REGULATING THE ADMINISTRATION OF MOOD-ALTERING DRUGS TO JUVENILES: ARE WE LEGALLY DRUGGING OUR CHILDREN?

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Our youth now love luxury. They have bad manners, contempt for authority; they show disrespect for their elders and love chatter in place of exercise; they no longer rise when elders enter the room; they contradict their parents, chatter before company; gobble up their food and tyrannize their teachers.[2]

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[2] Socrates, 5th Century BC.

I. Introduction

Columbine killer Eric Harris massacred his fellow students and snickered while he did it.[3] Fifteen-year-old Kip Kinkel killed both of his parents, slept next to their dead bodies and went on to kill two students and wound twenty-five others at school the next morning.[4] Thirteen-year-old Chris Fetters killed her favorite Aunt.[5]

Are these just wicked and unruly juveniles, or is there a common denominator correlating these and other similar adolescent violent acts? Interestingly, all three of these youths were taking some form of Prozac, an anti-depressant belonging to the class of drugs known as selective serotonin reuptake inhibitors (SSRIs).[6] Although these drugs and their long-term effects are not fully understood, they are nonetheless being prescribed to millions of children.[7] In fact, one million six hundred thousand and sixty four (1,664,000) antidepressant prescriptions for children were dispensed in 1998 alone.[8] Currently about six million children in the United States are on some type of psychotropic medication.[9]

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3 *See* DeForrest Smith, *Don't Ignore Role of Drugs in Incidents of Violence,* THE IDAHO STATESMAN, Dec. 20, 1999, at 10b *available at* LEXIS News Library.

4 *See id.*

5 *See id.* Chris Fetters was put on Prozac during court-ordered time spent in a psychiatric home for troubled youth. Dan Eggen, Life Without Parole, THE DES MOINES REGISTER, Jan. 5, 1997 at 1, *available at* LEXIS News Library. Both Chris and her mother contend it was Prozac which caused her to kill her great-aunt in a fit of rage induced by a rape at the hands of Fetters' ex-boyfriend. *See id.*

6 *See id.* Eric Harris was taking Luvox, and both Chris Fetters and Kip Kinkel were on Prozac. *See id.*

7 *Are Psychiatric Drugs Safe for Children,* THE WASHINGTON POST, May 4, 1999. Researchers are concerned about possible manic behavior in a small percentage of children taking psychotropic drugs. *See id.* In addition, many physicians prescribing such drugs have little training in the field. *See id.* A University of North Carolina study found that seventy-two percent of six hundred family doctors and pediatricians prescribed mood-altering drugs to children although only eight percent admitted to having received training or education in evaluating children in need of these types of drugs. *See id.* The same eight percent also admitted to having no training in managing the effect(s) of such drugs on children. *See id.*

8 *See id.*

9 *See* Jim Jaroff, *Drugging of Youths to Blame,* THE ARIZONA REPUBLIC, July 10, 1999 at B9, *available at* LEXIS News Library.

Persons on SSRI therapy may endure dissociative reactions, making them insensitive to the consequences of their behavior.[10] For example, in one out of twenty five children, the anti-depressant Luvox[11] causes mania, a type of psychosis depicted by feelings of exaggerated exhilaration as well as delusions of grandeur.[12] Eric Harris was taking Luvox when he shot and killed at Columbine; he laughed while he performed that nefarious act.[13]

The key to deciphering the phenomena associated with youth violence may lie with trusted medical profession's newly found "happy pills." In the past, children were disciplined and chastised for their actions. Now parents who regard their children as too animated, belligerent, or just as overall "problem" children may rush to their psychiatrists, who will likely dole out some sort of behavior pill. Is it a coincidence that Columbine-type violent acts were less prominent when mass drugging of our children was absent?

This paper will explore the interrelationship between violent juvenile behavior and juveniles taking a multiplicity of psychotropic drugs. Part I of the paper will discuss the history of children being treated with mood-altering drugs. Ritalin, one of the original drugs administered to children in the quest to control or repress behavior,[14] will be discussed, as will Federal Drug Administration (FDA) action on

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10 *See* Smith, *supra* note 3.

11 Luvox was approved by the FDA in 1997 for use in children for treatment of obsessive-compulsive disorder. Obsessive-compulsive disorder should not be confused or used interchangeably with depression. *See* Arianna Huffington, *After Littleton: Antidepressants in the Bloodstream,* THE WASHINGTON POST, May 6, 1999, *available at* http://www.arianna@ariannaonline.com/columns/index.html.

12 *See id.* Mania is defined as "a form of psychosis characterized by exalted feelings, delusions of grandeur. . . and overproduction of ideas." *Id.*

13 *See* Smith, *supra* note 3.

14 *See* Keith Hoeller, Ph.D., *Psychiatric Drugs Harm Children,* SEATTLE POST INTELLIGENCER, May 1997.

"Prior to the 1960's, most children were unlikely to ever see a child therapist of any kind. The mentally retarded were few and likely to be institutionalized. The children of the rich might be sent by their parents for psychoanalysis. The 1960s saw a sea change in the nation's handling of children. Mental health workers, who previously had trouble obtaining children for research, now gained access to children through our schools via the Head Start program, which required physical and mental evaluations. In 1961 the FDA approved Ritalin, a stimulant drug, for use with children and the "*learning disabilities*" movement was born, soon resulting in millions of children being administered powerful and addictive mind-altering drugs" *emphasis added.*

See id.

the newer anti-depressants.[15] Part II will address the issue of how adequately children are diagnosed with diseases that warrant administration of such psychotropic drugs.[16] This section also explores the possible relationship between violent acts and juveniles partaking of legitimate drugs. Part III provides an overview of the FDA approval process for psychiatric drugs and the extent to which children are considered in the pre-approval process.[17] Part IV discusses the parental push to use drugs as a short cut to traditional therapy methods.[18] Finally, Part V concludes that other tests should be conducted prior to administering mood-altering drugs to children that may induce them to commit violent acts which are out of character with their pre-drugged state.[19] Ultimately, medical practi-tioners must bear the burden of appropriately and adequately testing children and juveniles prior to dispensing drugs that may alter their sensitive nervous system. Pharmaceutical companies and regulatory agencies must ensure that proper short- and long-term studies have been performed which scrutinize the effects of these types of drugs on children of tender years.

II. The Ritalin/Prozac Controversey

A. *Ritalin—Before and After*

Attention Deficit Hyperactivity Disorder (ADHD) is a condition which manifests itself among children aged six to twelve who exhibit symptoms of "inappropriate lack of attention and impulsivity."[20] Ritalin, a controlled substance,[21] has been used in the United States for the past thirty years to treat ADHD type hyperactivity.[22] The issue of

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15 *See infra*, Part I.

16 *See infra*, Part II.

17 *See infra*, Part III. The FDA estimates it takes about eight and a half years to study a new drug before the agency can approve it for release to the public. *See* Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies*, FDA Consumer Special Report, Jan. 1995, *available at* http://www.fda.gov/fdac/special/newdrug/begin.html

18 *See infra*, Part IV.

19 *See infra*, Part V.

20 *See* Richard Welke, *Litigation Involving Ritalin and the Hyperactive Child*, DET. C. L. REV. 125, 127 (1990).

21 A controlled substance is any of a number of drugs or other chemical substances regulated under the Controlled Substances Act, 21 U.S.C. §321(g)(1). *See* COMPACT AMERICAN MEDICAL DICTIONARY 104 (1998).

22 *See id.* Ritalin is classified by the Drug Enforcement Agency (DEA) as a Schedule II

Ritalin's classification as a controlled substance has been a source of concern to the public at large.[23] In fact, simply prescribing Ritalin to children and adolescents is itself controversial.[24] The controversy also focuses on the use of other mood-altering drugs such as Prozac. *See id.*

Currently, more than three million children and adolescents in the U.S. are prescribed Ritalin.[25] Public consciousness regarding the use of Ritalin has skyrocketed due to the colossal increase in the number of prescriptions dispensed since 1990.[26] There is a split among opinions as to the rationale for such an increase in the number of children ingesting or being prescribed the drug. Advocates for the drug explain that the increase is merely due to an increasing awareness or understanding of the symptomatology of ADHD.[27] Opponents of the drug, however, insist that the drug is abused due to the over-diagnosis of ADHD.[28] The reason proffered for this continuous over-diagnosis is the lack of tangible laboratory or psychological tests to adequately test for the disorder.[29]

B. *Prozac—A Child's Panacea or Witches' Brew?*

Prozac was introduced to the United States on December 29, 1987.[30] Unbeknownst to the American people, when Eli Lilly (hereinafter, "Lilly"), Prozac's manufacturer, conducted tests on the drug in 1985, the drug proved to be only as effective as a placebo.[31] It was an FDA statistician who intimated that the outcome of the tests be surveyed differently (or manipulated) in order to justify results that

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controlled substance (C-II), similar to cocaine, morphine and other narcotics. *See id.* It should be noted, however, that Ritalin is not considered a narcotic. *See id* at 128. Specifically, Ritalin is used to control or minimize what is believed to be the disabling effects of ADHD. *See id.*

23 *See id* at 128.

24 *See id. See also* Peter Guerra, *A Tale of Two Drugs: Prescribing Ritalin and Prozac to Children,* COUNSELING TODAY, Feb. 1998, *available at* <http://www.counseling.org>.

25 *See* WELKE, *supra* note 20 at 127.

26 *See id.* The number of prescriptions for Ritalin has more than tripled since 1990. *See id.*

27 *See id.*

28 *See id.*

29 *See id.* Opponents insist many children are unnecessarily drugged because diagnosis of ADHD is based only on behavioral observation. *See id.*

30 *Prozac Truth, How Was Prozac Ever Approved?,* http://www.Prozactruth.com/fdalilly. htm. (last visited Jan. 28, 2000).

31 *See id.*

appeared more advantageous for the drug.[32] In 1986, Dr. Richard Kapit, a medical doctor from the FDA stated that Prozac "may exacerbate certain depressive symptoms and signs. Certain clinical risks of mild to moderate severity did appear to be associated with the use of Prozac. . ."[33] In the same year, the FDA safety review discovered that Lilly had not reported data regarding psychotic episodes that transpired during Prozac experimentation and trials.[34] Yet, despite the negative findings associated with Prozac, the FDA approved the drug for use in 1987.

Two months prior to approval, 27 deaths had occurred in the controlled clinical trials; 15 of these deaths were by suicide and another four were gun-related.[35] Since the debut of Prozac into American society many more deaths and adverse reactions have been reported.[36] Despite these alarming statistics, Prozac is still on the market, and is still administered to children.

At present, Lilly is engrossed in preparing of a new version of Prozac.[37] But as the company looks to introduce its new rendition, a volume of evidence exposing the antidepressant's shortcomings has surfaced.[38] Lilly's internal documents, some of which date back to the mid-1980's, demonstrate that the company has known for years that Prozac could cause a suicidal reaction in a small, but significant number of persons.[39] Additionally, three years prior to the FDA approval of Prozac, Germany's FDA counterpart, the BGA, had such serious concerns regarding the drug's safety that it declined to market the

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32 *See id.*

33 *Id.* Dr. Kapit suggested that Prozac be labeled accordingly so that physicians would be placed on notice of the possible exacerbation of the "vegetative manifestations of depressive illness." *Id.* He also recommended post-marketing studies that would target and appraise the seriousness of these conceivable risks. *See id.*

34 *See id.* Notwithstanding the lack of candor by the manufacturer, the FDA did not censure or reproach Lilly for what would appear to be a significant omission. *See id.*

35 *See id.* Fifteen deaths were from suicides, six occurred from overdose, four from gunshot and two by drowning. All deaths were directly correlated to ingestion of Prozac. *See id.*

36 *See id.*

37 Leah R. Garnett, *Prozac Revisited: As Drug Gets Remade Concerns about Suicides Surface,* THE BOSTON GLOBE, May 7, 2000. The fourteen year old patent is soon to expire, therefore Lilly is seeking approval for a "new" form of the drug. *See id.*

38 *See id.*

39 *See id.* Lilly researchers may have been pressured by top company officials to manipulate records from physicians who reported adverse reactions of patients on the drug. *See id.* For example, wording of "suicide attempts" was changed to "overdose." *See id.*

drug.[40] The decision was based on studies by Lilly itself which indicated that patients who previously showed no suicidal tendencies had a fivefold higher rate of both suicides and suicide attempts after taking the drug.[41] Lilly's own figures and data demonstrate that one in 100 previously nonsuicidal patients who ingested the drug in early clinical trials acquired a turbulent form of anxiety and agitation, causing them to attempt or actually commit suicide during the clinical trials.[42]

Notwithstanding the above, Eli Lilly and Co. continues to promote its drug and is also seeking FDA endorsement for a "once-a week" capsule.[43] Furthermore, and most significant for this paper, is Lilly's plan to win approval to market Prozac in formulations made especially for children.[44] Currently doctors are able to legally prescribe FDA-approved drugs for non-approved uses, such as prescribing a drug approved for adult use to children.[45] Formal FDA approval for the drug would allow manufacturers to actually market and target the drug specifically for kids.[46]

The prospect of winning FDA approval for yet another SSRI for use in children comes in the wake of much controversy over the adverse reactions which these drugs may have in young adults and pediatrics. As stated previously, the outbreak of youth violence has been a wake-up call for the American populace, who are now questioning the relationship of these psychotropic drugs and the rash of violent acts.[47] Despite fierce criticism from the Mental Health Community, a Colorado Board of Education took a bold step when it voted six to one in favor of a proposal that would discourage teachers from recommending the use of prescription drugs for students.[48] This type of

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40 *See id.*

41 *See id.* This was a threefold higher rate than those subjects who only took placebos. *See id.* This data appears to be pivotal and certainly significant enough to warrant further in depth studies that would either refute or confirm the findings.

42 *See id.*

43 *See id.* The new capsule would simply offer convenience. *See id.* Lilly is not purporting new medial benefits for the once a week version. *See id.*

44 *See id.*

45 *FDA Weighs Approval of Prozac for Children*, May 2, 1997, *available at* TH Online, News/World.

46 *See id.*

47 *See* JAROFF, *supra* note 9.

48 *Mental Health Experts Assail Colorado School Board Decision*, THE WASHINGTON POST, November 26, 1999at A14. "There are documented incidences of highly negative consequences in which psychiatric prescription drugs have been utilized for what are essentially problems of discipline which may be related to lack of academic success, the

local action should be applauded and implemented on a national basis until science is better equipped at providing acceptable answers regarding the Ritalin/Prozac controversy.

President Clinton hosted a White House conference on youth violence about three weeks after the Columbine High School shootings.[49] Although the President discussed issues associated with youth violence, such as gun control and violence in the entertainment industry, the discussion was devoid of any mention of the influence of prescription psychotropic drugs such as Ritalin, Luvox and Prozac.[50] Given the following highly publicized shootings, both the executive and the legislative branch should address the issue of a possible link regarding youth violence and legalized pill-pushing.

For example, on April 16, 1999, Shawn Cooper, a fifteen-year-old sophomore who was taking Ritalin fired two shotgun rounds scarcely missing students and school staff.[51] On April 20, 1999, Eric Harris, an eighteen-year-old senior at the infamous Columbine High School, killed a dozen students and a teacher with his friend, Dylan Kliebold. Both then committed suicide. Prior to the shooting, Harris had been taking Luvox,[52] an SSRI approved in 1997 by the FDA for children up to the age of seventeen for treatment of obsessive-compulsive disorder commonly known as OCD.[53] On May 20, 1999, T.J. Solomon, a 15-year-old from Georgia was currently being treated with Ritalin for depression. He shot and wounded six classmates.[54] On May 21, 1999, Kip Kinkel, a 15-year-old from Springfield, Oregon murdered his parents and continued to his school where he killed two students and

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resolution reads." *Id.*

49 Kelly Patricia O'Meara, *Doping Kids,* INSIGHT ON THE NEWS, June 28, 1999 at 10.

50 *See id.* The President proclaimed the conference as a strategy session to seek "the best ideas from people who can really make a difference: parents and young people, teachers and religious leaders, law enforcement, gun manufacturers, representatives of the entertainment industry and those of us here in government." *Id.*

51 *See id.* Ritalin is the most commonly prescribed stimulant for bipolar disorder. *See id.* This article has already established the difficulty of assessing with exactness the type, if any, psychiatric disorder suffered by young adolescents.

52 *See Marines Had Rejected Littleton Killer,* THE HOUS. CHRON., April 29, 1999, at 1, *available at* LEXIS, News Library. The package insert for Luvox carries a warning about suicide: "The possibility of suicide attempt is inherent in patients with depressive symptoms, whether these occur in primary depression or in association with another primary disorder such as obsessive-compulsive disorder. Close supervision of high risk patients should accompany initial drug therapy." *Id.*

53 *See* O'Meara, *supra* note 48.

54 *See id.*

wounded 25. Kinkel was on both Ritalin and Prozac.[55]

No evidence has been presented demonstrating that all or even some of the children who committed these deplorable acts watched similar television shows or listened to the same variety of music. Additionally, no causal connection to the use of illegal drugs, alcohol abuse or presence of an abusive environment has been established. What is certain is that all of the above adolescents were taking some form of a psychotropic drug to treat a diagnosed mental illness.[56] Were these youths in reality suffering from mental illness, or were they victims of a nation that has been led down a path where painful emotions are classified as mental illnesses that can only be treated with pharmaceuticals?[57]

Pediatric neurologist Dr. Fred Baughman does not believe that ADHD exists.[58] He postulates that the diagnosis of ADHD has turned into a contrived epidemic, and that the six million children presently being treated for ADHD are actually normal.[59]

Given the controversy over whether or not there is ample evidence that mental illnesses such as ADHD exist and the concern that long-term use of psychotropic drugs in children may result in brain damage,[60] the use of these drugs should be strictly curtailed until more scientific evidence and pediatric clinical trials prove both their efficacy and safety.[61]It should be noted that although this article deals with suicidal tendencies experienced by children due to a possible reaction to

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55 *See id.* Again, Prozac has not been approved by the FDA for pediatric use. *See id.*

56 *See id.* These psychotropic drugs have ben known to cause serious adverse effects when administered to children. *See id.* In fact, Ritalin has been known to mimic pharmacological actions similar to that of cocaine. *See id.*

57 *See id.* Bruce Wiseman, president of the Citizens Commission on Human Rights states: "If you think the Colombian drug cartel is the biggest drug dealer in the world, think again. It's your neighborhood psychiatrist. . .putting our kids on the highest level of addictive drugs." *Id.*

58 *See* O'MEARA, *supra* note 48. Interestingly, ADHD is at the top of the list of mental illnesses among children. *See id.*

59 *See id.*

60 *See id.* Dr. Peter Breggin, a psychiatrist and Director of the International Center for the Study of Psychiatry and Psychology as well as the author of "Talking Back to Prozac" has expressed concern with "the great deal of scientific evidence that stimulants cause brain damage with long-term use, yet there is no evidence that these mental illnesses, such as ADHD, exist." *Id.*

61 *See* May L. Harris, *Problems with Prozac: A Defective Product Responsible for Criminal Behavior?*, 10 J. CONTEMP. LEGAL ISSUES 359 (1999) (an excellent review of the history and present state of the Prozac controversy, including the use of the "Prozac defense").

a mood-altering drug, the same causal connection is being questioned in adults. For example, William Forsyth, Sr. stabbed his wife 15 times and then killed himself. Forsyth was on Prozac at the time. In interviews with family, friends, and medical professionals who had seen Forsyth prior to the incident, none noticed any hint of suicidal thoughts. Further, one survey found that 3.5% of depressed outpatients treated with Prozac became suicidal only after treatment with the drug. None had previous suicidal tendencies.

III. The Diagnosis—A Rush to Judgment?

The number of school-age children presently consuming mood- or mind-altering medication leads to the question of how these children are diagnosed to be in such dire need of these desensitizing drugs. The diagnosis of ADHD is illustrative of the lack of objective medical tests to authenticate what is termed a "mental disorder."[62] The diagnosing physician must rely on criteria designated as "soft signs"[63] to fashion a diagnosis of ADHD. These "soft signs" are not dispositive of a particular disorder; thus, a child "needing" Ritalin is generally identified without the support of discernible biochemical or physiological evidence.[64] Diagnostic criteria involving "soft signs" are difficult to ascertain because not all patients will exhibit each sign and similarly diagnosed patients may exhibit varying symptoms.[65] Given these shortcomings, practitioners acknowledge that diagnosing ADHD or other psychiatric disturbances with the use of "soft signs" is flawed and weak.[66]

The American Psychiatric Association (APA) publishes the Diagnostic and Statistical Manual of Mental Disorders (DSM), a manual which lists methods used by medical professionals to "organize the exceedingly complex area regarding disorders of the human

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62 *See* WELKE, *supra* note 20 at 130. Mental disorders, unlike medical disorders, are inherently more difficult to diagnose, given the lack of "hard signs" which would be visible by objective medical tests and would conclusively indicate the presence or absence of the disorder at issue. *See id.*

63 *See id.* An example of a "soft sign" is a patient complaining of a feverish sensation or just not feeling up to par. *See id.* A "hard sign" on the other hand would be a test result indicating a certain bacterial infection. *See id.*

64 *See id* at 130.

65 *See id.*

66 *See id* at 132.

mind."[67] The following, in part, is the diagnosis criteria as listed in the DSM III-R for ADHD:

DIAGNOSTIC CRITERIA FOR 314.01. ATTENTION-DEFICIT HYPERACTIVITY DISORDER. NOTE: Consider a criterion met only if the behavior is considerably more frequent than that of most people of the same mental age. A disturbance of at least six months during which at least eight of the following are present:

(1) often fidgets with hands or feet or squirms in seat (in adolescents, may be limited to subjective feelings of restlessness)

(2) has difficulty remaining seated when required to do so

(3) is easily distracted by extraneous stimuli

(4) has difficulty awaiting turn in games or group situations

(5) often blurts out answers to questions before they have been completed

(6) has difficulty following through on instructions from others (not due to oppositional behavior or failure of comprehension), e.g., fails to finish chores.

(7) has difficulty sustaining attention in tasks or play activities

(8) often shifts from one uncompleted activity to another

(9) has difficulty playing quietly

(10) often talks excessively

(11) often interrupts or intrudes on others, e.g., butts into other children's games

(12) often does not seem to listen to what is being said to him or her

(13) often loses things necessary for tasks or activities at home or at school (e.g. toys, pencils, books, assignments)

(14) often engages in physically dangerous activities without considering possible consequences (not for the purpose of thrill-seeking), e.g. runs into street without looking.[68]

A cursory glance at the above list may cause the ordinary person to question whether their "slightly naughty" child really has ADHD and should be on Ritalin (rather than in their room with television privileges revoked). How many young children sit still, never talk back, never interrupt, etc.? Ritalin opponents are skeptical of the use of the above

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67 *See* WELKE, *supra* note 20 at 132.

68 *See id* at 135-36. The most recent description of the diagnostic criteria for ADHD are found in the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV) 83-85 (4th ed. 1994).

characteristics, which they believe provide little guidance in diagnosing ADHD, and are thus poor bases for treating children with a drug known to have a series of adverse reactions.[69]

Conversely, advocates for Ritalin use in children and adolescents refer opponents to studies showing that children with ADHD have discrete dissimilarities in brain functioning when compared with children not diagnosed with ADHD.[70] Notwithstanding these studies, the advocates do concede that there are still no definitive conclusions on the appropriate intervention in children thought to suffer from ADHD.[71]

IV. FDA Approval of Mood-Altering Drugs for Juviniles

A. *New Drug Application Process—Overview*

Since 1938 the FDA has enjoyed the role of regulator for any new drugs wishing to penetrate the US market.[72] Drug manufacturers must apply for FDA approval in order to market a new drug.[73] The process begins by requiring the filing of a New Drug Application (NDA) through which interested sponsors propose their new drug to the FDA for sale and distribution in the U.S.[74] The NDA must include the following: the results of and any other information pertinent to clinical tests, the components of the drug and full composition, results of animal studies conducted, drug reaction in the human body, and a description of how the drug is manufactured, processed and packaged, including all quality control measures.[75]

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69 *See id* at 136-38. *See also infra* note 100 for the adverse reactions of the drug Ritalin.

70 *See id* at 137.

71 *See id.* The National Institute of Mental Health in Bethesda, Maryland found high levels of the neurotransmitter dopamine, the chemical associated with the hyperactivity associated in children with ADHD. *See id.* Additionally, the study also indicated that Ritalin decreased the dopamine concentrations. *See id.* Still, the Institute acknowledges this data is not dispositive that Ritalin is the only treatment of choice. *See id. See also* Victor W. Henderson, *Stimulant Drug Treatment of the Attention Deficit Disorder,* 65 S. CAL. L. REV. 397 (Nov. 1991).

72 *See* Drug Applications, Center for Drug Evaluation and Research, *available at*: http://www.fda.gov/ cder/regulatory/applications/NDA.htm (last visited June 30, 2000).

73 *See* 21 C.F.R. §314 (1998).

74 *See supra* note 72. *See also* http://www.fda.gov/cder/regulatory/applications/ NDA.htm for a complete summary of the New Drug Application Process.

75 *See* Dixie Farley, *Benefit vs. Risk: How FDA Approves New Drugs,* FDA Consumer

The results of the animal and human clinical trials are gathered during the Investigational New Drug (IND) Application Process and become part of the NDA.[76] There are three types of INDs; this discussion need only deal with one type: the "Investigator IND."[77] An Investigator IND is submitted by a doctor who undertakes the immediate supervision of the administration and dispensing of the drug under review.[78] This type of IND may be submitted by physicians who wish to study a drug currently unapproved or a drug already approved for a different use than that sought by the physicians.[79]

It is mandatory that the IND contain data in three progressive areas.[80] First the IND application must include data pertaining to pre-clinical animal pharmacology and Toxicology Studies.[81] This information should encompass any previous use in humans, including any foreign data that is available.[82] Second, the IND must also contain adequate background on the manufacturing process, including but not limited to the composition, stability, and controls utilized while manufacturing the drug.[83] Finally, detailed clinical protocols and investigator information outlining any possible and unnecessary risk to subjects must be provided.[84]

Special Report Jan. 1995, *available at* http://www.fda.gov.fdac/special/newdrug/benefits.html (last visited June 30, 2000).

76 *See* 21 C.F.R. §312 (1998).

77 The other two types are: (1) Emergency Use IND, which authorizes the FDA to use certain experimental drugs in emergency situations which do not permit submission of an IND and (2) Treatment IND, which is used for experimental drugs which show promise in clinical testing for life-threatening situations. *See Investigational New Drug Process Application Process, available at* http://www.fda.gov/cber/ ind/ind.htm (visited July 30, 2000); 21 C.F.R. §312 (1998). This type of IND is submitted during the final stages of clinical trials and while the FDA review is occurring. *See id.*

78 *See* 21 C.F.R. §312 (1998).

79 *See id.*

80 *See id.*

81 *See id.* This data helps to determine whether the compound is sufficiently innocuous for testing in humans. *See id.*

82 *See id.*

83 *See* 21 C.F.R. §312 (1998). This information is necessary to ensure that the manufacturer is able to adequately supply invariable shipments of the drug. *See id.*

84 *See id.* In addition, information regarding the skills and expertise of the clinical investigators must be included along with pledges to obtain informed consent from the research subjects. *See* 21 CFR 56 (a). Once this information is included, a review of the study by an institutional review board adhering to the investigational new drug regulations may begin. *See id.*

After the IND has been submitted, the manufacturer or sponsor of the drug must wait thirty calendar days before commencing clinical trials.[85] Throughout this waiting period, the FDA has occasion to evaluate the IND again for security and safety purposes, in order to insure that research participants will not be placed in peril.[86] The FDA requires poof of efficacy as well as safety for all new drugs seeking approval.[87] In analyzing the term "safe or safety" it must be recognized that absolute safety is not feasible.[88] As such, the FDA considers a drug "safe" if the studies find that its benefits outweigh its risks.[89]

B. *FDA Approves "Some" Mood-Altering Drugs for Children*

Given the above standard, the issue becomes whether the risks that appear to be surfacing in treating children and adolescents with mood-altering drugs outweigh the benefits afforded to both the adolescent patients, and society at large. Until that question can be answered within a reasonable degree of certainty, the FDA should tighten the regulatory belt that permits these drugs to be administered to children.

The following list of psychotropic drugs indicates the labeling presently approved by the FDA (see Table I)[90]. Most of the drugs as noted, are approved only for adult use:

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85 *See* 21 C.F.R. §312 (1998).

86 *See id.*

87 *See* Farley, *supra* note 75.

88 *See id.* Drugs always carry the risk of an adverse reaction. *See id.*

89 *See id.*

90 *See Psychotropic Drugs: Current Labeling, available at* http://www.fda.gov/cder/present/dia4-2000/diadm/sld016.htm (last visited June 29, 2000).

Table I

Generic Name	Trade Name	Approved Indications	Ages Labeled
Citalopram	Celexa[91]	Depression	Adults Only
Fluoxetine	Prozac[92]	Depression, Obsessive Compulsive Disorder, Bulimia Nervosa	Adults
Mirtazapine	Remeron[93]	Depression	Adults
Nerfazodone	Serzone[94]	Depression	Adults

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91 *See* PHYSICIANS DESK REFERENCE, NURSE'S DRUG HANDBOOK 428 (2000), [hereinafter PDR]. "Celexa, Classification: Antidepressant, Uses: Treatment of depression in those with DSM-III or DSM-III-R category of major depressive disorder, side effects in part (for central nervous system): Activation of *mania/hypomania,* dizziness, insomnia, *agitation,* somnolence, insomnia, anorexia, paresthesia, migraine, hyperkinesia, vertigo, hypertonia, extrapyramidal disorder, neuralgia, dystonia, abnormal gain, hypesthesia, ataxia, *aggravated depression, suicide attempt,* confusion, *aggressive reaction,* drug dependence, depersonalization, hallucinations, euphoria, *psychotic depression,* delusions, *paranoid reaction,* emotional lability, panic reaction, *psychosis." Id* (emphasis added).

92 *See id* at 65. "Prozac, Classification: Antidepressant, Uses: Depression, obsessive-compulsive disorders, bulimia nervosa, Side effects (CNS in part): A large number of side effects have been reported for this drug. Listed are those with a reported frequency of greater than 1%, Headache (most common), *activation of mania or hypomania,* insomnia, anxiety, nervousness, dizziness, fatigue, sedation, decreased libido, drowsiness, lightheadedness, decreased ability to concentrate, tremor, disturbances in sensation, *agitation,* abnormal dreams. *Although less frequent than 1%, some clients may experience seizures or attempt suicide."* *Id* (emphasis added).

93 *See id* at 925: "Remeron, Classification: Antidepressant, tetracyclic, Uses: Depression, Special Concerns in part: The effect of mirtazapine for longer than six weeks has not been evaluated, although treatment is indicated for six months or longer. *Safety and efficacy have not been determined in children.* Side effects (CNS in part): Somnolence, dizziness, activation of *mania or hypomania, suicidal ideation,* sedation, drowsiness, abnormal dreams, *abnormal thinking,* tremor, confusion, hypesthesia, apathy, *depression,* hypokinesia, vertigo, twitching, *agitation, anxiety,* amnesia, hyperkinesia, paresthesia, ataxia , delirium, delusions, *depersonalization,* dyskinesia, *hallucinations, neurosis, hostility,* increased reflexes, *emotional lability,* euphoria, *paranoid reaction." Id* (emphasis added).

94 *See id* at 963: "Serzone, Classification: Antidepressant, Uses: Maintenance treatment of depression and for depression in hospitalized clients. Special concerns: Use with caution in clients with a recent history of MI, unstable heart disease and taking digoxin, or a *history of mania.* Use with caution during lactation. *Safety and efficacy have not been determined in individuals below 18 years of age.* There is a possibility of a *suicide attempt in depression* that may persist until significant remission occurs. Side effects (CNS in part): Dizziness, insomnia, *agitation,* somnolence, lightheadedness, *activation of mania or hypomania,* confusion, memory impairment, *abnormal dreams,* decreased concentration, psychomotor retardation, tremor, hypertonia, twitching, *depersonalization, hallucinations, suicide thoughts/attempt, euphoria, hostility, abnormal thinking, etc." Id* (emphasis added).

Paroxetine	Paxil[95]	Depression, OCD, Panic Disorder	Adults
Sertraline	Zoloft[96]	Depression, OCD, Panic Disorder	Depression labeled in adults, OCD labeled down to 6 years
Vanlafaxine	Effexor[97]	Depression, General Anxiety Disorder (GAD) OCD	Adults
Fluvoxamine	Luvox[98]	OCD	Adults down to 8 years

95 *See id* at 1032: "Paxil, Classification: Antidepressant, Uses: Treatment of major depressive episodes, panic disorder with or without agoraphobia and obsessive-compulsive disorders. Safety concerns (as relevant to this paper): *Safety and efficacy have not been determined in children.* Side effects (CNS in part): Headache, somnolence, insomnia, *agitation*, seizures, tremor, *anxiety, activation of mania or hypomania*, dizziness, *nervousness, drugged feeling, CNS stimulation*, amnesia, *depression, emotional lability*, vertigo, *abnormal thinking, alcohol abuse*, convulsions, *possibility of a suicide attempt, depersonalization, hallucinations, lack of emotion, manic reaction, paranoid reaction, etc." Id* (emphasis added).

96 *See* PDR, at 1202: "Zoloft, Classification: Antidepressant, Uses: Treatment of depression with reduced psychomotor agitation, anxiety and insomnia. Obsessive-compulsive disorders in adults and children. Treatment of panic disorder, with or without agoraphobia. Special Concerns (in part): *Safety and efficacy have not been determined in children.* The possibility of a *suicide attempt* is possible in depression and may persists until significant remission occurs. Side Effects (CNS in part): Headache, insomnia, somnolence, agitation, *nervousness, anxiety*, dizziness, tremor, fatigue, impaired concentration, yawning, paresthesia, hypesthesia, twitching, hypertonia, confusion, abnormal dreams, *aggressive reaction*, amnesia, apathy, delusion, *depersonalization, depression, aggravated depression, emotional lability, euphoria, hallucinations, neurosis, paranoid reaction, suicide ideation or attempt, abnormal thinking*, etc." *Id* (Emphasis added).

97 *See id* at 1354: "Effexor, Classification: Antidepressant, miscellaneous, Uses: Treatment of depression, Side Effects (CNS in part): *Anxiety, nervousness*, insomnia, *mania, hypomania*, seizures, *suicide attempts*, dizziness, somnolence, tremors, abnormal dreams, *abnormal thinking, depersonalization, depression, emotional lability, apathy, CNS stimulation, euphoria, hallucinations, hostility*, hyperkinesia, incoordination, increased libido, *psychosis, psychotic depression*, sleep disturbance, etc.." *Id* (emphasis added).

98 *See id* at 660: "Luvox, Classification: SSRI, Uses: Obsessive-compulsive disorder for adults, adolescents, and children. Investigational: Treatment of depression. Special Concerns: Use with caution in clients with a *history of mania*, seizure disorders, etc. . . .. *Safety and efficacy have not been determined in children less than 18 years of age.* Side Effects (CNS in part): Somnolence, insomnia, nervousness, dizziness, tremor, *anxiety*, hypertonia, *agitation*, depression, CNS stimulation, amnesia, apathy, *manic reaction, psychoses*, fatigue, malaise, agoraphobia, convulsion, *delirium, delusion, depersonalization*, drug dependence, hallucinations, *hostility, hysteria, paranoia, phobia*, etc." *Id* (Emphasis added).

Buspirone HCL	BuSpar[99]	GAD	Adults
Methylphenidate HCL	Ritalin[100]	ADD, Narcolepsy	Down to 6 years
Dextroamphetamine	Dexedrine[101]	ADD, Narcilepsy	Down to 6 years
Anafranil	Clomipramine[102]	OCD	Down to 10 years
Clonidine HCL	Catapres[103]	Antihypertensive	Down to 12 years[104]

Of the drugs listed above, only six out of the 13 were labeled for ages twelve and under. In fact, Dr. Thomas Laughren, FDA team leader for psychiatric drug products admitted, "if we approve a drug for depression in adults, we know it will be applied in kids" as well.[105]

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99 *See id* at 328: " BuSpar, Classification: Nonbenzodiazepine, antianxiety agent, Uses: anxiety disorder, short-term use to relieve symptoms of anxiety. Special Concerns: *Safety and efficacy in children less than 18 years of age not established.* Side effects (CNS in part): Dizziness, drowsiness, insomnia, fatigue, *nervousness, excitement*, dream disturbances, noise intolerance, *euphoria, depersonalization, hallucinations, suicidal ideation*, seizures, decreased concentration, confusion, *anger or hostility, depression*, etc.." *Id* (emphasis added).

100 *See id* at 898: "Ritalin, Classification: CNS stimulant, Uses: Attention-deficit disorders in children as part of overall treatment regimen, Narcolepsy. *Safety and efficacy in children less than 6 years of age have not been established,* Side effects (CNS in part): nervousness, insomnia, headaches, dizziness, drowsiness, *depressed mood (transient), toxic psychoses*, dyskinesia, Tourett's syndrome, Psychologic dependence, etc.." *Id* (emphasis added).

101 *See* PDR at 245: "Dexedrine, Classification: CNS stimulant, Uses: Attention deficit hyperactivity disorder in children, narcolepsy. Special Concerns: Use in children *less than three years of age for ADD and in children less than 6 years of age for narcolepsy. (Emphasis added)*

102 *See id* at 442: "Clomipramine, Classification: Antidepressant, tricyclic, Uses: Obsessive-compulsive disorder in which the obsessions or compulsions cause marked distress, significantly interfere with social or occupational activities, or are time-consuming. Panic attacks and cataplexy associated with narcolepsy. Special Concerns and side effects: Safety has not been established for use during lactation or *in children less than 10 years of age*. Hyperthermia, especially when used with other drugs. Increased risk of seizures. *Aggressive reactions*, asthenia, anemia, etc." *Id* (emphasis added).

103 *See id* at 444: "Catapres, Classification: Antihypertensive, Centrally acting antiadrenergic, Uses: Mild to moderate hypertension, Investigational: Alcohol withdrawal, attention deficit hyperactivity disorder, etc.., Side effects (CNS in part) and special concerns: *Safe use in children not established,* drowsiness, sedation, *confusion, nervousness, restlessness,, anxiety, mental depression* increased dreaming, insomnia, *hallucinations*, delirium, *agitation." Id* (emphasis added).

104 *See Psychotropic Drugs: Current Labeling, supra* note 90.

105 *See* Joyce Howard Price, *Another Risk for Kids? Lots of them on Prozac*, THE WASHINGTON TIMES, September 7, 1998. Dr. Laughren also conceded that there were only a "handful of studies" regarding the effects of these medications in children. *See id.*

C. *New Regulation Brings Hope for Pediatric Patients*

The FDA, in recognizing the risks of inadequate drug studies for the pediatric population, proposed that manufacturers of certain new and marketed drugs conduct special studies to provide adequate labeling for the use of these products in children.[106] The proposed rule became final on April 1, 1999.[107] As noted by the Agency, most drugs and biologics have not been adequately tested in the pediatric populace.[108] If drugs are not adequately tested, labeling will lack proper directions for safe and effective use.[109] This is precisely the issue with prescribing mood-altering drugs that have only been tested and approved for adult use. If a proper pediatric dose is not known, a physician will probably estimate the dosage based on the child's weight. Without adequate clinical testing, a physician cannot be assured the drug is safe to be administered to a child or young adult.

The lack of pediatric labeling information poses significant risks for increase in adverse reactions for treated children.[110] In addition to a possible increase in adverse reactions due to improper or incomplete labeling, children may also undergo inadequate treatment due to "under-dosing." Children may also not benefit from potentially potent and efficacious medications because physicians may choose to prescribe existing, less effective medications in the wake of insufficient pediatric information regarding a new medication.[111] Therefore the pediatric patient in these cases may not be privy to the more recent therapeutic advances.[112] This rule requires that manufacturers provide sufficient data and information on which to base directions for pediatric use.[113] Hopefully, it will aid the medical community when dispensing

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106 *See* 62 FR 43900.

107 *See* 63 FR 66632, Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 21 C.F.R. §§201, 312, 214, 601 (1998).

108 *See* 63 FR 66632.

109 *See id.*

110 *See id.* The scarcity in labeling exposes the pediatric patient to the risk of age-specific adverse reactions which may have been unexpected from clinical adult experience. *See id.*

111 *See id.*

112 *See id.* Physicians may also require their pediatric patients to ingest the medication in makeshift formulations. *See id.*

113 *See* 63 FR 66632. Manufacturers are to submit required assessments of pediatric safety and effectiveness twenty months after the effective date of the rule. *See id.* The FDA may waive or defer these assessments. *See id.*

potentially harmful, albeit essential, medications to the young.

This rule also addresses previous steps taken by the FDA to address the issue of inadequate pediatric testing. For example, the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research had devised and implemented a "Pediatric Plan" which advocated voluntary development of pediatric data during the drug development process, which would continue after marketing.[114] Further developments resulted from what is known as "the 1994 Rule,"[115] a regulation promulgated by the FDA which requires manufacturers of marketed drugs to survey existing data and ascertain whether that data was sufficient to support additional pediatric use information in the drug's labeling.[116]

The FDA has also drafted guidelines to aid in the generation of an "adverse reactions"[117] section of labeling for human prescription drugs and biologics.[118] This is the first in a series of guidance documents intended for industry in an attempt to make the labeling process more consistent and user-friendly for both prescribers and patients.[119] The guidance document is divided into two subsections. The first provides an overview highlighting the most serious adverse reactions, which occur more commonly and generally result in clinical interventions.[120] The second section deals in greater detail with the significance of adverse reaction data obtained from the clinical trials.[121]

Emphasis is placed on the severity, frequency and strength of causal association when determining which reactions merit inclusion in the adverse reactions section.[122] The information included will also be parsed to include only that most useful to clinicians when making

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114 *See id.*

115 *See* 59 FR 64240.

116 *See id.* If the manufacturer concludes that existing data warrant modification of the label's pediatric use information, the manufacturer must propose a supplemental new drug application (NDA) to the FDA soliciting approval of the labeling change. *See id.*

117 *See* 21 C.F.R. §201.57(g). An adverse drug reaction is an undesirable effect, reasonably associated with the use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. *See id.*

118 *See* 65 FR 38563, June 21, 2000. *See also Guidance for Adverse Reactions Labeling,* FDA Talk Paper, June 23, 2000 *available at* http://www.fda.gov/cder/guidelines.htm (visited June 29, 2000).

119 *See Guidance for Adverse Reactions Labeling,* FDA Talk Paper, June 23, 2000 *available at* http://www.fda.gov/cder/guidelines.htm (visited June 29, 2000).

120 *See id.*

121 *See id.*

122 *See id.*

treatment decisions; long and exhaustive lists of every reported adverse event would be counterproductive.[123]

Presumably, the "Guidance for Adverse Reactions Labeling" document will advance as a milestone in modern pharmaceutical practice. In the case of the SSRI's and/or Ritalin prescriptions, the new labeling will undoubtably highlight the possibility of suicidal tendencies as well as any other relevant and significant adverse reactions. This is particularly useful in this area, where general practitioners or pediatricians who may or may not possess the essential expertise have the authority to prescribe these types of mood/mind-altering drugs to youngsters. Implementation of the "Guidance" should be prompt and precise in order to assure patients that their doctors are fully aware of what they are dispensing. By passing these regulations, the FDA has clearly marked the road for further advances in regulating the manufacturers of their many wonder pills.

V. Less Drugs, More Human Interaction

Are parents at fault for providing anti-depressant or mood-altering pacifiers in order to rapidly placate their child? Although parents are delighted at their fortune in having borne a healthy child, many parents also yearn for a little extra; they want their children to excel in academics, athletics and even appearance.[124] But what price are parents willing to pay for their offspring's success? Parents are sometimes caught up in the race for perfection, leaving their children lagging behind.[125] If a child is experiencing behavioral problems at school, the parent obsessed with perfection may choose the fast track to solving the issue at hand. That short cut may begin with a trip to the pediatrician or psychiatrist, and end with a prescription for "behavior pills" in hand. Thus, Ritalin may be administered to a child that will just not "sit still" in the hopes of erasing or preventing the stigma of being called a

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123 *See* 65 FR 38563. This section is not intended to be a complete summary of all information in the adverse reactions section. It contains only the following: serious and critical adverse reactions described in other labeling sections, the most commonly occurring adverse reactions, and the most recurrent adverse reactions which result in clinical intervention, such as termination of the drug, change in dosage, or need for concomitant medication to treat an adverse reaction symptom. *See id.*

124 *See* Therese Powers, *Race for Perfection: Children's Rights and Enhancement Drugs*, 13 J.L. & HEALTH 141 (1998-99).

125 *See id* at 141.

"problem."[126]

As mentioned previously, Ritalin is usually administered to combat the symptoms of ADHD.[127] Yet, the symptoms of ADHD are so difficult to diagnose that it often becomes challenging to differentiate between a child suffering from ADHD and one that simply needs more attention or discipline.[128] Ritalin is a stimulant drug, yet society is content to treat a hyperactive child with such a remedy, since the cost is low and the results are usually immediate.[129] But how low is the actual cost? While the monetary cost of the pills themselves may prove to be financially tolerable to parents, the uncertain side effects indicate that the real cost may be their children's psychiatric futures.

In light of this, perhaps society should reconsider the *real* cost, and initiate the weaning process. While prescriptions of Ritalin are up 20 percent since 1989, the percentage of children receiving psychotherapy dropped from 40 percent to 25 percent.[130] A greater focus on therapy may prove as efficacious (or more so) than the fast-track route with drugs. Let's eliminate our lazy culture's propensity to medicate problems rather than solve them.[131]

VI. Conclusion

It is estimated that about two billion prescriptions of varying drugs are filled yearly in the U.S., indicating that Americans bank on the marvels of science to rejuvenate their bodies and cure their afflictions.[132] But these small miracle pills do not come at a meager price. Researching and synthesizing a new drug is not only a time-consuming and costly venture, it also has been likened to finding a

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126 *See id* at 141-42.

127 *See id.*

128 *See id* at 143.

129 *See* POWERS, *supra* note 124.

130 See Arianna Huffington, *Attention Deficit on Risks of Legal Drugs,* THE WASHINGTON TIMES, December 9, 1998 at A18.

131 *See id.* Dr. Peter Breggin, author of "Talking Back to Ritalin" and "Talking Back to Prozac" states, "Behaviors are signals that should be interpreted and understood, not suppressed." *See id.*

132 *See* Jeffrey P. Cohn, *The Beginnings: Laboratory and Animal Studies, available at* http://www.fda.gov/fdac/special/newdrug/begin.html (last visited June 30, 2000). To the American people, popping pills is a common happening; a method of keeping their health at an optimum. *See id.*

needle in a haystack.[133] The only sure way to ascertain whether a drug will be effective against a disease/condition in humans is to actually test the drug in humans. But this unavoidably raises a host of ethical questions.[134] For example, women and children have traditionally been overlooked in clinical drug trials.[135] Children in particular are not usually included in clinical trials until the effects of the test compound have been determined in the adult population.[136] This becomes problematic when dosing is at issue. Without pediatric participation in clinical trials, scientists cannot reasonably offer guidance regarding dosing or side effects.[137] Children are not adults in smaller sized bodies; they may metabolize or absorb drugs at a different rate than adults do.[138]

Clinical trials involving children are even more crucial today since children and adolescents have become the "hot new market" for antidepressants.[139] Although Prozac has been shown to be beneficial in easing adult depression, the effect of the drug in a young, growing body has not yet been determined.[140] Despite this fact, thousands of children in the US, some as young as pre-schoolers, are prescribed Prozac and other mood-altering drugs that have only been approved by the FDA for adult use.[141]

Dr. Donald L. Rosenblitt, medical director of the Lucy Daniels Center for Early Childhood in Cary, North Carolina states "the

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133 *See id.* Many times, scientists or chemists must synthesize thousands of compounds before finding the consummate drug to pass muster under the FDA's risk/utility test for approval. *See id.*

134 *See id.* An example of the ethical issue is whether it is just to give a human patient a placebo (sugar pill) even though a known effective treatment is accessible. *See id. See also* Leonard H. Glantz, *Research with Children,* 24 AM. J.L.& MED. 213 (1998) (generally discussing the issues involved of conducting research with pediatric subjects).

135 *See* COHN, *supra* note 132.

136 *See id.* An exception is when the drug is directly intended to treat a childhood disease. *See id.*

137 *See id.*

138 *See* Paula Botsein, *Why FDA is Encouraging Drug Testing in Children,* FDA Consumer Special Report (January 1995) *available at* http://www.fda.gov/fdac/special/newdrug/kidmed.html (visited 6/30/00).

139 See Mary Leonard, *Children, the Hot New Market for Antidepressants,* THE BOSTON GLOBE, May 28, 1997. Peppermint-flavored Prozac may soon be on the market for pediatric and adolescent use. *See id.*

140 *See id.*

141 *See* PRICE, *supra* note 105. From 1996 to 1997, the amount of children ages five and under being prescribed anti-depressants rose at an alarming rate, from eight thousand to forty thousand. *See id.*

enormous weight of evidence, so far, is that anti-depressants do not help childhood depression."[142] Dr. Rosenblitt further states that while agitation and nervousness are common side effects in children who use Prozac, the drug can also precipitate "psychotic panic" in seriously troubled youngsters.[143] Since Ritalin was approved by the FDA in 1955, teen suicides have more than tripled.[144] Even child psychiatrists who advocate the use of these type of drugs for some depressed children concede the need for more intense research and study regarding short and long term effects on children.[145]

It is up to American parents and consumers alike to lobby for stricter legislation to change the present regulatory scheme to a more stringent one. One possible suggestion would be to prohibit physicians from prescribing medications to the pediatric population without specific FDA approval. Although the American Medical Association may think this overly intrusive, parents must resort to such means absent other more stringent measures.

Even FDA regulation is not sufficient by itself. We must also demand better testing in the research and development laboratories of the synthesizers of these drugs, as well as in legislation requiring stringent post-approval monitoring for adverse drug reactions.[146] Manufacturers must be held accountable for their products.

Finally, we must end the "quick fix" mentality of parents and physicians. In some schoolrooms 20 percent of the students are on Ritalin. And the number is growing.[147] The federal government's National Institute of Mental Health estimates that by the end of the year 2000 about ten million children will be taking some form of a psychiatric drug.[148] This nation has conducted "a 40-year war on *illegal*

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142 *See id.*

143 *See id.* "I've seen some disturbed children who've become psychotic, or deranged, after taking Prozac." *Id.*

144 See Deborah Carson, *Children at Risk from the Mental Health Cartel,* LAS VEGAS REVIEW-JOURNAL, March 19, 2000 at 1D.

145 *See* PRICE, *supra* note 105. "We don't know about their long-term effects. Children are not just small adults." *Id.*

146 *See* Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare,* 49 CATH. U.L. REV. 449 (2000). (discussing in part the FDA pre-approval mechanism as well as suggestions for post-market monitoring of unexpected side effects associated with prescription drugs).

147 *See* CARSON, *supra* note 144.

148 *See id.*

drug use."[149] It is now time to stage a "war on legal drug pushing." The protection of American children must again be a primary interest.

149 *See id.*