such research. In Bradley's pioneering article, he thanks Smith, Kline, and French Laboratories for supplying the benzedrine." Singh 90.

⁶⁴*Id.* at 88.

⁶⁵Diller 24-25. Bradley performed his experiment on twenty-one boys and nine girls, ages five to fourteen. Singh 88.

⁶⁶Charles Bradley, "The Behavior of Children Receiving Benzedrine," 94 *Am. J. Psychiatry* 577 (1937).

⁶⁷*Id.*; Singh 88.

⁶⁸Bradley, *supra* note 66; Diller 24-25. In other words, the drug's effect was not at all paradoxical—the stimulant "stimulated" the children's ability to focus.

The psychostimulant most widely used for the treatment of AD/HD has always been methylphenidate. First synthesized in Europe in 1944, it was the brainchild of doctors who wanted to prescribe a stimulant that would not cause addiction.⁶⁹ It was not until 1955, however, that the drug was approved for use in the United States by the FDA to treat mild depression and narcolepsy. Its use was limited at this point because relatively few clinical trials had been conducted on its safety and efficacy. In the late 1950s and early 1960s, however, additional trials were conducted that showed both the power of the drug and its potential uses, and in 1961, the FDA amended methylphenidate's official list of indications to include treatment for certain behavior problems.⁷⁰ By the mid-1960s, Ritalin, the brand-name version of the drug, had become the primary substance used for the treatment of behavior. An estimated 150,000 children were taking the medication in 1970.⁷¹

In 1971, however, the Drug Enforcement Administration (DEA) imposed restrictions on the psychostimulants and designated both methylphenidate and amphetamine to be Schedule II drugs under the Controlled Substances Act (CSA).⁷² Schedule II is a category that includes drugs with a significant risk of abuse.⁷³ These restrictions by the DEA had several consequences. First, they required quotas to be set on the amount of psychostimulant medication produced in a given year. The avowed aim of these quotas was two-fold: 1) to ensure that legitimate medical need was satisfied; and 2) to limit the diversion of drugs for illegal purposes.⁷⁴

⁶⁹Diller 21.

⁷⁰*Id.* at 24-25. According to Lawrence Diller, Ritalin research fueled many grants and academic careers in the 1960s. *Id.*

⁷¹*Id.* at 27.

⁷²21 U.S.C. § 801. Statement of Terrance Woodworth, Deputy Director, Office of Diversion Control, DEA, United States Department of Justice, in *Ritalin Use Among Youth*, *supra* note 9.

⁷³*Id.* For a drug to be classified as Schedule II, it must meet three criteria: 1) It has to have a high potential for abuse; 2) it has to have a currently accepted medical use in treatment in the United States; and 3) it has to show that abuse may lead to severe psychological or physical dependence. Statement of Chairman Dan Burton, in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11. Schedule I, the most dangerous category, is reserved for heroin, LSD, and other drugs that can be used only experimentally.

⁷⁴Section 306(a) of the Controlled Substances Act. Each year, an aggregate production quota (APQ) for each Schedule II drug is set based on sales and inventory data supplied by the manufacturers, as well as on information supplied by the FDA

Second, the DEA restrictions required doctors to use special forms whenever they dispensed psychostimulant drugs.⁷⁵

Despite this new regulation, psychostimulant use was on the rise by the start of the 1980s. In 1980, it was estimated that between 270,000 and 541,000 elementary school children in the United States were receiving psychostimulants on a daily basis. By 1987, this number grew to 750,000.⁷⁶ These numbers, however, were relatively low. Records kept by the DEA on the annual production quotas of methylphenidate reveal that psychostimulant usage simply exploded in the 1990s. In 1990, the methylphenidate quota stood at 1768 kilograms. It rose to 5110 kilograms in 1993, 10,410 kilograms in 1995, and 13,824 kilograms in 1997. By 2000, the quota increased to over 14,000 kilograms.⁷⁷

III. Schools

In examining the regulation of information relating to AD/HD, we look first at the schools. We begin our inquiry here for a number of reasons. First, a large number of AD/HD sufferers are children, and children spend much of their time in educational settings. Second, the precipitating events leading to the diagnosis of AD/HD in children almost always occur at school.⁷⁸ Teachers, who work closely with students and spend hours each day with them, are usually the first to realize that a child might have the disorder. Third,

regarding medical and research needs. The government then gives each company a manufacturing quota (MQ) to provide for these needs. “Methylphenidate: A Background Paper,” *supra* note 37.

⁷⁵This requirement is perceived as burdensome by some doctors and by many patients because prescriptions must be written in the doctor’s office rather than phoned in to a pharmacy.

⁷⁶Diller 33.

⁷⁷Statement of Terrance Woodworth, *supra* note 72; Statement of Chairman Michael Castle, in *Ritalin Use Among Youth*, *supra* note 9; “Methylphenidate: A Background Paper,” *supra* note 37; Diller 33-34.

⁷⁸Livingston, *supra* note 2.

Congress has already considered steps to regulate the flow of AD/HD information in the school setting. Its work can provide a valuable model for potential regulation in other areas.

The core characteristics of AD/HD—inattention, hyperactivity, and impulsivity—pose tremendous problems for teachers. In a typical classroom, students are expected to sit at their desks each day for hours and absorb—usually passively—the information communicated by the teacher at the front of the room. Even under the best of circumstances, completing the curriculum and teaching children to behave properly are demanding tasks for teachers.⁷⁹ But with shrinking budgets, teachers have to manage increasingly larger classes that produce more distractions and permit less flexibility.⁸⁰ In such a setting, one unruly student can cause complete chaos.⁸¹ When a child with AD/HD fidgets with his hands or feet, talks with classmates at inappropriate times, leaves his seat without permission, or blurts out answers when the teacher is speaking, it can be very disruptive to classroom instruction and disturb the educational process for all children.

Psychostimulant medications, however, offer the teacher an easy way to make a child compliant. They make children “sit down, shut up, keep still, and pay attention.”⁸² Teachers who are overwhelmed will sometimes suggest to parents that their child suffers from AD/HD because they know that such a diagnosis usually results in medication, and they do not see any other way of controlling the student. In some cases, teachers are willing to take this radical step even if the teacher is not familiar with the intricacies of the diagnosis or the student does not present any of the symptoms of the disorder. And when this technique proves successful

⁷⁹DuPaul and Stoner 139.

⁸⁰Diller 90.

⁸¹Michele Meyer, “Should Your Child Really be on Ritalin?” *Better Homes and Gardens*, September 1, 2003, p. 284.

⁸²Eberstadt, *supra* note 19.

and teachers see tangible results in the classroom, this makes them more likely to mention AD/HD to the parents of other children who are disruptive.⁸³

Large and unruly classes are not the only problem. Outcome-based educational systems also place enormous demands on teachers. Such systems are based on the notion that every student “can and should be brought” to perform at some minimal standard in the curriculum.⁸⁴ This notion derives, in turn, from the egalitarian view that all children are entitled to an equally effective education at the expense of the public. Once a school district adopts an outcome-based educational system, however, teachers cannot simply pass uncooperative and inattentive students on to the next grade at the end of the school year—a practice known as “social promotion.” Under outcome-based programs, teachers become directly accountable for the performance of their students in the classroom. They therefore become desperate to find ways to enable students to perform at the mandated level.⁸⁵ The AD/HD diagnosis, and the medication that often comes with it, is a powerful lure to teachers in such a setting.⁸⁶

The increasing willingness of teachers to consider and talk about AD/HD also derives from the fact that there has been greater awareness about child and adolescent mental illness in recent years. As educational professionals—both teachers and administrators—learn more about AD/HD and become more at ease with

⁸³As Ken Livingston has written, “[W]hen it is difficult or inconvenient to change the environment, we do not think twice about changing the brain of the person who has to live in it.” Livingston, *supra* note 2.

⁸⁴*Id.*

⁸⁵*Id.*

⁸⁶Livingston provides some empirical data regarding this phenomenon. He documents how, throughout the United States, the increase in the number of AD/HD referrals closely tracks the adoption of outcome-based educational systems and notes how states with these systems seem to have higher levels of Ritalin consumption than states without them. He points out that the difference is small, amounting to only approximately .3 grams of Ritalin per 100 population. He notes, however, that this difference is statistically significant. *Id.*

the lexicon of mental health, they become more willing to talk with parents about subjects that, years ago, would have been “farmed out” to other, medically-trained professionals. As one writer has suggested, teachers are increasingly seeing themselves not only as educators but as therapists as well.⁸⁷

However, these factors—larger classes, outcome-based educational systems, and greater awareness of mental illness in children—are only part of the story. Even if a teacher or school administrator is inclined to discuss AD/HD and provide information about the disorder, it is essential to understand that a teacher’s provision of information about AD/HD has little effect by itself. It is the combination with another factor—namely, the willingness and eagerness of parents to receive this information—that creates the problem. For a variety of reasons, parents are often unusually receptive when a teacher provides information about AD/HD. First, parents are hopeful that the medication that comes with the diagnosis will improve their child’s poor self-esteem and confidence.⁸⁸ For children who may be borderline-AD/HD and who exhibit many of the disorder’s symptoms, school is not an easy place to be, either academically or socially. Many of these children experience demoralization and poor self-esteem on a regular basis. For a parent, it is a horrible thing to have to observe

⁸⁷*Id.* Commentators have also suggested that teachers have been pushed by school administrators to have children labeled as afflicted with AD/HD. The reason for this, or so the theory goes, is that schools can get extra dollars in special education money for each child with AD/HD. But this is ridiculous for a number of reasons. First and foremost, it is difficult to imagine school administrators approaching teachers and asking them to label students with AD/HD for the purpose of raising money for the district. Schools are short of money, but that they would propose branding a student with a potentially stigmatizing label to raise a few extra dollars is simply absurd. Second, as Bruce Hunter, public affairs director at the American Association of School Administrators, has said, “any grant payments were too low, given the cost of providing special education, to push schools to boost the number of AD/HD kids.” Quoted in John Merlloe, “Public Schools: Pushing Drugs?” *Investor’s Business Daily*, October 16, 1997. Third, in recent years, the financial incentive to label children with AD/HD has been removed. Judith E. Heumann, former Assistant Secretary for Special Education and Rehabilitative Services at the U.S. Department of Education, said the following in this regard: “Increasing the number of children who take behavioral drugs will not increase the size of a school district’s IDEA [Individuals with Disabilities Education Act] grant. IDEA funds are distributed to states and school districts based on the size of the jurisdiction’s population of school age children and the relative number of those children who live in poverty. Funds are not distributed based on the number of children identified as disabled and in need of special education. There was a formula change that, in fact, took place in 1997 when we reauthorized the IDEA so that incentive would be removed.” Statement of Judith E. Heumann, Assistant Secretary for Special Education and Rehabilitative Services, U.S. Department of Education, Washington, D.C., in *Behavioral Drugs in Schools: Questions and Concerns*. Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Education and the Workforce, United States House of Representatives, 106th Congress, September 29, 2000 (Washington, D.C.: U.S. Government Printing Office, 2000), online at <http://commdocs.house.gov/committees/edu>.

⁸⁸Singh 20-21.

a child constantly depressed and sad. Therefore, if there exists a way to combat such problems, it is easy to see why a parent would jump at the opportunity. Ilina Singh, using a fictional child named Tom, describes the chain of events that many parents imagine:

Ritalin combats deficiencies in the brain, allowing a child, Tom, to control his impulsiveness. Now Tom can sit still in his chair at school, which allows him to take good notes and copy down his homework assignments. His teacher begins to praise his improved work, and other students begin to notice that Tom is really not as wild as he once was. Those students now approach Tom, wanting to be his friend. The combined effects of success at school, the teacher's praise, and his peers' sociability provide Tom with newfound confidence and self-esteem.⁸⁹

And it is not only the child's poor self-esteem that the parents are worried about. They are also concerned about their own demoralization. Raising a child who has persistent educational and attentional difficulties is not an easy task. Internally, parents are often exasperated with their out-of-control children and blame themselves for their child's shortcomings. Externally, they constantly face accusations, whether express or implied, that they are inadequate and uncaring.⁹⁰ Under such trying circumstances, when a teacher comes along and says that there may be a biological explanation for their child's problems, parents are almost always willing to listen such a suggestion. If brain chemistry is to blame, not only are the parents not at fault; they can also ensure that their child receives appropriate treatment with medication. This, then, is the second reason that parents are willing to listen to teachers: an AD/HD diagnosis and medication often makes parents feel better about themselves.

Third, parents are generally impressionable to the comments that a teacher makes. Students spend a great

⁹⁰*Id.* at 1-2. It is not surprising, then, that rates of parental stress are higher among parents of AD/HD children. *Id.* at 27.

deal of their time at school, and the teachers serve *in loco parentis*. Furthermore, in modern American society, it is often the case that both parents work. They are not able to spend much time with their children, and they often look to schools and teachers to fill the gap. Therefore, when a teacher makes a comment about AD/HD to a parent, very often the parent is inclined to accept the teacher's words at face value.

Fourth, and most importantly, parents are willing to accept information about the disorder because they know that an AD/HD diagnosis and medication might provide their child with an advantage over other students. We live in an increasingly competitive age, where parents strive to get their children into the "right" nursery schools and spots at the most competitive colleges are fiercely fought over. Parents look for anything that will give their child an edge over others. If science, in the form of new medications, offers a way to boost concentration and thereby improve performance, parents often ask why their kids should not have this advantage. Thomas Armstrong best summarized the appeal of medication in his book *The Myth of the A.D.D. Child*. He writes, "Many middle and upper-middle class parents see Ritalin and related drugs almost as 'cognitive steroids' that can be used to help their kids focus on their schoolwork better than the next kid."⁹¹ Given this belief, it is not surprising that psychostimulants are most often prescribed in middle- and upper-class schools, where performance demands are often strongest.^{92,93}

⁹¹Cited in Eberstadt, *supra* note 19; Thomas Armstrong, *The Myth of the A.D.D. Child* (New York: Dutton, 1995). Although parents hope to increase a student's performance through medication, it may very well have the opposite effect and prevent the student from learning. Katherine Bryson, a State Representative in the Utah House of Representatives, relates: "I taught school myself in California back in the mid 1970s. I had kids who were in my little fifth grade class who were going out and being medicated at noon and coming back in the classroom, and they were literally what I would term zombies for the rest of the afternoon. Now, that was not a situation where I could help meet their educational needs. They were in a position where they were not receptive. They could not be receptive, and it was a wonderful classroom. They were now compliant. Yes, they were compliant, but were they teachable and were they learning anything? I do not believe so." Statement of Hon. Katherine Bryson, State Representative, Utah House of Representatives, in *Protecting Children*, *supra* note 4.

⁹²This is a form of "cosmetic psychopharmacology." Cosmetic psychopharmacology is the use of psychotropic medication for non-therapeutic enhancement. The phrase was coined by Peter Kramer in his influential book, *Listening to Prozac*. Peter Kramer, *Listening to Prozac* (New York: Viking, 1993), p. 273.

⁹³It should be pointed out that the AD/HD diagnosis not only offers children a way to boost their concentration; it also gives them access to special resources at school. The benefit most commonly cited is extra time on tests and standardized examinations. The number of people granted an unlimited-time allowance for the SAT doubled between 1991 and 1996, from 17,000 to about 35,000. There have been similar increases with regard to the administration of graduate-level exams. In the 1996-1997 academic year, for example, 160 students received special accommodations when taking the Law School Admission Test (LSAT), compared with only 10 students five years earlier. Diller 163. With the benefits that can come from extra time or

With the readiness of the teachers to provide this information and the willingness of the parents to receive it, it should not be surprising that information about AD/HD is free-flowing. There is, however, a strong (and perhaps obvious) policy justification for regulating the flow of this information—namely, that those who are providing the information (the teachers) are probably not the ones best qualified to be doing so. Although teachers spend a great deal of time with children in the classroom and are frequently the first to recognize learning and/or behavioral problems, the basic and inescapable fact is that teachers are not doctors, and they are not diagnosticians.⁹⁴ They usually know little, if anything, about AD/HD, its symptoms, and forms of treatment.⁹⁵ Furthermore, they are not skilled in understanding the normal range of behaviors, despite all their training and their continual exposure to a large and heterogeneous group of students.⁹⁶ In the case of AD/HD, such an understanding is essential, since AD/HD is a disorder in which many common behaviors are included among the symptoms. Teachers, for example, often do not understand that, as one doctor points out, “there are some normal behavioral traits of stubbornness, shyness, and loudness that are annoying but that are not abnormal and do not deserve to be treated with medication.”⁹⁷ It is the diagnosis of a trained physician that should be paramount in determining whether a child is suffering from the disorder.

special accommodation on such high stakes exams, it is hardly surprising that more and more parents have been visiting their children’s doctors demanding some sort of official diagnosis. Eberstadt, *supra* note 19. As Mary Eberstadt relates, this is, in a way, “affirmative action for affluent white people.” *Id.*

⁹⁴Written Statement of the National Mental Health Association, in *Protecting Children*, *supra* note 4; testimony of E. Clarke Ross, CEO of Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD), in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11.

⁹⁵Congressman Michael Castle (R-DE) perhaps explained the problem best when he wrote, “We have enough trouble training our teachers to teach math, English, or whatever the subject matter may be.” Statement of Congressman Michael Castle, in *Protecting Children*, *supra* note 4.

⁹⁶Statement of William Carey, *supra* note 4. This should not be surprising. Even doctors with tremendous expertise in psychiatry over many years have difficulty easily distinguishing the normal from the abnormal. As Dr. William Carey has said, “I have been studying this for 35 years, and I see a great deal of overdiagnosis of normal behavior as being such things as AD/HD.” *Id.*

⁹⁷*Id.*

Despite their lack of medical training, teachers and school administrators have not been shy about providing parents with information about AD/HD. In some cases, they have even gone so far as to diagnose children with the disorder and have told parents that their children would not be allowed to attend school and continue in their classes if they did not take medication.⁹⁸ And in several of these cases, not only has the student been expelled after the parents failed to comply with the school's order; school officials also asked state child protective agencies to judge the parents unfit on charges of medical neglect. The experience of Patricia Weathers,⁹⁹ a mother in Mill Brook, New York, provides an illustration:

Near the end of the first grade, the school principal took me into her office and said that unless I agreed to put Michael [Patricia's son] on psychiatric drugs the school would transfer him to a special education center for children with behavior problems. As a parent, I felt extremely pressured by the school's staff at this point. The teacher, school psychologist, and principal were all telling me that putting my son on drugs was the right thing to do. [Weathers then followed the school's advice and put her son on Ritalin].

I didn't notice any difference at first [with the Ritalin], but eventually I began getting reports that Michael was not socializing with other kids, and that he was withdrawn. This was completely out of character for Michael who was normally very social and outgoing. It got worse. When Michael was in the third grade, my grandmother saw Michael just standing by himself at the far corner of the playground staring at his feet. I also began receiving reports that Michael had started chewing on things, pencils, erasers, and paper, even his clothing. His behavior was getting more and more bizarre.

Instead of recognizing the effects the drugs were having on my son, the school's psychologist claimed Michael now had a "social anxiety disorder and needed to see a psychiatrist." She immediately produced the name and the number of the psychiatrist I was to call. The psychiatrist talked to Michael for fifteen minutes and, again, with the aid of the school reports, diagnosed him with social anxiety disorder. She handed me a prescription for an antidepressant and told me it was a wonder drug for kids. On October 5, 1999, Michael started taking the antidepressant. Shortly afterwards, he told his teacher he was hearing a male voice in his head telling him to do bad things. [Soon after, Weathers took her son off the drugs].

⁹⁸Ilina Singh found that mothers were often told by teachers that their children had AD/HD even before the children had been formally tested. Singh 138.

⁹⁹As mentioned above, Patricia Weathers is also President of Parents for Label and Drug Free Education.

This led to a downward chain of events, which culminated in the school calling Child Protective Services on my husband and I, and charging us with medical neglect. The charge was for failing to give Michael the necessary medication and failure to follow the psychiatrist's advice of hospitalization. The only reason my son was not removed from my custody that day was that I had obtained an independent psychological evaluation in which the psychologist stated that Michael did not require hospitalization. If it were not for this, he would have been taken from our home.¹⁰⁰

Such coercive tactics by teachers and educational administrators have affected thousands of families across the country.¹⁰¹ They have even affected Neil Bush, brother of President George W. Bush, who faced pressure by a Houston school to medicate his son Pierce with Ritalin.¹⁰²

Dangerous situations such as these compelled the federal government to act, and Congress obliged with H.R. 1170, the Child Medication Safety Act of 2003. The bill passed the House of Representatives in May 2003 and was then sent to the Senate, where it languished in committee and died.¹⁰³ The particular goal of the legislation was to require states to establish policies and procedures that prohibited school teachers and administrators from forcing parents to medicate their children as a prerequisite for the child attending school.¹⁰⁴ This prohibition is stated in Section 2(a) of the bill. A more general goal was to regulate the provision of information about AD/HD. This is clear from the bill's legislative history. House Report 108-121, which accompanies H.R. 1170, cites, in its explanation of the Child Medication Safety Act and its purposes, testimony by Dr. William Carey before the Subcommittee on Education Reform. Dr. Carey stated:

¹⁰¹On August 7, 2002, *The New York Post* told Michael's story. Within a few days of publication of the article, over 65 parents came forward to describe how their school districts had used various methods of coercion and intimidation to strong-arm them into drugging their children. See Statement of Patricia Weathers in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11.

¹⁰²Written statement by Dr. Karen Effrem, in *Ritalin Use Among Youth*, *supra* note 9.

¹⁰³The bill passed the House by a vote of 425 to 1.

¹⁰⁴Several states had already taken a similar step. In Utah, for example, a bill was introduced to prohibit school teachers and administrators from recommending that a child use psychotropic drugs. See Utah H.B. 123 (2002).

In the last two decades the United States has experienced a great increase in the diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) and its treatment with stimulants. Not only child health professionals but now also a wide variety of unqualified persons, such as preschool teachers and acquaintances, are freely offering the diagnosis and confidently urging parents to accept their judgment and obtain drug treatment, such as methylphenidate (Ritalin), for the child... . This chaotic situation urgently requires intervention at several levels, including the Federal government.¹⁰⁵

Although the Child Medication Safety Act was well intentioned, it was flawed because it was overinclusive. The legislation provided major disincentives for open communication between school personnel and parents on a whole host of issues, not just on information relating to whether a child has AD/HD.¹⁰⁶ As I have emphasized in the foregoing discussion, teachers should not take on the role of doctor and effectively diagnose a student with AD/HD. Teachers, however, do serve important functions when it comes to the treatment of AD/HD—in particular, they serve as valuable conduits for information. For example, when a child is already on medication, teachers provide doctors with information on the medication’s effectiveness in the school setting.¹⁰⁷ This information, in turn, is used to determine the proper dose of medication.¹⁰⁸ The Child Medication Safety Act, however, would have impeded teachers when carrying out such a function because it would have made teachers who had legitimate health concerns about students reluctant to communicate those concerns for fear of violating the strictures of the statute.

The proposed legislation did attempt to accommodate legitimate teacher interventions. It provided a rule of construction in Section 2(b), which read as follows:

¹⁰⁶Written statement of Audrey Spolarich, Chair, Coalition for Children’s Health, in *Protecting Children*, *supra* note 4. Using the vocabulary of constitutional law, the legislation was not narrowly tailored. The means were not well suited to the ends.

¹⁰⁷Russell A. Barkley, “Foreward,” in DuPaul and Stoner x-xi.

¹⁰⁸The increasing use of medications that only need to be taken once a day—medications such as Concerta, Metadate CD, Adderall XR, Ritalin LA, and Strattera—has reduced the involvement of school teachers and staff in the administration of medications. Nevertheless, school personnel are still relied upon heavily in many instances. *Id.*

Nothing in subsection (a) shall be construed to create a Federal prohibition against teachers and other school personnel consulting or sharing classroom-based observations with parents or guardians regarding a student's academic performance or behavior in the classroom or school, or regarding the need for evaluation for special education or related services under section 612(a)(3) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(3)).¹⁰⁹

It is difficult to see, however, how these words would have any real effect in actual practice. Teachers, never certain whether their comments about a student would fall under the general prohibition provided for in Section 2(a) of the law or under the more permissive rule of construction of Section 2(b), would, in all likelihood, refrain from commenting at all about a student. The bill, therefore, would have resulted in a system where teachers would be afraid to engage the parents and express themselves openly.¹¹⁰ Ultimately, it would have made teachers too cautious to assist those children who truly need their help.¹¹¹

Thus, the Child Medication Safety Act was not well targeted to the ills it was designed to address. Perhaps this is one of the reasons that it died in the Senate. Should Congress decide to take up this issue again in future years, it will need to put in place a better mechanism—one that ensures both that parents are not coerced into putting their kids on psychotropic drugs and that teachers have an outlet should they need to communicate their concerns about a child. With the Child Medication Safety Act, Congress addressed the former concern, but not the latter. Despite the bill's shortcomings, it is valuable as a model because it shows that regulation is indeed possible when it comes to the provision of information about a disease or condition. Furthermore, the lessons learned with the Child Medication Safety Act can perhaps be applied in future legislation designed to regulate the other sources of information about AD/HD.

¹¹⁰Statement of Lance Clawson, in *Protecting Children*, *supra* note 4.

¹¹¹Written statement of Audrey Spolarich, *supra* note 106. These problems mean that the bill, even if passed, might have faced First Amendment challenges on vagueness grounds. The Supreme Court has ruled unconstitutional laws that are so vaguely written “that persons of average intelligence must guess at their meaning and application.” *See* “Free Speech,” online at the web site of the Electronic Privacy Information Center (http://www.epic.org/free_speech). Vague laws “chill” speech because people subject to such laws often keep silent out of fear that their intended conduct might be illegal. *Id.* The Child Medication Safety Act would almost certainly face challenges for “chilling” speech.

IV. Media (Internet and Direct-to-Consumer Advertising)

We now turn our attention to another major source of information about AD/HD: the media. Unlike the educational system, which focuses on instances of AD/HD in children, media sources provide relevant information about the disorder to children and adults alike. Discussions about “the media,” however, are somewhat ambiguous, as “the media” comprises a number of different components, each of which provides information about the disorder. Television, newspapers, and magazines all carry news reports and feature presentations that describe the prevalence of AD/HD in American society and the people who have suffered from the side effects of medication.¹¹² There are also countless books and articles on the subject, written by AD/HD specialists, as well as by those who suffer from the disorder and who feel that they have something to share.¹¹³ In this article, however, I shall focus on two areas of the media that have had a disproportionate impact on the dissemination of information about AD/HD: the Internet and direct-to-consumer (DTC) advertising. I will look at these areas in turn.

The Internet

¹¹²Diller says that these news reports are overly formulaic, as well as oversimplified, especially on television. He writes: The usual formula is to begin with the reporter commenting on the “new” diagnosis of [AD/HD] and the explosive growth in Ritalin use, followed by the provocative question: Are children being overdrugged in our classrooms? Two families will be presented: one with a child whose “life was saved” by Ritalin, contrasted with another whose child experienced intolerable side effects or underwent an undesirable personality change on Ritalin. Next the “experts” appear in front of impressively filled bookshelves in their offices, or striding down a hospital corridor. Each expert (usually two) gets about 15-20 seconds for a statement. Then the camera cuts back to the children—one happily playing in the schoolyard, apparently cured of his malady, the other at home, lovingly protected by his parents from the vagaries of medical science. The segment closes with the reporter solemnly intoning, “ADD and Ritalin—cure or curse? Make sure you check with your doctor.” Finally, the news anchor may ad-lib a remark to colleagues in the studio that may reflect insensitivity, misunderstanding, or worse. Diller 137.

¹¹³Texts in the second category include Benjamin Polis’s wonderful *Only a Mother Could Love Him*, which offers the youth perspective on the disease. See Benjamin Polis, *Only a Mother Could Love Him* (New York: Ballantine Books, 2004). There is also a text by Chris A. Zeigler Dendy and Alex Zeigler entitled *A Bird’s Eye View of Life With ADD and AD/HD*. See Chris A. Zeigler Dendy and Alex Zeigler, *A Bird’s Eye View of Life With ADD and AD/HD* (Cedar Bluff, Alabama: Cherish the Children, 2003). The authors spoke with 12 teenagers afflicted with AD/HD who told about their experiences and provided advice. It should be noted, however, that books written by sufferers, especially adolescent sufferers, are quite rare. This is a shame, as some doctors often are mistaken about the true nature of the disease. Polis decided to write his book after hearing an expert on “60 Minutes” in Australia explain why kids with AD/HD behave as they do. Polis said, “This guy was describing the way us kids felt. And I thought, ‘This guy doesn’t know.’ I thought he was wrong.” Laurie Tarkan, “Attention Disorder Advice, by One Who Knows,” *The New York Times*, August 26, 2003.

Use of the Internet to find information regarding illness has grown tremendously in recent years. One survey assessing the sources of information that people use to find out about conditions and treatments found that 79.2% of respondents turned to general health sites on the Internet.¹¹⁴ In the case of AD/HD, however, this willingness to use the Internet causes problems. There is so much information online about the disorder that anyone perusing the various AD/HD web sites is likely to be overwhelmed by the glut of information. Parents looking for a summer camp with a supportive environment for children with AD/HD or ones worried about their AD/HD kids behind the wheel of a car can find web sites in Japanese, Dutch, and English to address their needs and concerns. There are sites that say that nearly all people have AD/HD, and others that say that AD/HD is a fraudulent medical diagnosis and that no one has the disease. There are sites that cater to Christian AD/HD sufferers, as well as ones geared toward women, teens, families, and preschoolers. There are sites exhibiting artwork created by those afflicted with AD/HD and sites that describe Chinese herbal treatments for the disorder. There are countless reports, studies, and pamphlets to be found online. Furthermore, the Internet is a popular gathering place for individuals involved with AD/HD. There are hundreds of AOL chat groups devoted to the condition.¹¹⁵ For people navigating this mass of information, it is not at all clear where to look for the best and most up-to-date information on the disorder.

The greatest cause for concern, however, is the fact that little of the information presented seems to be completely objective. Most of the web sites seem to be geared toward one point of view or another. In general terms, most AD/HD sites on the Internet seem to fall into one of two categories. First, there are the obvious zealots and partisans. These are the web sites created by individuals or organizations that

¹¹⁴See Carol Rothkopf, "The DTC Information Process," presentation at an FDA public meeting on direct-to-consumer promotion, September 22 and 23, 2003, online at <http://www.fda.gov/cder/ddmac/P1Rothkopf/index.htm>.

¹¹⁵Diller 132-133. On June 29, 2004, I entered "ADHD" into the Internet search engine "Google." 2,130,000 websites were listed. On September 6, 2004, I did the same search, and 2,170,000 sites were listed. With over two million different web sites listed, the fact that 40,000 new sites were added over a two-month span hardly makes much of a difference.

make it clear that they harbor a particular point of view about AD/HD and about how (and whether) it should be treated. Although some of the web sites in this category strongly support the AD/HD diagnosis, most are ones that openly denounce AD/HD and the drugs used to treat the disorder. Adhdfraud.com and ritalinfraud.com are two web sites, for example, that are open in their disdain for the disorder. (Indeed, from the very names of these web sites, their position is obvious.) Such sites are plentiful, yet they do not pose all that much of a danger, because a person who is searching for objective information and comes upon one of these sites understands immediately that the creators of the site adhere to a particular position.¹¹⁶

Much more alarming are the web sites that fall into the second category, sites created by those whom I refer to as the “hidden zealots.” These are the web sites that put themselves forward as places to obtain objective information on AD/HD yet have a hidden agenda. The most obvious examples of web sites in this category are those set up and run by the pharmaceutical companies. Such sites are usually presented as places where one can find clear and unbiased information about AD/HD. The pharmaceutical companies, however, have a vested interest in making people buy their medications, so their presentation of facts about the disorder is subtly geared toward that end. For example, the address of one popular pharmaceutical company-sponsored web site is the seemingly innocuous “ADHDinfo.com.” When one goes to this site and clicks on the link to the page discussing “Responsible Treatment,” the first thing that appears on the computer screen is a discussion about the use of psychostimulant medications.¹¹⁷

Even more dangerous, though, is the web site of an organization called Children and Adults with Attention-Deficit/Hyperactivity Disorder, or CHADD. Founded in 1987, CHADD is by far the largest organization

¹¹⁶What is ironic, though, is that these organizations that disfavor the AD/HD diagnosis make it more visible by their efforts in creating web sites.

¹¹⁷As of January 16, 2005.

devoted to AD/HD. It has become the “voice” of the disorder in recent years, and it is for this reason that I devote considerable discussion to it here.¹¹⁸ CHADD puts itself forward as “the nation’s leading non-profit organization serving individuals with Attention-Deficit/Hyperactivity Disorder (AD/HD).”¹¹⁹ Although the group organizes lectures, operates chat and discussion boards, issues an electronic newsletter, and produces a bi-monthly magazine (entitled *Attention!*), the centerpiece of its efforts is its “exceedingly active” web site, www.chadd.org, where online information sheets, medical resources, policy papers, and items for sale can all be found.¹²⁰

CHADD, however, is not as objective as it makes itself out to be. It consistently portrays AD/HD as a neurobiological disorder and is biased in favor of the use of medication to treat the condition.¹²¹ Furthermore, it has a shameful history of taking money from the drug companies. This came to light in 1995 after the group launched a campaign to have the DEA deregulate the prescription of methylphenidate by reclassifying it as a Schedule III drug under the CSA. CHADD publicly cited a number of reasons for its petition:

- 1) Since the DEA is required to approve an annual production quota (APQ) for methylphenidate, there always looms the possibility of a drug shortage if the demand grows in a given year and exceeds the supply.¹²²

¹¹⁸Diller 131. CHADD is also a lobbying organization with tremendous influence and power. When the IDEA was first being considered in 1990, there was a debate about whether to include AD/HD as one of the disabilities that would qualify people for services. CHADD and ADDA (another AD/HD “self-help” organization) lobbied hard for its inclusion. Phyllis McClure, who for 24 years represented the NAACP Legal Defense and Education Fund (which opposed the inclusion of AD/HD in the IDEA), remembers the pressure exerted by the groups during the IDEA drafting process. Their lobbying of her could almost be considered harassment, she told Diller: “They followed me all the way out to the airport once. They just wouldn’t let go.” Diller 149-150. When the IDEA drafters ultimately decided to exclude AD/HD, CHADD, in coordination with other groups, generated over 4000 letters to members of Congress, key Congressional committees, and the Department of Education. These groups also used their influence to persuade senators and congressmen to exert pressure on the Department of Education to reconsider the inclusion of AD/HD in the IDEA. These efforts paid off. In September 1991, the Department of Education issued a Policy Clarification Memorandum ordering schools to include AD/HD as a covered disability under the IDEA. Diller 150; Eberstadt, *supra* note 19.

¹¹⁹See www.chadd.org (last checked February 18, 2005).

¹²⁰*Id.* When one types “ADHD” into the online search engine Google, CHADD’s web site comes up first.

¹²¹For example, one fundraising letter from 1997 urged readers “to [fight] these battles of misinformation, innuendo, ignorance and outright hostility toward CHADD and adults who have a neurobiological disorder.” Cited in Eberstadt, *supra* note 19.

2) Deregulation will aid doctors by allowing them to dispense prescriptions simply by calling the pharmacy. Under the existing CSA regime, prescriptions for psychostimulants are required to be written in triplicate, and refills cannot be dispensed via telephone. The proposed change will also aid patients, who are inconvenienced because they have to visit their doctors every time their prescriptions run out.

3) Methylphenidate's Schedule II classification stigmatizes patients. The authors of *Driven to Distraction*, a well-known AD/HD treatise, claimed that one of the most common problems in treating the disorder is that "some pharmacists, in their attempt to comply with federal regulations, make consumers [of methylphenidate] feel as though they are obtaining illicit drugs."¹²³

Although these were all valid justifications, it was soon revealed that something else was behind CHADD's efforts at deregulation. While CHADD awaited the DEA's decision, a television documentary revealed that Ciba-Geigy (now called Novartis), the pharmaceutical company that manufactures Ritalin, had contributed \$748,000 to CHADD from 1991 to 1994. Moreover, the documentary reported, CHADD officials had never disclosed the existence of this money or its source to the organization's own members or to the public.¹²⁴ This revelation gave rise to concerns about whether pharmaceutical companies were unduly influencing CHADD's agenda.¹²⁵ Deregulation would obviously be immensely valuable for these companies. Even today, however, CHADD refuses to admit that Ciba-Geigy's financial contributions were related the DEA deregulation petition.

The DEA eventually took action on the petition. It issued a scathing report that stated the following:

It has recently come to the attention of the DEA that Ciba-Geigy, the manufacturer of the methylphenidate product marketed under the brand name Ritalin, contributed \$748,000 to CHADD from 1991 to 1994. The DEA has concerns that the depth of the financial relationship with the manufacturer was not well known to the public, including CHADD members that have relied upon CHADD for guidance as it pertains to the diagnosis and treatment of their children. [Ciba-Geigy] stands to benefit from a change in scheduling of methylphenidate.¹²⁶

¹²⁴Anne Manne, "Cries unheard," *Arena Magazine*, April 1, 2003, p. 47.

¹²⁵Diller 39-40.

The DEA also noted that “of particular concern” was the fact that most of the AD/HD material prepared for public consumption by CHADD did not address the potential or actual abuse of Ritalin.¹²⁷ Instead, the drug was portrayed “as a benign, mild substance that is not associated with abuse or any serious side effects.”¹²⁸ The DEA made clear, however, that in reality “there is an abundance of scientific literature which indicates that methylphenidate shares the same abuse potential as other Schedule II stimulants.”¹²⁹

In the years since this scandal, CHADD has attempted to rehabilitate its image.¹³⁰ Yet charges of collusion with the pharmaceutical industry continue to linger and affect CHADD’s credibility. Critics not only continue to cite the deregulation petition of the mid-1990s, which is seen as a betrayal of those afflicted with AD/HD; they point to the continued appearance of impropriety by the organization. Note the following exchange between E. Clarke Ross, CHADD’s CEO, and Congressman Dan Burton, during a September 2002 hearing before Congress:

¹²⁷ “Methylphenidate: A Background Paper,” *supra* note 37.

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ CHADD’s rehabilitation efforts have proved difficult, as the organization continues to receive substantial funds from the pharmaceutical industry. As of August 2002, pharmaceutical financial support constituted 18% of CHADD’s budget. Testimony of E. Clarke Ross, *supra* note 94. CHADD officials, however, have attempted to justify the organization’s use of pharmaceutical funds. As one official has said, “The organization and the diagnosis itself is not one that is real popular among people who want to donate money. They want to donate to the heart association, *et cetera*, so getting funds is a little more difficult than, say, other nonprofit organizations that work for kids. However, when we do accept pharmaceutical money, it is accepted and a contract is signed which says in no way will they have anything to do with, any say with how the organization runs the projects. . . . And CHADD solely directs the projects of the organization.” Statement of Mary Robertson, Past President of CHADD, in *Ritalin Use Among Youth*, *supra* note 9. Even the drug companies have tried to step in to help CHADD rehabilitate its image. Novartis, for example, said that although it had provided (in the years since the scandal) unrestricted educational grants to CHADD for projects such as a public service announcement on AD/HD and the translation of some AD/HD literature into Spanish, it believed that such grants were appropriate. “Novartis believes that comprehensive care for all patient populations includes education and support as well as medication. Novartis is proud to help CHADD and other credible third-parties that provide valuable information to many people.” Cited in Frontline: “AD/HD Lawsuits,” online at <http://www.pbs.org/wgbh/pages/frontline/shows/medicating/backlash/lawsuits.html>. Novartis’s words, at first glance, make sense. It must be remembered, however, that drug company support of CHADD is different from drug company support of the American Diabetes Foundation or the American Cancer Society. The reason: psychostimulants are Schedule II—and hence potentially highly addictive—drugs regulated under the CSA. See Statement of Peter Breggin, in “Medicating Kids: The Business of AD/HD,” online at <http://www.pbs.org/wgbh/pages/frontline/shows/medicating/experts/business.html>.

Congressman Burton: I would also like to end by saying, Mr. Ross, I do—we had what was called the “Keating Five” here in Washington. We had five Senators that met with Mr. Keating on the savings and loan crisis, and I don’t believe any of those Senators really intentionally did anything wrong, but the appearance of impropriety was very great and they got a heck of a lot of bad publicity when the savings and loan debacle took place. And for you to get hundreds of thousands of dollars from Novartis, which manufactures Ritalin, and your organization does advocate that children should use that, it gives the appearance—

Mr. Ross. We do not advocate any brand drug.

Mr. Burton. Well, I—

Mr. Ross. We advocate a multimodal treatment which may include medication—

Mr. Burton. I understand.

Mr. Ross [continuing]. And the products are never discussed.

Mr. Burton. Regardless—I understand, but the appearance is that they’re feeding you to deal with this problem in that way, and I would just suggest, if there was a better way to fund your organization, even if it is only 18 percent, it would be helpful, because if you were in the U.S. Senate or the House and that happened, you would have a heck of a problem.¹³¹

Even putting aside, though, CHADD’s credibility problems and its conflicts of interest, the information actually provided on the organization’s web site shows that CHADD is far from a clearinghouse of objective information. CHADD claims on its web site (as Clarke Ross suggested in his Congressional testimony cited above) that it advocates a multimodal approach to the treatment of AD/HD, including the use of behavior management techniques, individual and family counseling, and medication when required. But a closer look at the web site makes one question whether CHADD really does support such treatment. There is a subtle, but clear, emphasis on medication use throughout the organization’s web site. For example, when I recently¹³² looked at the site’s home page, I was immediately confronted with a box at the top of the screen entitled “What’s New?” The first two items listed in the box related to the use of certain medications—Adderall XR (a psychostimulant) and antidepressants. Similarly, at the bottom of the same page, there is an offer for a “discount prescription card.”¹³³ As Lawrence Diller says, “CHADD’s leadership will dispute this [emphasis on medication], and its literature seems to advocate a multimodal model of treatment—but

¹³²On February 25, 2005.

¹³³See www.chadd.org.

close reading will reveal an emphasis on medication. . . .”¹³⁴

CHADD is the organization that, through its web site, is providing a great deal of information about AD/HD to the general public. However, CHADD’s ties to the pharmaceutical industry and its advocacy of medication are alarming. Is this the kind of organization that we want providing much of our information about a medical disorder? The answer is clearly no.¹³⁵ Therefore, it pays to ask the following question: Is there any way to control CHADD and other similar “hidden zealot” organizations and regulate the information that they release on their web sites? It is not clear that much can be done. Current First Amendment law gives individuals and organizations great freedom to post what they want on the Internet. In 1997, in *Reno v. American Civil Liberties Union*, the Supreme Court unanimously held that the Internet, a “unique and wholly new medium of worldwide human communication,” was deserving of full First Amendment protection.¹³⁶ In an opinion written by Justice Stevens, the Court explained its reasons for such a holding:

Through the use of chat rooms, any person with a phone line can become a town crier with a voice that resonates farther than it could from any soapbox. Through the use of Web pages, mail exploders and newsgroups, the same individual can become a pamphleteer. As the District Court found, “the content of the Internet is as diverse as human thought.” We agree with its conclusion that our cases provide no basis for qualifying the level of First Amendment scrutiny that should be applied to this medium.¹³⁷

The result of the Court’s holding is that in any free speech issue relating to the Internet, established rules and principles of First Amendment jurisprudence apply. If I was to post on a web site an article criticizing a famous scholar, actor, or politician, I could not be sued for libel unless there was proof of “actual malice.”¹³⁸

¹³⁴Diller 130.

¹³⁵*Id.* at 131-132. Diller relates that some parents, after attending a few CHADD meetings, have called him to ask if he knows of an organization for families who do not want to give medication to their children with AD/HD. They feel that within CHADD, there is little tolerance for those who are opposed to the use of medication. Diller 130.

¹³⁶*Reno v. American Civil Liberties Union*, 521 U.S. 844, 850 (1997); see “Free Speech,” online at the web site of the Electronic Privacy Information Center (http://www.epic.org/free_speech).

¹³⁸See *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); the web site of the First Amendment Center, online at <http://www.firstamendmentcenter.org>.

Similarly, speech that serves to educate, such as the speech of CHADD—speech that does not fall under any of the well-known “exceptions” in First Amendment law, such as obscenity or “commercial speech”—is entitled to the highest degree of First Amendment protection.¹³⁹

However, even if free speech concerns limit the ability to regulate, the United States government does not have to subsidize these groups in any way. The federal government, however, has continued to deal with CHADD, for example, despite its checkered history. In August 2002, CHADD received a grant of \$750,000 from the Centers for Disease Control and Prevention to establish and operate a National Resource Center on AD/HD.¹⁴⁰ CHADD has also benefited from a Center for Mental Health Services \$150,000 subcontract with the American Institutes for Research “to conduct community forums and increase participation within CHADD for the purposes of cultural competence and diversity promotion in order to better educate the public about AD/HD and related childhood mental disorders.”¹⁴¹ In the future, the government should refuse to award such grants and contracts. It is not clear that this would have much of a fiscal impact, given the other sources of revenue—especially pharmaceutical company money—that these “hidden zealot” organizations receive. But at least it would prevent these groups from putting the U.S. government “stamp of approval” on its materials.

Direct-to-consumer (DTC) advertising

The other major source of information about AD/HD within the media is direct-to-consumer (DTC) adver-

¹³⁹I have asserted throughout much of this paper that CHADD may in fact be something more than a mere “educator” providing information to the AD/HD masses. I have stated that CHADD may also be “selling” a particular point of view about AD/HD—that it is a biological disorder to be treated with medication. Even if this is true, it does not mean that CHADD’s speech would be considered “commercial speech” for First Amendment purposes. CHADD’s speech *is* primarily educational. The commercial overtones that taint many of the organization’s messages are incidental to the educational nature of the speech.

¹⁴⁰Testimony of E. Clarke Ross, *supra* note 94.

¹⁴¹*Id.*

tising.¹⁴² DTC advertising allows pharmaceutical manufacturers to present their products to mass audiences through television, radio, print, and the mail. The use of these different means of communication to market drug products is important, given the ultra-competitive nature of the brand-name pharmaceutical industry and the competition provided by generic substitutes.¹⁴³

Just as people have been using the Internet more and more to find information about different conditions and treatments, they are also increasingly using DTC advertisements to get their information. In 2002, 81% of people surveyed said that they had seen or heard an advertisement for a prescription drug within the previous three months.¹⁴⁴ In 2005, that number has likely grown. The effect of DTC advertising has been so great that it would not be an exaggeration to say that it has, in many ways, transformed the way people think about disease and medication. For example, as Stephen Ceccoli points out, many Americans, simply as a result of DTC advertising, can recognize prescription drugs based on simple catch phrases or color associations. They know AstraZeneca's heartburn drug, Nexium, as the "purple pill" and Pfizer's Viagra as "the little blue pill."¹⁴⁵

In recent years, spending by pharmaceutical companies on product promotion and DTC advertising has

¹⁴²Pharmaceutical manufacturers generally produce three kinds of DTC advertisements. First, "help-seeking" advertisements mention an illness or a disorder but do not mention any drug by name. Such advertisements encourage people to speak with their doctors about their condition. Second, "reminder" advertisements mention a particular drug but do not mention what the drug is used for. Finally, "product claim" advertisements (the most common kind of DTC advertisements) mention both a particular product and the condition the product is intended to treat. Ceccoli 155. Of the three different kinds of advertisements, the FDA regulates "reminder" and "product claim" advertisements. "Help-seeking" advertisements are not regulated by the FDA. Statement by Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, before the Senate Special Committee on Aging, July 22, 2003, online at <http://www.fda.gov/ola/2003/AdvertisingofPrescriptionDrugs0722.html>.

¹⁴³Ceccoli 154.

¹⁴⁴Kathryn Aikin, Division of Drug Marketing, Advertising, and Communications, U.S. Food and Drug Administration, "Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results," October 22, 2002, online at <http://www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out/>.

¹⁴⁵Ceccoli 156. Despite its tremendous impact on modern American society, DTC advertising is a relatively new phenomenon. It was only in the early 1980s that drug companies began marketing their products directly to patients. Statement by Janet Woodcock, *supra* note 142. Throughout most of the twentieth century, drug companies promoted their products exclusively to physicians. Carol Lewis, "The Impact of Direct-to-Consumer Advertising," *FDA Consumer*, U.S. Food and Drug Administration, March-April 2003, online at <http://www.fda.gov/fdac/features/2003/203.dtc.html>.

grown at a rapid rate.¹⁴⁶ According to the National Institute for Health Care Management Research and Educational Foundation (NIHCM), pharmaceutical companies spent approximately \$2.5 billion on DTC advertising in 2000—up from \$1.1 billion in 1997, \$610 million in 1996, and \$44 million in 1990.¹⁴⁷ Again, the figures for 2005 are likely much higher. To grasp just how much money is involved in these promotional efforts, consider the following: In 2000, more money (\$160.8 million) was spent on DTC advertising for a single drug—Merck’s now-discredited arthritis and acute pain drug, Vioxx—than was spent to promote Pepsi (\$125 million) or Budweiser (\$146 million).¹⁴⁸

When it comes to AD/HD in particular, DTC advertising has likewise had a tremendous impact. This can perhaps best be seen by looking at the case of Strattera, the newest AD/HD drug on the market. Eli Lilly, the manufacturer of Strattera, has hoped that the drug will help make up for the loss of revenue that resulted after the expiration of the company’s patent on Prozac several years ago.¹⁴⁹ These hopes are not unrealistic because Strattera has a number of unique competitive advantages over rival AD/HD drugs. Perhaps its main selling point is that it is the first drug specifically approved to treat adult AD/HD. This gives the company broader market reach, since it is the only market participant allowed to advertise to adults with AD/HD.¹⁵⁰ Second, Strattera is a non-stimulant, which means that it does not have many of the side effects that traditionally come with stimulants, such as addiction, weight loss, and insomnia. Strattera may play a major role in the treatment of individuals who do not respond at all to the stimulants or who do not respond

¹⁴⁶Ceccoli 155. The importance of advertising in general can be seen from the following fact: On the whole, pharmaceutical companies actually spend more money on marketing and promotion than on research and development. Families USA, a non-profit organization, looked at the SEC financial reports of nine major pharmaceutical firms. In its report, “Profiting from Pain,” the group found that all nine companies spent more on marketing, advertising, and administration (MAA) than on research and development (R&D). Furthermore, eight of the nine companies spent more than twice as much on MAA than on R&D. For the nine firms, the average percentage of revenues devoted to MAA was 27%, compared to just 11% for R&D. See Families USA, *Profiting from Pain: Where Prescription Drug Dollars Go* (Washington, D.C.: Families USA Foundation, 2002), online at <http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249>; Ceccoli 133.

¹⁴⁷Cited in Ceccoli 155; Diller 139.

¹⁴⁸Cited in Ceccoli 156.

¹⁴⁹Editorial, “As Prozac fades, Strattera soars,” *The San Francisco Chronicle*, December 29, 2003, p. A14.

¹⁵⁰Linda Liu, Frost & Sullivan, “Strattera: Redefining Success in AD/HD Therapy,” October 8, 2003, online at http://www.hospitalpharma.com/PressReleases/pressrel.asp?ROW_ID=258.

well to such drugs.¹⁵¹ Third, because Strattera is a non-stimulant, it is the first AD/HD drug that is not a Schedule II controlled substance. Therefore, Eli Lilly can market the drug more effectively with samples.¹⁵²

To promote all these benefits, Eli Lilly has launched a marketing campaign unprecedented in scope. The company has flooded the consumer market with advertisements. It has paid for thousands of television commercials on channels such as Nickelodeon and Lifetime.¹⁵³ It has placed advertisements in two-dozen publications, including Redbook, Parade, and Good Housekeeping.¹⁵⁴ People have also seen Strattera advertisements in brochures, letters, flyers, pharmacy counter displays, billboards, newspapers, on the radio, in the mail, and, of course, on the Internet. Such an aggressive approach by the company has paid off. Physicians wrote more than one million prescriptions for Strattera in its first six months on the market.¹⁵⁵ Prescriptions doubled to two million during the next three months KSKen ShaitelmanKSKen Shaitelman.¹⁵⁶ Such figures mean that Strattera has had the most successful launch of any psychiatric medication in history.¹⁵⁷

How, however, does this huge advertising blitz affect consumers and their overall access to information about AD/HD? One thing is for certain: there is clearly *more* information about AD/HD in the marketplace. And this increased volume of information serves important functions. It helps educate consumers about AD/HD. It serves to increase the detection of the disorder and alert people who may not be receiving needed treatment. As was mentioned above in connection with the discussion of the “four communities” study, there is great concern among mental health professionals that many people with AD/HD are not receiving appropriate treatment. DTC advertisements clearly serve a valuable function in ferreting out these individuals.¹⁵⁸ Increased information flow also educates consumers about the drugs available to treat the

¹⁵¹DuPaul and Stoner 194.

¹⁵²Herman Saftlas, “Lilly’s Pipeline of Plenty,” *Business Week Online*, December 9, 2002, online at http://www.businessweek.com/investor/content/dec2002/pi2002129_5751.htm.

¹⁵⁸That DTC advertisements allow people to play a more proactive role in maintaining their health is clear. In a survey, Kathryn Aikin and John Swasy asked participants: “Has an advertisement for a prescription drug ever caused you to look for

disorder.

Less obvious, however, are the ways in which the pharmaceutical companies' DTC campaigns harm consumers. First, there is the problem that DTC advertisements sweep indiscriminately. Although the message contained in the advertisements may reach untreated individuals who need help, it also reaches those individuals who are perfectly healthy yet worry about undiscovered health problems. That savvy marketing campaigns can seduce people into thinking that they are sick when they are not is a major concern.¹⁵⁹ In 2002, 18% of survey respondents said that an advertisement for a prescription drug had led them to ask a physician about a medical condition or illness that they had not talked to a doctor about before.¹⁶⁰ When it comes to AD/HD, this capacity to influence is particularly worrisome. The symptoms of the disorder are so common—fidgeting, short attention span, impulsivity, etc.—that anyone hearing them in the context of an advertisement will think that he has a medical disorder. “Are you disorganized?” says one Strattera advertisement. “Do you procrastinate, fidget, lose things?” As Sally Satel relates, this sounds like just about everyone.¹⁶¹

more information, for example, about the drug or about your health?” 51% said yes. Kathryn Aikin and John Swasy, U.S. Food and Drug Administration, “Analysis of the Effects of Direct-to-Consumer Advertising on Patient Information-Seeking Behavior,” October 22, 2002, online at <http://www.fda.gov/cder/ddmac/Presentations/aiknDIAdtc701/>. Physicians also believe that DTC advertising can positively influence their interactions with their patients. For example, most doctors seem to think that because their patients saw a DTC advertisement, they asked more thoughtful questions. Statement by Janet Woodcock, *supra* note 142.

¹⁵⁹Dr. Arthur Caplan, chairman of the Department of Ethics at the University of Pennsylvania Medical School, suggests that drug companies may be pushing “self-generated diseases” to sell medicines to individuals who do not have actual problems but who can be led to believe they might by savvy marketing campaigns. Bill Hendrick, “Attention, please,” *The Atlanta Journal-Constitution*, September 14, 2003, p. 1LS. Other practitioners and scholars also subscribe to such a view. See, e.g., David Healy, *The Creation of Psychopharmacology* (Cambridge, Massachusetts: Harvard University Press, 2002) (especially p. 372, regarding the marketing of depression).

¹⁶⁰Statement by Janet Woodcock, *supra* note 142.

¹⁶¹Sally Satel, M.D., “ADD Overdose?” *The Wall Street Journal*, July 23, 2003, online at http://aei.org/news/newsID.18076.filter.all/news_detail.asp.

Another major problem with DTC advertisements is that they make people believe that all of their problems are biologically based and that taking a pill will make all the problems disappear. The advertisements, in other words, overstate the efficacy of drugs.¹⁶² With regard to AD/HD, although there has been an increasing push in recent years to recognize the disorder as biologically based, there is still a consensus among experts that AD/HD is a disorder influenced by factors other than biology, such as learning disabilities, family dynamics, classroom size, and economic and cultural issues.¹⁶³ (Recall the NIMH guidelines on multimodal treatment, which try to take into account all these non-biological factors.) When DTC advertisements for a particular medication minimize the importance of social and environmental factors in treatment, they do a disservice to people who are using the medication, because these people are often convinced that the pill is a panacea. Therefore, these individuals do not seek out treatments targeted at the non-biological causes of the disorder.¹⁶⁴

A final concern about DTC advertisements is that they often understate the side effects of medications. In a 2002 survey, of those respondents who stated that a DTC advertisement had caused them to seek more information about a drug, 61% said that they were looking for information about side effects.¹⁶⁵ In fact, in the letters that the FDA issues to pharmaceutical companies about misleading DTC advertisements, “inadequate conveyance of risk information” is one of the most common violations cited.¹⁶⁶ As a result of such deficiencies, doctors often find that they have to provide additional information to patients and correct

¹⁶²In a survey released in January 2003, 58% of respondents agreed strongly that DTC advertisements make drugs seem better than they really are. Lewis, *supra* note 145. Also, approximately 75% of doctors said that DTC advertisements make patients think that a drug works better than it actually does. *Id.*

¹⁶³Diller 103.

¹⁶⁴Put another way, this improper focus on medication is the result of a lack of balance in advertising. Large pharmaceutical companies make billions of dollars a year in profits. They have tremendous resources and can afford to put money into expensive advertising campaigns. However, alternative therapies—such as cognitive-behavioral therapy or psychotherapy—do not have that kind of marketing muscle.

¹⁶⁵Statement by Janet Woodcock, *supra* note 142.

¹⁶⁶*Id.*

misconceptions about the medications. It is easy to see why doctors feel the need to do this. Information about a medication's side effects is crucial for a patient. It often plays a key role in whether the individual is willing to start treatment using a particular medication. If the medication, for example, causes insomnia or weight loss, as some AD/HD drugs do, a person may want to avoid the drug. Even Strattera, which is billed as a drug that avoids the heinous problems associated with stimulants, has its own set of side effects.

Despite the advantages discussed above, it is clear that DTC advertisements are harmful to consumers in a number of ways. Can anything be done, however, to limit the harmful effects of these advertisements? Regarding the understatement of risk information by the drug companies, the FDA can certainly send out letters, as it has done, warning the companies about deceptive practices. The agency certainly has the authority to do this pursuant to Section 502(n) of the Federal Food, Drug, and Cosmetic Act.¹⁶⁷ If the problem persists, governmental authorities can also bring suits against offending pharmaceutical manufacturers. In New York, for example, Attorney General Eliot Spitzer sued GlaxoSmithKline for hiding vital information from the public about the safety and efficacy of Paxil, a drug designed to combat depression, social anxiety disorder, and a variety of other illnesses.¹⁶⁸

However, as to the other problems inherent in DTC advertisements—the companies tricking people into thinking they are sick, and people believing that pills are a panacea—it does not appear that there is any easy solution. This is largely a result of First Amendment concerns.¹⁶⁹ The Supreme Court's decision in 2002 in *Thompson v. Western States Medical Center* makes clear that FDA restrictions on the flow of

¹⁶⁷21 U.S.C. 352(n). Section 502(n) of the Federal Food, Drug, and Cosmetic Act provides the FDA with authority to regulate prescription drug advertisements.

¹⁶⁸Jonathan Mahler, "The Antidepressant Dilemma," *The New York Times Magazine*, November 21, 2004.

¹⁶⁹Much of my discussion here on the First Amendment is based upon a wonderful and extremely comprehensive—albeit industry-friendly—article by George W. Evans and Arnold I. Friede, entitled "The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis," 58 Food Drug L.J. 365 (2003).

information from drug manufacturers to consumers is subject to First Amendment review.¹⁷⁰ The scope of this review depends substantially upon the form of a given DTC advertisement. However, with all of the forms of advertisement currently used by the drug companies, it appears that the companies and their advertisements will receive substantial protection from regulation. For example, there are the advertisements that do not promote a specific product in a commercial manner, but rather act to educate consumers—e.g., “help-seeking” advertisements, which simply describe particular conditions and encourage consumers to see their doctor for diagnosis and treatment.¹⁷¹ Such advertisements are entitled to the highest degree of First Amendment protection, and any attempt to regulate them triggers the highest degree of judicial scrutiny—strict scrutiny. When governmental restrictions are evaluated under this standard, courts require the government to meet a very strict burden before the restrictions are upheld.

All of the other kinds of DTC advertisements currently in use by the drug companies largely fall into the category of “commercial speech.” Communication is categorized as commercial speech to the extent that it aims to promote directly the purchase of a specific product. For example, the DTC advertisements in magazines and on television that push Strattera and that encourage consumers to ask their doctors if Strattera might be right for them are considered instances of commercial speech.¹⁷² With such speech, the FDA has “somewhat greater latitude in controlling manufacturer efforts to promote product sales,” but it still faces difficult hurdles in its attempts to regulate.¹⁷³

In *Central Hudson Gas & Electric Corporation v. Public Service Commission*, the Supreme Court formulated a four-pronged test to evaluate governmental restrictions on commercial speech.¹⁷⁴ When it comes to the

¹⁷⁰ *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002).

¹⁷¹ Evans and Friede, 58 Food Drug L.J. at 425.

¹⁷² *Id.*

¹⁷³ *Id.* at 367.

¹⁷⁴ *Central Hudson Gas & Electric Corporation v. Public Service Commission*, 447 U.S. 557, 566 (1980).

regulation of DTC advertisements, each of these prongs poses distinct problems. The first, and threshold, prong of the test looks at whether the speech is “false or misleading” in any way. Commercial speech that creates a false basis for commercial transactions or is misleading in some overt way can be restricted and/or banned. Courts, however, are reluctant to conclude that commercial speech is false or misleading unless the government provides evidence to substantiate its claim of deception.¹⁷⁵ This requirement poses tremendous problems for the FDA. The FDA has established no standards or procedures for determining whether a given communication is false or misleading. For example, as George W. Evans and Arnold I. Friede point out, the FDA has not decided whether communications can be interpreted on their face or whether they require a “harder look.”¹⁷⁶

Even if the FDA did have procedures in place, it is not clear that the agency could make the requisite showing that certain DTC advertisements are false or misleading. People most commonly consider DTC advertisements to be false or misleading because the advertisements provide an incomplete picture of the drugs at issue, omitting important information about side effects, efficacy, etc. However, such omissions, even if proven conclusively, do not necessarily cause the DTC advertisement to be false or misleading. The Supreme Court has stated, in several instances, that the fact that truthful commercial speech may not convey “exhaustive information” about a product does not automatically make it false or misleading.¹⁷⁷ Evans and Friede write, “Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.”¹⁷⁸

Given how difficult it is to show that a given DTC advertisement is false or misleading, proponents of

¹⁷⁵Evans and Friede, 58 Food Drug L.J. at 384.

¹⁷⁶*Id.* at 385.

¹⁷⁷*Id.* at 411. See *Central Hudson*, 447 U.S. at 562. See also *Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977) (holding that “incomplete” attorney advertising was not inherently misleading).

¹⁷⁸Evans and Friede, 58 Food Drug L.J. at 384.

governmental regulation usually have to turn to the other three prongs of the *Central Hudson* test. These prongs mandate that commercial speech can be regulated only if it advances a “substantial” government interest, where the proposed regulation “directly advances” the government interest asserted, and where the regulation is “not more extensive than is necessary to serve that interest.”¹⁷⁹ Like the part of the test looking to see whether the speech is “false or misleading,” however, each of these prongs poses problems for those pushing for governmental regulation of DTC advertisements. Perhaps the most troublesome prong is the one requiring the government to articulate its “substantial interest” in regulation. Those advocating stricter FDA regulation of DTC advertisements have pointed to a number of potential governmental interests that would justify the regulation of DTC advertisements. Over the years, however, courts have found few of these interests to be “substantial,” much less legitimate. For example, perhaps the most common governmental interest asserted to justify regulation of DTC advertisements is that regulation would prevent consumers from using drugs unnecessarily or inappropriately (e.g., when, although healthy, consumers are convinced after viewing a savvy DTC advertisement that they have an illness). Such a justification, however, is based on an unsupported assumption on how people act. The Supreme Court in *Western States* said that the use of such unsupported assumptions constituted disfavored governmental paternalism.¹⁸⁰ In that case, the Court noted that if the government had argued that a restriction on compounded drug advertising was necessary as a result of a fear that such advertising would “put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway,” such a fear would fail to justify the restriction.¹⁸¹ The Court stated that “a fear that people would make bad decisions if given truthful information” cannot validate a restriction on “the dissemination of truthful commercial information.”¹⁸²

¹⁷⁹ *Central Hudson*, 447 U.S. at 566.

¹⁸⁰ See *Western States*, 122 S. Ct. at 1507-1508; Evans and Friede, 58 Food Drug L.J. at 425-426.

¹⁸¹ See *Western States*, 122 S. Ct. at 1507.

¹⁸² *Id.*; see also Evans and Friede, 58 Food Drug L.J. at 379.

Similarly, the FDA might assert that regulation of DTC advertisements would serve the economic and fiscal interest of the government—by, for example, “operating so as to reduce Medicare costs through regulations that effectively suppress DTC advertisements and thereby suppress demand for advertised drugs.”¹⁸³ But such a justification is also problematic, because the idea of keeping people ignorant of potentially appropriate medical treatments in order to advance the government’s economic and fiscal goals is morally questionable, and therefore may not be seen as legitimate. Furthermore, as Evans and Friede point out, it is not clear that a government’s desire to limit costs is a cognizable interest under the *Central Hudson* test.¹⁸⁴

Even assuming that the FDA can articulate a “substantial” interest in restricting DTC advertisements, it is still questionable whether the governmental restrictions would “directly advance” the substantial interest asserted or whether they would be “not more extensive than is necessary to serve that interest.”¹⁸⁵ With regard to the question of “direct advancement,” the issue, in other words, is whether the restrictions on speech “will in fact alleviate the asserted harm to a material degree.”¹⁸⁶ In the case of DTC advertisements, it will be difficult for the FDA to satisfy this requirement. As suggested above, there are many sources of information in the marketplace for pharmaceuticals—and especially so when AD/HD is involved. Many speakers, other than the drug manufacturers, communicate information. Take CHADD, for example. Even if the FDA did regulate drug manufacturer speech and DTC advertisements, consumers nonetheless would still be exposed to messages from these other speakers—messages that cause a similar harm. Therefore, restrictions on DTC advertisements would not in fact alleviate the asserted harm to any material degree.¹⁸⁷

The final prong of the *Central Hudson* test—looking to whether the government’s restriction on speech is

¹⁸³Evans and Friede, 58 Food Drug L.J. at 425.

¹⁸⁴See *id.* at 437, note 388.

¹⁸⁵*Central Hudson*, 447 U.S. at 566.

¹⁸⁶*Edenfield v. Fane*, 507 U.S. 761, 770-771 (1993).

¹⁸⁷Evans and Friede, 58 Food Drug L.J. at 386, 427.

“narrowly tailored” so that the restriction is not more extensive than is necessary to serve the “substantial interest” asserted by the government—is likewise difficult for the government to meet. Courts assess whether a regulation is “narrowly tailored” by looking to the “fit” between the means used by the government (the restriction) and the ends sought (the elimination of the harm). Although the fit between the means and ends do not have to be perfect, some precision is necessary. Courts will assess that precision by looking to the availability of regulatory alternatives.¹⁸⁸ Therefore, if the FDA seeks to have any restriction on DTC advertising upheld, it has to show that there are no other, less-burdensome alternatives to the restriction that would allow it to achieve its objectives. In the case of DTC advertising, however, a less-speech-restrictive alternative is available: the use of disclaimers and disclosures to limit any harm stemming from problematic DTC advertisements.¹⁸⁹ The FDA was unable to satisfy this prong in *Western States*, with the Court noting that the legislative record contained “no hint that the Government even considered . . . alternatives” to its outright restriction on speech.¹⁹⁰

Given all these obstacles in the First Amendment arena, it is not clear that much can be done to alleviate many of the harms that stem from DTC advertisements. If the FDA seeks to have greater success in the future in regulating DTC advertising, it needs to take several steps. First, the agency needs to develop clear standards and procedures for determining when exactly a DTC advertisement is to be considered “false or misleading.” Second, the agency has to be creative in defining new and substantial interests that it can assert to justify regulating drug manufacturer speech. This is no easy task, given that a wide variety of rationales for regulation have already been asserted before the courts, and nearly all of them have been struck down. Third, the FDA must also cope with the reality that the harms that it seeks to combat derive from many different sources. A restriction solely on DTC advertisements would not do all that much to eliminate

¹⁸⁸ *Id.* at 386-387.

¹⁸⁹ *Evans and Friede*, 58 Food Drug L.J. at 387, 428.

¹⁹⁰ *Western States*, 122 S. Ct. at 1507; *Id.* at 387.

these harms. This fact alone might discourage the FDA from engaging in further efforts to regulate DTC advertising. The “inevitability” of certain messages reaching consumers may convince agency officials that the FDA’s resources are better spent elsewhere. Finally, the FDA should consider whether there are other, less-speech-restrictive alternatives that would allow it to achieve its objectives. Expanded use of disclaimers and more extensive disclosures by drug manufacturers may provide at least a limited remedy for some of the problems caused by suggestive and savvy DTC advertisements.

V. Doctors

In the previous section, I described Eli Lilly’s efforts to market Strattera through a massive DTC advertising campaign. This story, however, was incomplete. In addition to its focus on consumers, the company also targeted another key constituency—doctors.¹⁹¹ To promote the benefits of Strattera to physicians, the company added, in the first six months of 2003, 4000 sales representatives to its already gargantuan U.S. sales force of 5300. Between January and June 2003, these representatives made 542,000 presentations to physicians.¹⁹² The company also made a concerted effort¹⁹³ to seek out psychiatrists in particular—a strategy that differentiated the company from its competitors.¹⁹³

These efforts were worthwhile, because Eli Lilly understood that even with all its advertising directed at consumers, it is the doctors who ultimately diagnose patients and prescribe medication. Patients may be convinced, after viewing a DTC advertisement, that they have AD/HD, but if they want a prescription for

¹⁹¹According to an October 2002 GAO report, “Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001.” United States General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177 (Washington, D.C.: GAO, 2002), p. 3.

¹⁹²Editorial, “As Prozac fades, Strattera soars,” *supra* note 149. This number dwarfs the 270,000 pitches made by Concerta representatives and the 163,000 by Adderall representatives during the same time period. *See id.*

¹⁹³Liu, *supra* note 150.

Strattera, Ritalin, Adderall, or any of the other AD/HD drugs, they are going to have to visit their doctors. This power of prescription—combined with the fact that doctors, more than any other party, are the ones expected to be knowledgeable about AD/HD and the range of treatments for the disorder—means that doctors are some of the most important providers of information about AD/HD.¹⁹⁴

A number of factors, however, have conspired to prevent doctors from carrying out their responsibility to patients to provide complete and accurate information about AD/HD. Perhaps the single most important factor has been the rise of managed care in the United States. For a number of reasons, managed care systems cause tremendous problems for doctors.¹⁹⁵ First and foremost, they limit the amount of time that physicians can spend with patients. This is a cause for great concern when AD/HD is involved. As suggested above, because of the interpretive nature of the AD/HD diagnosis and the high degree of comorbidity that is present, diagnosing the disorder is immensely difficult. Doctors need to conduct a comprehensive and thorough assessment to be certain that a given individual is afflicted with AD/HD. This includes direct observation, as well as review of a person's developmental, social, academic, and medical history. It should also include input from parents, spouses, friends, teachers, and supervisors.¹⁹⁶ Such an assessment, needless to say, takes time.¹⁹⁷ Pressed to get things done quickly by managed care "utilization reviewers," doctors are often not able to perform the full work-up that they need to do.

¹⁹⁴In other words, the physician is the "learned intermediary."

¹⁹⁵For a more detailed discussion on how managed care systems affect the practice of psychiatry, see Alan A. Stone, "Psychiatry and the Law," in *Harvard Guide to Psychiatry* (Cambridge, Massachusetts: Belknap Press, 1999), pp. 798-823; Alan A. Stone, "Paradigms, Pre-Emptions, and Stages: Understanding the Transformation of American Psychiatry by Managed Care," *International Journal of Law and Psychiatry*, Vol. 18, No. 4, pp. 353-387 (1995); Alan A. Stone, "Managed Care, Liability, and ERISA," *Forensic Psychiatry*, Vol. 22, No. 1, pp. 17-29 (March 1999).

¹⁹⁶Statement by Michael M. Faenza, President and CEO, National Mental Health Association, in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11.

¹⁹⁷Dr. David Fassler, chairman of the Council on Children, Adolescents, and Their Families of the American Psychiatric Association, says, "You can't do [diagnosis] in one or two sessions. A comprehensive evaluation means getting a detailed history of the child's early development, medical conditions and problems in school and with friends, as well as meeting with the child and the family." Susan Gilbert, "Gains in Diagnosing Hyperactivity," *The New York Times*, June 20, 2000, p. 8. According to Diller, a sound and ethical evaluation of someone for AD/HD takes approximately four hours. Diller 212.

This time limitation on doctors has tremendous implications for the provision of AD/HD information. If doctors are not doing the comprehensive and thorough evaluation that is required to diagnose AD/HD, they do not know whether a patient truly has the disorder or not. And if they do not know the true condition of the patient, how could they possibly be in a position to provide accurate information to the patient about effective methods of treatment? Lacking a full and complete picture of the patient's condition, many doctors have resorted to using AD/HD medication as a diagnostic tool and engage in the practice of prescribing medication presumptively. However, for reasons discussed below, this practice is one that is deeply flawed.

A second problem caused by managed care systems is that they do not readily pay for access to specialists. Most managed care plans allow patients to see specialists only after a referral by a primary care doctor. The primary care doctor, however, is given a limited and preset amount of money (called a capitation fee) to handle all of a patient's problems. If the primary care doctor refers a patient to a specialist, he will lose a portion of that capitation fee and suffer direct economic loss. Therefore, there is a built-in disincentive for primary care doctors to make specialist referrals. If the primary care doctor does actually provide a referral, that is not the end of the story, however. There are additional restrictions that patients and medical practitioners have to contend with. The specialist is usually allowed to provide to the patient only one full visit of about 50 minutes and two 20-minute follow-up appointments to monitor the results of medication.¹⁹⁸ The result of all this is that the people best qualified to provide information about AD/HD—certain psychiatrists with specialized AD/HD training, as well as behavioral-developmental pediatricians—are not doing so.¹⁹⁹

¹⁹⁸Diller 169.

¹⁹⁹This is not only a problem relating to lack of access. It is also a problem of shortage. There is a major national shortage of child and adolescent psychiatrists. There are only about 7400 child and adolescent psychiatrists in America; the number of children and adolescents believed to suffer from mental illnesses, however, is between 15 and 20 million. Even in areas where there are many of these physicians, the average wait to see one is approximately six weeks. Mahler, *supra* note 168; Statement of Lance Clawson, in *Protecting Children*, *supra* note 4. The American Academy of Child and Adolescent Psychiatry (AACAP) has recommended Congressional action to remedy this problem, including passage of the Child Healthcare Crisis Relief Act,

Not only are the people best qualified to provide information not doing so; the lack of access to AD/HD specialists means that primary care doctors, who often do not have the necessary training and knowledge to deal with AD/HD, *are* the ones providing information about the disorder. In a survey conducted at New York University, only 34% of 400 primary care doctors said that they felt “very” or “extremely” knowledgeable in treating AD/HD.²⁰⁰ Yet in the vast majority of cases, it is these doctors who are providing information about the disorder to patients. Such results are disturbing, to say the least. These doctors simply have not undergone the training required to conduct extensive AD/HD evaluations. In patient interviews, they do not know what to ask or what to look for. And in the treatment of the disorder, they are often similarly clueless. For example, there are at least fifteen different medications used to treat AD/HD. There is Dexedrine, Adderall, Concerta, Ritalin, and Strattera, to name a few. How are primary care doctors to choose among these drugs? They cannot—they simply do not have the training or the necessary clinical experience to differentiate these drugs.²⁰¹ Specialists at least are more familiar with these medications because of their specialized training and because they presumably prescribe these medications on a more regular basis and therefore have a better opportunity to observe their clinical effects.

As a result of this lack of specialized knowledge and unfamiliarity with treatment modalities, many of the doctors who diagnose and treat AD/HD make assumptions that are completely incorrect. For instance, it is a common practice among doctors to engage in “off-label” prescribing—i.e., the prescribing of a medication “in a different dose, for a longer duration of time, for a different age group, or for a different medical

H.R. 1359, bipartisan legislation sponsored by Representatives Patrick Kennedy (D-RI) and Ileana Ros-Lehtinen (R-FL), which would have encouraged individuals to enter children’s mental health professions through the creation of education incentives. The bill lapsed, however, at the conclusion of the 108th Congress. *Id.*

²⁰⁰Cited in Donna Halvorsen, “Growing up restless,” *Star Tribune* (Minneapolis, MN), September 16, 2003, p. 1E.

²⁰¹One might posit that the primary care doctor would choose a drug after examining its side effects. But this assumes too much—most doctors do not know anything about side effects. According to the FDA, less than one percent of doctors actually know the side effects of the drugs that they are prescribing. Cited in Mary Ann Block, D.O., in *Attention-Deficit/Hyperactivity Disorder*, *supra* note 11. (This brings to mind an apt quote by Voltaire: “Doctors pour drugs of which they know little, / To cure diseases of which they know less, / Into human beings of whom they know nothing. Cited in Ceccoli 1.) There is no way that doctors can talk knowledgeably to a patient about side effects if they themselves do not know about them.

indication than recommended in the prescribing information.”²⁰² When primary care doctors engage in off-label prescribing in treating AD/HD, they often do so on the mistaken assumption that AD/HD medications affect adults and children similarly. Therefore, they just adjust the dosage according to the age of the patient. But these physicians fail to grasp one basic fact—adults and children often metabolize drugs in different ways. The liver, where many mechanisms of drug metabolism occur, may be relatively much larger in a child than in an adult. As one writer puts it, “compare a 60-pound child with a three-pound liver to a 200-pound adult with a four-pound one.”²⁰³ Furthermore, the amount of time that a drug remains in the blood can differ tremendously in the two populations.²⁰⁴ Therefore, drugs that work just fine in adults may not be best for children, and vice versa.²⁰⁵

Similarly, as stated above, many doctors also use AD/HD medications as diagnostic tools, saying to their patients, “Let’s try the drug and see if it works.” In other words, if the drug seems to improve attention, the patient is assumed to have AD/HD. But this reasoning is flawed, because most AD/HD drugs work

²⁰²E. Clarke Ross, “When It Comes to Diagnosing and Treating AD/HD, ‘Evidence-Based’ Methods Best,” *Orlando Sentinel Tribune*, September 7, 2003, p. G4. Doctors are supposed to tell patients when they are prescribing a drug for off-label purposes, but many do not do so. As Lawrence Diller relates, there are a number of reasons for this—“absent-mindedness, haste, or concern that the information will unnecessarily worry the patient and make compliance less likely.” Diller 268.

²⁰³Karen Patterson, “A Dearth of Data,” *The Dallas Morning News*, April 13, 2003, p. 1H.

²⁰⁴*Id.* There is yet another difference that primary care doctors often fail to recognize: Children’s brains are still developing, and there is great concern about the effect of psychotropic drugs on brain functioning. This is not something that the doctors have to worry about with adults.

²⁰⁵Historically, there has not been much pharmaceutical research examining the effects of drugs in children. There are a number of reasons for this: First, finding people willing to volunteer for the work and commit to it for a period of many years is no simple task. In any extended research study, the attrition rate is high, but this is especially true when the subjects are children. Children tend to become easily bored and lose interest in the project. Furthermore, they eventually leave for college, thereby precluding further follow-up. Jeffrey Kluger, “Medicating Young Minds,” *Time Magazine*, November 3, 2003, p. 48. (Even though thousands of studies have been undertaken on Ritalin and AD/HD, very few have followed into adulthood children who took the drug. Diller 42.) Approximately 40% of children drop out of long-term research studies before the work is done. Kluger, “Medicating Young Minds.” Second, most parents are justifiably concerned about the side effects of untested drugs. Third, many studies require the use of brain scans, and such scans involve at least a little exposure to radiation—a fact most parents are reluctant to embrace, particularly if their children are not suffering from any disorder and are simply being used as a “control” to establish the look of a healthy brain. (Getting good scans from children with AD/HD presents an additional problem, as holding still is not something they do well.) Kluger, “Medicating Young Minds.” Congress, however, has attempted to address this lack of pediatric research by enacting the FDA Modernization Act of 1997. The FDA now provides an additional six months of exclusive marketing rights to any company examining a drug’s effects on a minimum of 100 children for more than six months. Kluger, “Medicating Young Minds.” As a result of this incentive, pediatric research has grown over the last seven years.

for everyone, regardless of the presence of AD/HD. Psychostimulants such as methylphenidate allow nearly everybody to concentrate on things that they find boring.²⁰⁶ Judith Rapaport of the NIMH, in studies conducted during the mid-1970s and early 1980s, showed convincingly that psychostimulants improve the ability of most people to concentrate on tasks requiring good attention, regardless of whether they have AD/HD.²⁰⁷ Attentional improvement after psychostimulant treatment therefore is not at all diagnostic of AD/HD.²⁰⁸ But doctors who have no expertise with psychostimulants are not likely to know this.

A third and final problem with the managed care system is that it has increased pressure on doctors to prescribe medication rather than spend time talking with patients or their families. Managed care companies pay physicians more for “cutting” or “zapping” or prescribing medication than for talking with patients (something known as “cognitive time”).²⁰⁹ But in the diagnosis and treatment of AD/HD, “cognitive time” is essential. It is not only when the doctor is evaluating the patient; it is also when a dialogue takes place between patient and doctor. The patient can ask questions about AD/HD during this time and follow up about treatment. It is also the time that the patient can alert the doctor about prior treatments and about individual attitudes relating to the use of medication in general.

Although the managed care system is certainly the cause of many problems affecting doctors’ ability to provide information about AD/HD, there are other sources of blame. A second key factor affecting AD/HD information provision is the influence of the pharmaceutical companies on physicians. At the beginning of Part V, I discussed Eli Lilly’s attempts to target doctors in the company’s promotion of Strattera. This,

²⁰⁶ See Statement of Lawrence Diller, in *Ritalin Use Among Youth*, *supra* note 9.

²⁰⁷ Livingston, *supra* note 2.

²⁰⁸ “Methylphenidate: A Background Paper,” *supra* note 37.

²⁰⁹ Diller 168. Also, note that by prescribing medication rather than engaging in “cognitive time,” physicians can see more patients than they would otherwise. Therefore, the economic incentives under managed care favor the use of medication. Peter N. Spotts, “Chemical Kids,” *The Christian Science Monitor*, March 6, 2003, p. 14.

however, is part of a larger effort. Pharmaceutical companies understand how important doctors are to their plans to sell their products; therefore, they are not content to merely expand the size of their sales forces or make more product presentations. Their promotion efforts take a variety of other forms as well: sponsorship of academic research and educational programs, informal interactions between pharmaceutical company representatives and doctors, and outright bribery. These additional efforts, however, have a major effect on the quality and quantity of the information that patients receive. Since this is true not only with AD/HD, but with other illnesses as well, much of my discussion in the following section will focus on the problem as it exists in medicine as a whole.

To understand how the information provided to patients is tainted by doctors' associations with the drug companies, it is first necessary to look at some of the different ways that these companies seek to win the "hearts and minds" of doctors. First, the drug companies influence doctors by sponsoring their academic research. Virtually all AD/HD researchers take money from the pharmaceutical industry to conduct studies and run their laboratories. The concern is that this money is influencing the outcome of the research and distorting the evidence base of health care.²¹⁰ One study examining this issue looked at a series of 332 randomized trials, the results of which were published between January 1999 and June 2001 in eight surgical journals and five medical journals. The authors found a clear association between industry funding and pro-industry findings.²¹¹ There is also evidence to suggest that researchers do not publish negative findings.²¹²

All this has led Arnold Relman, a Harvard professor and former editor of the *New England Journal of Medicine*, to say, "The academic institutions of this country are allowing themselves to be the paid agents

²¹⁰Ray Moynihan, "Who pays for the pizza? Redefining the relationships between doctors and drug companies" (Part 1: Entanglement), *British Medical Journal* 326: 1189-1192 (May 31, 2003), online at <http://bmj.bmjournals.com/cgi/content/full/326/7400/1189>.

²¹¹See Mohit Bhandari, Jason W. Busse, Dianne Jackowski, Victor M. Montori, Holger Schünemann, Sheila Sprague, Derek Mears, Emil H. Schemitsch, Dianne Heels-Ansdell, and P.J. Devereaux, "Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials," *Canadian Medical Association Journal*, Vol. 170, No. 4, February 17, 2004, online at <http://www.cmaaj.ca/cgi/content/abstract/170/4/477>.

²¹²Statement of Lawrence Diller, in "Medicating Kids," *supra* note 130.

of the pharmaceutical industry.”²¹³

Second, pharmaceutical companies play a major role in the education of doctors. To renew their licenses, doctors are usually required to participate in continuing medical education (CME) classes. These classes, however, are largely subsidized by the drug companies.²¹⁴ Most CME classes are taught by experts who are selected and paid by the companies producing the drugs being discussed, and the experts’ lectures, more often than not, emphasize the medical benefits of those drugs. Although some of this information does serve to educate doctors, most of it is simply marketing disguised as education.²¹⁵ The drug companies also influence medical education through more informal means. Pharmaceutical representatives “detail” the doctors—i.e., they teach them about their company’s products. The representatives—a major presence all over, but especially at teaching hospitals—work hard to persuade attending physicians and residents to prescribe the drugs produced by their companies. The result of all of this—the CME classes and the informal “detailing”—is that most doctors nowadays learn which drugs to use, and how to use them, from individuals working for the pharmaceutical industry.²¹⁶

Third, there is outright bribery. Pharmaceutical companies provide countless free “goodies” to doctors. Often these are small tokens. They include, for example, free pens, flashlights, promotional notepads, and company-branded stethoscopes. Medical students, interns, and residents in particular rely a great deal on these gifts. The companies, however, also provide much more expensive treats. These include direct gifts of travel or accommodation; tickets to sponsored dinners and social or recreational events; stock or equity

²¹³Quoted in Moynihan, “Entanglement,” *supra* note 210.

²¹⁴Arnold S. Relman, “Your Doctor’s Drug Problem,” *The New York Times*, November 18, 2003, p. 25. As one writer has put it, the result of this is that if a doctor today is too principled to participate in pharmaceutical-sponsored education, that doctor does not receive much education at all, since so much of it is now financed by the drug industry. See Abigail Zuger, “When Your Doctor Goes to the Beach, You May Get Burned,” *The New York Times*, February 24, 2004, online at <http://www.nytimes.com>.

²¹⁵Relman, *supra* note 214.

²¹⁶*Id.*

holdings in the companies themselves; funding for medical schools, academic chairs, or lecture halls; paid speaking engagements, ranging from \$250 to \$20,000 a year; paid consultancies, at salaries usually less than \$10,000 but sometimes providing up to \$120,000 a year; and paid positions on advisory boards.²¹⁷ AD/HD expert Lawrence Diller writes that he has been offered \$100 if he would listen to someone talk about AD/HD for 15 minutes on the telephone and then fill out a five-minute questionnaire.²¹⁸

Many of the ways in which the pharmaceutical companies seek to purchase the allegiance of doctors are extremely creative—so much so that a few of the techniques have their own nicknames. The “dine and dash” goes as follows: A doctor orders takeout Chinese food, and when he goes to the restaurant to pick up his order, a pharmaceutical company representative is there, ready to talk with him about the company’s newest drug. Then, when the food is ready, the representative pays the bill. (This tactic is especially popular near teaching hospitals, where drug company representatives are certain to encounter hungry residents on their breaks.) The “gas and go” is another way that pharmaceutical representatives seek to influence doctors. The representative approaches the doctor at the gasoline pump as he is filling up his car with gas after work. While the tank is being filled, the doctor is a captive audience, and the drug company representative can ply his company’s wares. When the car is all ready to go, the representative thanks the doctor for his time and then pays the cashier.²¹⁹

Why is this pharmaceutical company activism a problem? The physician-patient relationship is a fiduciary one, and implicit in this is an obligation for the physician to avoid conflicts of interest. Doctors should be concerned about what is best for their patients, not what kind of benefit they themselves will receive from the drug companies. Gifts from the pharmaceutical industry create tremendous conflicts of interest, and these conflicts in turn affect the information that doctors provide to their patients about AD/HD and

²¹⁷Moynihan, “Entanglement,” *supra* note 210.

²¹⁸Diller, “Medicating Kids,” *supra* note 212.

²¹⁹Katherine S. Mangan, “Strong Medicine for Doctors,” *The Chronicle of Higher Education*, January 9, 2004, p. 28.

other disorders and illnesses. To see that this is so, all one has to do is look at doctors' prescription habits. Doctors often prescribe the drugs produced by the companies providing the free gifts and benefits, even when these drugs are more expensive or have no benefit over cheaper alternatives.²²⁰ In an often-cited 1992 study published in the journal *Chest*, researchers secretly tracked doctors' use of two drugs before and after all-expense-paid educational trips to tropical resorts. They found that prescriptions for the two drugs more than tripled after the trips, an effect that lasted for more than a year, while the use of equivalent drugs stayed the same.²²¹

Sometimes, when a doctor favors a more expensive drug or a newer drug and there is no medical basis for doing so, it is the result of a conscious thought process by the doctor. The doctor might purposely prescribe the drug to thank the drug company for its free dinner or for supporting a particular research proposal. More often, though, it seems that when a doctor favors a drug company's products, he is doing so unconsciously. Almost all doctors, when surveyed, say that their clinical judgment and prescribing habits are unaffected by the activities of drug companies.²²² But this belief is completely erroneous, as the following anecdote, provided by Abigail Zuger of *The New York Times*, illustrates:

²²⁰Dan Shapiro, "Drug Companies Get Too Close for Med School's Comfort," *The New York Times*, January 20, 2004, p. D5. This is to say nothing of the fact that the free benefits provided to doctors will also make the doctor more likely to choose a medication over a non-drug treatment. Also, note that by prompting doctors to overprescribe expensive drugs, the free gifts and benefits are increasing the cost of prescription medicines. Mangan, *supra* note 219.

²²¹Cited in Zuger, *supra* note 214. See J.P. Orlowski and L. Wateska, "The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. There's No Such Thing as a Free Lunch." *Chest* 1992, 102: 270-273.

²²²See Zuger, *supra* note 214. Surveys also reveal, though, that doctors are less confident about the ability of other physicians to resist the free gifts and benefits of the pharmaceutical industry. Relman, *supra* note 214. Abigail Zuger writes, "A doctor I know maintains a fairly typical relationship with the pharmaceutical industry. He deplores its influence on medical practice and worries that his colleagues' prescribing habits are increasingly swayed by omnipresent drug advertisements and sales agents pumping new products. Regarding his own independence and integrity, though, my friend has no doubts. He feels that, as a man of science, he is trained to recognize an advertisement when he sees one, and to file it away in that corner of his brain reserved for potentially biased information." Zuger, *supra* note 214.

A new AIDS drug was introduced into the marketplace a while ago, with some interesting features that set it apart from older drugs. For one thing, it was a new class of drug whose potency was not altogether certain; for another, it was a long-acting drug that could be taken once a day—a wonderful and liberating detail for patients otherwise tethered to a twice- or thrice-daily schedule. The drug was released into the marketplace with a minimum of published information on its success in patients—not an unusual occurrence in these days of rapid drug approvals. The pharmaceutical company’s representatives outdid themselves, introducing their new product with lunches, dinners and far-flung focus groups. My friend [who Zuger says was convinced that he was not affected by the pharmaceutical company’s advertisements], a little skeptical of the drug, took full advantage of these opportunities to learn all about it. After many conversations with the drug representatives, a half-dozen nice meals and a few trips to warm, sandy beaches, he had plenty of information. Time passed. More studies were done. The new drug seemed to perform somewhat less effectively than had been hoped. Advisory bodies began to warn that in some situations, the new drug should not be used at all: it was so ineffective it could get patients into trouble. My friend, nothing if not conscientious, went through his list of patients to identify those with H.I.V. infection who were on the new drug, so that he could contact them and change their pills. The next time I ran into him he was a little subdued, newly conscious of the power of subliminal advertising. “It turns out I had an awful lot of people on that silly drug,” he said. “I honestly can’t imagine how that happened.”²²³

Given all these problems and the seeming inability of doctors to provide unbiased and objective information about illness and treatment, is there anything that can be done to remedy the situation? With regard to the issues posed by managed care, a solution for many of the problems will come only with a complete overhaul of the health care system in the United States. If or when such an overhaul does take place, it should ideally provide for a system that balances “the increasing market pressures for efficiency” with the need for doctors to spend ample time to correctly diagnose and treat patients.²²⁴ Also needed are better reimbursement schemes for primary care physicians so that they do not face any disincentive when referring patients to specialists. Specialists are often the ones who possess the necessary knowledge and training to help patients suffering from a particular disorder or illness. This is especially the case with AD/HD.

Concerns about the influence of the pharmaceutical companies on physicians have already led to a number of

²²⁴ See Statement of Lance Clawson, in *Protecting Children*, *supra* note 4.

attempts at reform. The American Medical Association, for example, has issued new guidelines restricting the giving of gifts to doctors. In 2002, the pharmaceutical industry's trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA), also enacted voluntary guidelines designed to discourage the most egregious instances of corporate bribery, such as the lavish meals and the expense-paid trips to sunny resorts that have no educational purpose.²²⁵ ²²⁶ Furthermore, a number of academic medical centers have implemented changes in their programs. They have developed policies that restrict access to medical students and residents. The University of Michigan, the University of Iowa, and Columbia University, among others, have limited pharmaceutical industry sponsorship of educational activities, imposed restrictions on the contact of drug representatives with trainees, and banned gifts.²²⁷ Finally, the American Medical Student Association has been conducting a nationwide campaign called PharmFree that aims to bring an end to the free gifts, the lavish lunches, the sponsored CME classes, and the paid consultancies. Students are encouraged to sign a special PharmFree pledge that commits them to seek out unbiased health care information and to take a revised Hippocratic oath, which reads as follows: "I will make medical decisions . . . free from the influence of advertising or promotion. I will not accept money, gifts, or hospitality that will create a conflict of interest in my education, practice, teaching, or research."²²⁸

Unfortunately, many of these attempts at reform, and others, have failed to address the issue sufficiently. According to Mildred Cho, a biomedical ethicist at Stanford University and someone with an interest in doctors' conflicts of interest, the new guidelines have "generally done little more than endorse the myriad

²²⁵Mangan, *supra* note 219. Meals and gifts in excess of \$100 are discouraged, as are gifts that do not have an educational use. Therefore, as one writer points out, an \$80 medical dictionary or stethoscope would be considered reasonable under the guidelines. Also, tactics as the "dine and dash" and the "gas and go" are now officially condemned under the guidelines. *Id.*

²²⁶That these guidelines were adopted voluntarily is perhaps not so much a response to concerns from academics and practitioners as a desire to make a pre-emptive move, before Congress can act on the problem.

²²⁷Shapiro, *supra* note 220.

²²⁸Ray Moynihan, "Who pays for the pizza? Redefining the relationships between doctors and drug companies" (Part 2: Disentanglement), *British Medical Journal* 326: 1193-1196 (May 31, 2003), online at <http://bmj.bmjournals.com/cgi/content/full/326/7400/1193>.

forms of the existing interactions.”²²⁹ Author and reporter Ray Moynihan agrees with Cho. He writes, “Under the industry’s new voluntary code covering relationships with health professionals, if a company flies 300 doctors to a golf resort, reimburses their costs, pays them to attend, and educates them about the company’s latest drug, in order to train them to become members of the company’s stable of paid speakers, the entire activity would be in compliance.”²³⁰ Unfortunately, the medical establishment—and in particular, the medical educational establishment—tolerates all this. It does not want to do anything to jeopardize the support of the pharmaceutical industry.²³¹ It also does not seem to care at all about how these policies affect patients and the provision of information.

Reform, however, is achievable. Any viable and sustainable effort at change requires that the relationship between physicians and industry be redefined. *All* hospitals and academic institutions should put in place guidelines that ensure that doctors are practicing on the basis of evidence rather than promotion.²³² Such guidelines should include, for example, restrictions on the interaction between pharmaceutical company representatives and doctors; prohibitions on individuals or organizations with conflicts of interest teaching CME classes; restrictions on physicians’ acceptance of “goodies”; and prohibitions on researchers accepting drug company sponsorship.²³³ Furthermore, pharmaceutical industry groups need to regulate themselves more stringently—perhaps by adopting *mandatory* guidelines. Should they fail to do this, Congress will be compelled to act. Only if steps such as these are taken can we ensure that conflicts of interest in medicine disappear and that doctors are providing information on the basis of what is best for the patient, not themselves.

VI. Conclusion

²²⁹Moynihan, “Entanglement,” *supra* note 210.

²³⁰*Id.*

²³¹Relman, *supra* note 214.

²³²Mangan, *supra* note 219.

²³³Moynihan, “Disentanglement,” *supra* note 228.

In this article, I have discussed three of the most important sources of information about AD/HD—the schools, the media, and doctors. Part III, relating to the schools, describes an area in which substantive regulation has been attempted. Congress, in deliberating on the merits of the Child Medication Safety Act of 2003, stated in clear and explicit terms its belief that information about AD/HD emanating from the schools should be regulated. This makes sense: Allowing teachers and other education professionals to provide information about a disorder when they are not qualified to do so should not be permitted. Nor should teachers and administrators be allowed to condition attendance at a school upon the use of certain medications. Despite the fact that the Child Medication Safety Act failed to pass Congress, the mere drafting of the Act shows the legislature’s understanding that regulation of the flow of information about illness and medication may be necessary to ensure the safety and welfare of individuals.

Part IV, relating to the media, describes an area where regulation is certainly needed, but, as a result of constitutional and statutory limitations, such regulation is not likely to be forthcoming. The two most prolific media sources of information about AD/HD—the Internet and DTC advertising—each present certain problems. The Internet is an area where free speech and First Amendment concerns are paramount. This makes effective governmental regulation nearly impossible. DTC advertising, in contrast, is an area that is regulated by the FDA. With its current authority, however, the FDA cannot do much to control the savvy marketing campaigns in which the pharmaceutical companies trick people into thinking they are sick and/or make people believe that pills will solve all their problems. This is largely because of First Amendment concerns that limit the government’s ability to regulate commercial speech.

Finally, Part V, relating to doctors and their role in the provision of AD/HD information, describes an area where little substantive regulation has been attempted, despite its urgency. However, unlike with the

media, where there are various limitations on regulation, the regulation of doctors is a task that is easily achievable. Although many of the problems stemming from the rise of managed care will be fixed only with a complete overhaul of the health care system in the United States, much can be done to limit the influence that pharmaceutical companies have on physicians. Although major restrictions on doctor-pharmaceutical company interaction are extreme and will likely face resistance from many quarters, such restrictions must be implemented. The nation's health is at stake.

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