

FOCUSING IN ON ADDERALL

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INTRODUCTION

When the United States Congress passed the Controlled Substance Act in 1970, amphetamines were listed as Schedule II drugs, meaning that they have a high potential for abuse, and that such abuse leads to severe psychological or physical dependence.¹ Cocaine, opium, and morphine are examples of drugs that are listed in the same category.² Today, various forms amphetamines are prescribed to 1.5 million children annually in the United States.³

This paper will focus on the prescription drugs ADDERALL and ADDERALL XR (both hereinafter Adderall), the most commonly used drugs used to treat Attention-Deficit/Hyperactivity Disorder (hereinafter ADHD) in the United States today.⁴ It will investigate whether the benefits gained from Adderall use actually outweigh the harms that necessarily enjoin. Part I will set forth a background detailing the history of Adderall, including both its intended use to treat ADHD, and its abused use as a recreational drug. In Part II, this article will examine the problems caused by Adderall, paying special attention to both the Health Canada ban, and the FDA investigation. Part III will explore the alleged benefits of Adderall use and comparatively analyze them in relation to the problems. Finally, Part IV proposes solutions to the problem, and provides recommendations for reform. Ultimately, this article will suggest that the FDA engage in certain reforms to create a policy that better balances the harms and benefits of Adderall use in the United States when making its decision to approve the drug.

¹ 21 U.S.C. § 812(b)(2)

² United States Department of Justice. (2007). *Controlled Substances in Schedule II*. Retrieved October 24, 2007 from http://www.deadiversion.usdoj.gov/schedules/listby_sched/sched2.htm.

³ Children's Hospital Boston. (2005). *Adderall Response*. Retrieved October 24, 2007 from <http://www.childrenshospital.org/clinicalservices/Site457/Documents/Adderall%20Response.pdf>

⁴ ADDERALL XR Medication Information. (2007). *About ADDERALL XR*. Retrieved October 11, 2007 from http://www.adderallxr.com/about_adderallxr/index.asp.

I. BACKGROUND

Before it is possible to engage in a harm-benefit analysis of Adderall, it is first necessary to provide pertinent background information that showcases the drug's history, and discusses its current status today. Specifically, the purposes of this section are to establish Adderall's uses in the United States- both legally, and recreationally. Although a plethora of amphetamine-based concoctions have been used since the stimulant was first synthesized in 1887⁵, it is important to note that the purpose of this paper is solely to examine Adderall.

A. The History of Adderall as a prescription drug

Approved by the FDA in the 1960's, a drug named "Obetrol" was used primarily as a weight-loss medication to treat obesity.⁶ Obetrol, however, never became popular, and eventually was not profitable enough to stay on the market. Eventually, in 1994, Rexar Pharmaceuticals sold the Obetrol formula rights to Richwood (now Shire Richwood).⁷ And, in 1996, Adderall was approved by the FDA for treatment of ADHD in children.⁸ Adderall first was introduced in the form of instant-release capsules, but later was made available in an extended-release form (ADDERRALL XR).⁹

Both forms of Adderall have the exact same amphetamine-based ingredients and identical composition, with the only difference being the amount of time by which they are released into the body.¹⁰ The Adderall composition is also identical to the original

⁵ PBS Frontline. (2007). *A Social History of America's Most Popular Drugs*. Retrieved October 24, 2007 from <http://www.pbs.org/wgbh/pages/frontline/shows/drugs/buyers/socialhistory.html>.

⁶ Drabs, Julia. (2005). *Drugs for the Treatment of Attention-Deficit Hyperactivity Disorder*. Retrieved November 2, 2007 from faculty.smu.edu/jbuynak/Med%20chem%20ppt.ppt.

⁷ Id.

⁸ ADDERALL XR Medication Information. (2007). *About ADDERALL XR*. Retrieved October 11, 2007 from http://www.adderallxr.com/about_adderallxr/index.asp.

⁹ Id.

¹⁰ Id.

Obetrol form.¹¹ Specifically, Adderall is comprised of four active ingredients, each of which make up an equal 25 percent portion of the drug.¹² These ingredients are: dextroamphetamine saccharate, dextroamphetamine sulfate, amphetamine aspartate monohydrate, and amphetamine sulfate.¹³ As is common with most drugs, there are also a number of inactive ingredients, but the mixture of the four amphetamine-based salts above give Adderall its effects. Adderall is prescribed in either 5, 10, 15, 20, 25, or 30 mg doses.¹⁴

As mentioned, the FDA approved the use of Adderall as treatment for ADHD. ADHD is a neurological condition related to the brain's chemistry and anatomy.¹⁵ ADHD manifests itself as a persistent pattern of inattention or hyperactivity/impulsivity that occurs at a much more frequent and severe level than is typically observed in people at comparable levels of development.¹⁶ Although most commonly used in children, adults can sometimes be prescribed Adderall for “Adult ADHD”.¹⁷ Specifically, Adderall is approved for use in children over the age of three.¹⁸ It is also sometimes prescribed for use as treatment for narcolepsy, but ADHD is by far the most common prescription reason.¹⁹

¹¹ Drabs, Julia. (2005). *Drugs for the Treatment of Attention-Deficit Hyperactivity Disorder*. Retrieved November 2, 2007 from faculty.smu.edu/jbuynak/Med%20chem%20ppt.ppt.

¹² ADDERALL XR Medication Information. (2007). *Prescription Information*. Retrieved October 11, 2007 from http://www.adderallxr.com/assets/pdf/prescribing_information.pdf.

¹³ Id.

¹⁴ Id.

¹⁵ ADHD.com (2007). *What is ADHD?* Retrieved October 11, 2007 from http://www.adhd.com/parents/parents_adhd.jsp.

¹⁶ Id.

¹⁷ Adult ADHD. (2007). *Resources for People with ADHD*. Retrieved October 24, 2007 from <http://www.adult-adhd.com/>.

¹⁸ Iannelli, Vincent, M.D. (2005). *Adderall and Adderall XR for ADHD*. Retrieved October 24, 2007 from <http://pediatrics.about.com/od/adhd/a/adderall.htm>.

¹⁹ ADDERALL XR Medication Information. (2007). *Prescription Information*. Retrieved October 11, 2007 from http://www.adderallxr.com/assets/pdf/prescribing_information.pdf.

By nature of its mixture of amphetamine-based salts, Adderall is a stimulant.²⁰ The stimulant effects of Adderall are the reason for its use in ADHD treatment. That is, the drug is used to aid in controlling the attention span and minimizing hyperactivity in children who are diagnosed with ADHD.²¹ The makers of Adderall claim that the drug is thought to restore the balance of the naturally occurring chemicals, dopamine and norepinephrine, available in the brain.²² However, Adderall's stimulant effects create a problematic alternative use for the drug.

B. Adderall Abuse

Because amphetamines are listed as Schedule II Drugs under the Controlled Substance Act²³, and because Adderall contains amphetamines, Adderall is considered to be a Schedule II Drug. As such, it is deemed to have a high potential for abuse.²⁴ And, as is often the case with drugs that have such potential, it is certainly abused.

According to Columbia University Health Services, Adderall can have “speed-like” effects when used by those who do not have ADHD.²⁵ Many adolescents and young adults snort Adderall to get high, believing it to be a “safe alternative” to cocaine – which of course, it is not.²⁶ A 2004 study conducted by “Partnership for a Drug Free America” revealed that one in ten teenagers tried Adderall without a prescription.²⁷ Dangerous side

²⁰ Iannelli, Vincent, M.D. (2005). *Adderall and Adderall XR for ADHD*. Retrieved October 24, 2007 from <http://pediatrics.about.com/od/adhd/a/adderall.htm>.

²¹ Id.

²² ADDERALL XR Medication Information. (2007). *About ADDERALL XR*. Retrieved October 11, 2007 from http://www.adderallxr.com/about_adderallxr/index.asp.

²³ 21 U.S.C. § 812(b)(2)

²⁴ Id.

²⁵ Health Services At Columbia. (2007). *Go Ask Alice!* Retrieved November 2, 2007 from <http://www.goaskalice.columbia.edu/3703.html>.

²⁶ Id.

²⁷ Smith, Emily. (2005). *Oregon Daily Emerald*. *Prescription: Concentration*. Retrieved November 2, 2007 from <http://media.www.dailyemerald.com/media/storage/paper859/news/2005/05/02/News/Prescription.Concentration-1967188.shtml>.

effects from such recreational use of Adderall include: respiratory problems, heart arrhythmia, psychotic episodes, toxic shock, increased aggression, and even death.²⁸

Shire Richwood, the makers of Adderall, acknowledge the drug's addictive nature by way of a warning label on the drug's container that reads: "taking amphetamines for long periods of time may lead to drug addiction".²⁹ Some psychologists consider Adderall (when used recreationally) to be a gateway drug, because it effects the same part of the brain as cocaine and methamphetamine.³⁰

Another form of Adderall abuse that has been occurring at exponentially increasing rates in recent years is the use of Adderall by college students as a "study aid". Because of the stimulant-nature of the drug, many college students find they can concentrate longer, and stay awake for long periods of time. Many fail to realize, however, that abuse of Adderall in this way, without a doctor's prescription, is both extremely dangerous, and illegal. According to a 2002 John Hopkins University study, as many as 20% of college students nationwide have illegally used Adderall to enhance studying.³¹

The easy ability of teens and college students to get their hands on Adderall for abuse purposes seems to be the result of two factors: receiving the drug from a friend

²⁸ Health Services At Columbia. (2007). *Go Ask Alice!* Retrieved November 2, 2007 from <http://www.goaskalice.columbia.edu/3703.html>.

²⁹ Smith, Emily. (2005). *Oregon Daily Emerald*. *Prescription: Concentration*. Retrieved November 2, 2007 from <http://media.www.dailyemerald.com/media/storage/paper859/news/2005/05/02/News/Prescription.Concentration-1967188.shtml>.

³⁰ Id.

³¹ Callahan, Blake. (2004). *The Greyhound*. *Student Adderall Abuse on the rise*. Retrieved November 2, 2007 from <http://media.www.loyolagreyhound.com/media/storage/paper665/news/2004/10/26/News/Student.Adderall.Abuse.On.The.Rise-780786.shtml>.

who does have a prescription³², or convincing a doctor to give them a prescription because they “cannot concentrate”, even though they do not legitimately have ADHD.³³ In fact, health officials at Indiana and Purdue Universities report seeing up to five college students a day that ask for Adderall prescriptions.³⁴ Later on in this paper, we will investigate whether or not there is sufficient evidence to suggest that doctors prescribing Adderall for students who do not have ADHD is a significant problem.

II. INVESTIGATING ADDERALL’S HEALTH RISKS

We already know that Adderall is a stimulant, but what exactly does that mean? Among other effects, stimulants can lead to increased cardiovascular activity. The next step in laying the ground work for an adequate harm-benefit analysis of Adderall, is to investigate the problems and health risks brought on by Adderall. It is appropriate to do this by focusing only on cases where people are using Adderall legally (ie: under a doctor’s prescription). It first makes sense to detail the one-time ban of Adderall in Canada. During the same period of time, the FDA launched an investigation of Adderall in the United States, which will be covered in the second portion of this section.

A. Health Canada Bans Adderall

In the summer of 2004, Shire voluntarily released a report to all drug regulatory agencies across the world that use its Adderall product.³⁵ Shire’s report confirmed 20 sudden deaths worldwide in patients that had been taking Adderall.³⁶ The report also

³² Id.

³³ Hupp, Staci. (2006). *Students Abusing ADHD Drugs*. Retrieved November 2, 2007 from <http://www.dpna.org/5adhddrugs.htm>.

³⁴ Id.

³⁵ Rosack, Jim. (2005). *Psychiatric News*. *Canada Reverses Ban on ADHD Medication*. Retrieved November 2, 2007 from <http://pn.psychiatryonline.org/cgi/content/full/40/19/2>.

³⁶ Id.

confirmed that none of the deaths involved overdose, misuse, or abuse.³⁷ In other words, all 20 deaths involved patients taking Adderall legally, and as prescribed by their doctor. The report also indicated that 14 of the deaths involved children, and the other 6 adults.³⁸ Although none of the 20 deaths occurred in Canada, Canada's Health Products Directorate (Health Canada) – Canada's version of our FDA- announced on February 9, 2005 that it was recalling Adderall from the Canadian market.³⁹ Its decision to ban the use of Adderall in Canada was based solely on the Summer 2004 Shire report.⁴⁰ Health Canada concluded from their review of the report that they had reason for concern due to the serious adverse effects the report had linked to Adderall users.⁴¹

In addition to the 20 sudden deaths, the internal Shire report also indicated 12 instances of stroke from Adderall users that, like the 20 who died, were taking Adderall legally and in accordance with doctor's instructions.⁴² The same report was made available to drug regulatory agencies throughout the world, but Canada was the only country that decided to recall Adderall based on the findings.⁴³

After all Canada Adderall sales were ceased, Shire requested that Health Canada's decision be reviewed by a panel of "independent outside" experts.⁴⁴ Shortly thereafter, Health Canada formed the "Adderall XR New Drug Committee", which included a pediatric cardiologist, a physician specializing in pediatric developmental and behavioral

³⁷ Id.

³⁸ Id.

³⁹ Lamb, Tom. (2005). *Drug Injury Watch*. *Adderall: Health Canada Allows Shire's ADHD Drug Back on Market*. Retrieved November 2, 2007 from http://www.drug-injury.com/druginjurycom/2005/09/adderall_health.html.

⁴⁰ Id.

⁴¹ Rosack, Jim. (2005). *Psychiatric News*. *Canada Reverses Ban on ADHD Medication*. Retrieved November 2, 2007 from <http://pn.psychiatryonline.org/cgi/content/full/40/19/2>.

⁴² Id.

⁴³ Id.

⁴⁴ Id.

disorders, and a pharmacoepidemiologist.⁴⁵ The committee reviewed a substantial amount of documents that were supplied both by Shire, and by Health Canada.⁴⁶ Ultimately, when the committee concluded its investigation, they found that "an increased risk of sudden cardiac death and/or stroke with Adderall XR compared to alternate active treatments has not been proven."⁴⁷ Although the committee also found that "such an increase [in risk of sudden cardiac death associated specifically with Adderall XR use] has not been ruled out due to limitations in the data currently available for analysis", it still recommended that Adderall be placed back on the market in Canada, so long as certain steps were followed by Shire, and by Health Canada.⁴⁸

Although most of these steps that Shire was to take before Health Canada would allow Adderall back on the market were procedural in nature and had to do with warning label restrictions, one of them was key in terms of what this paper is arguing. That is, the committee recommended that Health Canada seek expert medical consultation advice in an effort to identify what specific family history or other "cautions" might lead individuals to be at an increased Adderall-related health risk.⁴⁹ The committee recommended this in hopes that it would provide for a more effective harm-benefit analysis of Adderall- something this paper will soon argue needs to be done at current day. Specifically, the committee thought such expert consultation would allow for better "assessment of benefit versus risk for individual patients".⁵⁰

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ Id.

⁴⁹ Id.

⁵⁰ Id.

On August 24, 2005, six months after the Adderall recall, Health Canada officially announced that it was allowing re-introduction of Adderall onto the Canadian market.⁵¹ Such a recall reversal is not common in Canada, especially in such a short period of time.⁵² That is, however, how it remains today. Adderall is available for use in Canada, and ever other country it normally was used in.

B. The FDA Investigation and cases of American Adderall-related death

As mentioned, the Summer 2004 Shire report was not only made available to Canada, but rather to all countries using Adderall, including the United States. The FDA reviewed the exact same report that Health Canada did, but decided to take a very different course of action. FDA's findings from the Shire report data were that "the rate of sudden deaths and strokes in Adderall XR users was not significantly higher than the background rate".⁵³ The background rate refers to the average incidence rate of such events expected to occur in people naturally (ie: by not taking the drug in question).⁵⁴

The FDA Adderall investigation was conducted entirely based upon their MedWatch program, which relies on voluntary reporting from the drug companies.⁵⁵ The FDA has admitted in the past that such MedWatch reporting generally only accounts for about 1% of all such occurrences of harm from a drug.⁵⁶ Furthermore, according to Dr.

⁵¹ Lamb, Tom. (2005). *Drug Injury Watch. Adderall: Health Canada Allows Shire's ADHD Drug Back on Market*. Retrieved November 2, 2007 from http://www.drug-injury.com/druginjurycom/2005/09/adderall_health.html.

⁵² Rosack, Jim. (2005). *Psychiatric News. Canada Reverses Ban on ADHD Medication*. Retrieved November 2, 2007 from <http://pn.psychiatryonline.org/cgi/content/full/40/19/2>.

⁵³ Lamb, Tom. (2005). *Drug Injury Watch. Adderall: Health Canada Allows Shire's ADHD Drug Back on Market*. Retrieved November 2, 2007 from http://www.drug-injury.com/druginjurycom/2005/09/adderall_health.html.

⁵⁴ Id.

⁵⁵ Baughman, Fred Dr. (2006). *NewsTarget. Neurologist Dr. Fred Baughman talks about the fraud of ADHD and the poisoning of US Children*. Retrieved November 21, 2007 from <http://www.newstarget.com/020227.html>.

⁵⁶ Id.

Fred Baughman, the FDA had been lobbying Health Canada behind the scenes in 2005 to not take Adderall off the market.⁵⁷

The problem, however, has never entirely gone away, and additional deaths have been reported. While the FDA has not confirmed these additional deaths to be Adderall-related, they did issue a request on January 6, 2006.⁵⁸ According to Medical News Today, this January 2006 FDA request involved asking its Drug Safety and Risk Management advisory committee to examine ways of studying factors that make Adderall-users at risk of cardiovascular problems.⁵⁹ This seemed to be a very similar request to the one that the independent committee in Canada recommended upon Health Canada – more than six months earlier.

Adderall-related health complications have also spurred a plethora of law suits in the United States. In *Zammit v. Shire US, Inc.*, a Michigan case, the plaintiff alleged that his use of Adderall, which he obtained by doctor's prescription in 2002, caused him to experience "a pounding heartbeat, tightness in his chest, palpitations, and nausea."⁶⁰ The plaintiff ultimately suffered a heart attack, and brought a product liability claim against Shire in the *Zammit* case.⁶¹ However, the court found that Shire was entitled to summary judgment based on Michigan statutory immunity, and the case was promptly dismissed.⁶² Unless the plaintiff can show that the FDA acted in a fraudulent manner in approving Adderall, *Zammit* makes it clear that Shire has immunity protecting itself from product liability claims.

⁵⁷ Id.

⁵⁸ Pringle, Evelyn. (2006). *Adderall's Rollercoaster Year*. Retrieved November 21, 2007 from http://www.lawyersandsettlements.com/articles/00071/adderall_investigation.html.

⁵⁹ Id.

⁶⁰ *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 763 (D. Mich. 2006)

⁶¹ Id.

⁶² Id.

The remaining legal avenue for recourse in Adderall injury and death cases seems to be to sue the doctor prescribing it - if they can prove that such prescription was negligent. In *Brannan v. Northwest Permanente, P.C.*⁶³, that is exactly what the plaintiffs alleged. Specifically, the plaintiffs asserted that the doctor violated the standard of care by failing to wean the plaintiff off habit forming drugs, and by prescribing Adderall in the first place to somebody who has shown a predisposition to addiction of habit-forming drugs in the past.⁶⁴ In addition, the plaintiff alleges that the doctor broke the care of duty in prescribing the Adderall because she: drank a pot of coffee each morning, had a family history of hypertension, and that the doctor failed to prescribe the lowest possible dosage and failed to properly treat a mental health disorder.⁶⁵ In *Brannan*, the court denied the defendant's motion for summary judgment finding that there was a genuine dispute of material fact with respect to the standard of care and causation.⁶⁶ Although the case is still being litigated, it at least serves as one possible route for victims suffering from Adderall-related injuries to seek recourse. But is that enough? And should Adderall even be on the market today?

III. THE HARM-BENEFIT ANALYSIS

Now that we have established what has been done, it is time to determine what *should* be done. In analyzing the dilemma of whether or not Adderall should ultimately be on the market in the United States, we examine a simple question: do the benefits gained by using Adderall to treat ADHD in children outweigh the associated harms?

⁶³ *Brannan v. Northwest Permanente, P.C.*, 2006 U.S. Dist. LEXIS 72429 (D. Wash. 2006)

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

A. The Case Against Adderall Use

As Neurologist Dr. Fred Baughman puts it, the exponential increase in the diagnosis of ADHD in America's youth over the past decade is nothing but a fraud.⁶⁷ Baughman takes issue, not only with the use of Adderall to treat ADHD, but also with the idea of considering ADHD as a disease that needs treatment in the first place.⁶⁸ He contends that Adderall is being used at alarmingly high rates, and is actually "poisoning the children of the US".⁶⁹ Baughman argues that the symptoms developed at a 1987 conference of the American Psychiatric Association, for which they recommend doctors use in diagnosing ADHD, were written in such a manner that "half the population" would have ADHD.⁷⁰ He attributes this to nothing more than a marketing scheme that the drug companies, such as Shire, engage in to sell more product.⁷¹

Baughman certainly has a point. To put his claim to a test, I went to Adderall's own website. Very prominently displayed on the home page was a link asking you to click to see if you "might have signs or symptoms of ADHD".⁷² They had separate categories to click on for children, teens, and even for adults.⁷³ In looking over the symptoms for adults, I noticed Adderall's website marketed them in a way that suggestively asks questions – as opposed to simply listing the symptoms.⁷⁴ Among them were: Do you have difficulty following instructions? Do you find yourself losing or

⁶⁷ Baughman, Fred Dr. (2006). NewsTarget. *Neurologist Dr. Fred Baughman talks about the fraud of ADHD and the poisoning of US Children*. Retrieved November 21, 2007 from <http://www.newstarget.com/020227.html>.

⁶⁸ Id.

⁶⁹ Id.

⁷⁰ Id.

⁷¹ Id.

⁷² ADDERALL XR Signs and Symptoms. (2007). *About ADDERALL XR*. Retrieved October 11, 2007 from http://www.adderallxr.com/childhood_adhd/sign-symptom/index.asp.

⁷³ Id.

⁷⁴ Id.

forgetting things often? Do you experience difficulty waiting in line or for your turn? Do you find that you frequently "wander off" mentally?⁷⁵ There were a number of others, but my initial reaction was that they seemed to be very common problems that most Americans probably consider themselves to have from time to time. So, to further explore my curiosity, I decided to take the "Screening Tool" which was basically a quiz with more questions similar to the ones above.⁷⁶ In confirming my suspicions, the results sure enough came back that "I may have ADHD, and should consult my doctor to see if Adderall is right for me".

I think this story about the quizzes on Adderall's website, their clear attempt at making a diagnosis for you, and the way in which they are advertised, go a long way in backing Dr. Baughman's theory that the use of Adderall to "treat" ADHD is nothing more than a massive advertising scheme to make profits.

It is important to re-affirm that the purpose of this paper is not to discredit the existence of ADHD, but rather to examine whether the use of Adderall is a good idea. However, the first debate of ADHD's legitimacy obviously plays a large role in whether or not Adderall should be used to treat it. After all, if there is no disease, there is no need for a treatment right? Shire is obviously a company trying to make a lot of money, so it makes sense for them to market their products, including Adderall, in a manner which helps their sales. But does it really help society?

Let's take another step, and actually concede Dr. Baughman's argument that ADHD is a phony disorder that was spun out of control by drug companies to make a

⁷⁵ Id.

⁷⁶ Id.

profit.⁷⁷ In doing so, we take the stance that ADHD is a legitimate and serious disorder. If this is the case, the argument becomes whether children are better off facing those symptoms without treatment, or subjecting themselves to the risks of Adderall-related health problems and addiction. I can confidently state that, if I were to have a child diagnosed with ADHD, I would much rather him or her suffer from the symptoms as described on Adderall's website⁷⁸, than the effects of the drug Adderall.

Beyond the sudden deaths, heart attacks, strokes, and risk of addiction, there are a wide range of other Adderall side effects- ones that manufacturer Shire acknowledge.⁷⁹ These include, but are not limited to: headache, decreased appetite, weight loss, insomnia, dry mouth, dizziness, increased heart rate, and mood swings.⁸⁰ Let's make one more hypothetical assumption for the sake of argument.

This assumption is that the FDA was right, and the 20 instances of sudden death among Adderall users were simply a result of the law of averages, and in no way shows that Adderall is a dangerous drug. To that, I argue that I still would prefer my son or daughter to be distracted and hyper over being hungry because they couldn't eat at dinner, or tired because they couldn't sleep at night. When weighing the risk of the effects of Adderall use against the benefits the drug provides, I clearly think the benefits are outweighed by the risks. But let's look at the other side of the story, and see what they think.

⁷⁷ Baughman, Fred Dr. (2006). *NewsTarget. Neurologist Dr. Fred Baughman talks about the fraud of ADHD and the poisoning of US Children*. Retrieved November 21, 2007 from <http://www.newstarget.com/020227.html>.

⁷⁸ ADDERALL XR Signs and Symptoms. (2007). *About ADDERALL XR*. Retrieved October 11, 2007 from http://www.adderallxr.com/childhood_adhd/sign-symptom/index.asp.

⁷⁹ Id.

⁸⁰ Id.

B. The Case For Adderall Use (And why it is wrong)

There certainly are those out there who take the position that Adderall serves a great purpose to American children. In fact, judging by the millions of Adderall prescriptions given to children, it appears that there are quite a number of doctors who take this view. It is probably safe to say that the majority of them do. Those who defend Adderall's use are quick to point out that the FDA determined that the deaths associated with Adderall were not statistically significant enough to warrant a recall. In fact, the FDA ruled that the numbers weren't any greater than the likelihood of an average child not taking Adderall suddenly dying.

While that might certainly be the case, it is also the case that the FDA has acknowledged that Adderall does pose cardiovascular-related threats to certain children. The FDA's January 6, 2006 request to further study the factors that cause higher risk in certain children is evidence of this.⁸¹ Is it worth rolling the dice, and seeing if your child is one of those that has an increased risk? Or is it better to refrain from Adderall use until we know for sure? Even if we did know for sure, do the side effects leave the children worse off than the benefits?

In November 1998, the National Institutes of Health hosted a conference of non-advocate, non-federal experts with the goal of establishing a professional consensus on a number of questions surrounding ADHD.⁸² A consensus panel at the conference concluded that "ADHD is a commonly diagnosed behavioral disorder of childhood that

⁸¹ Pringle, Evelyn. (2006). *Adderall's Rollercoaster Year*. Retrieved November 21, 2007 from http://www.lawyersandsettlements.com/articles/00071/adderall_investigation.html.

⁸² PBS. (2007). *Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder*. Retrieved November 21, 2007 from <http://www.pbs.org/wgbh/pages/frontline/shows/medicating/adhd/nih.html>.

represents a costly major public health problem.”⁸³ Specifically, the panel highlighted the problems as pertaining to psychological development.⁸⁴ The panel agreed that children with ADHD have “pronounced impairments and can experience long-term adverse effects on academic performance, vocational success, and social-emotional development which have a profound impact on individuals, families, schools, and society.”⁸⁵ Although the panel did reach a consensus, there was also strong criticism. While many in the camp that support Adderall use (even Shire themselves) point to this study as evidence that ADHD and its symptoms and effects are real and have a severe impact on the lives of children, I find it prudent to place emphasis on the panel’s final conclusion. “Finally, after years of clinical research and experience with ADHD, our knowledge about the cause or causes of ADHD remains largely speculative. Consequently, we have no documented strategies for the prevention of ADHD.”⁸⁶

If the cause is speculative, and nobody has developed an agreed upon strategy for prevention, then why are so many so quick to jump to the conclusion of a treatment? Maybe it is all about money, after all.

IV. WHERE DO WE GO FROM HERE?

It is clear that Adderall has side effects that simply are not good for children. Nobody wants to become addicted, lose sleep, or fail to get a healthy diet due to loss of appetite. It is also clear that certain children are at higher risks than others for serious cardiovascular problems stemming from Adderall use. One more thing we know is clear

⁸³ Id.

⁸⁴ Id.

⁸⁵ Id.

⁸⁶ Id.

is that the FDA has approved the use of the drug, and it will likely not recall it based on the nature of its current approval process. So, where do we go from here?

A. The Problem With the FDA's drug approval process

The FDA relies on the MedWatch program as a means of investigating problems caused by its approved drugs. This system relies heavily on self-policing on behalf of the drug industry.⁸⁷ It is sort of like having the fox guard the hen house.⁸⁸ Is this really the best way to regulate drugs? Often times the result of this process is that drugs get approved, and we wait to see if there is sufficient evidence of problems later on. Perhaps the burden should be more strongly shifted to the drug companies to establish that there aren't any problems prior to approval?

Another question that comes to light is how such a difference in response to the same Shire study was possible. Why is it that Health Canada decided Adderall was not safe in their country, but the FDA decided that the same drug was perfectly fine? One cynical but very plausible answer to this is the large role that drug companies play in the process. The drug companies are so powerful here that they have serious pull with the FDA. In fact, many, such as Shire, even fund FDA research. Canada's universal health care system makes it much less lucrative for the drug companies to establish lobbying efforts as strong as their American lobby.

This makes it easier for Canada to make a reasonable and unbiased determination when it comes to evaluating a drug's safety. Not to say that the FDA cannot do this, but

⁸⁷ Hasslberger, Sepp. (2005). *Adderall Deaths, Canada Suspends ADHD Drug, FDA Disagrees*. Retrieved November 21, 2007 from http://www.newmediaexplorer.org/sepp/2005/02/14/adderall_deaths_canada_suspends_adhd_drug_fda_disagrees.htm.

⁸⁸ Id.

perhaps it would be easier if they didn't have the drug companies looking over their shoulder?

In addition, as we saw from the *Zammit* decision, it is very difficult to successfully sue drug companies in the United States. If drug companies have that kind of insurance and protection against product liability claims, their incentive to go out of their way to ensure safety certainly drops a few levels.

B. A Plan of Action

In all fairness, it must be mentioned that the FDA relies upon the self-reporting MedWatch program because of its limited resources. It would not be possible in a country of our size to send FDA officers to every doctor's office to investigate every problem. However, it certainly is possible to implement a program that at least has a little more balance, and less drug company influence.

My first proposal to start creating more of a balance actually does not even have to do with reforms from within the FDA. Rather, it is premised on the idea of tort reform. It is unacceptable for so many states, Michigan included, to have statutes barring drug companies from product liability claims. These laws are clearly aimed at shifting a huge burden away from the drug company, and onto the doctor that uses their product, and even the party injured by their product. This is exactly what happened in the *Zammit* case.

Drug companies would have a greatly increased incentive to engage in much more testing and safeguarding of their products before rushing them to the market if they had a realistic worry about the possibility of big lawsuits. This isn't to say they don't face that threat now, because they do in certain situations. However, the many statutes used

out their similar to the one in *Zammitt* do a great job of minimizing that risk for the drug companies. By engaging in reform to shift that burden back to the drug companies, we will give them incentive to better test their products. Strong statutes barring product liability claims against drug companies, like the *Zammitt* statute, need to be repealed.

My second proposal does involve reforms within the FDA. This proposal is not to abandon the MedWatch program altogether, but rather to implement both a more rigorous approval process before the drug is allowed on the market in the first place, and a beefed up “policing agency” of the FDA.

The new rigorous approval process would involve a mandatory 1-year probationary period. That is, for all new drugs that do get through the process and become FDA-approved, they are “conditionally approved” for a one year probation period. During this time, there is an automatic heightened alert for the new drugs. The standard for recall would be much lower on the probationary drugs than in other drugs. If Adderall was such a probationary drug under my proposal during the time the Shire study came out, the 20 deaths in the study would certainly be enough to meet the burden of recall. In addition to the 1-year mandatory probationary period for newly approved drugs, the beefed up approval process would also involve a much stronger burden upon the drug company to prove safety, as opposed to a burden on the FDA to prove danger.

The policing agency element of my proposal first involves implementing much larger fines for drug companies when they violate FDA regulations. The idea is to use the significantly increased fine revenue to fund the extended police power of the FDA. Doing so might also encourage the drug companies to become less involved with the FDA-side of the research for financial reasons. This would be a good thing, because it would start to

separate the drug companies from the FDA – which is the ultimate light at the end of the tunnel.

It certainly will take a lot of work, and it is unrealistic to say that a few simple proposals, such as the ones I have explained above, will solve the problem. But if the FDA were to at least start taking steps in that direction, there is a possibility that we could someday reach that ultimate goal.

CONCLUSION

Adderall is a great example of the need for reforms in how the FDA goes about approving and regulating drugs in the United States. It also showcases the need for tort reform dealing with product liability claims against drug companies. Hopefully a drug like Adderall can serve as a catalyst for reform, before some other drug comes in, and does even more harm. If we aren't careful, it only will be a matter of time before the drug companies completely control the FDA. Then again, maybe they already do.