

## NOTE

### Off-Label: Combating the Dangerous Overprescription of Amphetamines to Children

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#### ABSTRACT

*A disturbing trend is emerging in pediatric medicine. Physicians are now prescribing Adderall, an amphetamine-based stimulant intended to treat attention deficit hyperactivity disorder (“ADHD”), to healthy children. Physicians are prescribing the drug to enhance academic performance. This practice can harm otherwise healthy children. It also helps divert more Adderall into the black market for amphetamines that pervades middle school, high school, and college campuses.*

*Adderall and other amphetamine-based medications have a high potential for abuse and may lead to physical and psychological dependence. Other adverse effects of these drugs include weight loss, insomnia, psychosis, and even sudden death in some children. Furthermore, the long-term effects of these amphetamines on children have not been studied and some physicians worry that the drugs may hinder brain development.*

*The current legal framework governing prescription drugs has failed to protect healthy children from the dangerous effects of unneeded amphetamines. The Controlled Substances Act classifies amphetamines as Schedule II drugs, and thus prohibits an individual from obtaining them without a written prescription. The Act, however, gives physicians wide latitude to prescribe controlled substances for any “legitimate medical purpose.” In addition, the*

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*Act does not require physicians, when prescribing a controlled substance, to report their diagnosis or medical purpose before writing the prescription. The law thus does little to deter physicians from prescribing amphetamine-based ADHD medication to children without ADHD.*

*States also have broad authority to regulate physicians and the prescription of medications, but current state laws address broad categories of drugs and are not finely tailored to prevent the off-label prescription of amphetamines to minors. Although some states have attempted to target controlled-substance abuse, most schemes lack an effective enforcement mechanism to find and punish physicians and pharmacies that violate the law.*

*This Note proposes a model state statute that will protect minors from the hazards of overprescribed amphetamine-based medications by (1) requiring prescribers to certify a diagnosis of ADHD before prescribing an amphetamine-based ADHD medication to a minor, (2) requiring the state to maintain a prescription-monitoring database to track off-label prescriptions, and (3) mandating minimum penalties for those who violate the statute.*

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## INTRODUCTION

“We’ve decided as a society that it’s too expensive to modify the kid’s environment. So we have to modify the kid.”<sup>1</sup> Those are the words of Dr. Michael Anderson, a pediatrician in Canton, Georgia whose interview appeared on the front page of the *New York Times*.<sup>2</sup> Dr. Anderson believes that the real problem facing troubled school children is low grades stemming from unsatisfactory schools.<sup>3</sup> His solution for this problem: Adderall.<sup>4</sup> Dr. Anderson prescribes Adderall to his low-income patients not to treat attention deficit hyperactivity disorder (“ADHD”), which he believes is “made up,” but to improve their academic performance.<sup>5</sup> He does not prescribe Adderall to patients “who are getting A’s and B’s,” he prescribes it to children with lower grades whose families cannot afford tutoring or other methods of assistance.<sup>6</sup> Dr. Anderson may be motivated by social justice and a desire to counterbalance income inequality, but other physicians warn of the dangers of prescribing stimulants to children who do not need them. Dr. Nancy Rappaport, for example, argues that treating all children who exhibit academic or behavioral troubles with stimulants can be harmful.<sup>7</sup> “The child may have other problems—trauma, dyslexia, or mental illness”—that could go undiagnosed and untreated.<sup>8</sup> Furthermore, Adderall can have serious adverse effects including insomnia, slowed growth, aggression, hallucinations, and mania.<sup>9</sup>

Dr. Anderson is not the only physician using Adderall for off-label<sup>10</sup> purposes.<sup>11</sup> Dr. William Graf is a pediatric neurologist who

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<sup>1</sup> Alan Schwarz, *Attention Disorder or Not, Pills to Help in School*, N.Y. TIMES, Oct. 9, 2012, at A1 [hereinafter Schwarz, *Pills to Help in School*].

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Nancy Rappaport, *The Art of ADHD: Can We Free Children from ‘Chemical Straightjackets’?*, HUFFINGTON POST (Oct. 12, 2012, 5:50 PM), [http://www.huffingtonpost.com/nancy-rappaport/the-art-of-adhd-can-we-fr\\_b\\_1961744.html](http://www.huffingtonpost.com/nancy-rappaport/the-art-of-adhd-can-we-fr_b_1961744.html).

<sup>8</sup> *Id.*

<sup>9</sup> ADDERALL (CII) 11–12 (rev. Mar. 2007) [hereinafter ADDERALL LABEL], available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2007/011522s040lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/011522s040lbl.pdf).

<sup>10</sup> “Off-label” refers to the legal prescription of a drug for a purpose other than one for which the drug has been approved by the FDA. Kelli Miller, *Off-Label Drug Use: What You Need to Know*, WEBMD, <http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know> (last visited Dec. 31, 2013). This includes using a drug to treat a different condition or a different segment of the population from the one for which the drug was approved. *See id.*

<sup>11</sup> Adderall is only indicated for the treatment of ADHD and narcolepsy. *See* ADDERALL

treats low-income patients in New Haven, Connecticut.<sup>12</sup> He advocates allowing parents of children without ADHD to choose whether to give them Adderall.<sup>13</sup> Dr. Graf believes physicians can ethically prescribe Adderall to these children as long as side effects are monitored, though he admits “we still don’t know how these drugs biologically affect the developing brain.”<sup>14</sup> Likewise, pediatric endocrinologist Dr. Fuad Ziai has prescribed Adderall to about 800 children and adolescents for an off-label purpose.<sup>15</sup> He prescribes it for weight loss, a practice other pediatricians find “morally and medically questionable.”<sup>16</sup>

Some physicians also prescribe Adderall to children who may not need it in response to pressure from patients and their parents. High school students “fake symptoms to their parents and doctors to get prescriptions” for Adderall, hoping it will help them succeed in school and gain a competitive advantage.<sup>17</sup> Parents, who may have an even greater influence on the physician’s decision, often “push as hard for prescriptions as their children [do].”<sup>18</sup> One mother called her daughter’s doctor and obtained a prescription for Adderall without the physician ever examining or speaking to the girl herself.<sup>19</sup>

Other physicians and psychologists are concerned about the ease with which children are prescribed Adderall and other amphetamines: “Children have prefrontal cortexes that are not fully developed, and we’re changing the chemistry of the brain. That’s what these drugs do. It’s one thing if you have a real deficiency—the medicine is really important to those people—but not if your deficiency is not getting into Brown.”<sup>20</sup>

Both federal and state laws regulate the prescription of controlled substances such as Adderall. Unlike other controlled substances,

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LABEL, *supra* note 9, at 5. Because narcolepsy is rarely a problem for children, this Note will focus on the prescription of Adderall to children with and without ADHD. *See id.*

<sup>12</sup> Schwarz, *Pills to Help in School*, *supra* note 1.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *See* Elizabeth Cohen, *ADHD Drug Use for Youth Obesity Raises Ethical Questions*, CNN, Mar. 22, 2007, <http://www.cnn.com/2007/HEALTH/03/21/vs.adderall/index.html?iref=allsearch>.

<sup>16</sup> *Id.*

<sup>17</sup> Alan Schwarz, *Risky Rise of the Good-Grade Pill*, N.Y. TIMES, June 10, 2012, at A1 [hereinafter Schwarz, *Risky Rise*].

<sup>18</sup> *Id.*

<sup>19</sup> *See* Kendra Nichols, *The Other Performance-Enhancing Drugs*, CHRON. HIGHER EDUC., Dec. 17, 2004, at A41.

<sup>20</sup> Schwarz, *Risky Rise*, *supra* note 17.

however, Adderall is widely prescribed to minors for off-label purposes despite a lack of research studying its long-term effects on children.<sup>21</sup> Stricter regulation of Adderall prescription is necessary to protect healthy children from the drug's dangerous potential side effects.

This Note argues that current prescription drug laws are insufficient to protect the health and welfare of minors in light of the current trend towards overprescription<sup>22</sup> of amphetamine-based ADHD medications like Adderall.<sup>23</sup> To solve this problem, this Note proposes a model state statute with three main components. First, the statute would require, with some exceptions, that each physician sign a certification stating that they have made a positive diagnosis of ADHD or narcolepsy for each minor patient to whom they prescribe an amphetamine-based ADHD medication. Second, the statute would require the state to establish a database to collect information on the prescription of controlled substances within the state. The state board or agency responsible for the database must create an enforcement panel to specifically track the prescription of amphetamine-based ADHD medications to minors and investigate instances of potential abuse. Third, the statute would mandate minimum penalties for physicians and pharmacists who prescribe and dispense amphetamine-based ADHD medications in violation of the statute.

Part One of this Note provides a brief overview of the use of Adderall in the United States. This Part also explains the negative physical, psychological, and societal effects of Adderall and other amphetamine-based ADHD medications, especially when prescribed to minors without ADHD. Part Two summarizes federal and state law regulating the prescription of controlled substances. This Part explains why existing laws—both state and federal—are insufficient to combat the problem of off-label prescription of Adderall to minors. Part Three presents the model state statute and refutes the principal counterarguments to the statute.

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<sup>21</sup> See Cohen, *supra* note 15.

<sup>22</sup> "Overprescription" is a term used to describe a drug that is prescribed more often than necessary or in greater doses than necessary. See THE NEW OXFORD AMERICAN DICTIONARY 1220 (2001). In this Note, it is used as an umbrella term that encompasses off-label prescription.

<sup>23</sup> The arguments presented in this Note apply to all amphetamine-based medications indicated to treat ADHD. This includes Adderall, Vyvanse, Dextrostat, Dexedrine, and their generic equivalents. This Note uses the brand name "Adderall" for simplicity because Adderall appears to be the most popular of these medications.

## I. ADDERALL USE AND ITS ADVERSE CONSEQUENCES

Both on- and off-label use of Adderall in the United States has surged in recent years. Yet off-label use of Adderall and other amphetamine-based ADHD medications can have dangerous medical and social side effects. This Part describes both the surge in Adderall use and the deleterious effects that off-label use can have on children and adolescents.

### A. *Adderall Prescription and Use in the United States*

The American Psychiatric Association estimates that only five percent of school-aged children have ADHD.<sup>24</sup> But in 2007, Adderall and two other ADHD medications ranked among the top five drugs prescribed to children ages seventeen years and younger.<sup>25</sup> From 2007 to 2008, ADHD stimulants were prescribed more often than any other type of medication to children ages twelve to nineteen.<sup>26</sup> Another study reported that the prescription of ADHD medications to children increased forty-six percent between 2002 and 2010.<sup>27</sup> Adderall was the second most prescribed ADHD medication in these years.<sup>28</sup> Adderall sales increased 3136% from 2002 to 2006,<sup>29</sup> and over eighteen million total prescriptions for Adderall were issued in 2010 alone.<sup>30</sup>

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<sup>24</sup> *Attention-Deficit/Hyperactive Disorder: Data & Statistics*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/ncbddd/adhd/data.html> (last visited Dec. 31, 2013). The Centers for Disease Control estimate that 8.4% of children ages 3–17 were diagnosed with ADHD in 2013. *Fast Stats: Attention Deficit Hyperactivity Disorder*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/adhd.htm> (last updated November 21, 2013).

<sup>25</sup> Press Release, Agency for Healthcare Research and Quality, AHRQ and FDA to Collaborate in Largest Study Ever of Possible Heart Risks with ADHD Medications (Sept. 17, 2007), available at <http://archive.ahrq.gov/news/press/pr2007/adhdmedpr.htm>.

<sup>26</sup> QUIPING GU, ET AL., PRESCRIPTION DRUG USE CONTINUES TO INCREASE: U.S. PRESCRIPTION DRUG DATA FOR 2007–2008, at 5 (2010), available at <http://www.cdc.gov/nchs/data/databriefs/db42.pdf>.

<sup>27</sup> Grace Chai et al., *Trends of Outpatient Prescription Drug Utilization in U.S. Children, 2002–2010*, 130 PEDIATRICS 23, 23 (2012).

<sup>28</sup> *Id.* at 26.

<sup>29</sup> Joel Garreau, *A Dose of Genius*, WASH. POST, June 11, 2006, at D1.

<sup>30</sup> Toni Clarke, *Insight: Shortage of ADHD Drug Adderall Seen Persisting*, REUTERS, Jan. 1, 2012, <http://www.reuters.com/article/2012/01/01/us-adhd-adderall-shortage-idUSTRE80009E20120101>. In 2010, there were approximately 74.1 million children (under eighteen years of age) living in the United States. *Child Population: Number of Children (in Millions) Ages 0–17 in the United States by Age, 1950–2012, and Projected 2013–2050*, CHILDSTATS.GOV, <http://www.childstats.gov/americaschildren/tables/pop1.asp> (last visited Dec. 31, 2013).

Although part of this surge in Adderall prescriptions is attributable to an increase in the number of children diagnosed with ADHD,<sup>31</sup> it can also be explained in large part by the increasing prevalence of off-label prescription. One study of prescriptions issued to teenagers over a six year period found that in fourteen to twenty-six percent of doctor's appointments resulting in a prescription for a psychotropic drug (a category that includes amphetamine-based ADHD medications), the physician made no mental health diagnosis.<sup>32</sup> Dr. Keith Conners, a professor of psychiatry and behavioral sciences at Duke University, explains that to diagnose a child with ADHD, physicians must take "a detailed life history" and ask parents or teachers about the child's behavior.<sup>33</sup> Many physicians have abandoned these standard practices—"exams are generally cursory, prescriptions are freely given, even as trial runs 'just in case,' and justifications for treatment vary widely."<sup>34</sup> Dr. Charles Parker agrees: "We have a significant travesty being done in this country with how the diagnosis is being made and the meds are being administered . . . I think it's an abnegation of trust."<sup>35</sup> Psychiatrist Bruce J. Levin calls "[t]his approach to care . . . one small step for the medical-insurance-pharmaceutical industrial complex and one giant tragedy for mankind."<sup>36</sup>

Parents hoping to help their children succeed in competitive schools may exacerbate the problem by pressuring physicians into prescribing Adderall,<sup>37</sup> now commonly referred to as the "study drug."<sup>38</sup> Likewise, teachers faced with unruly children have learned "about the wonders of medication."<sup>39</sup> One study found that "over 50% of diagnoses of ADD/ADHD were initially made by teachers and that doctors seemed more or less to rubber-stamp such diagnoses."<sup>40</sup> Certain physicians are even referred to as "Ritalin mills" because of their will-

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<sup>31</sup> LARA J. AKINBAMI ET AL., ATTENTION DEFICIT HYPERACTIVITY DISORDER AMONG CHILDREN AGED 5–17 YEARS IN THE UNITED STATES, 1998–2009, at 1 (2011).

<sup>32</sup> Cindy Parks Thomas et al., *Trends in the Use of Psychotropic Medications Among Adolescents, 1994 to 2001*, 57 PSYCHIATRIC SERVICES 63, 66 (2006).

<sup>33</sup> Alan Schwarz, *Drowned in a Stream of Prescriptions*, N.Y. TIMES, Feb 3, 2013, at A1 [hereinafter Schwarz, *Stream of Prescriptions*].

<sup>34</sup> Marianne Kuzujanakis, Letter to the Editor, *A Tale of Adderall Abuse and Suicide*, N.Y. TIMES, Feb. 5, 2013, at A22.

<sup>35</sup> Schwarz, *Stream of Prescriptions*, *supra* note 33.

<sup>36</sup> Bruce J. Levin, Letter to the Editor, *A Tale of Adderall Abuse and Suicide*, N.Y. TIMES, Feb. 5, 2013, at A22.

<sup>37</sup> Laura L. Finley, *Our Drugs Are Better Than Yours: Schools and Their Hypocrisy Regarding Drug Use*, 10 CONTEMP. JUST. REV. 365, 373 (2007).

<sup>38</sup> Schwarz, *Risky Rise*, *supra* note 17.

<sup>39</sup> Finley, *supra* note 37, at 374.

<sup>40</sup> *Id.*

ingness to hand out ADHD medications like Ritalin and Adderall on demand.<sup>41</sup> These statistical studies and personal anecdotes indicate that physicians are prescribing far more Adderall than is necessary to treat children with ADHD.

*B. Adderall's Harmful Effects: Reasons to Limit Its Use*

*1. Medical Reasons to Limit the Prescription of Adderall to Children*

Adderall is a psychotropic stimulant made from amphetamine and dextroamphetamine.<sup>42</sup> Adderall XR is the same medication in an extended-release form.<sup>43</sup> Although Adderall is indicated to treat ADHD and narcolepsy,<sup>44</sup> Adderall XR is indicated to treat only ADHD.<sup>45</sup> The FDA reviewed no other uses when it approved the drug. Adderall's FDA-required label explains that its effectiveness for long-term use was not evaluated in controlled trials.<sup>46</sup> Furthermore, the label states that the long-term effects of amphetamines such as Adderall on children "have not been well established."<sup>47</sup>

The known side effects of Adderall can be serious, even fatal.<sup>48</sup> Common side effects include loss of appetite, insomnia, abdominal pain, emotional lability, vomiting, nervousness, and nausea.<sup>49</sup> More

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<sup>41</sup> *Id.* at 369.

<sup>42</sup> ADDERALL LABEL, *supra* note 9, at 3.

<sup>43</sup> James Pavisian, *The Case For Human Ingenuity: How Adderall Has Sullied the Game*, 48 WASHBURN L.J. 175, 178 (2008).

<sup>44</sup> ADDERALL LABEL, *supra* note 9, at 5. Dexedrine Spansule and Dextrostat are also indicated to treat ADHD and narcolepsy. DEXEDRINE (DEXTROAMPHETAMINE SULFATE) SPANSULE SUSTAINED RELEASE CAPSULES (CII) 1-2 (rev. May 2013) [hereinafter DEXEDRINE SPANSULE LABEL], available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/017078s046lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/017078s046lbl.pdf); DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE TABLETS (CII) (2013), available at <http://www.accessdata.fda.gov/spl/data/9d7719c8-2666-4e47-a953-656488d9e11b/9d7719c8-2666-4e47-a953-656488d9e11b.xml>.

<sup>45</sup> ADDERALL XR (MIXED SALTS OF A SINGLE-ENTITY AMPHETAMINE PRODUCT) DEXTROAMPHETAMINE SULFATE, DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, AMPHETAMINE SULFATE CAPSULES, CII 3 (rev. June 2013) [hereinafter ADDERALL XR LABEL], available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/021303s024lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021303s024lbl.pdf). Vyvanse is also indicated to treat only ADHD. VYVANSE (LISDEXAMFETAMINE DIMESYLATE) CAPSULES, FOR ORAL USE, CII 3 (rev. June 2013) [hereinafter VYVANSE LABEL], available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/021977s028lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021977s028lbl.pdf).

<sup>46</sup> ADDERALL LABEL, *supra* note 9, at 5.

<sup>47</sup> *Id.* at 11.

<sup>48</sup> The adverse effects of the other amphetamine-based ADHD medications are very similar or identical to those detailed in this paragraph. See ADDERALL XR LABEL, *supra* note 45, at 4-8, 17; DEXEDRINE SPANSULE LABEL, *supra* note 44, at 2-3, 6, 9-10; VYVANSE LABEL, *supra* note 45, at 4-8, 26.

<sup>49</sup> ADDERALL LABEL, *supra* note 9, at 11-12, 16.

serious effects include cardiovascular, central nervous system, and gastrointestinal problems,<sup>50</sup> as well as slowed growth and slowed weight-gain in children.<sup>51</sup> Sudden death has been reported where children with existing heart abnormalities take standard doses of stimulants like Adderall.<sup>52</sup> Amphetamines can also cause heart attacks and other heart problems in healthy children and adolescents if taken in excess of normal doses or combined with alcohol.<sup>53</sup>

In addition to these physical side effects, standard doses of Adderall can cause psychotic, manic, and addictive symptoms in children.<sup>54</sup> As a Schedule II controlled substance,<sup>55</sup> Adderall has “a high potential for abuse” and “may lead to severe psychological or physical dependence.”<sup>56</sup> Withdrawal symptoms include depression, anxiety, and extreme fatigue.<sup>57</sup> “Tolerance, extreme psychological dependence, and severe social disability” have also been reported.<sup>58</sup> Recently, for example, a young man named Richard Fee suffered the tragic consequences of an addiction to Adderall.<sup>59</sup> Richard served as class president while on a full scholarship to Greensboro College and planned to attend medical school.<sup>60</sup> During college he occasionally used Adderall to help him study for exams and write papers.<sup>61</sup> After graduation he began to use either Adderall or Vyvanse daily, alternating between the two drugs.<sup>62</sup> Richard soon developed insomnia, paranoia, delusions, severe mood swings, and depression.<sup>63</sup> When he finally stopped taking Adderall, the withdrawal worsened these symptoms.<sup>64</sup> After two weeks of abstaining from Adderall, Richard hanged

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<sup>50</sup> *Id.* at 6–7.

<sup>51</sup> *Dextroamphetamine and Amphetamine*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601234.html> (last updated Dec. 30, 2013).

<sup>52</sup> ADDERALL LABEL, *supra* note 9, at 6; ADDERALL XR LABEL, *supra* note 45, at 4–5.

<sup>53</sup> Shaheen E. Lakhan & Annette Kirchgessner, *Prescription Stimulants in Individuals With and Without Attention Deficit Hyperactivity Disorder: Misuse, Cognitive Impact, and Adverse Effects*, 2 *BRAIN & BEHAV.* 661, 671 (2012).

<sup>54</sup> ADDERALL LABEL, *supra* note 9, at 6–7; ADDERALL XR LABEL, *supra* note 45, at 5.

<sup>55</sup> ADDERALL LABEL, *supra* note 9, at 11.

<sup>56</sup> 21 U.S.C. § 812(b)(2) (2012).

<sup>57</sup> Monica Kim Sham, Note, *Down on the Pharm: The Juvenile Prescription Drug Abuse Epidemic and the Necessity of Holding Parents Criminally Liable for Making Drugs Accessible in Their Homes*, 27 *J. CONTEMP. HEALTH L. & POL’Y* 426, 433 (2011).

<sup>58</sup> ADDERALL LABEL, *supra* note 9, at 11; ADDERALL XR LABEL, *supra* note 45, at 11.

<sup>59</sup> Schwarz, *Stream of Prescriptions*, *supra* note 33.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

himself.<sup>65</sup> Although the majority of stimulant users do not develop psychosis, “the sheer volume of prescriptions leads to thousands of cases every year.”<sup>66</sup>

Because of the potential for abuse and addiction, doctors should be wary about starting young children on Adderall. There is a good chance they may become addicted and require increasingly higher doses.<sup>67</sup> The lack of controlled studies on the long-term effects of Adderall on children<sup>68</sup> counsels limiting off-label prescriptions until further research is completed. In the past, many drugs that were commonly prescribed to children off-label were later found to cause significant harm. For example, the antidepressants Paxil and Celexa were commonly used to treat children without depression until 2005, when the FDA added a warning label to both drugs indicating a risk of suicide in children and stating that they were not approved for pediatric use.<sup>69</sup>

Despite the aforementioned risks, drugs like Adderall can be an effective treatment for ADHD and narcolepsy.<sup>70</sup> For some children with those conditions, Adderall’s benefits may greatly outweigh its risks. But given the known adverse effects of Adderall,<sup>71</sup> such risks should not be taken with children’s health where there is no medical need. Adderall and other amphetamine-based ADHD medications should thus only be prescribed to children who need them to treat a genuine medical condition.

## 2. *Social Reasons to Limit the Prescription of Adderall to Children*

Off-label prescription of Adderall to minors hurts school communities and society as a whole. Overprescription has fueled a black market for Adderall, especially among children and adolescents.<sup>72</sup> Prescription medication is the drug of choice for twelve- and thirteen-

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<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Dextroamphetamine and Amphetamine*, *supra* note 51.

<sup>68</sup> See ADDERALL LABEL, *supra* note 9, at 5, 11.

<sup>69</sup> Alicia T.F. Bazzano et al., *Off-Label Prescribing to Children in the United States Outpatient Setting*, 9 *ACAD. PEDIATRICS* 81, 84 (2009). This article also discusses the harmful effects of cispriide and promethazine, medications previously prescribed to children for off-label purposes. *Id.*

<sup>70</sup> George J. DuPaul & George P. White, *ADHD: Behavioral, Educational, and Medication Interventions*, *EDUC. DIG.*, Mar. 2006, at 57, 59 (2006).

<sup>71</sup> See *supra* notes 48–58 and accompanying text.

<sup>72</sup> See Helia Garrido Hull, *Regression by Progression: Unleveling the Classroom Playing Field Through Cosmetic Neurology*, 33 *U. HAW. L. REV.* 193, 206 (2010).

year-old children.<sup>73</sup> Of these prescription drugs, ADHD stimulants are among the three most commonly-abused categories.<sup>74</sup> In 2012, 7.6% of twelfth-grade students in America used Adderall without a prescription or not in compliance with physician orders.<sup>75</sup> Several studies indicate that over fifteen percent of children with prescriptions for Adderall have given or sold their medication to other students.<sup>76</sup> An even higher number were asked to give or sell their ADHD medication.<sup>77</sup> The prescription of Adderall and other amphetamine-based ADHD medications for off-label uses introduces more of these drugs into schools, which in turn has the potential to seriously harm children. When children take Adderall from classmates without parental or physician supervision, they are far more likely to suffer the adverse health effects described above.<sup>78</sup> These children may have unknown heart abnormalities,<sup>79</sup> may already take medications contraindicated with Adderall,<sup>80</sup> or may take the drug in excessive doses.<sup>81</sup> Furthermore, children have been subject to criminal investigation and prosecution for selling Adderall to their classmates.<sup>82</sup> Reducing the flow of unneeded Adderall into schools is necessary to stop this growing drug market and to protect students.

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<sup>73</sup> SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2006 NATIONAL SURVEY ON DRUG USE AND HEALTH: NATIONAL FINDINGS 20 (2007), available at <http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6results.pdf>.

<sup>74</sup> *DrugFacts: Prescription and Over-the-Counter Medications*, NAT'L INST. ON DRUG ABUSE, <http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications> (last updated May 2013).

<sup>75</sup> *Id.*

<sup>76</sup> See Christiane Poulin, *Medical and Nonmedical Stimulant Use Among Adolescents: from Sanctioned to Unsanctioned Use*, 165 CAN. MED. ASS'N J. 1039, 1041 (2001) (studying Canadian adolescents).

<sup>77</sup> See Sean Esteban McCabe, Christian J. Teter & Carol J. Boyd, *The Use, Misuse and Diversion of Prescription Stimulants Among Middle and High School Students*, 39 SUBSTANCE USE & MISUSE 1095, 1103 (2004).

<sup>78</sup> See Hull, *supra* note 72, at 217.

<sup>79</sup> See *supra* note 52 and accompanying text.

<sup>80</sup> See ADDERALL LABEL, *supra* note 9, at 5–6, 7–10 (listing contraindications and drug interactions).

<sup>81</sup> See *id.* at 11–12 (explaining potential consequences of Adderall abuse and overdose).

<sup>82</sup> See Dan Goldberg, *Mount Olive Student, 13, Is Charged with Selling Adderall at High School*, STAR-LEDGER (Newark) (Sept. 17, 2010, 7:15 PM), [http://www.nj.com/news/local/index.ssf/2010/09/13-year-old\\_charged\\_with\\_selli.html](http://www.nj.com/news/local/index.ssf/2010/09/13-year-old_charged_with_selli.html); Magdalene Landegent, *Teens Charged with Selling, Buying Adderall at School*, LE MARS DAILY SENTINEL (Dec. 22, 2010), <http://www.lemarssentinel.com/story/1689798.html>; see also Douglas Steinke, *6th-Graders Suspended After Foray into Prescription Pills*, PROVIDENCE J., Mar. 24, 2001, at A-1.

Older children also use Adderall to get high,<sup>83</sup> which may lead to illicit use of other drugs. Adderall and cocaine affect the same neurotransmitters in the brain, and studies have found cross-addiction between the two drugs.<sup>84</sup> One study followed children who were prescribed stimulants and found that they were more prone to cocaine addiction as young adults.<sup>85</sup> Use of Adderall can also lead to overstimulation, driving adolescents to use similarly addictive anxiety medications such as Xanax or Klonopin in order to calm their nerves.<sup>86</sup> The combination of stimulants and anti-anxiety medications can cause depression, leading these same adolescents to seek or be prescribed antidepressants,<sup>87</sup> which can increase suicidal thoughts and behavior.<sup>88</sup>

Finally, prescribing Adderall to students without ADHD raises ethical implications for society. Some scholars argue that using Adderall as an “academic steroid” degrades academics in the same way anabolic steroid use tarnishes competitive sports.<sup>89</sup> Adderall is given to students with ADHD in order to bring them up to the same general level of concentration as healthy students.<sup>90</sup> Adderall thus helps equal the playing field and allows children with ADHD to compete with their peers. Prescribing Adderall to students without ADHD reestablishes the uneven playing field; it raises the bar and students with ADHD once again cannot compete.<sup>91</sup> This is particularly problematic for standardized testing, which is used to judge students from different classes and different schools on a neutralized scale.<sup>92</sup> Whatever one thinks of the value of standardized tests, the use of unneeded stimu-

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<sup>83</sup> Stefanie Stolz, *Adderall Abuse: Regulating the Academic Steroid*, 41 J.L. & EDUC. 585, 586 (2012).

<sup>84</sup> *Behavioral Drugs in Schools: Questions and Concerns: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Educ. and the Workforce*, 106th Cong. 16 (2000) (statement of Peter R. Breggin, M.D., Director, Center For the Study of Psychiatry and Psychology).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Antidepressant Medications for Children and Adolescents: Information for Parents and Caregivers*, NAT'L INST. OF MENTAL HEALTH, <http://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/antidepressant-medications-for-children-and-adolescents-information-for-parents-and-caregivers.shtml> (last visited Dec. 31, 2013).

<sup>89</sup> See Hull, *supra* note 78, at 194; Pavisian, *supra* note 43, at 176; Stolz, *supra* note 83, at 587.

<sup>90</sup> See Hull, *supra* note 78, at 194.

<sup>91</sup> *Id.*

<sup>92</sup> Allen Calvin, *Use of Standardized Tests in Admissions in Postsecondary Institutions of Higher Education*, 6 PSYCHOL. PUB. POL'Y & L. 20, 24 (2000).

lants makes the tests unfair to students with ADHD and those not taking the medication at all.<sup>93</sup> Furthermore, many schools give students diagnosed with ADHD extra time to take exams.<sup>94</sup> Students who are prescribed Adderall but are in fact healthy may also receive extra time.<sup>95</sup> Students who are on Adderall but do not have ADHD may thereby get extra time and the extra focus from Adderall, giving them an unfair advantage over their classmates.<sup>96</sup>

In addition to any ethical problems this may cause, tipping the scales back in favor of children without ADHD may frustrate the purpose of U.S. education policy. As one scholar explains, some courts have held that the Equal Protection Clause requires education for handicapped and nonhandicapped children alike,<sup>97</sup> and Congressional enactments such as the Education for All Handicapped Children Act<sup>98</sup> indicate that U.S. law and policy seek to protect handicapped children and augment their education in order to ensure equal opportunities.<sup>99</sup> If healthy children are given an edge with drugs they do not need, it will be difficult to give children with learning disabilities an equal opportunity to compete, thereby hindering the success of these statutory schemes. Scientific study of the effectiveness of Adderall as a cognitive enhancer for children without ADHD is still lacking.<sup>100</sup> But the overwhelming use of Adderall as a study drug<sup>101</sup> indicates that these ethical and social concerns cannot be summarily dismissed.

## II. THE LEGAL FRAMEWORK GOVERNING THE PRESCRIPTION OF CONTROLLED SUBSTANCES AND ITS LIMITATIONS

Health care is governed by a complex web of federal and state laws. This Part lays out the primary ways in which the federal and

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<sup>93</sup> Shawn Romer, Note, *Combating the Unfair Competitive Edge: Random Drug Testing Should Be Implemented in Standardized Testing to Deter Illicit and Unfair Use of Prescription Stimulants*, 21 J.L. & HEALTH 151, 159 (2008) (explaining that Adderall increases concentration, decreases distraction, and gives students the energy to study more hours).

<sup>94</sup> Stolz, *supra* note 83, at 587.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> Hull, *supra* note 78, at 211 (citing *Mills v. Bd. of Educ. of D.C.*, 348 F. Supp. 866, 875 (D.D.C. 1972); *Pa. Ass'n for Retarded Children v. Pennsylvania*, 334 F. Supp. 1257, 1258 (E.D. Pa. 1971)).

<sup>98</sup> Education for All Handicapped Children Act of 1975, Pub. L. No. 94-142, 89 Stat. 773.

<sup>99</sup> Hull, *supra* note 78, at 211-12.

<sup>100</sup> Kelline R. Linton, Comment, *Scholastic Steroids: Is Generation Rx Cognitively Cheating?*, 39 PEPP. L. REV. 989, 1015 (2012).

<sup>101</sup> Stimulants like Adderall are widely viewed as "smart pills" and off-label use of prescription stimulants is now the second most common form of drug use on college campuses, second only to smoking marijuana. Lakhani & Kirchgessner, *supra* note 53, at 662.

state governments regulate physicians, pharmacies, and the prescription of controlled substances like Adderall. Additionally, this Part addresses the failure of current laws to combat the off-label prescription of Adderall and other amphetamine-based ADHD medications to children.

#### A. *Federal Law Governing Prescriptions*

The Controlled Substances Act (“CSA”),<sup>102</sup> administered by the Drug Enforcement Agency (“DEA”), and the Federal Food, Drug, and Cosmetic Act,<sup>103</sup> administered by the Food and Drug Administration (“FDA”), are the seminal federal laws regulating prescription drugs. The Food, Drug, and Cosmetic Act governs the process for FDA approval of new drugs and ensures that drugs are not misbranded,<sup>104</sup> and the CSA governs the manufacture, labeling, sale, prescription, distribution, possession, and destruction of certain dangerous drugs.<sup>105</sup> The CSA classifies dangerous drugs into schedules based on their potential for abuse, their medical uses, and the likelihood that they will cause dependence.<sup>106</sup> Because it is an amphetamine, Adderall is listed as a Schedule II drug, as are the other amphetamine-based ADHD medications.<sup>107</sup> That means it has “a high potential for abuse” and “may lead to severe psychological or physical dependence.”<sup>108</sup> Listing Adderall and other amphetamines as Schedule II controlled substances is important: it serves as a warning to physicians and patients that these drugs can lead to abuse and addiction,<sup>109</sup> and it allows the DEA to restrict the use of these substances.<sup>110</sup> Such restrictions, however, are insufficient to protect children from off-label prescription. For example, the CSA makes it “unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner.”<sup>111</sup> The criminal penalties for violating this prohibition may deter some pa-

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<sup>102</sup> Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–971 (2012)).

<sup>103</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

<sup>104</sup> 21 U.S.C. §§ 352, 355.

<sup>105</sup> *Id.* §§ 801, 823, 825–27.

<sup>106</sup> *Id.* § 812.

<sup>107</sup> 21 C.F.R. § 1308.12 (2013).

<sup>108</sup> 21 U.S.C. § 812(b)(2).

<sup>109</sup> *See id.*

<sup>110</sup> *See id.* § 829(a).

<sup>111</sup> *Id.* § 844(a).

tients from obtaining Adderall without a prescription, but they do not prevent physicians from prescribing Adderall and other amphetamine-based ADHD medications to children without ADHD.

Furthermore, although the FDA must approve each new drug for specific indications before it may be sold and prescribed, once a drug is approved, “physicians are allowed to use that product for any medically appropriate use.”<sup>112</sup> The CSA does not limit the use of Adderall or other Schedule II drugs to the treatment of specific medical problems.<sup>113</sup> Instead, it limits the manner in which a physician may prescribe these drugs. For example, the CSA requires all prescriptions for Schedule II substances to be written (except in emergency situations) and prohibits refills of these prescriptions.<sup>114</sup> DEA regulations under the CSA also lay out a general provision requiring prescriptions for controlled substances to be for a “legitimate medical purpose.”<sup>115</sup> The DEA can suspend a physician’s registration to prescribe controlled substances if he violates this provision.<sup>116</sup> Courts, however, have struggled to define “legitimate medical purpose,”<sup>117</sup> and have generally only upheld penalties against physicians where those physicians acted intentionally outside the bounds of medicine or in bad faith.<sup>118</sup> The effect of this framework is that off-label prescription is permitted, does not require review by the FDA, and will not be prosecuted by the DEA, so long as the intended use is within the “practice of medicine.”<sup>119</sup> This allows physicians to prescribe drugs for an almost endless number of indications.<sup>120</sup> Thus, physicians are free to prescribe amphetamine-based ADHD medications for off-la-

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<sup>112</sup> Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion Prosecutions*, 64 *FOOD & DRUG L.J.* 441, 441 (2009).

<sup>113</sup> *See id.*

<sup>114</sup> 21 U.S.C. § 829(a).

<sup>115</sup> 21 C.F.R. § 1306.04(a) (2013).

<sup>116</sup> *See, e.g.*, Jayam Krishna-Iyer, M.D.; Suspension of Registration; Granting of Renewal Application Subject to Condition, 74 *Fed. Reg.* 459, 461 (Drug Enforcement Admin. Dec. 19, 2008).

<sup>117</sup> GERALD UELMEN, *DRUG ABUSE AND THE LAW SOURCEBOOK* § 1:24 (2012), available at Westlaw DRUGAB.

<sup>118</sup> *See, e.g.*, *United States v. Hurwitz*, 459 F.3d 463, 476–77 (4th Cir. 2006) (explaining that a doctor’s “good faith” is relevant when determining whether a prescription was given for a “legitimate medical purpose”).

<sup>119</sup> “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices—Information Sheet, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last updated Aug. 10, 2011).

<sup>120</sup> *See* Angela Olivia Burton, “They Use it Like Candy”: How the Prescription of Psychotropic Drugs to State-Involved Children Violates International Law, 35 *BROOK. J. INT’L L.* 453, 504 (2010) (“[P]hysicians may use FDA approved drugs ‘in whatever way they deem beneficial, as long as there is some evidence that it could be helpful.’” (quoting GLENN R. ELLIOTT & KATE

bel uses,<sup>121</sup> even though the FDA has approved them to treat only ADHD and narcolepsy.<sup>122</sup>

Off-label prescription of drugs is common in the practice of medicine and it can be beneficial, especially for patients suffering from rare or unstudied diseases where experimental treatments are necessary.<sup>123</sup> In the case of Adderall and other amphetamine-based ADHD medications, however, off-label prescriptions are not being used to treat some new or rare disease; they are being used to improve students' grades, help children lose weight, or satisfy the demands of persistent parents.<sup>124</sup> Researchers have yet to study the use of amphetamines for such purposes.<sup>125</sup> Until they do, children will continue to suffer the adverse effects described above<sup>126</sup> and possibly others that are as yet unknown. With no mechanism to prevent physicians from prescribing amphetamine-based ADHD medications to children for these controversial and unstudied purposes, federal law is insufficient to protect healthy children from the negative effects of these drugs.

### B. State Law Governing Prescriptions

States historically have had significant authority to protect the public health,<sup>127</sup> including through the licensing and regulation of physicians, pharmacists, and other medical professionals.<sup>128</sup> Several forms of state law restrict physicians' ability to prescribe controlled substances. Under state tort law, individuals can sue physicians for medi-

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KELLY, *MEDICATING YOUNG MINDS: HOW TO KNOW IF PSYCHIATRIC DRUGS WILL HELP OR HURT YOUR CHILD* 23 (2006)).

<sup>121</sup> See 21 C.F.R. § 1306.04(a) (2013) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose . . ."); Gentry, *supra* note 112, at 441–43.

<sup>122</sup> ADDERALL LABEL, *supra* note 9, at 5.

<sup>123</sup> See Miller, *supra* note 10.

<sup>124</sup> See Schwarz, *Pills to Help in School*, *supra* note 1 (discussing a pediatrician's willingness to prescribe Adderall to healthy children just to boost academic performance); Cohen, *supra* note 15 (describing the off-label use of Adderall for weight loss).

<sup>125</sup> See Cohen, *supra* note 15.

<sup>126</sup> See *supra* notes 48–58 and accompanying text.

<sup>127</sup> See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) ("[T]he police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health.").

<sup>128</sup> See, e.g., *Collins v. Texas*, 223 U.S. 288, 296 (1912) (recognizing the states' broad authority to regulate medical education and practice); *cf. also Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 (1975) ("States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions.").

cal malpractice if they believe they were wrongly prescribed a medication.<sup>129</sup> But malpractice suits only provide recourse for the specific plaintiff and only punish the specific defendant physician. Furthermore, they require the plaintiff to suffer a cognizable harm, understand the connection between that harm and the drug prescribed, and then decide to file suit.<sup>130</sup> Harm and causation are often difficult to prove,<sup>131</sup> and the majority of plaintiffs lose their medical malpractice cases.<sup>132</sup> Confounding the problem is the backlog of cases in American courts<sup>133</sup> and the high cost of litigating a malpractice suit.<sup>134</sup> This process is too costly and inefficient<sup>135</sup> to protect all, or even most, children without ADHD who are prescribed amphetamine-based ADHD medications.

Furthermore, state licensing boards can suspend or revoke the license of any physician violating controlled-substances law or otherwise abusing his privilege to prescribe.<sup>136</sup> This is an important tool for states, but enforcement requires some mechanism to detect violations by physicians. The efficacy of these boards also depends on the state's substantive law governing physicians and prescriptions. There are several broad themes in state legislation regarding the prescription of controlled substances. These themes, described in greater detail below, help demonstrate the general thrust of state controlled-substances law and provide insight into the broad perspective with which states approach regulation in this area.

### 1. Examination and Recordkeeping

Many state laws require physicians to complete a physical examination of each patient before prescribing a controlled substance.<sup>137</sup>

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<sup>129</sup> See 3 STEVEN E. PEGALIS, *AMERICAN LAW OF MEDICAL MALPRACTICE* § 17:9 (3d ed. 2005).

<sup>130</sup> See RESTATEMENT (SECOND) OF TORTS § 323 (1965).

<sup>131</sup> See Ryan McCarthy, Note, *Aegrescit Medendo: Addressing Barriers to Medical Malpractice Litigation Faced by the Elderly*, 18 *ELDER L.J.* 391, 406 (2011).

<sup>132</sup> THOMAS H. COHEN, U.S. DEPT. OF JUSTICE, BUREAU OF JUSTICE STATISTICS CIVIL JUSTICE DATA BRIEF NO. NCJ 203098, *MEDICAL MALPRACTICE TRIALS AND VERDICTS IN LARGE COUNTIES*, 2001, at 1 (2004).

<sup>133</sup> See, e.g., Manisha Bhatt, *Justice Delayed: The Ramifications of the Trial Court Budget Cuts*, *BOS. B.J.*, Fall 2011, at 46, 48–49 (2011); Lee Smalley Edmon, *Keeping Courtrooms Open in Times of Steep Budget Cuts*, *JUDGES' J.*, Winter 2012, at 18–19 (2012).

<sup>134</sup> See Kenneth C. Chessick & Matthew D. Robinson, *Medical Negligence Litigation Is Not the Problem*, 26 *N. ILL. U. L. REV.* 563, 567 (2006).

<sup>135</sup> See Richard Abel, *Forecasting Civil Litigation*, 58 *DEPAUL L. REV.* 425, 444 (2009) (explaining the high cost and slow pace of civil litigation).

<sup>136</sup> See e.g., *Sally v. Tex. State Bd. of Med. Exam'rs*, 351 S.W.3d 434, 438 (Tex. App. 2011).

<sup>137</sup> See, e.g., 49 PA. CODE § 16.92(b)(1) (2012).

This is an important requirement, but it is difficult to enforce and does little to prevent physicians from prescribing Adderall to children without ADHD because physicians can prescribe medication at their discretion, regardless of the examination results.

Most states also require physicians to maintain medical records documenting all prescriptions of controlled substances. Kansas, for example, requires physicians prescribing amphetamines to note in the patient's record "the purpose for which the drug is being given."<sup>138</sup> In New York, physicians must "maintain a written patient record of administration, dispensing and prescription of all controlled substances," which must "contain sufficient information to justify the diagnosis and warrant the treatment."<sup>139</sup> Such statutes are useful when federal or state enforcement agents investigate a particular patient, physician, or health care provider.<sup>140</sup> They are unlikely, however, to provide a highly effective deterrent from prescribing Adderall to children for off-label uses. As medical records are usually retained by a physician's office or hospital,<sup>141</sup> the information recorded is not automatically provided to state actors who might flag, track, and investigate the off-label use of controlled substances. Physicians who prescribe Adderall for off-label uses are at risk only if they have reason to be investigated; thus these regulations alone are not strong enough to deter the off-label prescription of Adderall to minors.

## 2. *Medical Purpose*

Another recurrent trend in state controlled-substance law is a general requirement that controlled substances be prescribed only for a genuine medical purpose. New York only allows physicians to "prescribe controlled substances for legitimate medical purposes or treatment,"<sup>142</sup> and Texas prohibits the prescription of controlled substances "except for a valid medical purpose and in the course of medical practice."<sup>143</sup> Regulations of this kind have been used to punish physicians who sell prescription drugs<sup>144</sup> or supply them to patients already ad-

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<sup>138</sup> KAN. STAT. ANN. § 65-2837a(b) (West 2008).

<sup>139</sup> N.Y. COMP. CODES R. & REGS. tit. 10, § 80.62(b) (2013).

<sup>140</sup> See, e.g., OKLA. ADMIN. CODE § 752:15-1-6(k)(2) (2001).

<sup>141</sup> See 30-17 MISS. CODE R. § 2640:1.4 (LexisNexis 2012); UTAH ADMIN. CODE. I. 156-37-602(3) (2013).

<sup>142</sup> N.Y. COMP. CODES R. & REGS. tit. 10, § 80.62.

<sup>143</sup> TEX. HEALTH & SAFETY CODE ANN. § 481.071 (West 2010).

<sup>144</sup> See, e.g., *Fisher v. La. State Bd. of Med. Exam'rs*, 352 So. 2d 729, 730-32 (La. Ct. App. 1977) (affirming the revocation of the license of a physician who sold controlled substances to a patient without medical justification).

dicted to controlled substances.<sup>145</sup> These regulations may also help deter such behavior by physicians who might otherwise consider engaging in these practices. For less culpable physicians who may just want to experiment with Adderall's effects or appease persistent parents, however, these regulations are too vague to be a robust deterrent, as the provisions give prescribers wide latitude to use controlled substances to treat any condition they deem legitimate.<sup>146</sup>

In addition to these general provisions, some states have enacted more specific regulations for particular controlled substances. Arkansas, for example, allows prescriptions for Schedule II stimulants (which include amphetamine-based ADHD medications) "for a legitimate medical indication. . . . includ[ing] ADHD and Narcolepsy."<sup>147</sup> If a prescriber wishes to use a stimulant for another purpose, an off-label use "may be justified with appropriate medical rationale and documentation of evidence-based research and experience."<sup>148</sup> New Jersey also restricts the use of amphetamines, such as Adderall, prohibiting their prescription for "weight management, dieting or any other anorectic purpose, or for the treatment of fatigue."<sup>149</sup> Likewise, Tennessee allows physicians to prescribe amphetamines only for a limited set of indications, including ADHD, narcolepsy, dementia, and chronic depression.<sup>150</sup> If prescribers licensed in Tennessee want to use amphetamines for other indications, they must receive approval for a clinical investigation from the State's Board of Medical Examiners.<sup>151</sup> Targeted regulations like these aim to prohibit off-label uses of controlled substances, especially amphetamines, and thus provide a good stepping stone to stricter limitations on the off-label prescription of Adderall and other amphetamine-based ADHD medications.

These provisions, however, have no enforcement mechanism,<sup>152</sup> making them ineffective at decreasing the off-label prescription of dangerous drugs. In 2011 alone, pharmacies filled over 3.7 billion prescriptions in the United States.<sup>153</sup> Every year an estimated 21 million

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<sup>145</sup> See, e.g., *People v. Anderson*, 105 Cal. Rptr. 664, 672 (Cal. Ct. App. 1972) (affirming the conviction of a physician for prescribing a narcotic, methadone, to six patients addicted to narcotic drugs).

<sup>146</sup> See *supra* text accompanying notes 112–22.

<sup>147</sup> 060-00-001 ARK. CODE R. § 7 (LexisNexis 2013).

<sup>148</sup> *Id.*

<sup>149</sup> N.J. ADMIN. CODE § 13:35-7.8(a) (2013).

<sup>150</sup> TENN. COMP. R. & REGS. 0880-02-14(3)(a) (2010).

<sup>151</sup> *Id.*

<sup>152</sup> See *supra* notes 147–51.

<sup>153</sup> *Total Number of Retail Prescription Drugs Filled at Pharmacies*, KAISER FAMILY FOUND., <http://kff.org/other/state-indicator/total-retail-rx-drugs/> (last visited Dec. 31, 2013).

of these prescriptions are for ADHD medications.<sup>154</sup> With numbers this high, millions of off-label prescriptions could be filled in violation of statutes like those described above without detection or penalty. States cannot curb off-label prescription without a mechanism that can sort through these billions of prescriptions, identify trends of off-label prescription, investigate identified prescribers, and penalize those who have violated the law.

### 3. *Prescription-Monitoring Programs*

The final category of state regulation provides a starting point to begin enforcing laws like those described above. At least forty states currently operate some form of “prescription-monitoring program.”<sup>155</sup> Prescription-monitoring programs use databases to collect and monitor prescription information sent electronically from pharmacies.<sup>156</sup> Most states use their databases to collect information on prescriptions of controlled substances from all four CSA drug schedules.<sup>157</sup> Though programs vary between states, most require at least the following information from dispensers of controlled substances: identity of the dispenser, name of patient, patient date of birth, date the prescription was filled, National Drug Code or other identifier of the substance dispensed, quantity of the substance dispensed, and Drug Enforcement Administration number or other identifier of the prescriber.<sup>158</sup>

These databases are a crucial first step towards enforcing limits on the prescription of controlled substances such as Adderall, but they are not enough. They are insufficient to curb off-label prescription to children for two reasons. First, the monitoring programs do not collect crucial information from physicians; most do not require physicians to report the patient’s diagnosis or the purpose of the

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<sup>154</sup> Schwarz, *Risky Rise*, *supra* note 17.

<sup>155</sup> KRISTIN M. FINKLEA, ERIN BAGALMAN & LISA N. SACCO, CONG. RESEARCH SERV., R42593, PRESCRIPTION DRUG MONITORING PROGRAMS 3 (2012).

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 4.

<sup>158</sup> See CAL. HEALTH & SAFETY CODE § 11165 (West 2012); DEL. CODE ANN. tit. 16, § 4798 (Supp. 2012); 14-118-11 ME. CODE R. § 5 (LexisNexis 2011); 105 MASS. CODE REGS. 700.012 (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.73 (2013). For a full list of state prescription-monitoring programs and their requirements see NAT’L ALLIANCE FOR MODEL STATE DRUG LAWS, WHO IS REQUIRED TO SUBMIT DISPENSING INFORMATION TO PRESCRIPTION MONITORING PROGRAM AND EXEMPTIONS TO REPORTING (2013) [hereinafter WHO IS REQUIRED TO SUBMIT], available at <http://www.namsdl.org/library/80EB9EFC-1372-636C-DD830013DA2254B2/>.

medication when prescribing a controlled substance.<sup>159</sup> Instead, physicians can use the databases to determine whether their patients already have prescriptions for the drugs they seek.<sup>160</sup> This structure may help prevent doctor-shopping<sup>161</sup> and drug abuse, but it is insufficient to curb off-label prescription because it does not accumulate information on patient diagnoses. Without this information, it is impossible to determine whether a drug has been prescribed off-label. Second, some states with prescription-monitoring programs do not mandate that physicians use the database, but instead make enrollment in the state's program voluntary.<sup>162</sup> These states usually require pharmacists and dispensing physicians to report prescriptions to the database, but do not require physicians to check the database before writing a prescription.<sup>163</sup> One problem with these voluntary systems is that not enough physicians participate. In Virginia, for example, only eleven percent of physicians have used the state's voluntary database.<sup>164</sup> Furthermore, where physician use of the monitoring program is voluntary, common sense dictates that the physicians who will use it are those that are already cautious—those that are unlikely to prescribe medications to children for unstudied purposes or solely because a child or parent has requested a prescription. There is nothing to deter physicians who are less cautious and choose not to use the database.

Moreover, collecting prescription information in a database alone does not reduce off-label prescription.<sup>165</sup> The states must develop

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<sup>159</sup> See generally WHO IS REQUIRED TO SUBMIT, *supra* note 158 (collecting state laws on reporting to prescription-monitoring databases).

<sup>160</sup> See FINKLEA ET AL., *supra* note 155, at 3.

<sup>161</sup> "Doctor-shopping" refers to the practice of seeking multiple prescriptions for the same drug from different doctors in order to abuse the substance. *Law: Doctor Shopping*, CTRS. FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/homeandrecationalsafety/Poisoning/laws/dr\\_shopping.html](http://www.cdc.gov/homeandrecationalsafety/Poisoning/laws/dr_shopping.html) (last updated July 11, 2012).

<sup>162</sup> See KAREN BLUMENSCHNEIN ET AL., INST. FOR PHARM. OUTCOMES & POLICY, UNIV. OF KY., REVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS IN THE UNITED STATES 9 (2010); NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, PRACTITIONER EDUCATION IN THE UTILIZATION OF PRESCRIPTION MONITORING PROGRAM (PMP) DATA 2 (2011) [hereinafter PRACTITIONER EDUCATION], available at <http://www.namsdl.org/library/80EB36EC-1372-636C-DD034B9478A89C2D/>.

<sup>163</sup> See PRACTITIONER EDUCATION, *supra* note 162, at 2; see also, e.g., VA. CODE ANN. § 54.1-2521, -2523 (Supp. 2012) (requiring "dispensers," not "prescribers," to send reports to prescription-monitoring database and authorizing, but not requiring, physician access to information in prescription-monitoring database).

<sup>164</sup> BLUMENSCHNEIN ET AL., *supra* note 162, at 21.

<sup>165</sup> Many programs merely collect prescription information and make it available to health-care providers. This is intended to reduce doctor-shopping by allowing physicians to determine whether a patient has already been prescribed a particular drug. See Laylan Copelin, *State Tests Database to Root Out 'Pill Mills'*, AUSTIN AM.-STATSMAN, Feb. 3, 2012, at A1.

methods for tracking particular substances prescribed to particular types of patients if they want to successfully curb the off-label prescription of amphetamine-based ADHD drugs to children. By separating the data received and flagging problematic prescriptions, states can better enforce laws restricting the prescription and distribution of controlled substances. For example, Texas, in addition to maintaining a general database of controlled substance prescriptions,<sup>166</sup> also tracks the prescription of psychotropic drugs to children who are under the protection of the state and certain children on Medicare.<sup>167</sup> Although this program is separate from the general prescription-monitoring program and is administered by a different agency,<sup>168</sup> it is an example of how states might organize and track the prescription of certain drugs to specific populations.

The success of prescription-monitoring programs is still to be determined. It is difficult to obtain data correlating the implementation of monitoring programs to decreased use of or deaths from controlled substances.<sup>169</sup> Whatever their efficacy may be, existing programs are just the first step. Alone, they amass a great amount of information into central repositories. In order to effect change, states must use this information to enforce the law. Without an enforcement structure, prescription-monitoring programs are not likely to lead to a significant decrease in the off-label prescription of amphetamines to children.

These principal tools used by states in regulating controlled substances, along with the CSA, have laid out a framework for reducing the abuse and overprescription of Adderall and similar drugs. Existing laws, however, approach controlled substances from a very broad perspective, classifying prescription drugs into only four schedules and giving physicians almost complete freedom to prescribe them for any “legitimate” purpose.<sup>170</sup> Reducing the off-label prescription of amphetamine-based ADHD medication to children requires a more targeted solution.

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<sup>166</sup> TEX. HEALTH & SAFETY CODE ANN. § 481.074(q) (West Supp. 2012).

<sup>167</sup> TEX. GOV'T CODE ANN. § 533.0161 (West 2012).

<sup>168</sup> *See id.*

<sup>169</sup> David B. Brushwood, *Maximizing the Value of Electronic Prescription Monitoring Programs*, 31 J.L. MED. & ETHICS 41, 45 (2003).

<sup>170</sup> *See supra* notes 106 & 115 and accompanying text.

### III. PROPOSED MODEL LEGISLATION TO PREVENT THE DANGEROUS OFF-LABEL PRESCRIPTION OF AMPHETAMINE-BASED ADHD MEDICATIONS TO CHILDREN

Although the federal government plays a significant role in regulating controlled substances, the states are in a unique position to help curb off-label prescription. States have the authority to grant and revoke medical licenses, and correspondingly have the power to regulate how physicians use those licenses.<sup>171</sup> Furthermore, states have fewer people to govern than the federal government and can therefore focus their resources on the prescribers within their borders. This Part proposes model state legislation that utilizes these facets of state government in order to combat the off-label prescription of amphetamine-based ADHD drugs to minors.<sup>172</sup> This Part also discusses the purpose behind the main provisions of the proposed statute and refutes the principal counterarguments to these provisions.

The proposed statute requires physicians to certify a positive diagnosis of ADHD or narcolepsy before prescribing amphetamine-based ADHD drugs to minors. The statute also sets out a process for obtaining prescription information from physicians and pharmacies, storing that information in a relational database, continuously searching and flagging that database for violations, and investigating any violations found. Three key provisions compose the core of the statute: a prescriber certification, a prescription-monitoring database, and minimum penalties.<sup>173</sup>

#### A. *Prescriber Certification*

First, the statute requires prescribers to certify that they have positively diagnosed a minor patient with ADHD or narcolepsy when prescribing an amphetamine-based ADHD medication to that minor.<sup>174</sup> Prescribers must complete and sign a standardized certification

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<sup>171</sup> See *supra* note 128 and accompanying text.

<sup>172</sup> Nothing in the CSA prohibits physicians from prescribing medications for off-label purposes. See Gentry, *supra* note 112, at 441–43. The CSA, however, does not preempt the field of prescriptions and controlled substances. 21 U.S.C. § 903 (2012). States can thus set stricter laws for controlled substances than those that exist at the federal level, so long as they are not in direct conflict with federal law. See *United States v. Locke*, 529 U.S. 89, 109 (2000) (citing *California v. ARC Am. Corp.*, 490 U.S. 93, 100–01 (1989)); see also *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1092 (D. Or. 2002) (“State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended, and the [ ]DOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board.”).

<sup>173</sup> The entire text of the proposed statute can be found in the Appendix to this Note.

<sup>174</sup> See Proposed Model Statute, *infra* App., § 3(a)(1).

form and send an electronic copy of that form to the state agency responsible for tracking prescriptions within seven days of writing the prescription.<sup>175</sup> Prescribers must also attach the form to the written prescription they give to the patient.<sup>176</sup> Because the CSA already requires physicians to write out prescriptions for Schedule II drugs (except in emergency situations),<sup>177</sup> this signed certification can easily be attached to the required written prescription. Like the CSA, the proposed statute provides an exception to this certification provision for genuine medical emergencies.<sup>178</sup> Under the statute, physicians may also petition the state medical board for permission to use one of the covered drugs for an experimental off-label use.<sup>179</sup>

The purpose of this provision is to restrict the off-label use of amphetamine-based ADHD medications at the source by preventing physicians from prescribing them (1) for controversial and still unstudied purposes, and (2) without first evaluating and diagnosing the patient. By limiting the prescription of amphetamine-based ADHD drugs to children with ADHD or narcolepsy, this part of the statute seeks to reduce the adverse health effects of these drugs and the negative societal impacts of overprescription.<sup>180</sup>

The medical community may contend that the prescriber-certification requirement prevents physicians from freely practicing medicine and prohibits potentially beneficial treatment options. Physicians, not legislatures, they may argue, are the medical experts and they should be permitted to use their experience and professional judgment to determine what drugs they will prescribe and to whom. The proposed statute leaves ample room for physicians to treat patients with amphetamine-based ADHD medications. It allows physicians to prescribe such medications to patients who, in the physician's judgment, present with ADHD or narcolepsy. The statute does not require physicians to use any specific diagnostic test, and does not lay out criteria for a positive diagnosis of either disorder. Furthermore, the statute only restricts the prescription of these drugs to minors.<sup>181</sup> Unlike adults, who have the power to discuss the risks and benefits of certain medications with their doctors, minors may have little say in

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<sup>175</sup> *Id.* § 3(a)–(d).

<sup>176</sup> *Id.* § 3(c).

<sup>177</sup> 21 U.S.C. § 829 (2012).

<sup>178</sup> Proposed Model Statute, *infra* App., § 2(b).

<sup>179</sup> *Id.* § 2(c).

<sup>180</sup> *See supra* Part I.B.

<sup>181</sup> *See* Proposed Model Statute, *infra* App., § 2(a) (“[I]t shall be unlawful for any prescriber to prescribe an amphetamine-based ADHD medication to a minor . . .”).

their own treatment. The statute simply seeks to protect children from adverse effects that they may not understand and may not want to bear in the future. The high potential for abuse and addiction associated with these drugs<sup>182</sup> means that children who begin taking them at a young age may find themselves addicted later in life through no fault of their own. These adverse health risks, combined with the negative effects that overprescription to minors has on society,<sup>183</sup> indicate that the benefits of a policy preventing most off-label prescription to minors outweighs any detriment.

Furthermore, the proposed model statute allows physicians to use amphetamine-based ADHD drugs, including Adderall, for off-label uses where the physician finds it medically necessary to do so. The statute allows physicians to prescribe these drugs to minors in cases of medical emergency without diagnosing the patient with ADHD or narcolepsy.<sup>184</sup> This exemption allows physicians to use their professional judgment in emergency situations without the fear of legal repercussions. Furthermore, if a physician believes that an off-label use would serve a legitimate medical purpose in a non-emergency situation, that physician can apply to the applicable state entity for authorization.<sup>185</sup> Thus, physicians are not completely restricted from using these drugs in experimental medical treatments. If they present valid proposals for alternative medical use, they should be able to test their theories. These provisions of the statute are particularly important in light of the absence of scientific research studying either the long-term effects of amphetamines on young children<sup>186</sup> or the consequences of their off-label use.<sup>187</sup>

### B. Prescription-Monitoring Database

The statute also requires each state to set up a relational database<sup>188</sup> to track the prescription of amphetamine-based ADHD

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<sup>182</sup> 21 U.S.C. § 812(b)(2) (2012).

<sup>183</sup> See *supra* text accompanying notes 48–58.

<sup>184</sup> Proposed Model Statute, *infra* App., § 2(b).

<sup>185</sup> *Id.* § 2(c).

<sup>186</sup> ADDERALL LABEL, *supra* note 9, at 5, 11.

<sup>187</sup> See Cohen, *supra* note 15.

<sup>188</sup> A relational database is a database that stores multiple fields of information, each in a separate column. *What Are Relational Databases?*, HOWSTUFFWORKS, <http://computer.howstuffworks.com/question599.htm> (last visited Dec. 31, 2013). By storing information this way, the database can create tables that compare different fields of information. *Id.* This makes searching for information simple and produces precise results. *Id.*

medications to minors.<sup>189</sup> Pharmacies are required to send all prescriptions for amphetamine-based ADHD medications to the database.<sup>190</sup> Pharmacies must also send the attached prescriber certification form.<sup>191</sup> The database must also collect the certification forms sent in electronically by physicians as a fail-safe.<sup>192</sup> The state agency responsible for monitoring the database must set up an automatic, periodic search of the database to identify and flag prescriptions of amphetamine-based ADHD medications for minors that are not accompanied by a prescriber certification.<sup>193</sup> In addition, the agency must appoint a panel of investigators (if an analogous body does not already exist) to investigate flagged prescriptions.<sup>194</sup>

Most states have, or plan to implement, a prescription-monitoring database,<sup>195</sup> so this should be an easy requirement with which to comply. A state that already has a database does not need to create a new one, but must make any necessary changes to allow its database to track prescriptions for amphetamine-based ADHD medications issued to minors.

Requiring a prescription-monitoring database that tracks and flags prescriptions for amphetamine-based ADHD medications without prescriber certifications creates an enforcement mechanism for the certification requirement. The database allows states to identify and investigate violations of the certification requirement and enforce the statute as a whole. By using a relational database, the state agency itself needs to do very little aside from ensuring that the information coming from pharmacies and prescribers is fed into the database. Once the information is entered, the database can automatically search its content at a set interval and flag prescriptions that violate the statute.<sup>196</sup> The database can thereby provide the agency with a list of prescriptions that must be investigated. This technology will allow

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<sup>189</sup> See Proposed Model Statute, *infra* App., § 5 (setting out features of the prescription-monitoring database).

<sup>190</sup> *Id.* § 4(b)(I).

<sup>191</sup> *Id.* § 4(b)(II).

<sup>192</sup> *Id.* § 3(d).

<sup>193</sup> *Id.* § 5(c).

<sup>194</sup> *Id.* § 5(d).

<sup>195</sup> See *Prescription Monitoring Frequently Asked Questions (FAQ)*, *supra* note 155.

<sup>196</sup> See *Using Stored Procedures*, JAVA TUTORIALS, <http://docs.oracle.com/javase/tutorial/jdbc/basics/storedprocedures.html> (last visited Dec. 31, 2013) (explaining that relational databases can use “stored procedures” to create routine functions that the database will continually perform); *What Are Relational Databases?*, *supra* note 188 (explaining that websites like Amazon.com use relational databases containing thousands of tables to quickly produce precise information at the needed time).

states to efficiently find potential violations and follow up on them. Data on the effectiveness of current prescription-monitoring programs is lacking, but one study found that databases significantly decrease the time required to investigate patients who appear to abuse prescription drugs.<sup>197</sup> By requiring physician participation,<sup>198</sup> the proposed database program will extend this benefit to investigations of physicians. In this way, the monitoring databases give states a strong tool with which to root out physicians who wrongly prescribe amphetamine-based ADHD medications to children.

One potential argument against requiring a prescription-monitoring database is that such programs are costly and time-consuming. The states, however, have already accepted most of the costs involved. At least forty states operate or are currently implementing prescription-monitoring databases.<sup>199</sup> The proposed statute adds specific provisions relevant to amphetamine-based drugs, but the required database search and the appointment of an investigative panel are not onerous tasks relative to the overall implementation and maintenance of a prescription-monitoring database. Furthermore, prescription drug abuse costs the nation billions of dollars every year<sup>200</sup> and drives up the cost of health insurance.<sup>201</sup> The cost required to set-up and monitor a database is a small price to pay in order to curb off-label prescription and abuse.

Another potential criticism of the proposed database is that it singles out one class of medications for investigation when hundreds of other drugs are also listed as controlled substances with the potential for abuse.<sup>202</sup> As explained above, amphetamines can have dangerous side effects,<sup>203</sup> their off-label prescription is rampant,<sup>204</sup> and their long-term effects on children have not been studied.<sup>205</sup> For these reasons, the model statute encourages states to begin by curbing the off-label

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<sup>197</sup> FINKLEA ET AL., *supra* note 155, at 9.

<sup>198</sup> See Proposed Model Statute, *infra* App., § 3(d) (requiring prescribing physicians to submit the statutorily required certification to the appropriate state agency).

<sup>199</sup> See FINKLEA ET AL., *supra* note 155, at 3.

<sup>200</sup> This figure includes, *inter alia*, hospital costs and resources spent on enforcing drug laws. Laxmaiah Manchikanti, *Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic?*, 9 PAIN PHYSICIAN 287, 293 (2006).

<sup>201</sup> James O'Toole, *How Prescription Drug Abuse Costs You Money*, CNNMONEY (Feb. 24, 2012, 6:08 PM), [http://money.cnn.com/2012/02/22/news/economy/prescription\\_drug\\_abuse/index.htm](http://money.cnn.com/2012/02/22/news/economy/prescription_drug_abuse/index.htm).

<sup>202</sup> See 21 C.F.R. §§ 1308.12–1308.15 (2013).

<sup>203</sup> See *supra* notes 48–58 and accompanying text.

<sup>204</sup> See *supra* Part I.A.

<sup>205</sup> ADDERALL LABEL, *supra* note 9, at 5, 11.

prescription of amphetamine-based medications to minors. The proposed legislation, however, is easily adaptable to other drugs. States can and should use it to track other commonly overprescribed drugs if they find that those medications are highly abused within their jurisdiction.

### C. *Minimum Penalties*

The statute also contains minimum penalties for prescribers and dispensers who violate its terms.<sup>206</sup> Minimum fines must be imposed on any prescriber who intentionally or knowingly prescribes an amphetamine-based ADHD medication to a minor other than in compliance with the terms of the statute.<sup>207</sup> The statute provides for suspension of the prescribing license of any prescriber who violates the statute more than three times.<sup>208</sup> Pharmacies are also subject to a fine if they do not comply with the requirements of the statute.<sup>209</sup>

The purpose of these minimum penalties is to give the proposed statute teeth. Without penalties, physicians would have little incentive to comply with the other provisions of the statute. It is true that physicians are already subject to federal criminal penalties<sup>210</sup> and medical malpractice claims<sup>211</sup> for abusing their privilege to prescribe controlled substances, but these have not proven sufficient to deter off-label prescription. Federal legislation defines the limits on prescribing controlled substances very broadly<sup>212</sup> and thus does not reach many of the activities prohibited by the proposed statute. As explained above, medical malpractice suits take time to move through the courts and require patients to discover the causal connection between the medication prescribed to them and its adverse effects.<sup>213</sup> Additionally, unlike litigation, this statute seeks to work prophylactically rather than wait until children actually suffer the harmful effects of amphetamines. The minimum penalties are thus necessary to deter off-label prescription and give the proposed statute effect.

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<sup>206</sup> See Proposed Model Statute, *infra* App., § 6.

<sup>207</sup> *Id.* § 6(a)–(b).

<sup>208</sup> *Id.* § 6(c).

<sup>209</sup> *Id.* § 6(d).

<sup>210</sup> See 21 C.F.R. § 1306.04(a) (2013).

<sup>211</sup> See *supra* notes 129–30 and accompanying text.

<sup>212</sup> See *supra* notes 109–19 and accompanying text.

<sup>213</sup> See *supra* notes 129–35 and accompanying text.

### CONCLUSION

Widespread off-label prescription of Adderall and other amphetamine-based ADHD medications has the potential to harm children's physical and psychological health. Off-label prescription also negatively impacts education and society as a whole. By adopting the proposed legislation, states can combat the adverse effects of off-label prescription and ensure that amphetamines are used in a manner evaluated and approved by the FDA.

## APPENDIX

**PROPOSED MODEL STATUTE****SECTION 1. DEFINITIONS**

(a) “ADHD” means Attention Deficit Hyperactivity Disorder.

(b) “Amphetamine-based ADHD medication” means any medication approved by the FDA to treat ADHD that contains amphetamine, dextroamphetamine, or a combination of both.

(c) “Applicable state agency” means the agency within the state government responsible for the prescription-monitoring database required by Section 5 of this Act.

(d) “Certification” means the form required by Section 3 of this Act.

(e) “Minor” means any person under eighteen years of age.

(f) “Prescriber” means any licensed physician or other licensed practitioner who prescribes a substance classified by law as a prescription-only substance.

(g) “Prescription-monitoring database” refers to a state-implemented database used to collect information about prescriptions within the state as required by Section 5 of this Act.

(h) “Schedule II controlled substance” refers to any substance listed in Section 1308.12 of Title 21 of the Code of Federal Regulations (21 C.F.R. § 1308.12).

**SECTION 2. PRESCRIPTION OF AMPHETAMINE-BASED MEDICATION TO A MINOR**

(a) Except as provided in Sections 2(b)–(c), it shall be unlawful for any prescriber to prescribe an amphetamine-based ADHD medication to a minor unless the prescriber has positively diagnosed the minor with ADHD, narcolepsy, or both disorders.

(b) In the case of a genuine medical emergency, a prescriber may prescribe an amphetamine-based ADHD medication to a minor without positively diagnosing the minor with ADHD, narcolepsy, or both disorders. The prescription shall be for no greater quantity of the substance than the prescriber deems necessary to treat the emergency issue. Any prescriber using this emergency provision must file with the applicable state agency within fourteen days a report detailing the emergency situation, the drug prescribed, the prescriber’s reasons for using the medication to treat the situation, and the amount of the drug prescribed.

(c) In any non-emergency situation, a prescriber seeking to prescribe an amphetamine-based ADHD medication to a minor that the prescriber has not positively diagnosed with ADHD, narcolepsy, or both disorders may do so only upon the express authorization of the state entity responsible for licensing prescribers.

### **SECTION 3. PRESCRIBER CERTIFICATION**

(a) Any prescriber prescribing an amphetamine-based ADHD medication to a minor patient must complete and sign a certification form. The certification form will:

- (I) include the following statement: “I certify that I have positively diagnosed this patient with ADHD, narcolepsy, or both disorders”;
- (II) require the prescriber’s signature under the statement in Section 3(a)(I);
- (III) require the prescriber’s Drug Enforcement Agency identification number or other identification number;
- (IV) require the name and dosage of the medication prescribed; and
- (V) require the patient’s name and date of birth.

(b) The applicable state agency shall create a standardized certification form and supply it to any prescriber, upon request, via electronic or paper delivery.

(c) The prescriber in Section 3(a) must physically attach the certification form to the written prescription and instruct the patient, or the patient’s guardian, to submit the certification form to the pharmacy with the prescription.

(d) Within seven days of issuing a prescription for an amphetamine-based ADHD medication to a minor, the prescriber in Section 3(a) must electronically transmit the certification form to the applicable state agency.

(e) Where the prescriber in Section 3(a) has already completed the certification as required by that Section for a particular minor in conjunction with a previous prescription for that minor, the prescriber may use the original certification form to meet the requirements of Sections 3(c)–(d) for all subsequent prescriptions to that minor for the same medication at the same dosage. The prescriber must still comply with Sections 3(c)–(d) but need not complete a new form. The prescriber must:

- (I) add the date of the new prescription to the old certification form; and

- (II) attach the updated form to the prescription and send it electronically to the applicable state agency as required by Sections 3(c)–(d).

#### **SECTION 4. RESPONSIBILITIES OF PHARMACY DISPENSERS**

(a) Any pharmacist or other person licensed to fill prescriptions who receives a prescription at a pharmacy for an amphetamine-based ADHD medication for a minor that does not have a certification from the prescriber attached must not fill the prescription without first contacting the prescriber and obtaining either:

- (I) a completed and signed certification;
- (II) a written or oral declaration from the prescriber that the prescribed dose of the medication is necessary to treat a genuine medical emergency; or
- (III) documentation from the state licensing entity expressly authorizing the prescriber to prescribe the medication pursuant to Section 2(c).

(b) Any pharmacy receiving a prescription for an amphetamine-based ADHD medication must electronically submit to the applicable state agency within seven days:

- (I) a copy of that prescription;
- (II) a copy of the prescriber certification or documentation from the state licensing entity expressly authorizing the prescriber to prescribe the medication pursuant to Section 2(c), unless the pharmacy received a declaration pursuant to Section 4(a)(II);
- (III) the National Drug Code for the medication;
- (IV) the dispenser's Drug Enforcement Agency identification number or other identification number;
- (V) the date the prescription was filled;
- (VI) the full name of the patient; and
- (VII) the birthdate of the patient.

#### **SECTION 5. PRESCRIPTION-MONITORING DATABASE**

(a) The applicable state agency, which may already exist or may be created to fulfill the requirements of this Act, is responsible for implementing and maintaining the database.

(b) If the applicable state agency is not currently implementing or maintaining a relational database or comparable program that collects or is capable of collecting information from prescribers and phar-

macies about prescriptions for amphetamine-based ADHD medications, it must create one.

(c) The applicable state agency must implement a mechanism to automatically search the database, at an interval that may be set by regulation, but that is no less than once per month, for prescriptions to minors of amphetamine-based ADHD medications that are not accompanied by either a prescriber certification or documentation from the state licensing entity expressly authorizing the prescriber to prescribe the medication pursuant to Section 2(c).

(d) The applicable state agency must appoint a panel or other group of persons, if an analogous group does not already exist, to investigate every flagged prescription.

(I) Each flagged prescription shall be given fourteen days before investigation begins. If, after fourteen days have expired, the prescriber of a flagged prescription has not submitted a certification for that prescription, the panel must investigate the prescription.

(II) Investigation shall begin by contacting the prescriber to request the required certification and should continue as the state or applicable state agency may require.

#### **SECTION 6. MINIMUM PENALTIES**

(a) The state shall establish a minimum fine for any prescriber who intentionally or knowingly prescribes an amphetamine-based ADHD medication to a minor without completing the certification required by Section 3 of this Act.

(b) The state shall establish a minimum penalty, greater than the fine established under Section 6(a), for a prescriber who intentionally or knowingly prescribes an amphetamine-based ADHD medication to a minor in violation of Section 2 of this Act.

(c) The state shall suspend the license, for an amount of time established by regulation or by the state licensing board, of a prescriber who intentionally or knowingly prescribes an amphetamine-based ADHD medication to a minor in violation of Section 2 of this Act on more than three occasions.

(d) The state shall establish a minimum fine for a pharmacist or other licensed dispenser who intentionally or knowingly violates Section 4 of this Act.