

IN THE STATE COURT OF DEKALB COUNTY
STATE OF GEORGIA

CURTIS W. REYNOLDS,)
 Administrator of the Estate)
 of JENNIFER BROOKE REYNOLDS,)
 Deceased,)
)
 Plaintiff,)
)
 v.)
)
 DR. BLANCA R. ANTON;)
 DR. GEORGE S. KLERIS;)
 DR. DWAYNE TIMOTHY DAUGHERTY;))
 DR. MARTHA J. LITTLE;)
 NOVARTIS PHARMACEUTICALS)
 CORPORATION)
)
 Defendants.)
 _____)

Civil Action File
No. 01A 76719-3

AFFIDAVIT OF PETER R. BREGGIN, M.D.

STATE OF NEW YORK)
) SS
 COUNTY OF _____)

Peter R. Breggin, M.D., being first duly sworn, deposes and states as follows:

1. I am a psychiatrist licensed to practice medicine in Virginia, Maryland, Washington D.C., and New York.
2. I have been in the full-time practice of psychiatry since 1968 and have a special interest and expertise in psychopharmacology and medication side effects. My credentials are included in my Curriculum Vitae and publication list, true and correct copies of which are attached as Exhibit A to this affidavit.



3. In preparation for my testimony in this case I have reviewed medical and pharmacy records of Jennifer Reynolds, the depositions of the doctors involved and the deposition of Mrs. Ellen Reynolds and I have interviewed Mrs. Reynolds by telephone. In addition, I have reviewed parts of the New Drug Application for Ritalin during a document production and a great deal of medical and scientific literature on Ritalin and the other common stimulant medications given to children and to Jennifer Reynolds.

4. Finally, I have reviewed copies of the Physicians' Desk Reference (the "PDR") for Ritalin for a number of years. True and correct copies of the 1998 PDR section pertaining to Ritalin (generic methylphenidate), are attached as Exhibit B.

5. The PDR is an encyclopedic compilation of Food and Drug Administration ("FDA") approved manufacturer's labeling for prescription medications. It is a common and widely recognized source for physicians to consult for information pertaining to medications available in the marketplace and their potential risks and benefits in the treatment of patients. As a matter of law, one looks to the PDR to find the manufacturers warnings to physicians about prescription medications.

6. From a review of the medical records of Jennifer Reynolds, and the other materials listed above, it is clear that Jennifer Reynolds suicide was not a volitional act as we normally understand that term. Her acts in taking her life were beyond her control as a result of toxic levels of Ritalin in her system. She reached this state following a long term addiction to Ritalin as a result of being prescribed it by her doctors over a long period of time without warning her or her parents of Ritalin's addictive properties and its serious psychiatric side effects. To use the legal terminology at issue here, which clearly fits, Jennifer Reynolds suicide

was the result of an uncontrollable impulse precipitated by Ritalin.

7. Inadequacies of the Ritalin Label

While the doctors failed to warn Jennifer Reynolds or her parents of the potentially toxic effects of Ritalin, it was not entirely their fault. This is the case because the warnings provided by Novartis for Ritalin were clearly inadequate as demonstrated by an analysis of the company's label for the drug.

The Novartis label for Ritalin is extraordinarily weak and misleading in regard to its failure to communicate the dangers of Ritalin abuse and addiction. The following analysis pertains to all labels up to the year 2002. The specific quotes can be found in all Ritalin labels in the past two decades. There has been little change in the Ritalin label since the early 1970s when the FDA enforced a major revision.

Drug labels are the result of a negotiation between the FDA and the drug company in which the FDA remains largely dependent on information provided by the drug company. Furthermore, the law permits a drug company to upgrade any of its warning without prior permission for the FDA. That is, a drug company has the power to correct a weak label on its own.

A. Specific Label Issues Concerning Abuse and Addiction

(1) The label begins by calling Ritalin a "mild" stimulant. In fact, Ritalin is among the very most powerful stimulants, comparable to amphetamine and methamphetamine, and even cocaine. (By contrast, caffeine might be called a "mild" stimulant, and even caffeine is addictive and has withdrawal symptoms.) The idea that Ritalin is "mild" provides false reassurance that it will not be as dangerously addictive and abuse prone as other stimulants.

(2) The label fails to mention that Ritalin is a controlled substance in Schedule II of the DEA. The label should also explain that Schedule II is the very highest schedule, indicating that Ritalin is among the most dangerously addictive and abuse prone drugs used in medicine. The label also fails to mention that requirement for special FDA controls on the production and prescribing of Ritalin as a schedule II drug.

(3) The label fails to mention that Ritalin is a drug of addiction comparable to amphetamine, methamphetamine, and cocaine. For example, Ritalin has similar effects to the above stimulants on the very same three neurotransmitter systems: serotonin, dopamine, and norepinephrine. Ritalin also impacts on same regions of the brain as the other stimulants.

Most drug labels identify the exact neurotransmitter systems that are known to be affected by a drug. The failure to do so for Ritalin seems purposeful to avoid comparisons to other stimulants and to avoid recognition of the potentially harmful effects known to be associated with over-stimulating these three neurotransmitter systems.

Because their biochemical effects on the brain are so similar, all of the stimulants also share the same basic adverse reactions profile and even the same "beneficial" effects. This similarity relates directly to Ritalin propensity to cause addiction and abuse, to cross-

addict with the other stimulants, and to lead addiction and abuse with the other stimulants, including amphetamine, methamphetamine, and cocaine.

(4) The label fails to mention various kinds of research evidence about the comparability of Ritalin, amphetamine, methamphetamine, and cocaine in terms of addiction, abuse, and tolerance. Animal and human literature demonstrate cross-addiction; animals and people substitute Ritalin for the other stimulant drugs.

(5) The label fails to mention the many reports of addiction, abuse, tolerance, withdrawal, and rebound made to the FDA Spontaneous Reporting System.

(6) The label fails to mention the widespread and at times epidemic addiction and abuse of Ritalin since the 1950s. There have been waves of epidemics of Ritalin abuse around the world, leading at one time to the banning of Ritalin in some European countries. There are indications that another Ritalin addiction and abuse wave is rising again in the USA.

B. Related Label Issues

The Closely related to the above, the label fails to mention the following:

(1) Ritalin is bought and sold as an illegal drug on public school and college campuses.

(2) Ritalin is snorted and injected intravenously, and that these methods of abuse pose special dangers in regard to physical injury and death.

(3) Ritalin is commonly stolen (diverted) for abuse purposes. Prescribed Ritalin is sold or given away by children to whom it is prescribed. It is also taken by parents, and otherwise misused and diverted. Thefts occur from school nursing offices.

(4) Younger children in increasing numbers are arriving at emergency rooms suffering from Ritalin abuse. Among pre-teens, Ritalin abuse now equals cocaine as a cause of admissions to emergency rooms.

(5) The DEA has written extensively about the growing danger of Ritalin addiction and abuse as national problem, and has tried to stem the tide of rising prescription use.

(6) The International Narcotics Control Board has for several years been warning about the increasing danger worldwide and in the USA concerning Ritalin abuse and addiction.

(7) The label fails to mention evidence that Ritalin permanently changes the brain of animals. Ritalin sensitizes the animal brain to react more powerfully to subsequent doses of Ritalin many weeks after the last dose of Ritalin.

(8) The label reference to "emotionally unstable" people being prone to addiction (boxed warning) is intentionally misleading. A person does not have to be emotionally unstable to become addiction and abuse prone.

(9) In addition to all the other omissions, the warning box is insufficient in size and emphasis.

(10) The drug company has never conducted appropriate long-term studies on the relationship between prescribed Ritalin use and later tendencies to abuse stimulants in young adulthood. Such a study has now been published by Lambert and colleagues whose long-term prospective study demonstrating an increased tendency for cocaine abuse in young adults who as children were exposed to normal prescribed doses of Ritalin (Lambert, 1998, and Lambert, and Hartsough, 1998). The drug company has yet to respond to that study, confirming the company's persistent failure to inform the profession and the public. Ritalin should be considered a "gateway drug" to addiction and abuse with other stimulants.

(11) The label does not specifically warn that the addiction and abuse issues have never been adequately studied.

(12) The label does not mention that prescribed doses of Ritalin can predispose to addiction, and instead mentions only increasing doses as a problem.

(13) The label does not mention withdrawal problems except in reference to "chronic abusive use" in the boxed warning. The fact that children routinely suffer from withdrawal problems is an important indicator of potential addiction and abuse.

(14) The label does not mention rebound problems. The fact that children suffer rebound (a form of withdrawal that involves an exaggeration of their previous symptoms) shows that the drug has addiction and abuse potential.

(15) In regard to the approval of the SR (longer-acting) form, the drug company was not required to do extensive research on Ritalin or methylphenidate itself. Instead, the FDA allowed the drug company to grandfather in the SR version. However, the original FDA approval of Ritalin took place in the 1950s. Two decades after that approval, the company's claims were found to be very excessive, and were curtailed as a result of a special inquiry by the FDA and the National Science Foundation.

However, the review carried out by the FDA and the National Science Foundation, while curtailing some excessive claims, did not demand that the drug undergo a more modern and effective approval process. The use of controlled clinical trials and the overall approval process in the 1950s was much less stringent than the current approval process, and no overall correction has ever been made in regard to that original inadequate testing.

Thus, the SR form was approved on the basis of very old and inadequate criteria. Furthermore, by lengthening the duration of action, the SR form very likely substantially affected the adverse reaction dangers and profile, and yet no extensive testing was required in this regard. The drug company was instead allowed to include the SR version in the very skimpy, outdated Ritalin label.

(16) For the approval of the SR version, and for its inclusion in the label, no specific research was carried out concerning addiction, abuse, withdrawal and rebound in animals or humans.

(17) The label fails to mention that no specific research was done on the SR form concerning addiction, abuse, withdrawal rebound, and other related issues in either animals or humans.

C. Further Implications of Label Inadequacies

As already noted, the overall inadequacy of the label plays a role in reassuring professionals and parts that the drug is relatively harmless. Any part of the label that fraudulently encourages the use of Ritalin plays a role in the overuse of the drug, and hence relates ultimately to children developing adverse effects, such as addiction and abuse. Here is a brief summary of the some of the overall problems with the label separate from the specific issues of addiction and abuse:

(1) The drug company has not done a general updating and overhaul of the Ritalin label since forced to revise its claims and to add an addiction and abuse section in the early 1970s (e.g., see the 1973 label for similarities to the current label). As a result, the Ritalin label remains very short, skimpy, and superficial by modern standards. Absent for example are the usual tables comparing the drug to placebo in regard to adverse effects. Absent are the typical long lists of adverse effects with their estimated frequencies. This is a very superficial and abbreviated label—which contributes to the impression that Ritalin is a relatively harmless drug, when it is not. This directly impacts on the issue of abuse and addiction.

In part as a result of the benign appearance of the Ritalin label, too many doctors believe that Ritalin is relatively harmless in comparison to other addictive drugs, such as Xanax or Valium. Yet Xanax and Valium have a lesser classification for addiction and abuse in the DEA schedule. Too many doctors are likely prescribe Ritalin without the concern or warnings to patients that they would express when prescribing other Schedule II drugs such as morphine and cocaine.

(2) By using the concept of "attention deficit" and "distractibility" (as well as other similar concepts), the label implies that Ritalin will help children improve their academic and scholastic achievement. In fact, the evidence is contrary to this; Ritalin often impairs higher cognitive abilities. The label should contain a statement that there is no evidence for improvement in academic or scholastic performance, or learning, and that to the contrary, Ritalin may impair higher level learning. Indeed, the label should also mention that there's no evidence for improvement in a child's psychological or social life, and may in fact impair it.

(3) By making references to potential physical disorders associated with ADHD, the label fosters a false belief in a biological basis for ADHD. These references include a reference to possible "minor neurological signs and abnormal EEG" and a mention that

"Nonlocalizing (soft) neurological signs ... and abnormal EEG may or may not be present." Similarly, the label states "a diagnosis of central nervous system dysfunction may or may not be warranted."

D. Comparison to Other Drug Labels

(1) Comparison to Other Stimulant Labels

Two other stimulant labels for Dexedrine (d-amphetamine) and Adderall (a mixture of amphetamines) provide a comparison. The labels for both containing a stronger boxed warning about addiction and also a special section entitled "Drug Abuse and Dependence." The classification in Schedule II is mentioned. The labels briefly mention tolerance, dependence, and withdrawal.

The relevant sections in the Dexedrine and Adderall labels are written to include all amphetamines as a single, comparable group. Since Ritalin is pharmacologically classified with the amphetamines in all knowledgeable sources, the label for Ritalin should at least meet the standards for the Dexedrine and Adderall labels, but does not. Meanwhile, the Adderall and Dexedrine labels suffer from many of the flaws found in the Ritalin label and by no means exemplify an adequate standard for labeling.

(2) Comparison to Sedative/Tranquilizer Labels

Xanax is a sedative tranquilizing agent that causes addiction and abuse. The Xanax's label contains a warning box for "Drug Abuse and Dependence" that is stronger than that found in the Ritalin label and also contains other references to issues related to addiction, dependence, withdrawal, and rebound. Yet Ritalin with its weaker label is in Schedule II (the highest addiction and abuse category) while Xanax is in Schedule IV.

8. Sources of Documentation:

The assertions made in this affidavit have a firm scientific basis in a many sources. Hundreds of relevant citations to the scientific literature are reviewed in the following books and peer-reviewed publications by this author:

(A) Sample of Relevant Peer-Reviewed Journal Publications by the Author:

(1) "What psychologists and psychotherapists need to know about ADHD and stimulants." Changes: An International Journal of Psychology and Psychotherapy 18:13-23, Spring 2000

(2) "The NIMH multimodal study of treatment for attention-deficit/hyperactivity disorder: A critical analysis." International Journal of Risk and Safety in Medicine, 13:15-22, 2000.

(3) "Psychostimulants in the treatment of children diagnosed with ADHD: Risks and mechanism of action." International Journal of Risk and Safety in Medicine 12:3-35, 1999. (Simultaneous publication of same report published in two parts in Ethical Human Sciences and Services; see below) --

(4) "Psychostimulants in the treatment of children diagnosed with ADHD: Part I: Acute risks and psychological effects." Ethical Human Sciences and Service 1:13-33, 1999.

(5) "Psychostimulants in the treatment of children diagnosed with ADHD: Part II: Adverse effects on brain and behavior." Ethical Human Sciences and Services 1:213-242, 1999.

(B) Sample of Relevant Books by the Author:

(1) Brain-Disabling Treatments in Psychiatry: Drugs, Electroshock and the Role of the FDA (Springer, NY, 1997)

(2) Reclaiming Our Children: A Healing Solution to a Nation in Crisis. (Perseus Books, Cambridge, MA, 2,000)

(3) Talking Back to Ritalin, Revised Edition. (Perseus Books, Cambridge, MA, 2001; originally published 1998).

(4) The Ritalin Fact Book. (Perseus Books, Cambridge, MA, 2002).

(C) Additional citations especially relevant to the addictive qualities of Ritalin:

(1) Drug Enforcement Administration (DEA). (1995, October). Methylphenidate (A background paper). Washington, DC: Drug and Chemical Evaluation Section, Office of Diversion Control, DEA, US Department of Justice.

(2) Drug Enforcement Administration (DEA). (1996). Conference report: Stimulant use in treatment of ADHD. Washington, DC: Drug and Chemical Evaluation Section, Office of Diversion Control, DEA, US Department of Justice.

(3) Ellinwood, E.H. & Tong, H.L. (1996). Central nervous system stimulants and anorectic agents. In M. N. G. Dukes (Ed.). Meyler's side effects of drugs: An encyclopedia of adverse reactions and interactions (Thirteenth Edition), pp. 1-30. New York: Elsevier

(4) Feussner, G. (1998). Diversion, trafficking, and abuse of methylphenidate. NIH consensus development conference program and abstracts: Diagnosis and treatment of attention deficit hyperactivity disorder.

pp. 201-4. Rockville, Maryland: National Institutes of Health. Also see Sannerud and Feussner (2000).

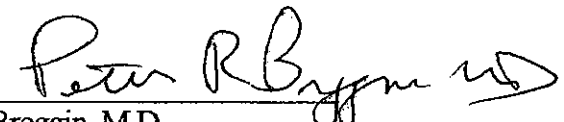
(5) International Narcotics Control Board. (INCB). (1995, February 28). Dramatic increase in methylphenidate consumption in US: Marketing methods questioned. INCB Annual Report 1995: Background Note No. 2. Vienna, Austria: Author.

(6) International Narcotics Control Board. (INCB). (1997, March 4). INCB sees continuing risk in stimulant prescribed for children. INCB Annual Report Background Note No. 4. Vienna, Austria: Author.

(7) Lambert, N.M. (1998). Stimulant treatment as a risk factor for nicotine use and substance abuse. NIH consensus development conference program and abstracts: Diagnosis and treatment of attention deficit hyperactivity disorder, pp. 191-200. Rockville, Maryland: National Institutes of Health.

(8) Lambert, N.M., & Hartsough, C.S. (1998). Prospective study of tobacco smoking and substance dependence among samples of ADHD and non-ADHD subjects. Journal of Learning Disabilities, 31, 335-352.

(9) Sannerud, C. and Feussner, G. (2000). Is Ritalin an abused drug: Does it meet the criteria for a Schedule II substance? In Greenhill, L., and Osman, B., Ritalin Theory and Practice, 2nd Edition, pp. 27-42. Larchmont, NY: Mary Ann Liebert, Inc.

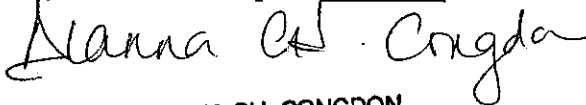
By: 
Peter R. Breggin, M.D.

Subscribed and sworn to before me

This 22 day of January, 2003.

Notary Public, State of New York

My commission expires 7-19-05



ALANNA CH. CONGDON
Notary Public, State of New York
No. 04HO6028069
Qualified in Tompkins County
Commission Expires 7/19/ 20 05