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'They Use it Like Candy' - How the Prescription of Psychotropic  
Drugs to State-Involved Children Violates International Law

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**“THEY USE IT LIKE CANDY”: HOW THE  
PRESCRIPTION OF PSYCHOTROPIC DRUGS  
TO STATE-INVOLVED CHILDREN  
VIOLATES INTERNATIONAL LAW**

*Angela Olivia Burton*\*

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"Psychotropic medications for young children should be used only when anticipated benefits outweigh risks. Parents should be fully informed and decisions made only after carefully weighing these factors. Children and adolescents must be closely monitored and frequently evaluated as the side effects common to some medications can be particularly difficult for children. At the same time, psychotropic medications can be lifesaving."<sup>1</sup>

"They use it like candy," said Elnorris Stone, a 25-year-old [California Youth Authority] parolee from Oakland. "Anybody who's considered hyper, who fights a lot, they prescribe it a lot. The medication fixes it."<sup>2</sup>

#### INTRODUCTION

There is widespread concern that children in the United States are being severely overmedicated with psychotropic drugs. Psychotropic drugs (also known as "psychoactive" or "psychiatric" drugs) act directly on the brain to affect behavior, emotion, or mood.<sup>3</sup> Because they are toxic chemicals with great potential for addiction, abuse, and diversion into the illegal drug trade, many are designated as controlled substances and their medicinal uses are stringently regulated by the international community under the 1971 United Nations Convention on Psychotropic Substances ("1971 Convention").<sup>4</sup> In 1995, the International Narcotics Control Board ("INCB"), which monitors the implementation of the 1971 Convention,<sup>5</sup> began to warn of an alarming increase in the prescription of psychotropic drugs to children in the United States. The INCB was especially concerned about the astronomical rise in pediatric prescriptions of methylphenidate (i.e., Ritalin), an amphetamine-type

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1. DARCY E. GRUTTADARO & JOEL E. MILLER, NAMI POLICY RESEARCH INSTITUTE TASK FORCE REPORT: CHILDREN AND PSYCHOTROPIC MEDICATIONS 2 (2004), available at [http://www.nami.org/Template.cfm?Section=press\\_room&Template=/ContentManagement/ContentDisplay.cfm&ContentID=15721](http://www.nami.org/Template.cfm?Section=press_room&Template=/ContentManagement/ContentDisplay.cfm&ContentID=15721).

2. Nancy Price, *They Use it Like Candy*, STOCKTON REC., Jan. 16 2000, available at <http://www.sjcite.info/kidrights.html> (reporting on the overuse of psychotropic medications among children in the custody of the California Youth Authority).

3. See RONALD T. BROWN & MICHAEL G. SAWYER, MEDICATIONS FOR SCHOOL-AGE CHILDREN: EFFECTS ON LEARNING AND BEHAVIOR 18 (1998); see also RITA WICKS-NELSON & ALLEN C. ISRAEL, BEHAVIOR DISORDERS OF CHILDHOOD 67 (3d ed. 1997) ("Medications that affect mood, thought processes, or overt behavior are known as psychotropic or psychoactive and thus the term psychopharmacological treatment is often employed.").

4. See Convention on Psychotropic Substances, *opened for signature* Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 157 [hereinafter 1971 Convention].

5. International Narcotics Control Board, Mandate of INCB, <http://www.incb.org/incb/en/mandate.html>.

stimulant drug most commonly prescribed to children diagnosed with Attention Deficit Hyperactivity Disorder ("ADHD").<sup>6</sup> Because of its high

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6. In a press release issued in conjunction with the publication of its 1996 report, the INCB stressed that methylphenidate was one of the first substances placed under international control in Schedule II of the 1971 Convention "due to its high abuse potential." Press Release, United Nations Information Service, INCB Sees Continuing Risk in Stimulant Prescribed for Children (Mar. 4, 1997), *available at* [http://www.incb.org/pdf/e/press/1996/e\\_bn\\_04.pdf](http://www.incb.org/pdf/e/press/1996/e_bn_04.pdf) [hereinafter Continuing Stimulant Risk]. In its 1995 Annual Report, the INCB pointed out that "3-5 per cent of all schoolchildren in the United States have reportedly been diagnosed as suffering from ADD [attention deficit disorder] and are treated with methylphenidate, frequently without the benefit of other forms of assistance recommended in treatment guidelines." INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1995, para. 91 (1995), *available at* [http://www.incb.org/incb/annual\\_report\\_1995.html](http://www.incb.org/incb/annual_report_1995.html). The Board noted an increase in abuse of methylphenidate, mainly among "adolescents who illegally obtain the substance in tablet form from children undergoing treatment for ADD." *Id.* The Board asked that U.S. authorities "carefully monitor future developments in the diagnosis of ADD in children and the extent to which methylphenidate and other stimulants (such as dexamfetamine and pemoline) are used in the treatment of ADD, in order to ensure that these substances are prescribed in accordance with sound medical practice as required under article 9, paragraph 2, of the 1971 Convention," *id.* at para. 93, and urged all "Governments to exercise the utmost vigilance in order to prevent 'overdiagnosing' of ADD in children and medically unjustified treatment with methylphenidate and other stimulants." *Id.* at para. 94.

In virtually all of its annual reports since 1995, the INCB has pointed out to the United States its concerns about over-diagnosis of ADD/ADHD, the ever-increasing prescription rates, diversion, and abuse of methylphenidate and other internationally controlled stimulants, and the persistence of direct-to-consumer advertising of psychotropic drugs. *See* INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1996, para. 90-95 (1996), *available at* [http://www.incb.org/incb/annual\\_report\\_1996.html](http://www.incb.org/incb/annual_report_1996.html); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1997, para. 151-154 (1997), *available at* [http://www.incb.org/incb/annual\\_report\\_1997.html](http://www.incb.org/incb/annual_report_1997.html); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1998, para. 101, 121, 134 (1998), *available at* [http://www.incb.org/pdf/annual-report/1998/en/AR\\_08\\_English.pdf](http://www.incb.org/pdf/annual-report/1998/en/AR_08_English.pdf) [hereinafter INCB 1998 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1999, para. 159-165 (1999), *available at* [http://www.incb.org/incb/annual\\_report\\_1999.html](http://www.incb.org/incb/annual_report_1999.html); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2000, para. 1-49, 161-165 (2000), *available at* [http://www.incb.org/incb/annual\\_report\\_2000.html](http://www.incb.org/incb/annual_report_2000.html) [hereinafter INCB 2000 REPORT] (extended discussion and analysis of "[o]verconsumption of internationally controlled drugs"); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2001, para. 200-201, 341-343 (2001), *available at* [http://www.incb.org/incb/annual\\_report\\_2001.html](http://www.incb.org/incb/annual_report_2001.html) [hereinafter INCB 2001 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2002, para. 173-176, *available at* [http://www.incb.org/incb/annual\\_report\\_2002.html](http://www.incb.org/incb/annual_report_2002.html) [hereinafter INCB 2002 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2003, para. 181-188

potential for abuse, methylphenidate was one of the first substances placed under international control in the 1971 Convention's Schedule II,<sup>7</sup> which is reserved for drugs constituting a "substantial risk to public health," while having only "little to moderate therapeutic usefulness."<sup>8</sup> Although agreeing with the notion that "with proper diagnosis, stimulants can be effective in treating [ADHD],"<sup>9</sup> the INCB has consistently criticized the excessive pediatric prescription of internationally controlled stimulant drugs in the United States, and has suggested that the high rates indicate an unjustified tendency to suppress and control normal childhood behaviors that adults (teachers and parents) find problematic, rather than to treat legitimate medical conditions.<sup>10</sup>

Concerns about overmedication are particularly pronounced with respect to children in state custody. State-involved children<sup>11</sup> are prescribed psychotropic drugs at stunningly high rates, far higher than other children in the general population.<sup>12</sup> It has been estimated that about 8–

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(2003), available at [http://www.incb.org/incb/en/annual\\_report\\_2003.html](http://www.incb.org/incb/en/annual_report_2003.html) [hereinafter INCB 2003 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2004, para. 145–149 (2004), available at [http://www.incb.org/incb/annual\\_report\\_2004.html](http://www.incb.org/incb/annual_report_2004.html) [hereinafter INCB 2004 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2005, para. 374, 139 (2005), available at [http://www.incb.org/incb/annual\\_report\\_2005.html](http://www.incb.org/incb/annual_report_2005.html); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2006, para. 87, 341 (2006), available at [http://www.incb.org/incb/annual\\_report\\_2006.html](http://www.incb.org/incb/annual_report_2006.html) [hereinafter INCB 2006 REPORT]; INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2007, para. 128–129 (2005), available at [http://www.incb.org/incb/annual\\_report\\_2007.html](http://www.incb.org/incb/annual_report_2007.html); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2008, para. 132–135, available at <http://www.incb.org/incb/en/annual-report-2008.html> [hereinafter INCB 2008 REPORT].

7. See Continuing Stimulant Risk, *supra* note 6.

8. See *infra* p. 16.

9. INCB 2000 REPORT, *supra* note 6, at para. 148.

10. See, for example, INCB 2000 REPORT, *supra* note 6, wherein the INCB expressed concern with "the frequent long-term use (beyond one year and sometimes indefinitely) of psychotropic substances for treating psychological reactions to social pressure without a diagnosis for a specific disorder." *Id.* at para. 15. The Board further pointed out that "[c]orrecting mood and behavior through controlled drugs is becoming widespread," *id.* at para. 16, and noted that "[t]he growing use of those substances for the treatment of school-age and also pre-school children, in the absence of universally accepted and validated definitions, diagnostic criteria and guidelines for such practice, has recently been the subject of concern." *Id.* at para. 19.

11. As used in this Article, the term *state-involved children* refers generally to youth under the age of 18 who are in state foster care systems or incarcerated in juvenile prisons ("detention facilities").

12. See, e.g., *Utilization of Psychotropic Medication for Children in Foster Care: Hearing Before the Subcomm. on Income Security and Family Support of the H. Comm.*

10% of children (six to eight million) under the age of 18 in the United States are prescribed medications for what are classified as mental health problems.<sup>13</sup> In comparison, recent reports indicate that, on any given day, up to 50% or more of children in some state foster care systems and juvenile prisons receive psychotropic medications.<sup>14</sup>

Given their often traumatic and unstable life experiences, it is unsurprising that many state-involved children exhibit emotional, cognitive, and behavioral symptoms associated with various psychiatric diagnoses.<sup>15</sup> Where drug treatment predominates over psychosocial and behavioral interventions for children's behavioral and mental health issues,<sup>16</sup>

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*On Ways & Means*, 110th Cong., 2d sess. 6–14 (2008) (statement of Julie M. Zito, Professor of Pharmacy and Psychiatry, Pharmaceutical Health Services Research, University of Maryland) [hereinafter *Zito Testimony*] (noting that youth in foster care and disabled youth “have the greatest likelihood of receiving complex, poorly evidenced, high cost medication regimens.”); Zima R. Raghavan et al., *Psychotropic Medication Use in a National Probability Sample of Children in the Child Welfare System*, 15 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 97, 97 (2005) (concluding that “children in child welfare settings are receiving psychotropic medications at a rate between 2 and 3 times that of children treated in the community”); Julie M. Zito et al., *Psychotropic Medication Patterns Among Youth in Foster Care*, 121 PEDIATRICS 157 (2008) (concluding that psychotropic drug treatment is three to four times more common for youth in foster care who receive Medicaid as compared to other Medicaid-eligible youth) [hereinafter *Psychotropic Medication Patterns*]; Stacy Hagen & Laurie Orbeck, *The Prescription of Psychotropic Medications in Foster Care Children: A Descriptive Study in St. Louis County—Executive Summary*, <http://www.d.umn.edu/sw/executive/hstacy.html> (summarizing a 1998 study that concluded that 34.5% of children in foster care in St. Louis County, Minnesota were receiving psychotropic medication in comparison to 15% of children in the general population).

13. ST. LUKE'S HEALTH INITIATIVES, FLASHPOINT: CHILDREN, ADOLESCENTS AND PSYCHOTROPIC MEDICATIONS 10 (2006), available at [http://www.slhi.org/publications/issue\\_briefs/pdfs/ib-2006-August.pdf](http://www.slhi.org/publications/issue_briefs/pdfs/ib-2006-August.pdf).

14. See *infra* p. 16.

15. Michael W. Naylor et al., *Psychotropic Medication Management for Youth in State Care: Consent, Oversight and Policy Considerations*, CHILD WELFARE, Sept.–Oct. 2007, at 175. “With few exceptions, youth in foster care have been physically or sexually abused, neglected or both,” *id.* at 176, and “children in foster care . . . have many unique risk factors, including emotional and physical sequelae of abuse and neglect, disrupted attachment relationships, and placement disruptions, which can all have an effect on clinical presentation.” *Id.* at 178; see also AM. ACAD. OF CHILD AND ADOLESCENT PSYCHIATRY, AACAP POSITION STATEMENT ON OVERSIGHT OF PSYCHOTROPIC MEDICATION USE FOR CHILDREN IN STATE CUSTODY: A BEST PRINCIPLES GUIDELINE (2005) available at [http://www.aacap.org/galleries/PracticeInformation/FosterCare\\_BestPrinciples\\_FINAL.pdf](http://www.aacap.org/galleries/PracticeInformation/FosterCare_BestPrinciples_FINAL.pdf).

16. See, e.g., Encarnacion Pyle, *Even Babies Getting Treated as Mentally Ill: Prescriptions on the Rise Even Though They Haven't Been Tested on Children*, COLUMBUS DISPATCH, Apr. 25, 2005, at A1, available at <http://www.dispatch.com/live/contentbe/dispatch/2005/04/25/20050425-A1-00.html>.

and where some doctors prescribe multiple psychotropic drugs even to very young children without any evidence of their pediatric safety or effectiveness,<sup>17</sup> these already vulnerable state-involved children are at particular risk for overmedication with psychotropic drugs.<sup>18</sup>

Speaking precisely to this issue, the 1971 Convention establishes an international monitoring and control system to protect the public from dangers associated with psychotropic drugs. By signing that treaty, the United States and other signatory countries agreed to abide by provisions designed to protect the public—including children—from unwarranted exposure to these highly toxic and addictive drugs. Yet, as will be further illustrated, conditions and policies persist in the United States that violate the 1971 Convention and, threaten the health, well-being, and, indeed, the very lives, of thousands of state-involved children.<sup>19</sup>

While a primary emphasis of the 1971 Convention was the minimization of the substantial risks to the public health posed by unregulated and excessive availability of psychotropic drugs, the convention recognizes that, when administered under strictly controlled conditions, the drugs may provide limited medical benefit.<sup>20</sup> To ensure that they are used as medicines only where the potential benefits clearly outweigh the potential public health risks, the 1971 Convention imposed a number of specif-

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The biggest public-health crisis facing the state and nation is the number of children with mental illness who fail to receive any care or treatment," said Michael Hogan, director of the Ohio Department of Mental Health. It's true children are more likely to get medication than counseling or other behavioral therapy if they go to their pediatrician or family doctor. But at the end of the day, meds are quite safe and effective."

*Id.*

17. Psychotropic Medication Patterns, *supra* note 12, at 162 (pointing out that although children in foster care, as a group, experience substantially more psychiatric disorders than non-foster care children, there is no basis for concluding that dispensing 3 or more "different psychotropic medication classes concomitantly to children in foster care represents a treatment advantage.").

18. See Susan dosReis et al., *Mental Health Services for Youths in Foster Care and Disabled Youths*, 91 AM. J. PUB. HEALTH 1094 (2001).

19. See, e.g., GABRIEL MYERS WORK GROUP, FLA. DEP'T OF CHILDREN & FAMILY SERV., REPORT OF GABRIEL MYERS WORK GROUP (2009), available at <http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/GabrielMyersWorkGroupReport082009Final.pdf> (detailing the panel's findings regarding the apparent suicide of Gabriel Myers, a 7-year old foster child, and the extent that the use of multiple psychotropic drugs was a contributing factor to his death); see also Carol Marbin Miller, *Child-Welfare Panel: Drugs Misused on Foster Kids*, MIAMI HERALD, Aug. 13, 2009, <http://www.miamiherald.com/2009/08/12/v-print/1183698/child-welfare-panel-drugs-misused.html> (reporting on Gabriel Myers Work Group report).

20. 1971 Convention, *supra* note 4, preamble.

ic restrictions on the use of psychotropic drugs. First and foremost, their use is strictly limited to legitimate "medical and scientific purposes."<sup>21</sup> And, to prevent undue influence by commercial interests on the public's perception and understanding of their risks and benefits, the convention requires the United States government to prohibit advertising of psychotropic drugs to the general public "with due regard to its constitutional provisions."<sup>22</sup> To minimize improper use, psychotropic drug labels must indicate such "cautions and warnings . . . as in [the government's] opinion are necessary for the safety of the user."<sup>23</sup> Further, the federal government must ensure that prescriptions for psychotropic drugs are issued "in accordance with sound medical practice and subject to such regulation . . . as will protect the public health and welfare."<sup>24</sup> In addition, the convention provides that a government may adopt "more strict or severe measures of control" than those provided for in the 1971 Convention, "if in its opinion, such measures are desirable or necessary for the protection of the public health and welfare."<sup>25</sup> Despite these internationally agreed-upon safeguards, the United States government persists in its failure to comply with these important mandates, putting the health and safety of hundreds of thousands of children at risk from illegitimate exposure to psychotropic drugs.

The vast majority of psychotropic drugs are prescribed to children "off-label"—that is, without the benefit of the same rigorous, scientific, clinically-derived safety and efficacy data required by the Food and Drug Administration ("FDA") in the United States for approval of drugs prescribed to adults.<sup>26</sup> The resulting absence of child-specific warnings or cautions as required by the 1971 Convention leaves physicians to the risky business of dispensing highly toxic, brain-targeting chemicals to still-developing children, with little more than small scale, anecdotal evidence from short-term experiments for the safety and efficacy of such chemicals.<sup>27</sup> The importance of regulatory approval and proper labeling

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21. *Id.* at art. 5.

22. *Id.* at art. 10(2).

23. *Id.* at art. 10(1).

24. *Id.* at art. 9.

25. *Id.* at art. 23.

26. See GLENN R. ELLIOTT & KATE KELLY, *MEDICATING YOUNG MINDS: HOW TO KNOW IF PSYCHIATRIC DRUGS WILL HELP OR HURT YOUR CHILD* 22 (2006).

27. *Id.* Elliott and Kelly noted that doctors prescribe medication off-label because

small experiments and anecdotal evidence says it works . . . if the medication seems to help, the clinician may publish what is called a case report, or simply tell colleagues, who pass it on to other colleagues. . . . This type of work, often just clinical reports based on a few patients, is much simpler, faster and far

is underscored by the fact that even drugs that have been approved by the FDA can cause serious risks to children's health and safety. For example, in 2005, the FDA withdrew approval for pemoline (marketed as Cylert), a stimulant drug listed in Schedule II of the 1971 Convention.<sup>28</sup> Pemoline, which was commonly used to treat children diagnosed with attention deficit hyperactivity disorder (ADHD), was ordered off the markets after the FDA found evidence that "the overall risk of liver toxicity from Cylert and generic pemoline products outweighs the benefits of this drug."<sup>29</sup>

Another recent incident involved concerns about the safety of Adderall XR, another drug widely used for the treatment of ADHD in children. The main ingredient in Adderall XR is amphetamine, a Schedule II substance under the 1971 Convention.<sup>30</sup> Approved by the FDA for use by children age six and older in 2001,<sup>31</sup> it was removed from the market in 2005 by the Canadian government in the wake of 20 reports of sudden unexplained death ("SUD") amongst children who had taken the drug.<sup>32</sup> The Canadian government returned Adderall XR to the shelves a few months later with additional safety warnings.<sup>33</sup> However, while it ac-

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cheaper than what the FDA requires. However, it is plagued with uncertainties about genuine efficacy and safety.

*Id.* at 23. To fill the gap left by the federal drug regulatory agency, the American Academy of Child and Adolescent Psychiatry advises physicians to "consider data from studies in adults in treating the target disorder and/or symptomatology, any clinical or anecdotal reports of use in child and adolescent patients, studies conducted outside the United States and the experience of colleagues." American Academy of Child and Adolescent Psychiatry, Prescribing Psychoactive Medication for Children and Adolescents (2001), available at [http://www.aacap.org/cs/root/policy\\_statements/prescribing\\_pschoactive\\_medication\\_for\\_children\\_and\\_adolescents](http://www.aacap.org/cs/root/policy_statements/prescribing_pschoactive_medication_for_children_and_adolescents).

28. For a description of scheduling of psychotropic substances under the 1971 Convention, see *infra* pp. 31–32.

29. U.S. Food & Drug Admin., Alert for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (marketed as Cylert) (Oct. 2005), <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126462.pdf>.

30. INT. NARCOTICS REVIEW BD., LIST OF PSYCHOTROPIC SUBSTANCES UNDER INTERNATIONAL CONTROL 5 (2003), available at <http://www.incb.org/pdf/e/list/green.pdf> [hereinafter GREEN LIST].

31. Centerwatch, Newly Approved Drug Therapies, Adderall XR, <http://www.centerwatch.com/drug-information/fda-approvals/drug-details.aspx?DrugID=725>.

32. U.S. Food & Drug Admin., Public Health Advisory for Adderall and Adderall XR (Feb. 9, 2005), available at <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm051672.htm>.

33. U.S. Food & Drug Admin., Adderall and Aderall XR (amphetamines) Information (Aug. 2005), available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111441.htm>.

knowledged the evidence of the sudden deaths, the FDA declined at that time to take any action, stating that it could not “conclude that recommended doses of Adderall can cause SUD,” but that it was “continuing to carefully evaluate these data.”<sup>34</sup> Two years later, in 2007, the FDA directed manufacturers of all drugs approved for the treatment of ADHD to develop “Patient Medication Guides” as part of their product labeling to highlight for patients the potential for increased risk of heart-related problems such as sudden death, stroke, and heart attacks, as well as increased risk of adverse psychiatric symptoms such as “hearing voices, becoming suspicious for no reason, or becoming manic, even in patients who did not have previous psychiatric problems.”<sup>35</sup>

Serious concerns have also arisen in recent years about the safety of psychotropic drugs that are not controlled under the 1971 Convention, but for which many of the same safety, efficacy, and effectiveness concerns exist. A recent example is the case of selective serotonin uptake inhibitors (“SSRIs”), a class of antidepressants often prescribed to children for symptoms associated with depression and anxiety disorders, including drugs such as setraline hydrochloride (marketed as Zoloft), paroxetine (marketed as Paxil), and fluoxetine (marketed as Prozac, which currently is the only medication approved by the FDA for use in treating depression in children age eight and older).<sup>36</sup> In 2003, amidst evidence of increased risk of suicidal thoughts and actions among children and adolescents treated with SSRIs, Britain’s FDA equivalent, the British Medicines and Healthcare Products Regulatory Agency, strongly recommended that physicians stop prescribing SSRIs (excluding Prozac) to children,<sup>37</sup> citing evidence that that the drugs “may do more harm than good in the treatment of depression in under-18s.”<sup>38</sup> Although declining to recommend against pediatric use of SSRIs at that time, two years later the FDA required that the labeling for all antidepressants include a “black box” warning—the most serious warning placed on the labeling of a prescription medication—about the increased risk of suicide to

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34. *Id.*

35. Press Release, U.S. Food & Drug Admin., FDA Directs ADHD Drug Manufacturers to Notify Patients about Cardiovascular Adverse Events and Psychiatric Adverse Events, (Feb. 21, 2007) available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108849.htm>.

36. See Nat’l Inst. of Mental Health, Treatment of Anxiety Disorders, <http://www.nimh.nih.gov/health/publications/anxiety-disorders/treatment-of-anxiety-disorders.shtml>.

37. Erica Goode, *British Warning on Antidepressant Use for Youth*, N.Y. TIMES, Dec. 11, 2003, at A1; see also Shankar Vedantam, *Britain Warns Against Giving Newer Antidepressants to Kids: Only Prozac’s Benefits Outweigh Risks, Health Officials Say*, WASH. POST, Dec. 11, 2003, at A2.

38. Vendatam, *supra* note 37; see Goode, *supra* note 37.

children.<sup>39</sup> More recently, a 2008 study that analyzed data from clinical trials found little evidence that the antidepressants studied were any more effective than a placebo in alleviating depression.<sup>40</sup>

In addition to their numerous safety risks, many of the touted benefits of psychotropic drugs to children are often highly overstated.<sup>41</sup> Despite the fact that stimulant drugs such as Ritalin (containing methylphenidate, a 1971 Convention Schedule II drug) are among the most studied with respect to their effects on children, “essentially nothing” was known until recently “about the long-term benefits and problems of stimulant treatment for ADHD and how early treatment may affect adolescence and adulthood.”<sup>42</sup> This situation changed dramatically in February 2010 when the Government of Western Australia released the *Raine ADHD Study*,

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39. Press Release, U.S. Food & Drug Admin., FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated with Antidepressant Medications (Oct. 15, 2004), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108363.htm>. An FDA report published in August 2009 and co-authored by Dr. Marc Stone, a senior medical reviewer in the FDA’s Center for Drug Evaluation and Research, confirmed that SSRIs increase the risk of suicidal thoughts or behavior in children and adolescents, and extended the warnings to young adults aged 18-25. MARC STONE ET AL., RISK OF SUICIDALITY IN CLINICAL TRIALS OF ANTIDEPRESSANTS IN ADULTS: ANALYSIS OF PROPRIETARY DATA SUBMITTED TO US FOOD AND DRUG ADMINISTRATION 5 (2009), available at [http://www.bmj.com/cgi/content/abstract/339/aug11\\_2/b2880](http://www.bmj.com/cgi/content/abstract/339/aug11_2/b2880).

40. Irving Kirsch et al., *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLOS MEDICINE 260, 256–66 (2008), available at [http://medicine.plosjournals.org/archive/1549-1676/5/2/pdf/10.1371\\_journal.pmed.0050045-L.pdf](http://medicine.plosjournals.org/archive/1549-1676/5/2/pdf/10.1371_journal.pmed.0050045-L.pdf). But see Jeffrey A. Bridge et al., *Clinical Response and Risk for Reported Suicidal Ideation and Suicide Attempts in Pediatric Antidepressant Treatment: A Meta-analysis of Randomized Controlled Trials*, 297 J. AM. MED. ASS’N 1683, 1683 (2007) (suggesting that the benefits of antidepressant medications likely outweigh their risks to children and adolescents diagnosed with major depression and anxiety disorders).

41. See *Zito Testimony*, *supra* note 12, at 9 (“Post-marketing studies are particularly important to identify and describe patient outcomes in terms of academic performance, social development and avoidance of negative outcomes, e.g. crime, substance abuse and school failure—in other words, beyond symptom control. In the current U.S. research environment, most medication research focuses on symptom improvement in short-term clinical trials which is necessary but not sufficient information to establish the role of medication in community-based pediatric populations.”); see also WORKING GROUP ON PSYCHOACTIVE MEDICATIONS FOR CHILDREN AND ADOLESCENTS, AM. PSYCHOLOGICAL ASS’N, REPORT OF THE WORKING GROUP ON PSYCHOACTIVE MEDICATIONS FOR CHILDREN AND ADOLESCENTS. PSYCHOPHARMACOLOGICAL, PSYCHOSOCIAL, AND COMBINED INTERVENTIONS FOR CHILDHOOD DISORDERS: EVIDENCE BASE, CONTEXTUAL FACTORS, AND FUTURE DIRECTION 25 (2006) (noting that “[u]nfortunately, growing evidence suggests that outcomes achieved in real-world community settings pale in comparison to those obtained in evidence-based clinical trials for both psychotherapy and medication.”).

42. ELLIOTT & KELLY, *supra* note 26, at 202–03.

which analyzes longitudinal data collected on 2,868 children from birth through age 14 as part of the Western Australian Pregnancy Birth Cohort.<sup>43</sup> Described as the first study to provide “a unique long-term view of a wide range of outcomes and their associations with the use of stimulant medication in the treatment of ADHD,” the project examines “the long-term social, emotional, school-based, growth, and cardiovascular outcomes associated with the use of stimulant medication in the treatment of ADHD.”<sup>44</sup> Notably, children diagnosed with ADHD who had been treated with stimulants were found to be 10.5 times more likely to have been identified by a classroom teacher as performing below age-level, and had “significantly greater diastolic blood pressure than children who had never received medication.”<sup>45</sup> While noting that limitations of the study “prevent any strong causal relationships from being identified, the authors suggested that the “lack of significant improvements in long-term social, emotional, and academic functioning associated with the use of stimulant medication” in the subject children indicates that further research is warranted “to better understand the *suspected* long-term social, emotional and educational benefits of stimulant medication in the treatment of ADHD.”<sup>46</sup>

The safety risks and overstatement problems described above are compounded by the fact that, in direct contravention of explicit provisions of the 1971 Convention, advertisements not only extoll the claimed virtues of various psychotropic drugs ubiquitous in the United States, they also frequently make false and/or misleading claims about the drugs<sup>47</sup> while simultaneously downplaying significant and serious risks.<sup>48</sup>

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43. See GRANT SMITH ET AL., RAINE ADHD STUDY: LONG-TERM OUTCOMES ASSOCIATED WITH STIMULANT MEDICATION IN THE TREATMENT OF ADHD IN CHILDREN (2010), available at [http://www.health.wa.gov.au/publications/documents/MICADHD\\_Raine\\_ADHD\\_Study\\_report\\_022010.pdf](http://www.health.wa.gov.au/publications/documents/MICADHD_Raine_ADHD_Study_report_022010.pdf).

44. *Id.* at 5.

45. *Id.* at 6.

46. *Id.* at 8 (emphasis added).

47. See CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD & DRUG ADMIN., 2005 REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 45 (2005), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM078935.pdf>. In 2005, the Center for Drug Evaluation and Research (CDER) (a division of the Food and Drug Administration which monitors advertising of prescription drugs and issues regulatory action letters to companies), issued 60 letters to drug companies for “prescription drug promotions deemed to be false, misleading, lacking in fair balance of risks and benefits or that promoted a product or indication before approval.” *Id.*

For an example of such a warning letter, see Letter from Robert Dean, Group Leader, Food & Drug Admin., to Kathryn Roberts, Director, Johnson and Johnson (Sept. 25, 2008), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceReg>

Although others have addressed some of the vexing problems related to the use of psychotropic drugs in children,<sup>49</sup> none have examined the obligations of the United States government under international law. This Article argues that the United States government has violated international law by failing to implement important mandates of the 1971 Convention, and this has significantly contributed to the unconscionable rise in unwarranted prescription and inappropriate administration of psychotropic drugs to children in state foster care systems and juvenile prisons in the U.S.

In Part I of this Article, I present a brief and grossly oversimplified explanation of the essential nature of psychotropic medications and how they interact with the human body. In Part II, I delineate the provisions and terms of the 1971 Convention that serve as the primary international legal authority governing the manufacture, distribution, and use of psychotropic drugs.<sup>50</sup> These provisions, which will be analyzed individually

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ulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm053998.pdf [hereinafter Johnson and Johnson Warning Letter]. This letter cites Johnson & Johnson for their advertisements of Concerta, whose active ingredient is methylphenidate, an internationally controlled drug under the 1971 Convention. The letter asserts that the subject ad was misleading because it overstated Concerta's efficacy by implying "that use of Concerta will lead to an improvement in academic performance throughout the day when this has not been shown by substantial evidence or clinical experience." *Id.* at 2. The letter also deemed a webpage entitled "After School," to be misleading because it asserted "improvement with Concerta in a broad array of adolescent after school activities, such as athletics, clubs, and performance in part-time jobs, when this has not been demonstrated by substantial evidence." *Id.* at 3. The letter observes that, "[w]hile Concerta has been shown to improve total scores on the Attention Deficit Hyperactivity Disorder Rating Scale (ADHD-RS), which measures ADHD symptoms such as fidgeting, not listening, and talking excessively, what has not been shown is that this improvement in ADHD-RS total scores is correlated with a positive effect on adolescents' ability to pursue interests and hobbies outside of school and to do "well in all areas of [their] daily life." *Id.* Other Concerta promotional material was found to be misleading because they omitted "material facts regarding the risk of long-term growth suppression" from treatment with the drug. *Id.*

48. Johnson and Johnson Warning Letter, *supra* note 47, at 3.

49. See, e.g., Connie Lenz, *Prescribing a Legislative Response: Educators, Physicians, and Psychotropic Medication for Children*, 22 J. CONTEMP. HEALTH L. & POL'Y 72 (2005); Stephen A. Talmadge, *Who Should Determine What is Best for Children in State Custody Who Object to Psychotropic Medication?*, 15 ANNALS HEALTH L. 183 (2006); Jennifer Albright, Comment, *Free Your Mind: The Right of Minors in New York to Choose Whether or Not to be Treated with Psychotropic Drugs*, 16 ALB. L. J. SCI. & TECH. 169 (2006); Maggie Brandow, Note, *A Spoonful of Sugar Won't Help This Medicine Go Down: Psychotropic Drugs for Abused and Neglected Children*, 72 S. CAL. L. REV. 1151, 1152 (1999).

in subsequent sections of this Article, include: a prohibition of direct-to-consumer advertising of psychotropic drugs, a limitation on use (for "medical purposes" only), and a mandate that prescriptions be issued in accordance with sound medical practice. Also, though it has not yet been ratified in the U.S., I will briefly outline in this part some of the important human rights principles embodied in the United Nations Convention on the Rights of the Child to further illuminate the United States government's positive law obligations to state-involved children under the 1971 Convention.

With that grounding, I will detail in Part III the shockingly high rates of psychotropic drug prescription to state-involved children. Throughout the country, on any given day, thousands of children in state custody are administered a variety of psychotropic drugs despite the known toxicities and addictive properties of these drugs. Ultimately, I will argue that the rise of this problematic trend is at least partially attributable to governmental policies instituted during the "Decade of the Brain," a period in the 1990s when the National Institute of Mental Health shifted its research focus from psychosocial and behavioral interventions to an emphasis on drug treatment as the first-line response to children's mental health problems.

In Part IV, I link the overmedication phenomenon to the United States' failure to prohibit direct-to-consumer advertising of psychotropic drugs despite the 1971 Convention's mandate and the nation's failure to regulate the off-label prescription of these drugs to children in violation of the convention's "medical purposes" requirement. I argue that these governmental omissions are in direct violation of the 1971 Convention and are major contributors to the excessive and inappropriate medication of state-involved children.

In Part V, I address the argument that current practices in the United States run afoul of the 1971 Convention's requirement that governments allow the use of psychotropic medications only for legitimate medical purposes. I argue that the United States government is in violation of the 1971 Convention for failing to prevent the use of psychotropic drugs as chemical restraints against state-involved children and for failing to ensure that state-involved children are not inappropriately prescribed psychotropic drugs to address arguably non-medical behaviors and conditions.

Finally, in Part VI, I draw on investigative research and government reports detailing substantial departures from generally accepted professional standards of diagnosis, monitoring, and follow-up in the administration of psychotropic drugs to children in state foster care systems and juvenile prisons, all to analyze how these egregious practices violate the

1971 Convention's mandate that psychotropic drugs be administered in accordance with sound medical practice. Then, in conclusion, I call on the United States Government to implement regulations and other appropriate measures to ensure compliance with its international legal obligation to protect state-involved children from nonmedically justified administration of psychotropic drugs.

#### I. SOME FACTS ABOUT PSYCHOTROPIC DRUGS

As a class, psychotropic drugs are toxic substances that act directly on the brain to "chemically alter mood, cognition, or behavior, their effect typically being achieved by altering the process of brain neurotransmission."<sup>51</sup> There are generally six classes of psychotropic medications: stimulants,<sup>52</sup> antipsychotics,<sup>53</sup> depressants, antidepressants,<sup>54</sup> anxiolytics (anti-anxiety),<sup>55</sup> and mood stabilizers.<sup>56</sup> These drugs are prescribed to

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51. THOMAS GRISSO, *DOUBLE JEOPARDY: ADOLESCENT OFFENDERS WITH MENTAL DISORDERS* 84 (2004); *see also* RITA WICKS-NELSON & ALLEN C. ISRAEL, *supra* note 3, at 67 ("Medications that affect mood, thought processes, or overt behavior are known as psychotropic or psychoactive and thus the term psychopharmacological treatment is often employed.")

52. Stimulants such as dextroamphetamine (Adderall, Dexedrine) and methylphenidate (Ritalin, Concerta) are used primarily to treat Attention Deficit Hyperactivity Disorder ("ADHD"). BROWN & SAWYER, *supra* note 3, at 91; *see also* NAT'L INST. OF MENTAL HEALTH, *TREATMENT OF CHILDREN WITH MENTAL DISORDERS* (2009), *available at* <http://www.nimh.nih.gov/publicat/childqa.cfm>.

53. *Antipsychotic* medications such as chlorpromazine (Thorazine), haloperidol (Haldol), clozapine (Clozaril), quetiapine (Seroquel), and risperidone (Risperdal) are used for psychosis (e.g., schizophrenia, mania, psychotic depression), severe ADHD unresponsive to other treatments, conduct disorder, and problematic behaviors such as uncontrollable agitation, aggression, or rage, self-injurious behaviors, and extreme impulsivity. ELLIOTT & KELLY, *supra* note 26, at 185; *see also* BROWN & SAWYER, *supra* note 3, at 33–34, 99–106.

54. Physicians prescribe *antidepressants* to children for such diverse conditions as depression, anxiety disorders, ADHD, bulimia, bedwetting, obsessive-compulsive disorder, and post-traumatic stress disorder, as well as uncontrollable agitation, aggression, obsessive behaviors, and self-injurious behaviors. ELLIOTT & KELLY, *supra* note 26, at 174.

55. *Antianxiety or anxiolytic* medications are typically used for anxiety disorders, behavior disorders, seizures, and panic attacks. *See generally* BROWN & SAWYER, *supra* note 3, at 32–33; ELLIOTT & KELLY, *supra* note 26, at 214–24.

56. Doctors prescribe *mood stabilizers*, including drugs such as lithium and the anti-convulsants (Depakote) and carbamazepine (Tegretol), for bipolar disorder, conduct disorder, aggressive behaviors, and labile mood with tantrums or rages. ELLIOTT & KELLY, *supra* note 23, at 115–17. *See generally*, BARBARA A. LEADHOLM, *PSYCHOACTIVE MEDICATIONS FOR CHILDREN AND ADOLESCENTS: ORIENTATION FOR PARENTS, GUARDIANS, AND OTHERS* 7–12 (rev. 2007), *available at* [http://www.mass.gov/Eeohhs2/docs/dmh/publications/psychoactive\\_booklet.pdf](http://www.mass.gov/Eeohhs2/docs/dmh/publications/psychoactive_booklet.pdf).

children for conditions such as ADHD, obsessive-compulsive disorder ("OCD"), depression, and bipolar (manic-depressive) disorder, as well as for non-disorder-specific behaviors such as severe aggression, sleep problems, and bedwetting.<sup>57</sup>

Best practices dictate that psychotropic drugs should be used only as a last resort, and never as the sole approach to addressing children's mental health needs.<sup>58</sup> The National Institute of Mental Health identifies a range of psychotherapies available to address mental health needs, including: cognitive behavioral therapy, dialectical behavior therapy, interpersonal therapy, and family-focused therapy, as well as other nonpharmaceutical approaches, such as light therapy, expressive or creative arts therapy, animal-assisted therapy, and play therapy.<sup>59</sup> Advocates of drug therapy claim that psychotropic drugs help stabilize behaviors and emotions that impair the abilities of some children to function at home, in school, and in interactions with their peers.<sup>60</sup> However, proponents recognize that these drugs can also worsen existing problems or create entirely new ones.<sup>61</sup> The risks posed by psychotropic drugs to the health and safety of children range from the fairly innocuous—e.g., dry mouth and headache—to more serious side effects, such as thyroid dysfunction, growth retardation, increased risk for polycystic ovary syndrome, abnormal weight gain, liver damage, heart failure, and death.<sup>62</sup>

Although many of the psychotropic drugs that are prescribed to children are not subject to international control, they nevertheless can raise the same significant safety and health concerns sought to be addressed by provisions of the 1971 Convention examined in this Article. These in-

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57. See *Psychiatric Medication for Children and Adolescents Part I—How Medications are Used*, FACTS FOR FAMILIES, (Am. Acad. of Child & Adolescent Psychiatry, Washington, D.C.), July 2004, available at [http://www.aacap.org/galleries/FactsForFamilies/21\\_psychiatric\\_medication\\_for\\_children\\_and\\_adolescents\\_part\\_one.pdf](http://www.aacap.org/galleries/FactsForFamilies/21_psychiatric_medication_for_children_and_adolescents_part_one.pdf).

58. See, e.g., CHILD WELFARE LEAGUE OF AM., STANDARDS OF EXCELLENCE FOR HEALTH CARE SERVICES FOR CHILDREN IN OUT-OF-HOME CARE 18 (Julie Gwin ed., rev. ed. 2007) ("Psychiatrists specializing in the treatment of children advise that psychotropic medication should not be used as the sole treatment for children with mental health disorders.").

59. National Institute of Mental Health, Psychotherapies, <http://www.nimh.nih.gov/health/topics/psychotherapies/index.shtml>.

60. See GRUTTADARO & MILLER, *supra* note 1, at 6.

61. ELLIOTT & KELLY, *supra* note 26, at 9.

62. See, e.g., Christoph U. Correll & Harold E. Carlson, *Endocrine and Metabolic Adverse Effects of Psychotropic Medications in Children and Adolescents*, 45 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 771 (2006); see also FLA. STATEWIDE ADVOCACY COUNCIL, RED ITEM REPORT: PSYCHOTROPIC DRUG USE IN FOSTER CARE 4 (2003), available at <http://psychrights.org/States/Florida/030701FloridaStatewideAdvocacyCouncilReport.pdf>; GRISSE, *supra* note 51, at 90.

clude: antidepressants (e.g., tricyclics such as clomipramine (Anafranil) and imipramine (Tofranil); SSRIs (e.g., escitalopram (Lexapro), fluoxetine (Prozac), paroxetine (Paxil), and sertraline (Zoloft)); typical and atypical antipsychotics (e.g., chlorpromazine (Thorazine), haloperidol (Haldol), aripiprazole (Abilify), quetiapine (Seroquel), risperidone (Risperdal), and ziprasidone (Geodon)); and mood stabilizers (e.g., Lithium, carbamazepine (Tegretol), and valproic acid (Depakote)).<sup>63</sup> The medications commonly prescribed to children that are deemed to be “controlled substances” are listed on the 1971 Convention’s “Green List,” and include: Schedule II methylphenidates and amphetamines primarily used to treat ADD/ADHD (e.g., methylphenidates marketed as Concerta, Focalin, Metadate, Methylin, and Ritalin, and amphetamines marketed as Adderall, Dextrostate, and Dexedrine); Schedule IV benzodiazapines, primarily used as anti-anxiety agents (e.g., alprazolam (Xanax), clonazepam (Klonopin), diazepam (Valium), and lorazepam (Ativan)); and the non-benzodiazapine sleep agent zolpidem (Ambien).<sup>64</sup> As described in the next section, the 1971 Convention mandates that governments implement and enforce strict controls over the prescription and use of Green List drugs.

## II. INTERNATIONAL LAW GOVERNING PSYCHOTROPIC DRUGS: THE 1971 CONVENTION

Due to the limited therapeutic value, highly addictive properties, and susceptibility to illegal trafficking of psychotropic drugs, the 1971 Convention<sup>65</sup> establishes strict guidelines for governmental control over the use of such drugs. Thus, while it recognizes that “the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted,”<sup>66</sup> the Convention emphasizes that “rigorous measures are necessary to restrict the use of such substances to legitimate purposes.”<sup>67</sup>

The World Health Organization (“WHO”) has sole responsibility for evaluating and making recommendations to the Commission on Narcotic Drugs about the level of international control to be applied to a particular drug.<sup>68</sup> Placement of a drug in a particular “Schedule” indicates the WHO’s determination as to the balance between a drug’s potential for

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63. See generally ELLIOTT & KELLY, *supra* note 26, at 151–224.

64. See GREEN LIST, *supra* note 30, at 5.

65. See 1971 Convention, *supra* note 4, preamble.

66. *Id.* at preamble.

67. *Id.* at preamble.

68. WORLD HEALTH ORG., WHO EXPERT COMMITTEE ON DRUG DEPENDENCE: THIRTY THIRD REPORT 1 (2003).

abuse and its medical usefulness. Accordingly, more restrictive controls are imposed as the potential for abuse increases and the medical usefulness of a particular psychotropic drug decreases. For example, substances such as lysergide ("LSD") are placed in Schedule I, indicating that its "liability to abuse constitutes an especially serious risk to public health" and that it has "very limited, if any, therapeutic usefulness."<sup>69</sup> Amphetamines (e.g., Adderall) and methylphenidate (e.g., Ritalin) are placed in Schedule II along with other psychotropic substances "whose liability to abuse constitutes a substantial risk to public health and which have little to moderate therapeutic usefulness."<sup>70</sup> The likelihood of abuse of Schedule III substances (e.g., various barbiturates such as amobarbital and pentobarbital, and the "date rape drug" flunitrazepam ("Rohypnol")) constitute a "substantial risk to public health" with "moderate to great therapeutic usefulness."<sup>71</sup> Schedule IV drugs such as pemoline (Cylert), diazepam (Valium), and lorazepam (Ativan) are deemed to have a "significant risk to public health" and "a therapeutic usefulness from little to great."<sup>72</sup>

Under the 1971 Convention, the United States must, "with due regard to its constitutional provisions," prohibit the advertisement of psychotropic drugs to the general public.<sup>73</sup> It must ensure that psychotropic drugs are used only for legitimate "medical and scientific" purposes<sup>74</sup> in ways that do not "compromise individual and public health,"<sup>75</sup> and make sure that psychotropic drugs are "supplied or dispensed for use by individuals pursuant to medical prescription only."<sup>76</sup> Furthermore, labels for these drugs must provide: "directions for use, including cautions and warnings, . . . necessary for the safety of the user."<sup>77</sup> Prescriptions must be issued in accordance with "sound medical practice,"<sup>78</sup> and the government must take "all practicable measures for the prevention of abuse of psychotropic substances."<sup>79</sup>

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69. *Id.* at 3.

70. *Id.* at 3.

71. *Id.* at 3.

72. *Id.* at 3.

73. 1971 Convention, *supra* note 4, art. 10(2).

74. *Id.* at art. 10(2).

75. U.N. DRUG CONTROL PROGRAMME, AMPHETAMINE-TYPE STIMULANTS: A GLOBAL REVIEW 3 (1996), available at [http://www.unodc.org/pdf/technical\\_series\\_1996-01-01\\_1.pdf#search=%22amphetamine-type%20stimulants%20a%20global%20review%22](http://www.unodc.org/pdf/technical_series_1996-01-01_1.pdf#search=%22amphetamine-type%20stimulants%20a%20global%20review%22).

76. 1971 Convention, *supra* note 4, art. 9(1).

77. *Id.* at art. 10(1).

78. *Id.* at art. 9(2).

79. *Id.* at art. 20.

The nature of psychotropic drugs as a threat to public health and safety is echoed in the United Nations Convention on the Rights of the Child ("CRC").<sup>80</sup> This treaty, ratified by every recognized government except the United States,<sup>81</sup> reflects the international community's recognition that children are particularly deserving of protection from the potentially devastating effects of unwarranted exposure to psychotropic drugs. Although it has not ratified the convention, the United States has signed it, and, as such, commentators and courts have argued that the United States is obligated to uphold its provisions both under the Vienna Convention's exhortation to refrain from doing anything that "would defeat the purposes and objects" of a treaty signed but not ratified by a government,<sup>82</sup> as well as under customary international law.<sup>83</sup>

The central motivating premise of the CRC is that "the best interests of the child shall be a primary consideration" in all actions undertaken by public and private institutions and governmental agents.<sup>84</sup> In accordance with that principle, Article 33 of the CRC explicitly provides that governments "shall take all appropriate measures, including legislative, administrative, social[,] and educational measures, to protect children from the illicit use of . . . psychotropic substances as defined in the relevant international treaties."<sup>85</sup> Concomitantly, governments must "undertake to ensure the child such protection and care as is necessary" for the child's well-being, and "ensure that the institutions, services[,] and facilities responsible for the care or protection of children . . . conform with the standards established by competent authorities, particularly in the areas of safety, health, in the number and suitability of their staff, as well as competent supervision."<sup>86</sup>

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80. Convention on the Rights of the Child, *opened for signature* Nov. 20, 1989, 1577 U.N.T.S. 3.

81. See Christina Okereke, Note, *The Abuse of Girls in U.S. Juvenile Detention Facilities: Why the United States Should Ratify the Convention on the Rights of the Child and Establish a National Ombudsman for Children's Rights*, 30 *FORDHAM INT'L L.J.* 1709 (2007).

82. Vienna Convention on the Law of Treaties art. 18, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331.

83. See Rebecca M. Stahl, Note, *"Don't Forget About Me": Implementing Article 12 of the United Nations Convention on the Rights of the Child*, 24 *ARIZ. J. INT'L & COMP. L.* 803, 811–12 (2007).

84. Convention on the Rights of the Child, *supra* note 81, art. 2.

85. Convention on the Rights of the Child, *supra* note 81, art. 33.

86. Convention on the Rights of the Child, *supra* note 81, art. 3. More generally, Article 19 of the CRC provides that children are to be protected from "all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation, . . . while in the care of parent(s), legal guardian(s) or any other person who has the care of the child." *Id.* at art.19. Additionally, children have the right to be free

These principles embodied in the Convention on the Rights of the Child further illuminate the international community's concern that children be protected from unwarranted exposure to psychotropic drugs. The overarching thrust of the 1971 Convention and the Children's Rights Convention is that governments should take all necessary measures to ensure that the public in general, and children in particular, are protected from the harmful effects of unregulated, medically unjustified uses of psychotropic drugs. With this legal framework as the backdrop, the next part of this Article documents the shockingly high rates at which state-involved children are prescribed psychotropic drugs while exploring the connection between the overmedication of state-involved children and the U.S. government's failure to aggressively regulate off-label prescription to children and direct-to-consumer advertising of psychotropic drugs.

### III. EPIDEMIC PSYCHOTROPIC DRUG PRESCRIBING TO UNITED STATES CHILDREN

Although psychotropic drugs have long been used (illegitimately) to control problematic behaviors of children in juvenile prisons,<sup>87</sup> psychotropic drug prescriptions to state-involved children, as well as to children in the general public, have exploded since the 1990s.<sup>88</sup> The following

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from economic exploitation, *id.* at art. 32, and from "all other forms of exploitation prejudicial to any aspects of the child's welfare." *Id.* at art. 36. Finally, Article 37 requires that "no child shall be subjected to torture or other cruel, inhuman or degrading treatment or punishment," and that "every child deprived of liberty shall be treated with humanity and respect for the inherent dignity of the human person, and in a manner which takes into account the needs of persons of his or her age." *Id.* at art. 37.

87. See, e.g., *Nelson v. Heyne*, 491 F.2d 352, 357 (7th Cir. 1974) (detailing abuses of psychotropic drugs in juvenile facilities and concluding that "the use of tranquilizing drugs as practiced by defendants constituted cruel and unusual punishment" in violation of the children's rights under the 14th Amendment to the United States Constitution.); *Pena v. N.Y. State Div. for Youth*, 419 F. Supp. 203, 204 (S.D.N.Y. 1976) (challenging the Goshen Annex for Boys, an institution within the New York State training school system, for their use of isolation, hand and feet restraints, and thiorazine and other tranquilizing drugs to control excited behavior of the children under the Eighth and Fourteenth Amendments); *Drugs in Institutions: Hearings Before the Subcommittee to Investigate Juvenile Delinquency of the Senate Committee on the Judiciary*, 94th Cong., 1st Sess. 2 (1975) [hereinafter *Drugs in Institutions*].

88. See generally Mark Olfson et al., *National Trends in the Treatment of Attention Deficit Hyperactivity Disorder*, 160 AM. J. OF PSYCHIATRY 1071 (2003); Mark Olfson et al., *National Trends in the Use of Psychotropic Medications by Children*, 41 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 514 (2002); Julie M. Zito et al., *Psychotropic Practice Patterns for Youth: A Ten Year Perspective*, 157 ARCHIVES PEDIATRICS & ADOLESCENT MED. 17, 17 (2003).

section details those astronomical increases and traces their evolution to the “Decade of the Brain,” during which time the federal government shifted the national focus from ecological factors in mental illness with an emphasis on psychosocial interventions to the biomedical view of mental illness as an organic brain disease best remediated with pharmaceuticals.

*A. Psychotropic Drugs Are Prescribed to State-Involved Children at Alarming Rates*

According to a widely-cited 2006 Brandeis University study, psychotropic drug prescriptions for teenagers skyrocketed 250% between 1994 and 2001.<sup>89</sup> The Brandeis researchers found that the proportion of visits that resulted in psychotropic prescription rose from 3.4% in 1994–1995 to 8.3% in 2000–2001, with the rate of such visits increasing 161.6% for youth ages fourteen to eighteen during that same period.<sup>90</sup> Strikingly, they also found that the proportion of these visits associated with a mental health diagnosis did not increase.<sup>91</sup> In fact, during this same period, no psychiatric diagnosis was recorded for 14 to 26% of the youths who were prescribed a psychotropic medication.<sup>92</sup> The authors concluded, somewhat diplomatically, that it was unclear whether the rapid increases in psychotropic drug prescriptions represented “a move toward greater access and more appropriate treatment or whether this represents an overreliance on medications.”<sup>93</sup>

Some view the dramatic shift toward psychotropic drug use in children as an indication of “better case finding, better diagnosing, and a realization that we do have active treatments that can benefit children.”<sup>94</sup> However, some critics see the increasing proliferation of pediatric psychopharmacology as evidence that psychotropic drugs are being used illegitimately under the guise of beneficial mental health treatment, to serve as a “chemical sledgehammer” to make state-involved children easier to manage.<sup>95</sup> Indeed, evidence shows that children in state custody are par-

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89. See generally Cindy Parks Thomas et al., *Trends in the Use of Psychotropic Medications Among Adolescents, 1994 to 2001*, 57 PSYCHIATRIC SERVICES 63 (2006).

90. *Id.* at 65–66.

91. *Id.*

92. *Id.*

93. *Id.* at 68.

94. *An Interview with Marilyn Benoit, M.D., President of the American Academy of Child and Adolescent Psychiatry*, STATE HEALTH LAWMAKERS' DIG. (Nat'l Conference of State Legislatures, Washington, D.C.), Spring 2003.

95. David Crary, *A Dilemma: Medications for Foster Kids*, BOSTON.COM, Mar. 13, 2007,

ticularly at risk of being prescribed psychotropic medications for problematic behaviors such as causing disturbances or acting out.<sup>96</sup> Although poor record-keeping makes it difficult to accurately determine the exact magnitude of the practice, the predominance of psychopharmacology as the intervention of choice in responding to the psychological needs of state-involved children is well-documented.<sup>97</sup>

For example, a 2001 report established that approximately 600 children who were enrolled in the Florida Medicaid system—most of which were in foster care and younger than age five—were prescribed drugs marketed to treat schizophrenia, an illness very rarely diagnosed in children of that age.<sup>98</sup> Jack Levine, then president of the Center for Florida's Children, noted that

[w]e make some basic assumptions about children who need medical care, assumptions about services that are supported by tax dollars, and especially about children who are in the care of state agencies.

An assumption I thought we made was that their care would never be appreciably different, in terms of medical carefulness and appropriateness of prescriptions, than everyone else's children.<sup>99</sup>

Levine's analysis suggested "a remarkable difference in how these children are being looked at, diagnosed, and treated," and he went on to warn that he was "starting to get scared."<sup>100</sup> Similarly frightening findings were made by the Texas Comptroller, Carole Strayhorn, who, in 2004, issued a scathing report on the Texas foster care system, charging that "astronomical amounts" of psychotropic medications were being dispensed to Texas foster children and that the Texas child welfare agen-

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[http://www.boston.com/news/nation/articles/2007/03/13/a\\_dilemma\\_medications\\_for\\_foster\\_kids/](http://www.boston.com/news/nation/articles/2007/03/13/a_dilemma_medications_for_foster_kids/).

96. *Id.* (Observing that "[c]oast to coast, states are wrestling with how best to treat the legions of emotionally troubled foster kids in their care. Critics contend that powerful psychiatric drugs are overused and say poor record keeping masks the scope of the problem.").

97. See Andrés Martin et al., *Multiple Psychotropic Pharmacotherapy Among Child and Adolescent Enrollees in Connecticut Medicaid Managed Care*, 54 *PSYCHIATRIC SERVICES* 72 (2003), available at <http://psychservices.psychiatryonline.org/cgi/reprint/54/1/72>.

98. Carol Marbin Miller, *Advocates Alarmed By Drugs Used for Kids: Medicaid Children Under 6 at Issue*, *MIAMI HERALD*, May 7, 2001, available at [http://www.vachss.com/help\\_text/archive/advocates\\_alarmed.html](http://www.vachss.com/help_text/archive/advocates_alarmed.html).

99. *Id.*

100. *Id.*

cy exercised “little meaningful oversight over these medications.”<sup>101</sup> Strayhorn found evidence that many Texas foster care children were administered psychotropic drugs, not for legitimate medical purposes, but rather, to generate more money for the child welfare agency and foster parents.<sup>102</sup>

Other accounts of prescribing practices with respect to state-involved children include a University of Minnesota study showing that nearly 35% of foster children in St. Louis County were receiving psychotropic medication compared with 15% of the general population,<sup>103</sup> and a 2003 report from the Florida Statewide Advocacy Council finding that over 50% of the children enrolled in the Florida Medicaid program (approximately 9,500) “had been treated with one or more psychotropic drugs in the year 2000.”<sup>104</sup> The ages of the Florida children ranged from less than one to seventeen.<sup>105</sup> Additionally, a host of investigative news reports in recent years attest to the sharp increase in prescriptions of psychotropic drugs to foster care children nationwide.<sup>106</sup>

A similar pattern is evident in juvenile prisons across the country. For example, an April 2002 study by the Oregon Youth Authority (“OYA”) found that 81% of girls in Oregon’s juvenile correctional facilities met the requirements for a psychiatric diagnosis and 72% were taking psychotropic medication.<sup>107</sup> The report similarly documented that 54% of

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101. CAROLE KEETON STRAYHORN, TEX. COMPTROLLER OF PUB. ACCOUNTS, FORGOTTEN CHILDREN: A SPECIAL REPORT ON THE TEXAS FOSTER CARE SYSTEM 199 (2004).

102. *Id.*

103. Hagen & Orbeck, *supra* note 12.

104. FLA. STATEWIDE ADVOCACY COUNCIL, *supra* note 63, at 4. The Florida study further documented that 44% of the children on psychotropic medications were not under the care of a physician, while others had no psychiatric diagnosis or had a diagnosis described as “other.” *Id.* at 12, 13. Thirty-eight percent of the children studied were given drugs without a signed consent from a parent, guardian or judge, as state law requires. *Id.* at 17. Moreover, 89% of the children had no records in their file to show they were being medically monitored. *Id.* at 18.

105. *Id.* at 5.

106. See, e.g., Gary Craig, *Potent Pills: More foster kids getting mood-altering drugs*, DEMOCRAT & CHRONICLE, Dec. 9, 2007; Gary Craig, *Issue Hasn't Had Much Scrutiny in N.Y.*, DEMOCRAT & CHRONICLE, Dec. 10, 2007; Crary, *supra* note 96; Editorial, *The Drugging of Foster Youth*, S.F. CHRON., June 11, 2006 (noting that California does not attempt to keep track of how many foster youth are given psychotropic drugs, and that members of a state created Blue Ribbon Commission on Foster care were caught off guard “when the overuse of psychotropic medications emerged as a major theme of foster youth talking about what is wrong with the system.”).

107. OR. YOUTH AUTH., MENTAL HEALTH AND FEMALE OFFENDERS IN THE CUSTODY OF THE OREGON YOUTH AUTHORITY 3 (2002), available at [http://www.oregon.gov/OYA/docs/female\\_mhgap.pdf](http://www.oregon.gov/OYA/docs/female_mhgap.pdf).

boys diagnosed with psychiatric conditions such as personality disorders and mental retardation were prescribed psychotropic drugs.<sup>108</sup> A 2000 survey of juvenile correctional facilities in Pennsylvania found that psychotropic drugs were prescribed to as many as 40% to 50% of the children in some of the state's juvenile prisons.<sup>109</sup> Further, a 2004 report by the New Jersey Office of the Child Advocate detailing the conditions of juvenile confinement in New Jersey's seventeen county juvenile detention centers revealed that, depending on the facility, anywhere from 10% to 50% of the children were taking psychotropic medications.<sup>110</sup>

Low-income children are also particularly susceptible. Medicaid is a major source of funding for mental health and related support services for children, and, as of 2005, it covered 26% of U.S. children.<sup>111</sup> In Texas, the prevalence of anti-psychotic drugs in the population of children receiving benefits from the Texas Medicaid Program increased by 164% between 1996 and 2000 and the use of atypical antipsychotics<sup>112</sup> increased by 494% over the same period.<sup>113</sup> A study of children and adolescents in low- and moderate-income families who received medical care through TennCare (Tennessee's managed care program for Medicaid enrollees and the uninsured) revealed that the use of antipsychotic drugs among low-income children nearly doubled between 1996 and

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108. *Id.*

109. Patrick Griffin, *Assessing Detained Youth in Pennsylvania*, 7:3 PA. PROGRESS: JUV. JUST. ACHIEVEMENTS IN PA. (Nat'l Ctr. for Juv. Just., Harrisburg, PA.), Dec. 2000, at 4, available at <http://www.ncjservehttp.org/NCJJWebsite/pdf/dec2000.pdf>.

110. NEW JERSEY OFFICE OF THE CHILD ADVOCATE, JUVENILE DETENTION CENTER INVESTIGATION: AN EXAMINATION OF CONDITIONS OF CARE FOR YOUTH WITH MENTAL HEALTH NEEDS—EXECUTIVE SUMMARY 4 (2004), available at [http://www.state.nj.us/childadvocate/publications/PDFs/1FINAL\\_JJ\\_Mental\\_Health\\_Exec\\_Sum.pdf](http://www.state.nj.us/childadvocate/publications/PDFs/1FINAL_JJ_Mental_Health_Exec_Sum.pdf).

111. The Henry J. Kaiser Family Foundation, Key Medicare and Medicaid Statistics, <http://www.kff.org/medicaid/upload/Key%20Medicare%20and%20Medicaid%20Statistics.pdf>.

112. See CHRISTINE CULHANE, MENTAL HEALTH RESEARCH INSTITUTE OF VICTORIA, A GUIDE TO PSYCHOTROPIC DRUGS 2 (2005), available at <http://www.mhri.edu.au/pdf/A%20GUIDE%20TO%20PSYCHOTROPIC%20DRUGS.pdf> ("Antipsychotics are used primarily in the treatment of psychoses. They diminish the agitation, delusions, hallucinations and thought disorder of these illnesses. . . . They are loosely divided into typical (older) agents and atypical (newer) agents. The main differences are in the side effect profiles. The newer drugs are less likely to produce parkinsonian symptoms or other movement problems.")

113. Nick C. Patel et al., *Trends in Antipsychotic Use in a Texas Medicaid Population of Children and Adolescents: 1996 to 2000*, 12 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 221, 223 (2002).

2001.<sup>114</sup> The percentage of psychotropic prescriptions to Tennessee's poor children jumped by 61% among preschoolers, 93% among those age six to twelve, and 116% among children age thirteen to eighteen.<sup>115</sup> Consistent with statistics in other states, a study of Connecticut's Medicaid managed care database concluded that the strongest predictor for whether a Connecticut child would be receiving psychotropic medications was state custody.<sup>116</sup>

These staggering statistics beg the question whether the behaviors of state-involved children are sufficiently aberrant to warrant such apparently heavy-handed medication practices. While some argue that the huge increase in the use of psychotropic medications among children during the 1990s indicates a greater awareness of treatments—both within the medical industry and society at large—that can better children's lives,<sup>117</sup> others describe the phenomenon as “child abuse on a grand scale.”<sup>118</sup> As Thomas Grisso, a well-known expert in juvenile justice and pediatric forensic psychology has stressed, even “beneficent interventions unrestrained can carry with them potential dangers to liberty and self-determination,” including the “potential overuse of medications to achieve behavioral control” of children.<sup>119</sup>

### *B. The 1990s: “Decade of the Brain”*

Studies have documented that pediatric psychopharmacotherapy in the United States increased dramatically during the late 1980s and through-

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114. William O. Cooper et al., *New Users of Antipsychotic Medications Among Children Enrolled in TennCare*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED. 753, 753 (2004).

115. *Id.*

116. Martin et al., *supra* note 98, at 76; *see also* Encarnacion Pyle, *supra* note 16. Pyle reported that, in July 2004, 31% of children ages 6 to 18 in foster and group homes were on psychotropics, and, as of January 2005, 22% of children in juvenile detention facilities were taking the drugs. Many of the children were prescribed five or more psychotropic drugs. Encarnacion Pyle, *supra* note 16. The investigation found that nearly 40,000 Ohio children on Medicaid were taking drugs for anxiety, depression, delusions, hyperactivity and violent behavior as of July 2004, and that Ohio spent over \$65 million on the drugs for kids in 2004. *Id.* The report also found that doctors in Ohio prescribed sedatives and mood-altering medications for nearly 700 babies and toddlers who were on Medicaid. *Id.*

117. *See An Interview with Marilyn Benoit, M.D.*, *supra* note 95.

118. Carol Marbin Miller, *Mind-Altering Drugs Given to Some Babies in DCF's Care*, MIAMI HERALD, Sept. 17, 2002, at A1 (quoting Richard Wexler, head of the Virginia-based National Coalition for Child Protection Reform).

119. GRISSO, *supra* note 51, at 17; *see also* SAMI TAMIMI, PATHOLOGICAL CHILD PSYCHIATRY AND THE MEDICALIZATION OF CHILDHOOD 15 (2002).

out the 1990s.<sup>120</sup> Psychopharmacology rests on the premise that certain behaviors or psychological conditions are evidence of organic disease stemming from brain dysfunction and/or genetic abnormality that are most effectively treated with psychotropic drugs that chemically alter the brain.<sup>121</sup> This understanding of psychiatric disorder or mental illness as biomedical "brain disease" marks a significant departure from previously dominant theories that recognize social-environmental factors as prominent contributors to mental, emotional, and cognitive disturbances.<sup>122</sup> Historically, the biomedical view of mental disorder gained its stronghold in 1980 with the publication of the third edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-III"). Despite the lack of scientific proof for its underlying theory of brain dysfunction, the DSM-III, "with its symptom-based orientation . . . contributed significantly to a biological vision of mental health—which stresses the neurosciences, brain chemistry, and medications—superseding the psychosocial vision that had dominated for decades."<sup>123</sup> This new paradigm of mental illness "focused on the symptoms of mental disorders rather than their causes and emphasized pharmacological treatments over talk therapy and behavioral changes."<sup>124</sup>

The United States government has played a central role in promoting the biomedical paradigm of mental disorder and the concomitant empha-

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120. See, e.g., Thomas et al., *supra* note 90, at 63–69 (2006) (finding that the proportion of office-based visits of 14 to 18 year olds that resulted in a psychotropic drug prescription rose from 3.4% in 1994-1995 to 8.3% in 2000-2001); Zito et al., *supra* note 89, at 17–25 (finding that, during the 1990s, psychotropic drug use among youth increased 2 to 3-fold across most categories of medication, nearly reaching the adult utilization rates); Olfson, *National Trends in the Use of Psychotropic Medications*, *supra* note 89 (documenting significant increases in psychotropic drug use among children and adolescents between 1987 and 1996, particularly stimulants and antidepressants).

121. Rick Mayes & Allan Horwitz, *DSM-III and the Revolution in the Classification of Mental Illness*, 41 J. HIST. BEHAVIORAL SCI. 249, 258 (2005). In this article, the authors endeavor to "explain the origins of the DSM-III, the political struggles that generated it, and its long-term consequences for clinical diagnosis and treatment of mental disorders in the United States." *Id.* at 249. Mayes and Horwitz argue that "[a] revolution occurred within the psychiatric profession in the early 1980s that rapidly transformed the theory and practice of mental health in the United States" wherein "mental illnesses were transformed from broad, etiologically defined entities that were continuous with normality to symptom-based, categorical diseases." *Id.* According to the authors, "[b]y the mid-1980s, . . . the historic shift from a psychosocial to a symptom-based view of mental health was complete" and "psychotherapy became the primary domain of clinical psychologists, counselors, and social workers," while "[p]sychopharmacological therapy became the private 'turf' of medically trained psychiatrists." *Id.* at 255–56.

122. *Id.*

123. *Id.*

124. *Id.*

sis on drug intervention. The National Institute of Mental Health ("NIMH"), the government agency that finances and conducts research on mental illness, funded field trials of the DSM-III and "legitimiz[ed] the results by granting them the government's seal of approval."<sup>125</sup> Government support for the brain disease vision of mental illness crystallized in 1989 with the designation by former President George Walker Bush of the 1990s as the "Decade of the Brain."<sup>126</sup> In his official proclamation Bush asserted that "millions of Americans are affected each year by disorders of the brain," and declared that the goal of the initiative was twofold: to enhance "public awareness of the benefits to be derived from brain research," and to focus government research on disorders and disabilities that affect the brain.<sup>127</sup>

In the aftermath of these developments, the NIMH de-emphasized funding for research into social, economic, and familial factors in mental disorders and prioritized research on brain dysfunction, genetics, and chemical imbalances.<sup>128</sup> This intensified quest to promote the concept of

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125. *Id.* at 261.

126. Proclamation No. 6153, 55 Fed. Reg. 29,553 (July 18, 1990). Bush's proclamation was preceded by a joint resolution of the House of Representatives and the Senate. H.R.J. Res. 174, 101st Cong. (1989).

127. Proclamation No. 6153, 55 Fed. Reg. 29,553 (July 18, 1990). Library of Congress, Project on the Decade of the Brain, <http://www.loc.gov/loc/brain> (to advance this goal, from 1990 to the end of 1999, the Library of Congress and the National Institute of Mental Health of the National Institutes of Health co-sponsored a variety of activities including publications and programs "aimed at introducing Members of Congress, their staffs, and the general public to cutting-edge research on the brain and encouraging public dialogue on the ethical, philosophical, and humanistic implications of these emerging discoveries.").

128. See generally *Neuroscience Research at NIH: Hearing Before the S. Comm. on Labor & Human Resources*, 104th Cong. (1996) (statement of Zach W. Hall, Director, National Institute of Neurological Disorders and Stroke & Carl Kupfer, Director, National Eye Institute & Alan I. Lesner, Director, National Institute on Drug Abuse), available at <http://www.hhs.gov/asl/testify/t960306d.html> (observing that "the treatment of brain disease has been transformed by two developments. First, the extent and pervasiveness of brain diseases has become more apparent, as the biological basis of such disorders as mental illnesses, alcohol abuse, and other drug addiction have become increasingly recognized. Second we are entering an era of treatment of brain disease. . . . A wide range of treatments for mental illness has greatly improved the lives of many people."); Edward G. Jones & Lorne M. Mendell, Editorial, *Assessing the Decade of the Brain*, 284 SCIENCE 739, 739 (1999).

Norbert Myslinki, a professor of pharmacology at the University of Maryland wrote in 2001 that "[a]nother indicator of the success of the Decade of the Brain is that the public increasingly views mental illness as a dysfunction of the brain, not a matter of choice, not a character defect, and not (as a few psychiatrists have argued) as an arbitrary label that society puts on undesirable behavior . . . . [L]awmakers . . . were able to understand

mental illness as brain disease, fueled by an infusion of government funding,<sup>129</sup> led to a shift in mental health treatment modalities toward primacy for drug therapies.<sup>130</sup> Government support came to be weighted heavily toward research into neuropsychological processes—"mapping the brain's biochemical circuitry"<sup>131</sup>—as an avenue for developing drugs to treat mental disorders.<sup>132</sup>

More specifically, during the Decade of the Brain, the U.S. government played a central role in promoting pediatric psychopharmacotherapy.<sup>133</sup> The federal government targeted the study of mental illness among children and adolescents as an explicit priority,<sup>134</sup> and NIMH funding for

[mental illness] is a physical disease of the brain, just as heart disease is a physical disease of the heart, and lung cancer is a physical disease of the lungs." Norbert R. Myslinski, *A Revolution in Brain Literacy*, DANA FOUNDATION (2001), <http://www.dana.org/news/cerebrum/detail.aspx?id=1470>.

129. For example, the 1997 budget for the National Institutes of Health "continue[d] the Administration's high-priority investment in biomedical and behavioral research, with a proposed budget of \$12.4 billion for NIH, a \$467 million or 4%, increase over FY 1996;" an additional \$99 million was targeted to five research areas "identified for emphasis by the Administration," including "research on the biology of brain disorders." Howard J. Silver, *Proposed Fiscal Year 1997 Budgets for Social and Behavioral Science Research*, 34 SOCIETY, 2, 21 (1996).

130. See George W. Albee, *Just Say No to Psychotropic Drugs!*, 58 J. CLINICAL PSYCHOLOGY 635, 637 (2002) (arguing that the generally accepted view that "most mental disorders are learned in pathological social environments was supported by a wide range of scientific research, until the organic psychiatrists took over the National Institute of Mental Health under Reagan.").

131. Proclamation No. 6153, 55 Fed. Reg. 29,553 (July 18, 1990).

132. See PN Tandon, *The Decade of the Brain: A Brief Review*, 48 NEUROLOGY INDIA 199 (2000).

133. Writing in 1990, the director of NIMH noted "[d]ramatic advances have occurred in child and adolescent mental health research during the past two decades. A scientific base is now in place that has given clinicians powerful new tools for diagnosing and treating a number of the mental disorders that afflict young people. The National Institute of Mental Health (NIMH) has played a central leadership role in stimulating and supporting this progress." NAT'L INST. OF MENTAL HEALTH, DEP'T OF HEALTH AND HUMAN SERV., NATIONAL PLAN FOR RESEARCH ON CHILD AND ADOLESCENT MENTAL HEALTH DISORDERS 7 (1990), available at [http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content\\_storage\\_01/0000019b/80/22/b0/74.pdf](http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/22/b0/74.pdf) [hereinafter NIMH NATIONAL PLAN].

134. See, e.g., *id.* See generally NAT'L INST. OF MENTAL HEALTH, PATHWAYS TO HEALTH: CHARTING THE SCIENCE OF THE BRAIN, MIND, AND BEHAVIOR: A RESEARCH STRATEGIC PLAN FOR THE NATIONAL INSTITUTE OF MENTAL HEALTH FISCAL YEARS 2000–2001, available at <http://www.nimh.nih.gov/about/strategic-planning-reports/pathways-to-health-charting-the-science-of-brain-mind-and-behavior.pdf>; DEP'T OF HEALTH & HUMAN SERV., MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 190 (1999), available at <http://www.surgeongeneral.gov/library/mentalhealth>; Mary L. Durham & Mary J. England, Commentary, *Research on Child and Adolescent Mental Health: NIMH's Blueprint for Change*, PERMANENTE J., Winter 2002, at 10–12, available at <http://xnet>.

research in the field of child and adolescent psychiatry expanded dramatically.<sup>135</sup> The NIMH's 1990 *National Plan for Research on Child and Adolescent Mental Health Disorders* clearly signaled the government's new, biomedically-oriented direction. Although it acknowledged, in passing, the role of environment in children's mental health issues, the *National Plan* firmly asserted that "[b]iology often sets the stage for trouble, as brain cells develop or function abnormally. We need to understand how this happens and how to set things right."<sup>136</sup> The plan highlighted the shift to pharmacological interventions; for example, it claimed that NIMH funding for lithium had "helped millions of adults with manic-depressive illness, and it may have additional therapeutic payoff for many children and adolescents with mental disorders."<sup>137</sup>

Before the 1990s, prescription rates of psychotropic drugs to children in the general population were relatively low.<sup>138</sup> However, it can be argued that the combination of the U.S. government's increased emphasis on brain research, its support for prioritizing biomedical approaches to treatment of psychiatric conditions, and its targeted focus on children and adolescents all contributed significantly to the meteoric rise in the prescription of psychotropic drugs to children since 1990, and to the rise among state-involved children in particular.<sup>139</sup> In the words of noted

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kp.org/permanentejournal/winter02/nimhs.html; WORKGROUP ON CHILD & ADOLESCENT MENTAL HEALTH INTERVENTION DEV. AND DEPLOYMENT, NAT'L ADVISORY MENTAL HEALTH COUNCIL, *BLUEPRINT FOR CHANGE: RESEARCH ON CHILD AND ADOLESCENT MENTAL HEALTH: EXECUTIVE SUMMARY AND RECOMMENDATIONS 1* (2001), available at <http://www.colorado.gov/bestpractices/mentalhealth/Blueprintformentalhealth.pdf>.

135. See Kimberly Hoagland & S. Serene Olin, *The NIMH Blueprint for Change Report: Research Priorities in Child and Adolescent Mental Health*, 41 J. AM. ACAD. CHILD ADOLESCENT PSYCHIATRY 760, 761 (2002) (noting that, as a result of NIMH's National Plan for Research on Child and Adolescent Mental Disorders, published in 1990, "research in the field of child and adolescent mental health expanded dramatically. In fact, from 1989 to 2000 the number of grants nearly doubled (from 460 to 775) and the research support almost tripled (from \$95 million to \$262 million)."

136. NIMH NATIONAL PLAN, *supra* note 135, at 16.

137. *Id.* at 17.

138. Thomas et al., *supra* note 90, at 64.

139. See, e.g., Cooper et al., *supra* note 115, at 753 (200% increase in prescriptions of antipsychotic medications among children and adolescents enrolled in Medicaid program in Tennessee from 1996 to 2001); Nick C. Patel et al., *Trends in Antipsychotic Use in a Texas Medicaid Population of Children and Adolescents: 1996 to 2000*, 12 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 221 (2002) (finding 160% increase in antipsychotics prescribed to children and adolescents enrolled in the Texas Medicaid program during the period 1996-2000; use of "atypical antipsychotics" jumped by almost 500% during same period); Daniel J. Safer et al., *Increased Methylphenidate Usage for Attention Deficit Disorder in the 1990s*, 98 PEDIATRICS 1084, 1085 (1996) (use of stimulant medication for the management of ADHD in the school setting increased approximately 250% from

Brandeis sociologist, Dr. Peter Conrad, "The 1990s may become known as the decade of psychotropic medication use in children."<sup>140</sup>

Along with its affirmative support for pediatric psychopharmacotherapy, the United States government has further contributed to the excessive reliance on psychotropic drugs to respond to the mental health needs of state-involved children via its blatant refusal to comply with the 1971 Convention's explicit prohibition of direct-to-consumer ("DTC") advertising of psychotropic drugs. Researchers have noted the influential effect of advertising in encouraging increased acceptance of, and demand for, psychotropic drugs, particularly after the FDA relaxed its rules on prescription drug advertising at the height of the Decade of the Brain in 1997.<sup>141</sup> As described in the forthcoming part, the government's failure to ban the advertising of controlled psychotropic drugs has rendered both the public and physicians more accepting of psychopharmaceutical intervention as the primary response to children's mental health issues, and, as a result, the health and safety of state-involved children has been significantly undermined.

#### IV. DIRECT-TO-CONSUMER ADVERTISING OF PSYCHOTROPIC DRUGS VIOLATES ARTICLE 10 OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

Along with its affirmative support for pediatric psychopharmacology (outlined in Part III above), the United States government has further promoted overprescription of psychotropic drugs to state-involved children by failing to comply with the 1971 Convention's explicit prohibition on advertising of controlled psychotropic drugs directly to the public. Recognizing that the intended and inevitable result of advertising is to increase demand and consumption of psychotropic drugs—a result diametrically opposed to the overarching goal of the 1971 Convention, Article 10(2) provides that each party "shall, with due regard to its constitutional provisions, prohibit the advertisement of [psychotropic] substances to the public."<sup>142</sup> Underscoring the convention's public health protection principle, the WHO has taken the position that DTC advertising should not be allowed for *any* prescription drug, let alone for the marketing of

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1990 to 1996); Zito et al., *supra* note 89, at 17–25 (observing a 200 to 300% increase in prevalence of psychotropic drug use in children from 1987-1996 and that six percent of youth under 20 years of age were on psychotropic medications in 1996).

140. Peter Conrad, Editorial, *Prescribing More Psychotropic Medications for Children: What Does the Increase Mean?*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED 829 (2004).

141. See, e.g., Thomas et al., *supra* note 90, at 68.

142. 1971 Convention, *supra* note 4, art. 10(2).

prescription drugs directed at children.<sup>143</sup> There is virtually universal international compliance with the psychotropic drug advertising prohibition; most industrialized nations do ban DTC advertising for all prescription drugs.<sup>144</sup> However, of the 183 signatories to the 1971 Convention, only the United States and New Zealand do not have statutes in place to effectuate the DTC advertising provision—and the U.S. does not even ban advertising for those prescriptions that contain internationally scheduled psychotropic substances.<sup>145</sup>

The advertising ban placed the onus on governments to prioritize public health needs over drug companies' profit-maximizing interests. The international agreement to prohibit DTC advertising of psychotropic drugs recognized the existence of an "inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical, and economic needs of providers and the public to select and use drugs in the most rational way."<sup>146</sup> Nevertheless, concurrent with its intensive promotion of biological psychiatry during the 1990s, the United States government progressively liberalized key elements of existing drug advertising regulations, thereby enhancing the drug companies' influence over public awareness, acceptance, and use of psychotropic drugs. As the following discussion demonstrates, the United States government has been complicit in elevating the commercial interests of the drug industry over the health and safety of children, effectively turning state-involved children into "cogs in the multi-million dollar pharmaceutical industry machine."<sup>147</sup>

The United States has never banned advertising of prescription drugs. In 1938, as a result of a proliferation of advertisements for a variety of

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143. WORLD HEALTH ORG., ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION para. 14 (1988) (citing criterion adopted at the 1988 World Health Assembly by consensus after discussion involving health workers, drug regulatory agencies, and consumers and industry representatives, and developed by WHO as part of its 1985 Revised Drug Strategy); see also BARBARA MINTZES, HEALTH ACTION INT'L, BLURRING THE BOUNDARIES: NEW TRENDS IN DRUG PROMOTION (1998), available at <http://www.haiweb.org/pubs/blurring/blurring.intro.html> [hereinafter BLURRING THE BOUNDARIES].

144. See BARBARA MINTZES, HEALTH COUNCIL OF CANADA, WHAT ARE THE PUBLIC HEALTH IMPLICATIONS?: DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS IN CANADA 5 (2006), available at [http://www.healthcouncilcanada.ca/docs/papers/2006/hcc\\_dtc-advertising\\_200601\\_e\\_v6.pdf](http://www.healthcouncilcanada.ca/docs/papers/2006/hcc_dtc-advertising_200601_e_v6.pdf) [hereinafter PUBLIC HEALTH IMPLICATIONS].

145. *Id.* at 5.

146. BLURRING THE BOUNDARIES, *supra* note 145, at 1 (quoting World Health Org. [WHO], *Clinical Pharmacological Evaluation in Drug Control*, EUR/ICP/DSE 173 (1993)).

147. Susan McBride, *Pharmaceutical Industry Practices and the Medicalisation of Childhood: Is Pathology for Sale?*, 23 WINDSOR REV. LEGAL & SOC. ISSUES 55, 55 (2007).

medicinal “cures,” the U.S. Congress enacted the Federal Food, Drug and Cosmetic Act (the “FFDCA”),<sup>148</sup> which established the FDA, required that drugs be proven safe before they are advertised,<sup>149</sup> and gave the FDA authority to consider drugs “misbranded” if their labeling or advertising is found to be misleading.<sup>150</sup> A 1962 amendment to the FFDCA gave the FDA authority to regulate advertising of prescription drugs, and prohibited the agency from requiring prior approval of any such advertisement’s content.<sup>151</sup>

The amendment did not craft any distinctions on the basis of an advertisement’s audience—for instance, between professional and lay audiences<sup>152</sup>—and, prior to the 1980s, drug companies advertised prescription drugs primarily in medical journals directed at physicians.<sup>153</sup> However, in the early 1980s, drug companies began advertising directly to the public in magazines and newspapers.<sup>154</sup> In response to constituents’ concerns, the FDA asked for a voluntary moratorium on prescription drug advertising in 1983 to allow for public hearings and research on the subject.<sup>155</sup> Two years later, while acknowledging “differences between healthcare professionals and consumers as recipients of drug promotion, such as differences in medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing,” the FDA withdrew the moratorium without making any regulatory changes to account for those differences, stating that the existing regulations provided “sufficient safeguards to protect consumers.”<sup>156</sup>

Under the FFDCA and implementing FDA regulations, prescription drug ads must identify the product, its quantitative composition, and

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148. Federal Food, Drug and Cosmetic Act, Pub. L. No. 75–717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399(b) (2006)).

149. Ziad F. Gellad & Kenneth W. Lyles, *Direct-to-Consumer Advertising of Pharmaceuticals*, 120 AM. J. MED. 475, 475 (2007).

150. 21 U.S.C. § 321(n) (2006).

151. Drug Amendments of 1962, Pub. L. No. 87–781, sec. 131, § 502, 76 Stat. 780, 791 (codified as amended at 21 U.S.C. 352(n) (2006)).

152. *Prescription Drug Promotion: Hearing Before the S. Subcomm. on Consumer Affairs, Foreign Commerce, & Tourism, S. Comm. on Commerce, Science, & Transportation*, 107th Cong. (2001) (statement of Nancy Ostrove, Deputy Director, Division of Drug Marketing, Advertising and Communications, Food & Drug Admin.), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115206.htm>.

153. See Notice of Public Hearing and Request for Comments: Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581, 42,582 (Aug. 16, 1995) [hereinafter 1995 Notice of Hearing]; DONNA VOGT, CONG. RESEARCH SERV., DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS (2005).

154. See 1995 Notice of Hearing, *supra* note 155.

155. *Id.* at 42,582.

156. *Id.*

“other information in brief summary relating to side effects, contraindications, and effectiveness.”<sup>157</sup> This “brief summary” provision mandates disclosure of *all* side effects, contraindications, and precautions on the product’s approved labeling.<sup>158</sup> The requirement, which apparently anticipated print advertisements only, is “generally fulfilled by including in the advertisement the sections of the approved labeling that discuss the product’s adverse event profile, contraindications, warnings, and precautions.”<sup>159</sup> Subsequent regulations added that product-claim broadcast advertisements<sup>160</sup> must include “information relating to the most common side effects and contraindications in the audio or audio and visual parts of the advertisement,” and, importantly, rather than including every known risk of the drug, a product-claim broadcast advertisement could make “adequate provision” for the consumer to obtain the information through some other venue.<sup>161</sup> However, before 1997 the FDA had not

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157. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(n) (2006); *see also* 21 U.S.C. §§ 352(a), 321(n), 202.1(e) (2006). (providing that drugs are deemed to be “misbranded” if their labeling or advertising is false or misleading in any particular or fails to reveal material facts).

158. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2 (1999), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf> [hereinafter FDA GUIDANCE FOR INDUSTRY].

159. 1995 Notice of Hearing, *supra* note 155, at 42,581.

160. *See id.* at 42,582 (recognizing three broad categories of DTC broadcast advertisements: (1) product-claim ads identify a particular drug by name and make safety and efficacy claims about the drug; (2) help-seeking ads discuss a disease or condition and direct the consumer to “ask your doctor” for more information, but do not mention specific treatments or drugs; because help-seeking ads do not mention specific drug products, they are not subject to the Act or FDA regulations; and (3) reminder ads mention the name of the drug and other limited information, but does not make any representations or suggestions about the drug(s)); *see also* 21 C.F.R. § 202.1(e)(2) (2009) (describing product claim ads and help seeking ads); FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1997) (explaining that, as of 1995, drug manufacturers primarily used reminder and help-seeking advertisements, which are exempt from the disclosure requirements).

161. 21 C.F.R. § 202.1(e)(1) (2008).

All advertisements for any prescription drug . . . except [reminder advertisements and help-seeking advertisements], shall present a true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness. Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in

issued any guidance for how the industry could satisfy the adequate provision alternative,<sup>162</sup> and, given the costs of most commercial broadcast advertising, "to include this kind of detailed information in television and/or radio advertising was thought by the drug industry to be too cumbersome and expensive."<sup>163</sup>

With the Decade of the Brain in full swing, the FDA implemented a major policy in 1997 that "dramatically changed the playing field by allowing the expansion of direct-to-consumer advertising into broadcast and electronic media."<sup>164</sup> The agency issued a *Draft Guidance for Industry* (the "guidance"), which became final in 1999.<sup>165</sup> This guidance made it much easier for drug companies to meet the requirement that broadcast advertisements contain extensive information about risks. It allowed drug companies to "omit detailed risk information (the 'brief summary') in broadcast full product ads if they stated a product's major risks and provided specified means to obtain more complete risk information, including toll-free phone numbers, websites, and print DTCA [direct-to-consumer advertising of prescription drugs]."<sup>166</sup> In the wake of the guidance, spending on DTC advertising of prescription drugs rapidly increased; today, it is a multi-billion dollar industry.<sup>167</sup>

As this brief historical overview suggests, the U.S. government's progressive relaxation of restrictions on prescription drug advertising has actively facilitated the Decade of the Brain goal of increasing public awareness regarding pharmaceutical interventions for mental health

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connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

*Id.* (Side effects and contraindications include among other things "side effects, warnings, precautions and contraindications.").

162. *Id.*

163. VOGT, *supra* note 155, at 17.

164. Gelland & Lyles, *supra* note 151, at 476.

165. See FDA Notice of Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171 (1997).

166. PUBLIC HEALTH IMPLICATIONS, *supra* note 146, at 14.

167. In 1991, the pharmaceutical industry spent roughly \$55 million on DTC advertising. See Simon Gilbody et al., Editorial, *Direct-to-Consumer Advertising of Psychotropics: An Emerging and Evolving Form of Pharmaceutical Influence*, 185 BRIT. J. PSYCHIATRY 1 (2004). By 1996, DTC advertising of prescription drugs had risen to \$791 million, and by 2003 had quadrupled to \$3.2 billion, and in 2005 reached \$4.2 billion. See KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS 2 (2007), available at [http://www.kff.org/rxdrugs/upload/3057\\_06.pdf](http://www.kff.org/rxdrugs/upload/3057_06.pdf); VOGT, *supra* note 155, at 3; see also U.S. GENERAL ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 1 (2002) (reporting that, as of 2002, spending on DTC advertising of prescription drugs had tripled in recent years and that "DTC advertising appears to increase prescription drug spending and utilization.").

problems. With that increased awareness has come greater acceptance and consumption of pharmaceuticals, not just by adults, but by children as well, all despite the significant risks involved.<sup>168</sup> For example, methylphenidate, the active ingredient in Ritalin, Concerta, and Metadate, is advertised directly to consumers and is the drug most commonly prescribed to children diagnosed with ADHD.<sup>169</sup> Methylphenidate, along with phencyclidine (commonly known as “PCP” or “angel dust”), is listed on Schedule II of the 1971 Convention’s “Green List”<sup>170</sup> as a substance that “constitutes a substantial risk to public health” with “little to moderate therapeutic usefulness.”<sup>171</sup> According to a 2009 National Institute of Drug Abuse (“NIDA”) funded study,<sup>172</sup> methylphenidate has many similarities with cocaine, and “can have structural and biochemical effects in some regions of the brain that can be even greater than those of cocaine.”<sup>173</sup> Commenting on the NIDA study, NIDA Director Dr. Nora Volkow observed that “non-medical use of methylphenidate and other stimulant medications can lead to addiction as well as a variety of other health consequences.”<sup>174</sup> Dr. Volkow underscored the danger of uncritical acceptance of Ritalin and other stimulants touted in DTC ads, emphasizing the paucity of knowledge about “how methylphenidate affects the structure of and communication between brain cells.”<sup>175</sup> Not surprisingly,

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168. See generally McBride, *supra* note 149.

169. See Matthew N. Strawn, Comment, *Recent Developments in Direct Consumer Advertising of Attention Deficit Disorder Stimulants and Creating Limits to Withstand Constitutional Scrutiny*, 19 J. CONTEMP. HEALTH L. & POL’Y 495 (2003).

170. GREEN LIST, *supra* note 30, at 5.

171. WORLD HEALTH ORG., WHO EXPERT COMMITTEE ON DRUG DEPENDENCE: SEVENTEENTH REPORT 14 (1970), available at [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_437.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_437.pdf).

172. Yong Kim et al, *Methylphenidate-Induced Dendritic Spine Formation and ΔFosB Expression in Nucleus Accumbens*, 106 PROCEEDINGS NAT’L ACAD. SCI. U.S. 2915 (2009).

173. Press Release, Nat’l Inst. of Health, U.S. Dep’t of Health & Human Serv., NIDA Study Shows That Methylphenidate (Ritalin) Causes Neuronal Changes in Brain Reward Areas: Similarities and Differences Compared to Cocaine were Found (Feb. 2, 2009), available at <http://www.nih.gov/news/health/feb2009/nida-02.htm> [hereinafter NIH Press Release]. But see Russell A. Barkley et al, *Does the Treatment of Attention-Deficit/Hyperactivity Disorder With Stimulants Contribute to Drug Use/Abuse? A 13-Year Prospective Study*, 111 PEDIATRICS 97, 97(2003) (finding “no compelling evidence” that stimulant treatment of children diagnosed with ADHD leads to an increased risk of substance experimentation, use, dependence, or abuse by adulthood).

174. NIH Press Release, *supra* note 175.

175. NIH Press Release, *supra* note 175.

the wisdom of dispensing methylphenidate to children remains highly controversial.<sup>176</sup>

Researchers have pinpointed direct-to-consumer advertising of prescription drugs as a key contributor to the explosive growth in the prescribing of psychotropic drugs to children in the United States. One study that examined prescribing trends for adolescents between 1994 and 2001 concluded that "direct-to-consumer advertising and other marketing strategies are key in encouraging greater use of psychotropics, particularly for the increased use found after 1999."<sup>177</sup> Notably, the FDA's draft guidance, which liberalized prescription drug advertising, became final in 1999.<sup>178</sup> Soon after that, in 2001, advertisements for Adderall, Concerta, and Ritalin began appearing in women's magazines and on cable television, which, according to one news reporter, marked "the first break from a 30-year old agreement between nations and the pharmaceutical industry not to market controlled drugs to consumers."<sup>179</sup>

The INCB has made clear that it considers the United States' failure to prohibit DTC advertising of psychotropic drugs to be an egregious viola-

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176. NAT'L HEALTH INST., DIAGNOSIS AND TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (1998), *available at* <http://consensus.nih.gov/1998/1998AttentionDeficitHyperactivityDisorder110html.htm> ("Despite progress in the assessment, diagnosis, and treatment of ADHD, this disorder and its treatment have remained controversial, especially the use of psychostimulants for both short- and long-term treatment."); *see also* Katherine Ellison, *Brain Scans Link ADHD to Biological Flaw Tied to Motivation*, WASH. POST, Sept. 22, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/09/21/AR2009092103100.html> ("For decades, attention-deficit hyperactivity disorder has sparked debate. Is it a biological illness, the dangerous legacy of genes or environmental toxins, or a mere alibi for bratty kids, incompetent parents and a fraying social fabric? With 4.5 million U.S. children having received a diagnosis of the disorder—and more than half of them taking prescription drugs to control it—the question has divided doctors and patients, parents and teachers, and mothers and fathers.").

177. Thomas et. al., *supra* note 90, at 63-69 ("Advertisements for medications for ADHD, social phobia, and depression are now common in various public media. . . . Such drug industry promotion combined with the practice of detailing to physicians may affect both the public and physicians. Increasing numbers of patients come to physicians asking for particular medications, and drug industry detailing can promote off-label uses more aggressively. Surveys have suggested increasing pressure on physicians to prescribe drugs that they may or may not feel are medically warranted, and the most common reason reported by physicians for inappropriate prescribing is patient demand.").

178. FDA GUIDANCE FOR INDUSTRY, *supra* note 160.

179. Karen Thomas, *Back to School for ADHD Drugs*, USA TODAY, Aug. 28, 2001, at D1; *see also* Strawn, *supra* note 171, at 495 ("As parents prepared their children for the start of the 2001 school year, they were greeted for the first time with advertisements pitching behavior control drugs for their children. . . . This pushing of the advertising envelope for prescription stimulants, like Ritalin, is contrary to a thirty-year old international agreement prohibiting the advertisement of such controlled substances.").

tion of the 1971 Convention and a serious threat to public health. In its 2000 annual report, the INCB noted that “[e]ffective but questionable sales promotion methods have often preceded increases in the consumption of psychotropic substances,” and reiterated that governments should “strictly implement the provisions of article 10 of the 1971 Convention, which prohibits the advertisement of psychotropic substances to the general public.”<sup>180</sup> In its 2001 annual report, alarmed by reports that methylphenidate was being “diverted for abuse by schoolchildren,” the INCB expressed concern about “legal loopholes in the United States that make possible public advertising of prescription drugs.”<sup>181</sup> In a press release issued that year, the INCB noted that promotion to the public of psychotropic drugs “frequently portrays drugs as common consumer goods,” and stressed that “the 1971 Convention on Psychotropic Substances prohibits the advertisement of psychotropic substances to the general public.”<sup>182</sup> Reprimanding the United States for its longstanding failure to comply with the advertising ban, in its 2002 annual report the Board pointedly observed that “[a]dvertising through media in the United States reaches consumers not only in the United States, but also in other countries where such advertising is prohibited in line with article 10, paragraph 2, of the 1971 Convention.”<sup>183</sup>

The INCB has explicitly linked DTC advertising to the “over-prescription of methylphenidate in the United States,” asserting that such over-prescription “may be the direct result of the direct-to-consumer advertising of that drug.”<sup>184</sup> In its 2006 annual report, the INCB stated that “[a]ggressive promotion and advertising to the general public, in contravention of the treaty obligations, may influence public perception about the availability of drugs on the unregulated market.”<sup>185</sup> Succinctly capturing the problematic effects of consumer advertising on children, the Board observed that public advertisement of controlled drugs used to treat ADD/ADHD “not only promotes their licit medical use and availability, but at the same time makes young people more aware of those drugs and thus more prone to illicitly consume them.”<sup>186</sup> The Board expressed concern that public advertising of ADD/ADHD drugs “may send

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180. INCB 2000 REPORT, *supra* note 6, at para. 22.

181. INCB 2001 REPORT, *supra* note 6, at para. 342.

182. Press Release, Int'l Narcotics Control Bd., Drug Taking Becoming Widespread Habit to Treat Social Problems, Warns UN Drug Control Body (Feb. 21, 2001), *available at* [http://www.incb.org/pdf/e/press/2001/press\\_release\\_2001-02-21\\_2.pdf](http://www.incb.org/pdf/e/press/2001/press_release_2001-02-21_2.pdf).

183. INCB 2002 REPORT, *supra* note 6, at para. 175.

184. *Id.*

185. INCB 2006 REPORT, *supra* note 6, at para. 18.

186. *Id.*

the wrong signal about their real psychoactive and misuse potential.”<sup>187</sup> Most recently, in its 2008 annual report, the Board again criticized the United States, pointedly urging “the governments in which companies undertake direct-to-consumer advertising for drugs containing internationally controlled substances to adopt and implement regulations to ban such advertisements, in compliance with Article 10 of the 1971 Convention.”<sup>188</sup>

While commentators vigorously debate the pros and cons of direct-to-consumer advertising of prescription drugs,<sup>189</sup> the essential question raised by the 1971 Convention’s advertising ban is the permissible scope of government regulation of such advertising under the United States Constitution’s limited protection for commercial speech.<sup>190</sup> Although a thorough examination of that question is beyond the scope of this Article, it is conceivable that narrowly drawn legislation banning DTC advertising of internationally controlled psychotropic drugs could withstand a constitutional challenge.<sup>191</sup> In any event, presumably with full knowledge of the United States’ constitutional free speech jurisprudence, the INCB remains steadfast and unequivocal, maintaining that the United States can and must comply with the 1971 Convention’s advertising ban. Unfortunately, the only enforcement mechanism available to the INCB to force compliance with the convention is its authority to “name and shame.”<sup>192</sup> Thus, it is up to the United States government to take the in-

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187. *Id.*

188. INCB 2008 REPORT, *supra* note 6, at para. 69.

189. See, e.g., PETER R. BREGGIN & GINGER ROSS BREGGIN, THE WAR ON CHILDREN OF COLOR: PSYCHIATRY TARGETS INNER-CITY YOUTH (1998); McBride, *supra* note 149 (contending that it contributes to the medicalization of childhood in particular.); Barbara Mintzes et al., *Influence of Direct to Consumer Pharmaceutical Advertising and Patients’ Requests on Prescribing Decisions: Two Site Cross Sectional Survey*, 324 BMJ 278 (2002); Lenz, *supra* note 49. See generally Gilbody et al., *supra* note 169. (arguing that DTC advertising increases consumer knowledge about prevalent health conditions and treatment options, and that the increased use of prescription drugs spurred by DTC advertising has enhanced the public’s health).

190. See, e.g., Miriam Shuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236, 2236–2239 (2007). But see Jonathan H. Marks, *The Price of Seduction: Direct-to-Consumer Advertising of Prescription Drugs in the US*, 64 N.C. MED. J. 292, 294, available at <http://www.ncmedicaljournal.com/nov-dec-03/ar110311.pdf> (arguing that the Supreme Court’s commercial speech jurisprudence “puts advertising first and thereby undervalues the importance and complexity of government regulation in the sphere of public health” and “ties the hands of legislators and threatens to undermine the efficacy of the FDA.”).

191. See Strawn, *supra* note 171.

192. 1971 Convention, *supra* note 4, at art. 19. (describing the Board’s function as “quasi-judicial” in overseeing the implementation of the conventions. If the Board finds

initiative to fulfill its commitment under the 1971 Convention and implement legislation banning psychotropic drug advertisements. A ban on DTC advertising of psychotropic drugs in compliance with the 1971 Convention would be a step in the right direction to begin to stem the growing tide of overmedication of state-involved children.

V. THE PRESCRIPTION OF PSYCHOTROPIC DRUGS TO CHILDREN AS CURRENTLY PRACTICED IN THE UNITED STATES VIOLATES THE 1971 CONVENTION'S "MEDICAL PURPOSES" RESTRICTION

The United States government must fulfill its obligation under the 1971 Convention to ensure that state-involved children are not prescribed psychotropic drugs without medical justification. Article 5 of the convention requires governments to limit, by appropriate measures, the use of drugs in Schedules II, III, and IV "to medical and scientific purposes."<sup>193</sup> The following examination of criteria, developed by the INCB to guide its work in monitoring the implementation of the 1971 Convention, provides the framework for analyzing the legitimacy of the extensive off-label prescription of psychotropic drugs to state-involved children in the United States. This analysis supports the conclusion that off-label prescription of psychotropic drugs to children does not meet the international requirement that use of controlled psychotropic drugs be restricted to "medical purposes."

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that the goals of the Convention "are being seriously endangered" by a country's failure to implement its provisions, it may "ask for explanations from" the government in question. The Board may call upon the Government "to adopt such remedial measures as shall seem under the circumstances to be necessary for the execution of the provisions" of the Convention, and, if satisfactory explanations are not forthcoming or the government fails to adopt remedial measures set out by the Board, the Board can call attention of the parties, the Council and The Commission to the matter, and the party under scrutiny "shall be invited to be represented at a meeting of the Board at which a question directly interesting it is considered."). These measures basically come down to "naming and shaming" as the penalty for violations of the 1971 Convention. *See generally* Sandeep Gopalan, *Alternative Sanctions and Social Norms in International Law: The Case of Abu Ghareib*, 2007 MICH. ST. L. REV. 785 (examining the role of shame and embarrassment in enforcing international law). According to Gopalan, "[s]haming in the international law arena is aimed at achieving the following outcomes—labeling a state as an offender, creating a reputation as a bad actor and non-cooperator, expulsion from international organizations, causing economic harm, shunning by other states and commercial entities, and mobilizing domestic public opinion against the offending regime or leader." *Id.* at 794.

193. 1971 Convention, *supra* note 4, art. 5(2) ("Each Party shall . . . limit by such measures as it considers appropriate the manufacture, export, import, distribution and stocks of, trade in, and use and possession of, substances in Schedules II, III and IV to medical and scientific purposes."). The convention restricts use of Schedule I substances to "scientific and *very limited* medical purposes." *Id.* at art. 7(a) (emphasis added).

Noting that the terms “medical purposes” and “medical use” are used in, but not defined in, existing international drug control conventions, the INCB set out criteria to elucidate those expressions in its 2003 annual report.<sup>194</sup> The INCB explained the term “medical purposes”—as used in Article 5 of the 1971 Convention—as a function of a drug’s “medical use”<sup>195</sup> (that is, its usefulness in medical therapy).<sup>196</sup> Legitimate medical uses for scheduled psychotropic drugs include “improving health and well-being” and “preventing and treating disease.”<sup>197</sup> Because “efficacy and safety are basic conditions that have to be established before [a scheduled] drug can be marketed,”<sup>198</sup> medical uses of psychotropic drugs “should be approved by the competent regulatory authority” of each country.<sup>199</sup> In addition to efficacy and safety, the INCB considers “availability and cost and the knowledge and experience of those prescribing . . . and administering [the drug],”<sup>200</sup> in order to establish compliance with the medical purposes requirement. Without sound evidence of therapeutic value as measured by these criteria, the usefulness of a scheduled drug for medical purposes is significantly diminished; such lack of evidence means the drugs “usefulness” becomes a subjective determination based solely on the drug’s “reputation for usefulness, which reflects the general opinion of practitioners or expert panels.”<sup>201</sup> Moreover, even with FDA approval or a favorable reputation within the medical community, the actual value of psychotropic drugs in addressing the problems

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194. See INCB 2003 REPORT, *supra* note 6, at para. 227–35.

195. *Id.* at para. 234 (“The ‘medical use’ of a substance can be stated as its utilization for the above-mentioned medical purposes in a given country.”).

196. “The type and degree of international control” for a substance which is being considered for scheduling under the 1971 Convention “must be based on two considerations: (a) the degree of risk to public health; and (b) the usefulness of the drug in medical therapy.” *Id.* at para. 229.

197. *Id.* at para. 233 (“[A] medicine . . . is a substance used, designed or approved for the following medical purposes: (a) Improving health and well-being; (b) Preventing and treating disease (including the alleviation of symptoms of that disease); (c) Acting as a diagnostic aid; (d) Aiding conception or providing contraception; (e) Providing general anaesthesia.”)

198. *Id.* at para. 231.

199. *Id.* at para. 234. In the United States, the Food and Drug Administration is the “competent regulatory authority” governing the approval for sale of prescription drugs, including internationally scheduled psychotropic drugs. U.S. Food & Drug Admin., Drugs, <http://www.fda.gov/AboutFDA/Basics/ucm192696.htm>.

200. INCB 2003 REPORT, *supra* note 6, at para. 230.

201. *Id.*

faced by state-involved children is substantially decreased where there are "safer alternatives for the same purposes."<sup>202</sup>

Assessed against these criteria, the conditions under which state-involved children are typically prescribed psychotropic drugs fail altogether to meet the 1971 Convention's "medical purposes" requirement. As described in more detail below, the use of psychotropic drugs as chemical restraints to control disruptive or problematic behavior of children in foster care and in juvenile prisons is emphatically *not* a "medical purposes" use. Moreover, many contest the notion that state-involved children who are labeled with a psychiatric diagnosis are actually suffering from a "disease" for which drug treatment is appropriate or necessary. This raises a legitimate concern because the majority of psychotropic drugs are prescribed to children off-label, without the benefit of FDA-reviewed and approved evidence of safety and efficacy for pediatric use. Finally, there is a notable lack of consensus among the medical community about the suitability of psychotropic drugs for pediatric use in light of the demonstrated and constantly emerging risks, uncertain benefits, and worrisome lack of knowledge about the long-term impact on children. Moreover, and perhaps most importantly, there are a wealth of safer alternatives for addressing the mental, behavioral, and emotional problems experienced by state-involved children. Given the serious problems associated with use of psychotropic drugs in children, it is urgent that the United States government take aggressive steps to comply with the 1971 Convention's medical purposes requirement.

#### *A. Chemical Restraint is Not a "Medical Purpose"*

The deliberate use of psychotropic medications to control nonconforming or problematic behavior of state-involved children for the convenience of others obviously violates the 1971 Convention's medical purposes requirement. According to the American Association of Child and Adolescent Psychiatry ("AACAP"), "chemical restraint" of a child is the use of a drug without a therapeutic purpose, but for the sole purpose of sedating and immobilizing the child.<sup>203</sup> Chemical restraint of children has

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202. INCB 2000 REPORT, *supra* note 6, at para. 2 (observing that "in the absence of perfect alternatives, many less than ideal . . . psychotropic substances continue to be used today as pharmaceuticals for the treatment of diseases and the alleviation of pain and other forms of human suffering. Their actual value in medicine always depends on the availability of safer alternatives for the same purposes.").

203. AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY, RECOMMENDATIONS FOR JUVENILE JUSTICE REFORM 70 (2d ed. 2005) [hereinafter JUVENILE JUSTICE REFORM RECOMMENDATIONS], available at <http://www.aacap.org/galleries/PracticeInformation/JJmonograph1005.pdf> ("Some juvenile justice systems use chemical restraint. . . . Chem-

been roundly condemned by the AACAP, the Child Welfare League, and Amnesty International.<sup>204</sup> Despite the fact that there is virtually no research to support the use of psychotropics on children for such conditions as “acute aggression,”<sup>205</sup> state-involved children are sometimes given these powerful, brain-altering chemicals simply for being aggressive, unruly, or otherwise problematic.<sup>206</sup>

Juvenile prison staff members are often given authority to forcibly inject children with psychotropic drugs on an “as needed” (“p.r.n”) basis “simply to stop the current aggressive outburst” of a child.<sup>207</sup> United States Department of Justice (“DOJ”) investigative letters reporting on conditions in juvenile prisons across the country have noted the routine use of psychotropic medications by juvenile prison staffs to restrain, punish, and sedate incarcerated children—sometimes simply for *annoying* behavior.<sup>208</sup> For example, federal investigators found that children in a

ical restraint is defined as using a medication without a therapeutic purpose, but for the sole purpose of sedation and . . . immobilizing the patient.”); *see also* THE ALLIANCE TO PREVENT RESTRAINT, AVERSIVE INTERVENTIONS, AND SECLUSION, IN THE NAME OF TREATMENT: A PARENT’S GUIDE TO PROTECTING YOUR CHILD FROM RESTRAINT, AVERSIVE INTERVENTIONS, AND SECLUSION 4 (2005), *available at* <http://www.tash.org/publications/inthenameoftreatment.pdf>.

204. JUVENILE JUSTICE REFORM RECOMMENDATIONS, *supra* note 205, at 70.

205. Grisso, *supra* note 51, at 91.

206. *See generally* BREGGIN & BREGGIN, *supra* note 191, at 65–86. Breggin notes that the DSM-III-R states that children diagnosed as suffering from “disruptive behavior disorders” are “characterized by behavior that is socially disruptive and is often more distressing to others than to the people with the disorders.” *Id.* at 67. The Breggins observe that the “‘illness’ consists of being disruptive to the lives of adults—a definition that seems tailored for social control.” *Id.*

207. GRISSO, *supra* note 51, at 90–91. This problem has been noted in other confinement contexts as well. *See, e.g.*, Kathleen Auerhahn & Elizabeth Dermody Leonard, *Docile Bodies? Chemical Restraints and the Female Inmate*, 90 J. CRIM. L. & CRIMINOLOGY 599, 604 (2000) (describing use of psychotropic medication as disciplinary tool in prisons, and that “the narratives [the inmates] present . . . demonstrate [that] jail and prison inmates in the United States are frequently medicated without diagnosis or proper psychiatric and physical assessments”); *see also* 42 C.F.R. § 483.13(a) (2009) (residents in long-term care facilities have “the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.”).

208. *See, e.g.*, Letter from Bill Lan Lee, Acting Assistant Att’y Gen., U.S. Dep’t of Justice, to Zell Miller, Governor, State of Georgia n. 5 (Feb. 13, 1998), *available at* <http://www.justice.gov/crt/split/documents/gajuvfind.php> [hereinafter Georgia Findings Letter] (stating that “[u]ntil recently, staff were also authorized to use medication—in the form of involuntary injections of psychotropic drugs—to restrain youths deemed out-of-control, on the authority of a ‘PRN’ (as needed) prescription by a psychiatrist and administered by the facility nursing staff.”). Similarly, a 2004 Department of Justice investigation into conditions at the Charles H. Hickey, Jr. School in Baltimore, Maryland found

Georgia facility “were subject to forced injections [of psychotropic drugs] as punishment for angering staff nurses, rather than as an appropriately monitored medical treatment to prevent injury to the youths or others.”<sup>209</sup> The investigators emphasized that the practice of giving juvenile prison staffs unrestrained authority to give psychotropic drugs to children on an “as needed” basis “is subject to dangerous abuses in a correctional setting.”<sup>210</sup>

Similar misuse of psychotropic drugs in the foster care setting is well-documented.<sup>211</sup> For example, a physician reviewing the medication records of children in the Texas foster care system found sparse support for the aggressive use of psychotropic medications discovered there. The report questioned whether the children had behaved in ways “sufficiently aberrant to warrant these medication practices,” and wondered whether the children had simply been “‘medicated’ into compliance for home expectations.”<sup>212</sup> The report alleged that some foster care parents sought out medication for children in their care not only to make them more

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that psychotropic medication decisions appeared to be “directed at behavior control rather than improved functioning, a practice that represents a substantial departure from generally accepted standards of treatment.” Letter from R. Alexander Acosta, Assistant Att’y Gen., U.S. Dep’t of Justice, to Robert L. Ehrlich, Jr., Governor, State of Maryland 27 (Apr. 9, 2004), available at [http://www.justice.gov/crt/split/documents/cheltenham\\_md.pdf](http://www.justice.gov/crt/split/documents/cheltenham_md.pdf). The investigators found that “youth are often prescribed sleep medications with little justification. These medications are often administered late in the afternoon, thus unnecessarily sedating youth early, making them less able to participate in evening programs.” *Id.* at 28. A 2007 report found that staff at the Marion Juvenile Correctional Facility in Marion, Ohio, used four-point restraints, bed restraints and forced medications to manage severely mentally ill youth. Letter from Wan J. Kim, Assistant Att’y Gen., U.S. Dep’t of Justice, to Ted Strickland, Governor, State of Ohio 12 (May 9, 2007), available at [http://www.justice.gov/crt/split/documents/marion\\_findlet\\_5-9-07.pdf](http://www.justice.gov/crt/split/documents/marion_findlet_5-9-07.pdf).

209. Georgia Findings Letter, *supra* note 210, at n5.

210. *Id.*

211. See sources cited *supra* note 106; *Potent Pills: More Foster Kids Getting Mood-Altering Drugs*, DEMOCRAT & CHRONICLE, Dec. 9, 2007 (investigating psychotropic drug use amongst New York foster children and questioning whether sharp increase in such use is “because they have so many needs” or whether drugs are “used more as a convenient way to straitjacket troublesome behavior”); Crary, *supra* note 96 (summarizing concerns about overmedication of foster children in Florida, Texas, California, and New York, and reporting that “[s]ome parents and advocacy groups say child welfare authorities routinely resort to drugs to pacify foster children without fully considering non-medication options”); Carol Marbin Miller, *1 in 4 Foster Kids on Risky Mind Medication*, MIAMI HERALD, Jan. 15, 2005, at 1A (noting evidence that some children in the care of the Florida Department of Children and Families are prescribed psychotropic medications simply to address behavioral problems).

212. STRAYHORN, *supra* note 102, at 204.

submissive during care, but, more nefariously, to get more money in public benefits.<sup>213</sup>

State-involved children are not only vulnerable to the misuse of psychotropic drugs for the purpose of behavior control; they are also at high risk of being wrongly diagnosed with a mental illness for which medication is then prescribed.<sup>214</sup> As compared to children in the general population, children in foster care and juvenile justice systems are disproportionately exposed to a variety of risk factors that may negatively impact their mental, emotional, and cognitive development, and which may lead to acting out behaviors and emotional disturbances.<sup>215</sup> Premature birth, prenatal drug and alcohol exposure, parents with mental illness or substance abuse problems, exposure to high levels of violence in their homes or communities, child maltreatment, and poverty are all risk factors that may contribute to acting out behaviors and cognitive, mental, and emotional difficulties.<sup>216</sup> The medicalization of these problems "is likely to result in frequent misdiagnosis—labeling of behavioral problems that result from interpersonal difficulties, realistic feelings that are not excessive or out of proportion to the child's real life experiences, or reactions to current life stresses as major psychiatric disorders needing possibly unnecessary medical treatment."<sup>217</sup>

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213. *Id.* at 199 (survey comments expressing concern that Texas foster children were "medicated for higher-level ratings [more money for agency and parents] instead of assisting foster parents in making these kids good citizens" and that children "were given astronomical amounts of medication. Diagnoses were altered to accommodate hallucination[s] which may have been induced by overmedication.").

214. As Comptroller Carole Strayhorn astutely observed in *Forgotten Children*:

Many foster children have psychological problems and are being treated with an array of medications to manage their symptoms. But even fundamentally normal children who have been taken from their homes and families can become aggressive and "emotionally reactive" due to a lost sense of trust and their conditions are only worsened by multiple placements and frequent caseworker turnover. As their feelings of instability increase, their emotions may erupt, and their caretakers then are, in the words of one child psychiatrist, "just chasing an untreatable problem with more medication."

STRAYHORN, *supra* note 102, at 199.

215. *See, e.g.*, Naylor et al., *supra* note 15 at 176.

216. Martin Irwin, Use of Psychiatric Medication in Foster Care Children in Onondaga County 1 (2002), (unpublished manuscript, on file with the author); TEX. DEP'T OF ST. HEALTH SERV., PSYCHOTROPIC MEDICATION UTILIZATION PARAMETERS FOR FOSTER CHILDREN [hereinafter FOSTER CHILD MEDICATION PARAMETERS], *available at* <http://www.dshs.state.tx.us/mhprograms/pdf/PsychotropicMedicationUtilizationParametersFosterChildren.pdf>.

217. Irwin, *supra* note 218, at 1. Irwin stresses that foster children's expressions of "unhappiness, sadness, worry and anger," which are appropriate and understandable res-

The use of psychotropic drugs to control nonconforming behavior of children is not a new phenomenon in the United States. For example, in 1975, the United States Senate heard testimony describing the “chemical straitjacketing” of thousands of children within the juvenile justice system and in other institutions.<sup>218</sup> The use of psychotropic drugs to chemically restrain state-involved children without medical justification clearly violates the medical purposes requirement of the 1971 Convention, and damages rather than improves the health and well-being of children who are subjected to this horrendous and illegal practice. The United States government must comply with its obligation under the 1971 Convention and put an end to this long-standing and egregious abuse of state-involved children.

*B. Contesting the Characterization of Childhood Behavior as “Disease”*

A fundamental pre-condition of legitimate medicinal use of a scheduled psychotropic drug under the 1971 Convention is the presence of “disease.”<sup>219</sup> Whether the widespread use of psychotropic drugs to address problematic behaviors exhibited by state-involved children constitutes a legitimate medical purpose under the 1971 Convention is highly questionable. The trend toward medicalization of child behavior can be seen as a key factor contributing to the increasing prescription of psychotropic drugs to state-involved children in the United States.

Medicalization of social problems has been described as “a process by which nonmedical problems become defined and treated as medical problems.”<sup>220</sup> Undergirding the contemporary expression of this process

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ponses to the reality of their lives “can easily be confused with depression, anxiety or bipolar disorder, ADHD or conduct disorder.” *Id.*; see also FOSTER CHILD MEDICATION PARAMETERS, *supra* note 218 at 2 (noting that foster children “often present with a fluidity of different symptoms over time reflective of past traumatic and reactive attachment difficulties that may mimic many overlapping psychiatric disorders. Establishment of rapport is often difficult. These multiple factors serve to complicate diagnosis.”).

218. *Drugs in Institutions*, *supra* note 88. The inappropriate use of psychotropic drugs as chemical restraints has been noted in other confinement contexts. See, e.g., Auerhahn & Leonard, *supra* note 209, at 604 (describing use of psychotropic medication as disciplinary tools in prisons, and observing that “jail and prison inmates in the United States are frequently medicated without diagnosis or proper psychiatric and physical assessments”); see also 42 C.F.R. § 483.13(a) (2009) (“The [nursing home] resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.”).

219. INCB 2003 REPORT, *supra* note 6, at para. 233.

220. PETER CONRAD, THE MEDICALIZATION OF SOCIETY: ON THE TRANSFORMATION OF HUMAN CONDITIONS INTO TREATABLE DISORDERS 5 (2007). Conrad elaborates:

is the idea that a broad array of mental, emotional, and behavioral manifestations are the result of chemical imbalances in the brain and that the right pill will correct this imbalance and make the problems go away.<sup>221</sup> The INCB has repeatedly expressed concern about the use of psychotropic drugs in the United States to address typical childhood behaviors and social difficulties. For example, in a 1996 press release, the INCB highlighted concerns expressed in its 1995 annual report about "the unprecedented sharp increase" in the "controversially extensive use" of methylphenidate in treating ADD in children.<sup>222</sup> The Board noted concerns that doctors prescribing methylphenidate might be "too often overlooking other causes for attention and behaviour problems" and "opting for an 'easy' solution for behavioral problems that may have complex causes."<sup>223</sup> The following year, the INCB said that abuse of amphetamine-type stimulants such as methylphenidate had reached "epidemic proportions," and stressed that "despite the warning issued a year ago, the issue still requires serious attention."<sup>224</sup> Observing that ADD is "a syndrome largely manifested in behavioral patterns" with the primary signs being "inattention, impulsivity, and, in some cases, hyperactivity," the INCB took special note of warnings about the highly subjective nature of "parents' and teachers' assessments of what constitutes 'inattention' and 'impulsivity.'"<sup>225</sup>

Dr. Hamid Ghodse, the immediate past president of the INCB, has denounced the "liberal use of a drug with the specific intention of modifying a child's behavior such that he or she becomes more compliant and

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The key to medicalization is definition. That is, a problem is defined in medical terms, described using medical language, understood through the adoption of a medical framework, or "treated" with a medical intervention. Thus, we can examine the medicalization of epilepsy, a disorder most people would agree is "really" medical, as well as we can examine the medicalization of alcoholism, or ADHD, menopause, or erectile dysfunction. While "medicalize" literally means "to make medical," . . . the main point in considering medicalization is that an entity that is regarded as an illness or disease is not ipso facto a medical problem; rather, it needs to become defined as one.

*Id.*

221. See generally Mayes & Horwitz, *supra* note 123.

222. Press Release, United Nations Information Service, Dramatic Increase in Methylphenidate Consumption in US: Marketing Methods Questioned (Feb. 28, 1996), available at [http://www.incb.org/pdf/e/press/1995/e\\_bn\\_02.pdf](http://www.incb.org/pdf/e/press/1995/e_bn_02.pdf).

223. *Id.*

224. International Narcotics Control Board, *supra* note 6.

225. *Id.*

less troublesome.”<sup>226</sup> Dr. Ghodse has asserted that children in the United States “who are prescribed drugs for attention-deficit hyperactivity disorder (ADHD) are often not ill,” and believes that “[w]e are medicalising something that is often not a medical condition,” and that psychotropic drugs are too often “used to counter social problems, sometimes without solid medical justification.”<sup>227</sup>

Indeed, the editors of the Diagnostic and Statistical Manual of Mental Disorders (“DSM-IV”)<sup>228</sup> themselves admit that the manual describes diagnoses “strictly in terms of patterns of [behavioral] symptoms that tend to cluster together. These symptoms can be observed by the clinician or reported by the patient or family members.”<sup>229</sup> The American Academy of Pediatrics (“AAP”) has noted that “the specification of behavior items, number of items, and level of impairment” required for a DSM-IV diagnosis of ADHD are simply reflections of “the current consensus among clinicians, particularly psychiatry.”<sup>230</sup> The AAP emphasizes that “[d]espite the agreement of many professionals working in this field, the *DSM-IV* criteria [for ADHD] remain a consensus without clear empirical data . . . [T]he behavioral characteristics specified in *DSM-IV*, despite efforts to standardize them, remain subjective and may be interpreted differently by different observers.”<sup>231</sup>

Given the deep uncertainties surrounding the origins of symptomatic patterns exhibited by those labeled with a psychiatric diagnosis, the lack of empirical support is unsurprising. In fact, the DSM-IV editors candidly acknowledge that “there is no objective marker that can identify a large majority of mental disorders; diagnosis is a judgment call based on an interview and/or observation of behavior.”<sup>232</sup> Acknowledging that

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226. *Psychotropic Drugs are Overprescribed in the West, According to UN Official*, REUTERS HEALTH, June 24, 2002, available at [http://www.vachss.com/help\\_text/archive/drugs\\_overprescribed.html](http://www.vachss.com/help_text/archive/drugs_overprescribed.html) (reporting on speech by Dr. Ghodse at 2002 annual meeting of the Royal College of Psychiatrists in London).

227. *Id.*

228. AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV) (4th ed. 2006).

229. American Psychiatric Association, What Is the DSM and What Is It Used For?, <http://www.psych.org/MainMenu/Research/DSMIV/FAQs/WhatistheDSMandwhatisitusedfor.aspx> (last visited Jan. 1, 2010).

230. Committee on Quality Improvement Subcommittee on Attention-deficit/hyperactivity Disorder, American Academy of Pediatrics, *Clinical Practice Guideline: Diagnosis and Evaluation of the Child With Attention-Deficit/Hyperactivity Disorder*, 105 PEDIATRICS 1158, 1160 (2000), available at <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/5/1158>.

231. *Id.* at 1162–63.

232. Albee, *supra* note 132, at 638.

“the cause of most mental disorders is currently unknown and subject to much speculation,” they caution that

[p]atients sharing the same diagnostic label do not necessarily have disturbances that share the same etiology nor would they necessarily respond to the same treatment. It is therefore critical to understand that the diagnostic terms and categories in the DSM represent only current knowledge about how symptoms cluster together. We fully expect that, over the coming decades, the DSM system will be radically reorganized as the etiologies of mental disorders become better understood.<sup>233</sup>

Nevertheless, various professional associations actively promote the view that mental disturbances are organic in nature. For example, while asserting that mental disorders represent “dysfunctions of the highest integrative functions of the human brain including cognition, or thought; emotional regulation; and executive function, or the ability of the brain to plan and organize behavior,” the American Psychiatric Association acknowledges that “brain science has not advanced to the point where scientists or clinicians can point to readily discernible pathologic lesions or genetic abnormalities that in and of themselves serve as reliable or predictive biomarkers of a given mental disorder or mental disorders as a group.”<sup>234</sup> The American Association for Marriage and Family Therapy flatly states on its website that “[m]ental illnesses are biologically based, meaning that chemicals or structures in the brain are not working as they are supposed to, resulting in symptoms that cannot be managed or overcome without treatment, often resulting in lives that are unstable and unfulfilled.”<sup>235</sup> The website goes on to state that “[d]ue to the biological basis of [childhood onset mental illness or “COMI”], psychiatric evaluation and treatment is generally necessary. The disorders associated with COMI usually require medications for symptom management.”<sup>236</sup>

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233. American Psychiatric Association, *supra* note 231.

234. Press Release, American Psychiatric Association, American Psychiatric Association Statement on Diagnosis and Treatment of Mental Disorders (Sept. 25 2003), *available at* <http://www.psych.org/MainMenu/Newsroom/NewsReleases/2003NewsReleases/mentaldisorders0339.aspx> [hereinafter APA Press Release].

235. American Association of Marriage and Family Therapists, AAMFT Consumer Update: Mental Illness in Children, [http://www.aamft.org/families/Consumer\\_Updates/MentalIllnessinChildren.asp](http://www.aamft.org/families/Consumer_Updates/MentalIllnessinChildren.asp).

236. *Id.* For two interesting articles refuting the mental illness as biological brain disease paradigm, see George W. Albee & Justin M. Joffe, *Mental Illness is NOT “an Illness Like Any Other”*, 24 J. PRIMARY PREVENTION 419 (2004) and Fred Baughman, *There Is No Such Thing as a Psychiatric Disorder/Disease/Chemical Imbalance*, 3 PLOS MEDICINE 1189, 1189 July 2006, *available at* <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0030318>.

These pronouncements are remarkable in light of the fact that the idea that there is irrefutable scientific evidence that mental illness is biologically based was soundly refuted by a panel of experts convened in 1998 by the National Institutes of Mental Health to study Attention Deficit Hyperactivity Disorder (“ADHD”).<sup>237</sup> The panel explicitly confirmed that there exists no evidence to establish ADHD, or any other psychiatric disorder, as a brain disease. “After years of clinical research and experience with ADHD,” the panel reported, “our knowledge about the cause or causes of ADHD remains largely speculative.”<sup>238</sup> Further, such a lack of scientific evidence “is not unique to ADHD, but applies as well to most psychiatric disorders, including disabling diseases such as schizophrenia.”<sup>239</sup> Thus, the conclusion that a child is suffering from a psychiatric disorder or mental illness is not based on biological or physiological measures, but on normative value judgments and subjective characterizations of the child’s behavior.<sup>240</sup> As explained by one physician, there are

no specific blood tests, brain scans, or any other procedure guaranteed to give us an unequivocal answer to any given child’s “real” problem. Instead, we must rely on what we see and hear during clinical visits and learn from taking a history to try to fit each child into the right diagnostic box, and the definition of who belongs in each box can change over time.<sup>241</sup>

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237. NAT’L INST. OF HEALTH, *supra* note 178.

238. *Id.*; see also BREGGIN & BREGGIN, *supra* note 191, at 53–55 (highlighting lack of proof for claims that mental illness is biomedically or genetically based); Albee & Joffe, *supra* note 238.

239. See NIH Consensus, *supra* note 239; see also ELLIOTT & KELLY, *supra* note 23, at 59 (“The fact that there is no definitive test for ADHD or other disruptive disorders further complicates the situation. The behaviors that we use to define these disorders are by no means specific to the disorder—they can arise from a variety of conditions or even represent normative behavior.”).

240. See, e.g., Baughman, *supra* note 238 (arguing that “[i]f there is a macroscopic, microscopic, or chemical abnormality, a disease is present. Nowhere in the brains or bodies of children said to have ADHD or any other psychiatric diagnosis has a disorder/disease been confirmed.”); see also APA Press Release, *supra* note 236 (rejecting the critique that “the lack of a diagnostic laboratory test capable of confirming the presence of a mental disorder constituted evidence that these disorders are not medically valid conditions,” but nevertheless acknowledging that “[i]n the absence of one or more biological markers for mental disorders, these conditions are defined by a variety of concepts,” including “the distress experienced and reported by a person who has a mental disorder; the level of disability associated with a particular condition; patterns of behavior; and statistical deviation from population-based norms for cognitive processes, mood regulation, or other indices of thought, emotion, and behavior.”)

241. ELLIOTT & KELLY, *supra* note 26, at 16.

If state-involved children are given psychotropic drugs on the premise that the drugs have medicinal value in the treatment of *disease*, it would arguably be necessary to demonstrate with sound evidence that the children are indeed suffering from a medical disease or illness.<sup>242</sup> To the extent that behavioral problems exhibited by state-involved children are largely the result of predictable and normal reactions to the stresses from their life experiences and are not evidence of medical disease or illness, "treatment" of these behaviors with psychotropic drugs is glaringly inconsistent with the medical purposes requirement set out in Article 5 of the 1971 Convention.

*C. Treating Children with Psychotropic Drugs "Off-Label": "Legitimate Medical Use"?*

Under Article 10 of the 1971 Convention, the United States government must "require . . . such directions for use, including cautions and warnings, to be indicated on the labels where practicable and in any case on the accompanying leaflet of retail packages of psychotropic substances, as in its opinion are necessary for the safety of the user."<sup>243</sup> However, the overwhelming majority of psychotropic drugs prescribed to children are prescribed "off-label," meaning that they have not been approved by the FDA for pediatric use. Consequently, their labels do not provide child-specific instructions for use or cautions or warnings necessary to ensure the safety of the children taking them.

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242. BROWN & SAWYER, *supra* note 3, at 14 (noting that use of medication for the management of behavioral problems in classroom settings for diagnostic entities, particularly ADHD, are more often based on insufficient normative data rather than on any solid scientific basis). Indeed, several years before the NIH Consensus Statement, Peter Breggin similarly observed:

There are some real diseases that produce brain damage and mental dysfunction. The defects can be genetic, as in a limited number of cases of Alzheimer's disease, in some forms of mental retardation, such as Down's syndrome, and in dementing disorders such as Huntington's chorea. In each case there is a generalized impairment of the brain, resulting in measurable losses of mental function, such as short-term memory, calculating, and abstract reasoning. These losses can be detected in clinical interview and often they can be roughly quantified on neuropsychological testing. But even in severe psychiatric disorders, such as "schizophrenia" or "manic-depressive disorder," brain function is not impaired, and no biological cause has been discovered . . . often the individual is functioning at a superior level of intelligence and mental ability.

BREGGIN & BREGGIN, *supra* note 191, at 54.

243. 1971 Convention, *supra* note 4, art. 10(1).

In its role as the “competent regulatory authority” of the United States government,<sup>244</sup> the Food and Drug Administration approves prescription drugs for sale and marketing.<sup>245</sup> Approval is granted only if the human studies conducted by the drug company support a drug’s safe and effective use by the tested populations.<sup>246</sup> As part of the approval process, manufacturers are required to submit proposed labeling, which must contain “a summary of essential scientific information needed for the safe and effective use of the drug,” including the product’s intended use—for example, the conditions it treats, the appropriate patient population, administration and dosage information, and contraindications, warnings, and precautions.<sup>247</sup> “Contraindication” describes “situations in which the drug should not be used because the risk of use . . . clearly outweighs any possible therapeutic benefit.”<sup>248</sup> “Warnings and precautions” describe “clinically significant adverse reactions . . . , other potential safety hazards . . . , limitations in use imposed by them . . . , and steps that should be taken if they occur,” and any other “information regarding any special care to be exercised by the practitioner for safe and effective use of the drug.”<sup>249</sup>

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244. See INCB 2003 REPORT, *supra* note 6, at para. 234.

245. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2006). See generally 21 C.F.R. §§ 314.50, 314.100–314.170 (2009).

246. See 21 C.F.R. 314.2 (2009); Althea Gregory, *Denying Protection to Those Most in Need: The FDA’s Unconstitutional Treatment of Children*, 8 ALB. L. J. SCI. & TECH. 121, 126–27 (describing in detail the FDA’s drug approval process). It is important to note that, in reporting the usefulness or potential benefits of psychopharmacotherapies for psychiatric disorders or their symptoms, researchers distinguish between *efficacy* and *effectiveness* of a particular treatment. As Grisso explains, in research into the *efficacy* of a psychopharmacological treatment, study patients are “selected according to rigorous specifications to ensure that they have the disorder for which the method is intended to be of benefit,” and the psychotropic medication is employed “under highly controlled conditions.” GRISSE, *supra* note 51, at 87. Grisso further notes:

Efficacy is expressed as the proportion of patients in the experimental group, compared to the proportion of patients in the control group, who demonstrate a specific beneficial outcome (as measured with standardized instruments). In contrast, a method’s *effectiveness* refers to its value in the real world where researchers cannot control the quality of its application. . . . [T]he effectiveness of a method of therapy refers to its value when ordinary clinicians in actual clinical settings provide it to whatever patients obtain their services.

*Id.*

247. 21 C.F.R. § 201.56 (2009).

248. 21 C.F.R. §§ 201.56(b)(1), 201.57(c)(5) (2009).

249. 21 C.F.R. § 201.57(c)(6)(i)–(ii).

The most common use of "off-label" prescription occurs when drugs approved for the treatment of adults are prescribed to treat children.<sup>250</sup> In the United States, "approximately 45% of medications used for the treatment of emotional or behavioral disturbances in children are [prescribed] off-label, [with] no approved use, medical or psychiatric, for patients under 18."<sup>251</sup> Additionally, only about one-third of psychotropic drugs are approved for psychiatric treatment of children; some of them, such as divalproex sodium (Depakote) and clonidine, "are approved for the treatment of specific *medical illnesses* in patients less than 18 years of age, but not for the treatment of *psychiatric disorders*."<sup>252</sup> Thus, most psychotropic drugs prescribed to children do not carry child-specific labeling information.<sup>253</sup>

Accurate labeling information is crucial to the safety and well-being of state-involved children who are prescribed psychotropic drugs. Prescription drug labels or packet inserts are "intended to provide all of the information judged to be necessary for the drug or biological to be used safely and effectively for the approved indication(s)."<sup>254</sup> However, doctors routinely prescribe psychotropic drugs to state-involved children without any clinically-tested proof that they are safe or effective for use in children, and with little or no label information to guide their decision-making as to if and how to use them.<sup>255</sup> Thus, the United States government's failure to require child-specific labeling of psychotropic drugs in compliance with the 1971 Convention's regulatory agency approval not

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250. See Charles J. Cote et al., *Is the "Therapeutic Orphan" About to be Adopted?*, 98 PEDIATRICS 118, 122 (1996).

251. *Health Care of Children in Foster Care: Hearing Before the Subcomm. on Income Security and Family Support of the H. Comm. on Ways & Means*, 110th Cong., 1st Sess. (2007) (statement of Michael Naylor, Director, Division of Child and Adolescent Psychiatry, Program Institute for Juvenile Research, University of Illinois-Chicago) [hereinafter *Naylor Testimony*]. As of 2007, the United States Government Accountability Office estimated that only about one-third of all prescription drugs prescribed to children have been studied and labeled for pediatric use. See U.S. GOV'T ACCOUNTABILITY OFFICE, PEDIATRIC DRUG RESEARCH: STUDIES CONDUCTED UNDER BEST PHARMACEUTICALS FOR CHILDREN ACT 1 (2007), available at <http://www.gao.gov/new.items/d07557.pdf> [hereinafter *BPCA REPORT*].

252. *Naylor Testimony*, *supra* note 255 (emphasis added).

253. Committee on Drugs, American Academy of Pediatrics, *Use of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS 181 (2002).

254. *Id.*

255. See Psychotropic Medication Patterns, *supra* note 12. Dr. Zito's study of psychotropic drug prescribing to youth in foster care noted "the prominent [off-label] use of patent-protected, expensive psychotropic medications" such as sertraline and escitalopram, which "comprised 74% of SSRI use in the study month, although neither drug has a labeled indication for the treatment of depression in children and adolescents." *Id.* at 161.

only violates the convention's medical purposes requirement, but more importantly, puts hundreds of thousands of children at grave risk of harm from exposure to powerful and addictive psychotropic drugs.

Off-label prescribing, even of controlled substances, is not illegal, and the FDA does not regulate the practice.<sup>256</sup> The standard for off-label prescribing of FDA-endorsed drugs is minimal; physicians may use FDA approved drugs "in whatever way they deem beneficial, as long as there is some evidence that it could be helpful."<sup>257</sup> Particularly with respect to psychotropic drugs under international control, the FDA's permissive stance seems untenable, given that the off-label use of psychotropic medications in children is "plagued with uncertainties about genuine efficacy and safety."<sup>258</sup>

Although there are laws designed to induce pharmaceutical companies to gather information about the safety and efficacy of their products in children, and to provide the same dosing and risk information as is required for adults, most psychotropic drugs commonly prescribed to state-involved children still do not contain this information.<sup>259</sup> However, while these laws have somewhat increased the number of prescription drugs that provide child-specific dosing and risk information, they have not, for the most part, resulted in psychotropic drug labeling changes sufficient to provide prescribers and parents with necessary use and risk informa-

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256. See 21 U.S.C. § 396 (2006) ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.").

257. ELLIOTT & KELLY, *supra* note 26, at 23.

258. *Id.* Using the example of how anticonvulsants approved by the FDA for controlling epileptic seizures in adults came to be widely used for treating bipolar disorder in children, Dr. Elliot explains that if a physician concludes that a medication seems to help with a condition for which the FDA has not given its approval, "the clinician may publish what is called a case report, or may simply tell colleagues, who pass it on to other colleagues. Word spreads, and others begin using it. Inevitably, it starts being used in children and adolescents too . . . . This type of work, often just clinical reports based on a few patients, is much simpler, faster, and far cheaper than what the FDA requires." *Id.*

259. See Best Pharmaceuticals for Children Act of 2007, Pub. L. No. 110-85, 121 Stat. 876 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.) (providing financial incentives to pharmaceutical companies for pediatric testing of on-patent drugs, a process for the study of off-patent drugs, a safety review of all drugs granted pediatric exclusivity, and the public dissemination of information from pediatric studies conducted); Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, 121 Stat. 866 (codified as amended in 21 U.S.C. § 355c (2006)) (codifying the authority of the FDA to require pediatric studies of certain drugs and biological agents.); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, sec. 111, § 505A, 111 Stat. 2296 (codified as amended at 21 U.S.C. § 355a (2006)).

tion.<sup>260</sup> Given the well-founded concerns about the safety of psychotropic drugs, particularly the long-term risks to children's developing brains,<sup>261</sup> the United States' continued failure to require regulatory approval for pediatric use of psychotropic drugs and appropriate child-specific labeling in contravention of the the 1971 Convention is egregious.

*D. Safer Alternatives to Psychotropic Drug Therapy Are Available*

A thorough assessment of the legitimacy of psychotropic drug use for state-involved children under the 1971 Convention requires a consideration of the availability of safer alternatives for addressing each child's presenting issues. The INCB stresses that the actual value of a scheduled psychotropic drug for medical purposes "always depends on the availability of safer alternatives for the same purposes."<sup>262</sup> Addressing this very issue, a comprehensive study examining the evidence base of psychopharmacological and psychosocial interventions for childhood disorders released in 2006 by the American Psychological Association (the "APA") stated that "[t]he preponderance of available evidence indicates that psychosocial treatments are safer than psychoactive medications."<sup>263</sup> Indeed, experts agree that most children and teenagers suffering from psychological problems do not require psychiatric medication; instead, as recommended by the APA Working Group, best practices indicate that

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260. See BPCA REPORT, *supra* note 255; see also Joseph Deveaugh-Geiss et al., *Child and Adolescent Psychopharmacology in the New Millennium: A Workshop for Academia, Industry, and Government*, J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 261, 264 (2006) (stating that "despite the many studies generated by the FDAMA [Food and Drug Administration Modernization Act], only about one third of drugs used in children have pediatric prescribing information in the product label. In psychopharmacology, of the 12 products granted exclusivity, the studies resulted in additional indications for just four products: sertraline for pediatric obsessive-compulsive disorder, and Adderall XR, Concerta, and atomoxetine for adolescent ADHD. The latter three were already intended for use in childhood ADHD, and the labeling was simply expanded to include use in adolescents. . . . [O]therwise, exclusivity studies of psychopharmacological agents have, for the most part, resulted in labeling language noting that clinical studies did not support a pediatric indication.").

261. See, e.g., Daryl Efron et al., *Prescribing of Psychotropic Medications for Children by Australian Pediatricians and Child Psychiatrists*, 111 PEDIATRICS 372, 373 (2003), available at <http://pediatrics.aappublications.org/cgi/reprint/111/2/372> (noting that "for many psychotropic medications it is not clear that the benefits outweigh the potential harms in children. Potential long-term effects are of concern, particularly given the increasing understanding of the susceptibility of the developing brain, biochemically and even microstructurally, to environmental influences.").

262. INCB 2000 REPORT, *supra* note 6, at para. 2.

263. WORKING GROUP ON PSYCHOACTIVE MEDICATIONS FOR CHILDREN AND ADOLESCENTS, *supra* note 41.

psychosocial interventions, most often involving the family, as well as the individual, can be effective in addressing children's problems.<sup>264</sup> Even in regard to those childhood conditions that are judged to be largely neurobiological in nature and responsive to medication treatments, most experts agree that medication should *never* be the sole treatment.<sup>265</sup>

There are a host of evidence-based approaches available to address children's mental health needs, including: cognitive behavioral therapy, assertiveness training, problem-solving skills training, traditional patient-therapist relationships, peer group therapy, functional family therapy, multi-systemic therapy, and systems therapy, to name a few.<sup>266</sup> As noted child mental health expert Dr. Thomas Grisso explains, there are a range of approaches to children's mental health that do not rely on drugs:

At one end of this spectrum is any mode of treatment primarily involving a therapist and a patient in conversation, for any theoretical or practical reason, focused on changing the patient's behavior, thinking, or emotional condition. At the other end is an intervention that seeks these changes by altering the environmental circumstances in which the patient is expected to function in everyday life. Midway along this spectrum are a variety of methods that involve direct work with the patient in the context of people and social systems that are important in the patient's life.<sup>267</sup>

Also taking note of the link between excessive and exclusive reliance on pharmacological treatment of mental disorders and psychiatric conditions and overconsumption of psychotropic drugs, the INCB has observed that "[t]here is a wide range of complementary or alternative treatment approaches for many of the mental disorders and painful conditions treated today with pharmaceuticals (psychotherapy, counseling, traditional medicine), and such alternatives may often be culturally more relevant and more effective."<sup>268</sup>

Nevertheless, despite the existence of these safer alternatives that may improve children's daily functioning without the serious risks associated with psychotropic drugs, treatment with psychotropic medication is the

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264. JOHN PRESTON ET AL., CHILD AND ADOLESCENT CLINICAL PSYCHOPHARMACOLOGY MADE SIMPLE 2 (2d ed. 2010).

265. *Id.* FOSTER CHILD MEDICATION PARAMETERS, *supra* note 218, at 3 (observing that "[g]iven the unusual stress and change in environmental circumstances associated with being a foster child, counseling or psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication.").

266. GRISSO, *supra* note 51, at 84–85; *see also* ELLIOTT & KELLY, *supra* note 26, at 227–239 (describing psychotherapies, natural treatments, and somatic treatments).

267. GRISSO, *supra* note 51, at 84–85.

268. INCB 2000 REPORT, *supra* note 6, at para. 28.

only treatment considered and implemented for dealing with the problematic behavior of large numbers of children in foster care and juvenile prisons. The availability of nondrug alternatives that rely on interpersonal relationships and support for the youth, his or her family, community, and the systems in which he or she operates substantially undermine the notion that administration of psychotropic drugs to children serves a "legitimate medical use" under the 1971 Convention, especially given the well-documented risks and lack of scientific evidence of their safety and efficacy.<sup>269</sup>

For all the above reasons—concerns about the validity of classifying childhood behaviors as disease; the availability of less harmful and potentially more beneficial therapies to address children's emotional, behavioral, and cognitive difficulties; and the virtually complete absence of scientific proof of the efficacy and safety of their use for childhood disorders—pediatric psychopharmacotherapy as commonly practiced in the United States does not satisfy the 1971 Convention's requirement that psychotropic drugs be strictly limited to use for "medical purposes."

#### VI. PSYCHOTROPIC DRUGS ARE NOT PRESCRIBED TO CHILDREN IN STATE CUSTODY IN ACCORDANCE WITH SOUND MEDICAL PRACTICE

Article 9 of the 1971 Convention imposes another requirement, distinct from, but integral to the "medical purposes" requirement of Article 5. Article 9 requires the United States government to ensure that psychotropic drugs are prescribed "in accordance with sound medical practice and subject to such regulation . . . as will protect the public health and welfare."<sup>270</sup> To ensure compliance with the sound medical practice requirement, the INCB insists that governments establish national standards for prescribing and administering psychotropic drugs.<sup>271</sup> In the United States, a number of professional organizations have published

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269. See, e.g., R. Elliott Ingersoll et al., *Children and Psychotropic Medication: What Role Should Advocacy Counseling Play?*, 82 J. COUNSELING & DEV. 337 (2004); Lidia Wasowicz, *Ped Med: Non-Drug Options Slighted?*, UPI.COM, July 16, 2007, [http://www.upi.com/Consumer\\_Health\\_Daily/Reports/2007/07/16/ped\\_med\\_nondrug\\_options\\_slighted/6725/](http://www.upi.com/Consumer_Health_Daily/Reports/2007/07/16/ped_med_nondrug_options_slighted/6725/);

270. 1971 Convention, *supra* note 4, art. 9(2) ("The Parties shall take measures to ensure that prescriptions for substances in Schedules II, III and IV are issued in accordance with sound medical practice and subject to such regulation, particularly as to the number of times they may be refilled and the duration of their validity, as will protect the public health and welfare.").

271. INCB 1998 REPORT, *supra* note 6, at para. 32 ("National health authorities should implement drug control measures and ensure that good prescribing and dispensing practices are established and followed and that patients are provided with complete and correct information.").

best practices guides for the use of psychotropic drugs in state-involved children,<sup>272</sup> and increasing numbers of states have enacted legislation and/or agency level guidelines aimed at setting standards and guidelines for monitoring psychotropic drug prescriptions for state-involved children.<sup>273</sup> However, despite the growing recognition of the urgent need for close control and monitoring of psychotropic drug prescriptions to state-involved children, to date, the federal government has not set national, uniform standards to ensure that they are prescribed and administered to state-involved children only for medical purposes and in accordance with sound medical practice. In the absence of such legislation, state-involved children are routinely subjected to egregious and flagrant violations of their right under the 1971 Convention to be free from illegitimate exposure to psychotropic drugs

The United States government itself has documented many of these abuses in juvenile prisons across the country. Pursuant to its authority under the Civil Rights of Institutionalized Persons Act of 1980 (CRIPA), the Attorney General investigates institutional conditions and may file lawsuits to remedy a pattern or practice of unlawful conditions uncovered.<sup>274</sup> The Attorney General is also authorized, under the Violent

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272. See, e.g., AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY, *supra* note 15; LISA HUNTER ROMANELLI ET AL., ANNIE E. CASEY FOUNDATION, MENTAL HEALTH PRACTICES IN CHILD WELFARE GUIDELINES TOOLKIT, (2009), available at <http://www.casey.org/Resources/Publications/pdf/MentalHealthPractices.pdf>; PETER J. JENSEN ET AL., ANNIE E. CASEY FOUNDATION, MENTAL HEALTH PRACTICE GUIDELINES FOR CHILD WELFARE (2009); NAT'L COMM'N ON CORR. HEALTH CARE, STANDARDS FOR HEALTH SERVICES IN JUVENILE DETENTION AND CONFINEMENT FACILITIES (2004); American Academy of Child and Adolescent Psychiatry, *Practice Parameter for the Assessment and Treatment of Youth in Juvenile Detention and Correctional Facilities*, 44 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 1085 (2005).

273. See Naylor et al., *supra* note 15, at 181 (the authors provide a table summarizing psychotropic medication consent procedures by state); see also Informational Letter from Office of Strategic Planning & Policy Dev., N.Y. State Office of Children and Family Serv., to Commissioners of Social Services et al. (Feb. 13, 2008), available at [http://www.ocfs.state.ny.us/main/sppd/health\\_services/manual.asp](http://www.ocfs.state.ny.us/main/sppd/health_services/manual.asp) (regarding The Use of Psychiatric Medications for Children and Youth in Placement: Authority to Consent to Medical Care).

274. In pertinent part, the Civil Rights of Institutionalized Persons Act provides that

[w]henever the Attorney General has reasonable cause to believe that any State or political subdivision of a State, official, employee, or agent thereof, or other person acting on behalf of a State or political subdivision of a State is subjecting persons residing in or confined to an institution . . . to egregious or flagrant conditions which deprive such persons of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States causing such persons to suffer grievous harm, and that such deprivation is pursuant to a

Crime Control and Law Enforcement Act of 1994, to sue administrators of juvenile justice systems where there is a pattern or practice of violating incarcerated juveniles' federal statutory and constitutional rights.<sup>275</sup> Over the years, pursuant to the Attorney General's authority under these laws, investigations by the Special Litigation Section (the "SLS")<sup>276</sup> of the United States Department of Justice, Civil Rights Division have called attention to numerous flagrant and dangerous departures from generally accepted medical practices in almost every area relating to the prescription and administration of psychotropic drugs in juvenile prisons across the country. The DOJ has documented a frightening array of substandard practices and substantial departures from generally accepted medical practices that not only constitute serious violations of children's constitutional rights, but, as the following analysis will demonstrate, also contravene the 1971 Convention's mandate that the government ensure that sound medical practices are followed in the prescription and administration of controlled psychotropic drugs.

Children in juvenile prisons are subjected to substantial departures from sound medical practices in almost every area of psychotropic drug administration. For example, DOJ investigations have documented fail-

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pattern or practice of resistance to the full enjoyment of such rights, privileges, or immunities, the Attorney General, for or in the name of the United States, may institute a civil action in any appropriate United States district court against such party . . . .

Civil Rights of Institutionalized Persons Act, Pub. L. No. 96-247, 94 Stat. 349, § 3(a) (1980) (codified at 42 U.S.C. § 1997-1997j).

275. Federal Civil Rights Statutes, 42 U.S.C. § 14141 (2006) (making it unlawful "for any governmental authority, or any agent thereof, or any person acting on behalf of a governmental authority, to engage in a pattern or practice of conduct by law enforcement officers or by officials or employees of any governmental agency with responsibility for the administration of juvenile justice or the incarceration of juveniles that deprives persons of rights, privileges, or immunities secured or protected by the Constitution or laws of the United States," and providing that "[w]henver the Attorney General has reasonable cause to believe that a violation of paragraph (1) has occurred, the Attorney General, for or in the name of the United States, may in a civil action obtain appropriate equitable and declaratory relief to eliminate the pattern or practice.").

276. The Special Litigation Section of the Civil Rights Division "protects the constitutional and federal statutory rights of persons confined in certain institutions owned or operated by, or on behalf of, state or local governments," including "facilities for individuals who are mentally ill and developmentally disabled, nursing homes, juvenile correctional facilities, and adult jails and prisons." Press Release, Dep't of Justice, Fact Sheet: Department of Justice Efforts to Protect the Rights of Servicemembers and Veterans (May 23, 2008), available at <http://www.justice.gov/opa/pr/2008/May/08-crt-462.html>.

ures to follow proper psychiatric diagnostic procedures,<sup>277</sup> and administration of psychotropic drugs to children by staff untrained in psychiatric diagnosis or psychopharmacology.<sup>278</sup> The failure to gain informed consent or court authorization for psychotropic drug treatment is pervasive,<sup>279</sup> and drugs are commonly used as the sole intervention for children's mental health problems, without any attempts to integrate appropriate psychotherapy or other types of counseling.<sup>280</sup> Documentation supporting the use of medications and medical charting is often incomplete or missing altogether,<sup>281</sup> and close monitoring of the effectiveness of pre-

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277. See, e.g., Letter from Loretta King, Acting Assistant Att'y Gen., U.S. Dep't of Justice, to David A. Patterson, Governor, State of New York 17 (Aug. 14, 2009), available at [http://www.justice.gov/crt/split/documents/NY\\_juvenile\\_facilities\\_findlet\\_08-14-2009.pdf](http://www.justice.gov/crt/split/documents/NY_juvenile_facilities_findlet_08-14-2009.pdf) [hereinafter New York Findings Letter] (finding that the majority of psychiatric evaluations at juvenile facilities "did not come close to meeting the criteria" for professional standards of care for youth in juvenile detention facilities; "[t]he evaluations typically lacked basic, necessary information, including justification for the diagnosis and evidence of prior record review. As a consequence, the treatment of youth with serious mental illness was based on poor information and was generally ineffective.").

278. See, e.g., Letter from R. Alexander Acosta, Assistant Att'y Gen., U.S. Dep't of Justice, to Jennifer M. Granholm, Governor, State of Michigan 14-15 (Apr. 19, 2004), available at [http://www.justice.gov/crt/split/documents/granholm\\_findinglet.pdf](http://www.justice.gov/crt/split/documents/granholm_findinglet.pdf) [hereinafter Michigan Findings Letter] (observing that the facility used "non-medical staff to dispense medications. Given that the staff have no training in pharmacology, side effect recognition, psychological aspects of medication compliance, or symptom management, this practice places both the youth and the facility at great risk. . . . We observed several occasions where medical personnel took it upon themselves to dispense especially dangerous medications.").

279. See, e.g., *id.* at 14 n.3 (noting that the facility "lack[ed] a formal policy regarding youth and/or parental consent to medication. Staff gave various answers when asked about the facility's practice regarding consent, evidencing the absence of a consistent practice.").

280. See, e.g., Georgia Findings Letter, *supra* note 210 (observing that the contract psychiatrist, who was not a specialist in child and adolescent psychiatry, spent his time "solely monitoring psychotropic medications, meeting with youths on medications for brief (five- to fifteen-minute) interviews once a month" and "[v]ery few youths in any of the[] facilities receive[d] any significant psychotherapy, skilled mental health counseling or behavior management"); Michigan Findings Letter at 13 (observing that the facility "fail[ed] to treat adequately youths with severe mental illnesses, lacks important protocols for psychotropic medication, and does not provide treatment planning tailored to the needs of the individuals with mental illness").

281. See, e.g., Michigan Findings Letter, *supra* note 282, at 12-13 ("Neither the psychiatrists, who prescribe a range of psychotropic medications, nor the security staff . . . provide any information for the medical chart. As a result of this system, the use and reasons for the use of anti-psychotic medication are not always clearly documented in the medical chart. A youth may be prescribed a psychotropic medication by a psychiatrist for a mental illness or for a contraindicated use, but because the medication would not be documented in the medical chart, the facility physician could be unaware of the exis-

scribed drugs or the side effects on children's health is often inadequate or absent.<sup>282</sup> Additionally, at least one government investigation uncovered serious breaches in security in the monitoring of distribution of drugs, resulting in numerous instances of hoarding and illicit trafficking of medication among youth.<sup>283</sup> The DOJ's assessment of conditions at a Georgia juvenile prison succinctly captures the essence of the egregious departures from sound medical practice across the nation:

For example, at the Bill E. Ireland YDC, there were no diagnoses or initial psychiatric evaluations prior to beginning medications; no interaction between psychiatrists and medical or direct care staff; insufficient monitoring of the efficacy and side effects of drugs; inadequate follow-up and re-evaluation; and deficient record keeping. The facility's contract psychiatrist has prescribed dangerously high dosages of medica-

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tence, purpose, or reason for the medication. This leads to a dangerous situation where follow-up on medical care may not be done, or adverse drug interactions may occur."); New York Findings Letter, *supra* note 281, at 20 ("Across the four facilities, there was a pervasive lack of documentation of either the target symptoms for the medications or monitoring of the effectiveness (or lack thereof) of medication on those target symptoms.").

282. Price, *supra* note 2 ("Wards [in California Youth Authority facilities] were prescribed Cylert, a [internationally controlled] central-nervous-system stimulant that can cause liver damage, but no follow-up liver-function tests were ordered."). Concluding that "the overall risk of liver toxicity from Cylert and generic pemoline products outweighs the benefits of this drug," the FDA withdrew approval of Cylert in 2005. See Safety Information, Food & Drug Admin., MedWatch, Cylert and Generic Pemoline Products, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanProducts/ucm151073.htm>; see also New York Findings Letter, *supra* note 281, at 21 (finding "substantial departures from generally accepted professional standards" in facilities' psychotropic medication practices; no charts were found "where youth were being monitored for abnormal involuntary movement. . . . [T]he psychiatrists confirmed that they did not routinely monitor for involuntary movements but one agreed that 'it would probably be a good idea.' In addition, there are no system-wide protocols specifying which medications require which laboratory examinations. Where laboratory examinations were conducted, they omitted critical information.").

283. See, e.g., Letter from R. Alexander Acosta, Assistant Att'y Gen., U.S. Dep't of Justice, to Brad Henry, Governor, State of Oklahoma 13 (June 8, 2005), available at [http://www.justice.gov/crt/split/documents/split\\_rader\\_findlet\\_6-15-05.pdf](http://www.justice.gov/crt/split/documents/split_rader_findlet_6-15-05.pdf). The investigators found that children "regularly hoard medication and either share it with or sell it to other youth." *Id.* In one instance, "a youth provided two pills of a psychotropic medication and two pills of an anti-depressant to two other youth who crushed the pills and snorted them. In another example, "a male youth swallowed eight pills during medication distribution. Over a two-week-period the youth had 'cheeked' some of his own medication and had received prescription medication from other youth." *Id.* In yet another situation "a male youth provided 13 pills to three other youth. The three youth took the pills without knowing what they were. One youth, with slurred speech, informed staff that he wanted to fly like Superman." *Id.*

tions (sometimes beginning youths on dosages five or six times acceptable starting dosages) without adequate evaluation or monitoring for serious side effects, as well as continued youths on non-therapeutic dosages of medications without taking adequate steps to determine their efficacy.<sup>284</sup>

The foregoing examples, documented by the United States government, clearly establish a nationwide pattern and practice of serious departures from sound medical practice in the use of psychotropic drugs among state-involved children in juvenile facilities. Similar conditions exist among children in foster care.<sup>285</sup> To comply with the sound medical practice requirement in Article 9 of the 1971 Convention, the United States government must promulgate nationally applicable standards and guidelines to protect state-involved children from these rampant and improper breaches of proper medical protocol.

#### CONCLUSION

The conditions under which children in the foster care and juvenile justice systems are prescribed psychotropic medications in the United States do not come close to satisfying the standards established by the 1971 United Nations Convention on Psychotropic Substances. In the final analysis, the indiscriminate and unchecked use of psychotropic medications is a threat of great magnitude to the health, safety, and well-being of state-involved children. In the eloquent and poignant words of one child:

#### Caged

I'm a child in a cage,  
 locked in a mental hospital for being underage  
 and not being on DCF's "page",  
 I'm the property of the state  
 And of workers earning minimum wage,  
 I'm restrained and tranquilized  
 Like an animal on a stage,  
 I'm shut-up and shut-away  
 But I'm not allowed to feel rage,  
 I'm just a child in foster care  
 Growing up in a cage.

-Anna, Age 16<sup>286</sup>

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284. Georgia Findings Letter, *supra* note 210.

285. See generally GABRIEL MYERS WORK GROUP, *supra* note 19; STRAYHORN, *supra* note 102.

286. Florida's Children First, Reflections of A Former Foster Children, [http://floridaschildrenfirst.org/fcf\\_RefDocuments\\_054\\_mental\\_health.htm](http://floridaschildrenfirst.org/fcf_RefDocuments_054_mental_health.htm) (last visited March 21, 2010).

Anna's words are echoed by Dr. Peter Breggin, who says that "[c]hildren don't have disorders. They live in a disordered world."<sup>287</sup> It is hoped that this Article will precipitate action by the United States government to closely study its obligations under the 1971 Convention on Psychotropic Substances, and take all necessary and appropriate measures to comply with its mandates. The government must act swiftly and aggressively to alleviate the unnecessary suffering of the thousands of children across America for whom the experience of being "restrained and tranquilized" has become disturbingly commonplace.

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287. BREGGIN & BREGGIN, *supra* note 191, at 86.