
PSYCHOTROPIC MEDICATION AND FOSTER CARE CHILDREN: A PRESCRIPTION FOR STATE OVERSIGHT

MICHELLE L. MELLO*

TABLE OF CONTENTS

I. INTRODUCTION.....	396
II. PSYCHOTROPIC MEDICATION	399
A. TREATMENT AND SIDE EFFECTS	399
B. USAGE	400
III. APPLICABLE FEDERAL LAW AND REGULATIONS.....	402
A. FDA NEW DRUG APPROVAL	402
B. PEDIATRIC DRUG RESEARCH	404
C. OFF-LABEL PRESCRIBING	407
D. LEGISLATION REGARDING HEALTH CARE FOR FOSTER CHILDREN	410
IV. HEALTH CARE SPENDING AND THE MEDICAID PROGRAM	411
A. MEDICAID ELIGIBILITY FOR CHILDREN IN FOSTER CARE	412
B. PRESCRIPTION DRUG COVERAGE UNDER MEDICAID	413
V. PSYCHOTROPIC MEDICATION AND MEDICAID FRAUD	414
A. HEALTH CARE FRAUD AND THE FALSE CLAIMS ACT.....	414
B. PSYCHRIGHTS’S MEDICAID FRAUD INITIATIVE AGAINST PSYCHIATRIC DRUGGING OF CHILDREN & YOUTH	415
C. GOVERNMENT ACCOUNTABILITY OFFICE INVESTIGATION	419
VI. RECOMMENDATIONS	420

* Class of 2012, University of Southern California Gould School of Law; B.A. Social Welfare and Legal Studies 2007, University of California, Berkeley. Many thanks to Professor Elyn Saks for her insight throughout the development of this Note, the members of the *Southern California Law Review* for their thoughtful comments and keen editing, and my family for providing steadfast support at all times.

A. MANDATORY MENTAL HEALTH SCREENINGS FOR CHILDREN IN FOSTER CARE	421
B. EVALUATION OF EVIDENCE FOR OFF-LABEL PRESCRIBING	422
C. DEVELOPMENT OF “RED FLAG” INDICATORS TO PROMPT ADDITIONAL OVERSIGHT	425
VII. CONCLUSION	427

I. INTRODUCTION

On April 16, 2009, seven-year-old Gabriel Myers locked himself in the bathroom of his Florida foster home and took his own life.¹ Just three weeks prior, Myers was prescribed Symbyax, a combination of antidepressant and antipsychotic drugs not approved by the U.S. Food and Drug Administration (“FDA”) for use in children.² Myers’s Department of Children & Families (“DCF”) records document a tragic history of neglect, allegations of sexual abuse, and movement between at least four foster care placements after removal from his mother’s care.³ Diagnosed with attention deficit hyperactivity disorder, mood disorder, and possibly depression, Myers took several medications including Lexapro and Vyvanse.⁴ After his death, DCF appointed a Work Group to assess Myers’s case as well as the use of psychotropic medication for other children in state foster care. While the Work Group determined that safeguards in Florida existed, the “core failures in the system . . . stem[med] from lack of compliance with [such safeguards] and . . . failures in communication, advocacy, supervision, monitoring, and oversight.”⁵

Giovan Bazan was only six-years-old when he was first treated with medication for hyperactivity.⁶ Years later, while taking Ritalin at a double dosage, he was prescribed an antidepressant after another physician saw

1. *Gabriel Myers*, FLA. DEP’T OF CHILDREN & FAMILIES, <http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/GMPresentation.pdf> (last visited Jan. 4, 2012).

2. Jon Burstein, *Suicide Investigators Look at Boy’s Medicine*, SUN-SENTINEL (S. Fla.), April 25, 2009, at 7B.

3. DCF first learned of Gabriel in June 2008 when police found him in a parked, running car with his unconscious mother who had “powder cocaine, alcohol, crack cocaine, marijuana and several non-prescribed medications” on hand. *Gabriel Myers*, *supra* note 1.

4. *Id.*

5. GABRIEL MYERS WORK GROUP, REPORT OF GABRIEL MYERS WORK GROUP 9 (2009), available at <http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/GabrielMyersWorkGroupReport082009Final.pdf>.

6. April Hunt, *Georgia Foster Kids Medicated at High Rates*, ATLANTA J.-CONST. (Feb. 23, 2011), <http://www.ajc.com/news/georgia-foster-kids-medicated-846324.html>.

him “so mellowed out that he barely reacted.”⁷ Twenty-year-old Bazan is now free of all medications and recognizes that “[t]hey start you on one thing for a problem, then the side effects mean you need a new medicine . . . [a]s a foster kid, I’d go between all these doctors, caseworkers, therapists, and [it] seemed like every time there was a new drug to try me on.”⁸

Misty Stenslie shuffled between thirty placements in eight states throughout the twelve years she spent in foster care.⁹ Her diagnoses included depression, oppositional defiant disorder, post-traumatic stress disorder, and a sleep disorder.¹⁰ She stated,

Because of the instability in my living situation, it seemed that the only option the professionals in my life were able to take for treating all of the diagnosed conditions was prescribing medication. . . . I was on more medications than I [can] count—usually without my knowing what the meds were for, how I should expect to feel, side effects to watch out for, or any plan for follow up.¹¹

According to the Surgeon General, nearly one in five children in the United States is affected by a mental health disorder.¹² A subject of rising concern is the use of psychotropic medication among the general youth population, with a potentially higher prevalence among children in the foster care system. Over the past decade alone, psychotropic medication use by youth has increased two- to threefold.¹³ While the rate of such use is estimated to be around 4 percent in the general youth population, the rate rises to a range of 13–52 percent among children in foster care.¹⁴ This discrepancy indicates that appropriate use of psychotropic medication for

7. *Id.*

8. *Id.*

9. *Prescription Psychotropic Drug Use Among Children in Foster Care: Hearing Before The Subcomm. on Income Sec. & Family Support of the H. Comm. on Ways & Means, 110th Cong. 31 (2008) [hereinafter *Hearing*] (statement of Misty Stenslie, Deputy Dir., Foster Care Alumni of Am.). She experienced “foster homes, group homes, shelter facilities, detention and correctional institutions, kinship care, and psychiatric/residential treatment.” *Id.**

10. *Id.*

11. *Id.*

12. SURGEON GENERAL, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 46 (1999); *Facts on Children’s Mental Health*, BAZELON CTR. FOR MENTAL HEALTH L., <http://www.bazelon.org/LinkClick.aspx?fileticket=Nc7DS9D8EQE%3D&tabid=378> (last visited Jan. 4, 2012).

13. LAUREL K. LESLIE ET AL., TUFTS CLINICAL & TRANSLATIONAL SCI. INST., MULTI-STATE STUDY ON PSYCHOTROPIC MEDICATION OVERSIGHT IN FOSTER CARE 1 (2010), available at http://tuftsctsi.org/About-Us/Announcements/~/_media/23549A0AA4DE4763ADE445802B3F8D6F.ashx.

14. *Id.*

youth in foster care merits special attention.

Child welfare state agencies are accountable for supporting the health and mental health needs of children taken into custody. Because these children are essentially “under the care, custody, and control of the state,”¹⁵ they often have no natural advocates or allies; thus, the state must care for and treat these children as a prudent parent would. General federal guidelines for the administration of health care to foster children exist, but states have ample discretion in developing and managing their programs and policies. While nearly all children in foster care are eligible for health care coverage under Medicaid, studies suggest that many of these youth are still not receiving adequate mental health care services.¹⁶

Several parties have begun to investigate whether children in foster care are being prescribed psychotropic medication outside of established federal guidelines. Notably, the prescription of pediatric medication is primarily conducted “off-label” because so few medications are approved by the FDA for use in children. When evidentiary support for such uses is lacking, concern about the appropriate use and administering of psychotropic medication for youth follows accordingly. An Alaska-based nonprofit organization, the Law Project for Psychiatric Rights (“PsychRights”), commenced in 2009 a Medicaid Fraud Initiative, contending that Medicaid is not permitted to reimburse states for certain off-label prescriptions commonly given to children.¹⁷ The Government Accountability Office (“GAO”), similarly investigated whether children in state care are being prescribed psychotropic medications outside of regulations and medical practice standards.¹⁸

The use of psychotropic medication is widely established as an effective form of mental health care treatment. The chief concerns about such use are therefore “whether, as part of a comprehensive treatment plan, such medications are necessary for a child in care and are properly prescribed, approved, administered, monitored, and discontinued as soon as

15. 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).

16. ROB GEEN, ANNA SOMMERS & MINDY COHEN, URBAN INST., MEDICAID SPENDING ON FOSTER CHILDREN 1 (2005), available at http://www.urban.org/uploadedPDF/311221_medicaid_spending.pdf.

17. *PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth*, PSYCHRIGHTS, <http://psychrights.org/education/ModelQuiTam/ModelQuiTam.htm> (last modified Dec. 13, 2011) [hereinafter *PsychRights Initiative*].

18. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-270T, FOSTER CHILDREN: HHS GUIDELINE COULD HELP STATES IMPROVE OVERSIGHT OF PSYCHOTROPIC PRESCRIPTIONS (2011).

medically appropriate.”¹⁹ This Note proposes that states develop a framework for psychotropic medication oversight for children in foster care that accounts for Medicaid’s reimbursement structure and is guided by safety concerns raised by off-label prescribing and inconsistent mental health assessment. The argument proceeds as follows.

Part II introduces psychotropic medication, particularly with respect to use by children in foster care. Part III then examines several applicable federal laws and regulations, including the FDA drug approval process, pediatric drug research legislation, the stance of the Federal Food, Drug, and Cosmetic Act (“FDCA”) on off-label prescribing, and legislation affecting health care for foster children. Part IV takes a brief look at Medicaid’s coverage of youth in foster care as well as its reimbursement structure for prescription drugs. Part V analyzes the PsychRights Medicaid Fraud Initiative as well as the GAO’s examination of state oversight of psychotropic medication prescriptions for foster children. Part VI proposes that states develop a framework for psychotropic medication oversight that accounts for the Medicaid reimbursement structure and most salient health and safety risks in the use of such drugs by children in foster care. Part VII concludes.

II. PSYCHOTROPIC MEDICATION

A. TREATMENT AND SIDE EFFECTS

The use of psychotropic medication is widely accepted within the mental health community as an effective form of treatment for several psychiatric disorders. Psychotropic medications “act directly on the brain to chemically alter mood, cognition, or behavior, their effect typically being achieved by altering the process of neurotransmission.”²⁰ They are commonly divided into six main categories: (1) stimulants; (2) antipsychotics; (3) antidepressants; (4) depressants; (5) anti-anxiety sedatives; and (6) mood stabilizers.²¹ Such medications are often used to treat conditions such as anxiety, depression, attention-deficit hyperactivity disorder (“ADHD”), obsessive-compulsive disorder, bipolar (manic-depressive) disorder, and psychosis.²² Although psychotropic medications

19. GABRIEL MYERS WORK GROUP, *supra* note 5, at i.

20. Angela Olivia Burton, “*They Use It Like Candy*”: *How The Prescription of Psychotropic Drugs to State-Involved Children Violates International Law*, 35 BROOK J. INT’L L. 453, 466 (2010) (internal quotation marks omitted).

21. *Id.* at 466.

22. AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY, FACTS FOR FAMILIES NO. 21: PSYCHIATRIC MEDICATION FOR CHILDREN AND ADOLESCENTS PART I—HOW MEDICATIONS ARE USED

are effective, they may produce side effects and pose substantial risks to health and safety. Such risks can “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.”²³

B. USAGE

Psychotropic medication use has “skyrocketed” over the last decade.²⁴ According to the Centers for Disease Control, antidepressants have become the most commonly prescribed drugs in the nation.²⁵ Of the 2.4 billion drugs prescribed in hospital and doctor visits in 2005, 118 million were antidepressants.²⁶ Adult use of such drugs tripled between 1988 and 1994 and between 1999 and 2000, and rose 48 percent from 1995 to 2002.²⁷ Children are similarly using a higher amount of psychotropic medication than in the past.²⁸ Psychotropic medications, however, are regularly developed and approved for adult use only; although children and adults may have some similar medical needs, they are biologically quite distinct. Medications effective for use in adults may not provide substantial benefits to children, given that “[t]here are dynamics of growth and maturation of organs, changes in metabolism throughout infancy and childhood, changes in body proportion, and other developmental changes that affect how drugs are metabolized.”²⁹ Certainly, “children are not small adults.”³⁰ While the rate of psychotropic medication use in children has risen, so have efforts to address the dearth of data for pediatric products.

Although the general youth population is using a historically high rate of psychotropic medication, the use of such medication among children in

1–2 (2004), available at http://www.aacap.org/galleries/FactsForFamilies/21_psychiatric_medication_for_children_and_adolescents_part_one.pdf.

23. Burton, *supra* note 20, at 467.

24. Elizabeth Cohen, *CDC: Antidepressants Most Prescribed Drugs in U.S.*, CNN (July 9, 2007), http://articles.cnn.com/2007-07-09/health/antidepressants_1_antidepressants-high-blood-pressure-drugs-psychotropic-drugs?_s=PM:HEALTH.

25. *Id.*

26. *Id.*

27. *Id.*

28. See Christopher Fisher, *Psychotropic Medications Are Over-Prescribed to Children*, BEHAV. MED. REP. (Apr. 24, 2010), <http://www.bmedreport.com/archives/12011> (warning of a “dramatic rise” in psychotropic medication use by children).

29. Michelle Meadows, *Drug Research and Children*, FDA CONSUMER, Jan.–Feb. 2003, at 12, 13 (internal quotation marks omitted).

30. Laura K. Bachrach, *Bare-Bones Fact—Children Are Not Small Adults*, 351 NEW ENG. J. MED. 924, 924 (2004).

foster care has become a subject of particular concern over the last ten years. Indeed, foster care youth tend to have a “disproportionately high prevalence of mental health disorders” as compared to the general youth population.³¹ This may be the result of several factors, including but not limited to “experiences and trauma associated with high-risk and often dysfunctional family settings, acute reactions to the trauma of being placed in foster care, and being separated from the biological parent.”³² Moreover, children in foster care often experience multiple changes in rapid time; new relationships, schools, family, friends, and surroundings force children into a “series of adaptations” that makes detection, assessment, and treatment of mental health disorders difficult.³³ Unlike many children in the general youth population, foster care children can have hundreds of people responsible for their care yet no parents or natural advocates.³⁴

Further, children in foster care account for less than 3 percent of all Medicaid enrollees, yet use 25 to 41 percent of all mental health expenditures within the Medicaid program.³⁵ This discrepancy suggests that children in foster care receive a disproportionate share of mental health services and their use of psychotropic medication should be subject to particular scrutiny. Indeed, one study suggests that foster care youth receive psychotropic medication at a rate three to four times higher than other children covered by Medicaid.³⁶ Research shows that such children are often prescribed more than one medication at the same time. For example, an assessment conducted in Texas in 2004 found that 72.5 percent of medicated foster care children were prescribed two or more classes of

31. NEAL HALFON, ALEX ZEPEDA & MOIRA INKELAS, UCLA CTR. FOR HEALTHIER CHILDREN, FAMILIES & CMTYS., MENTAL HEALTH SERVICES FOR CHILDREN IN FOSTER CARE 1 (2002), available at <http://www.healthychild.ucla.edu/Publications/ChildrenFosterCare/Documents/Mental%20health%20brief%20final%20for%20distribution.pdf> (“Several studies indicate that between 50 and 80 percent of children in foster care suffer from moderate to severe mental health problems.”).

32. *Id.*

33. *Id.*

34. *See, e.g., Hearing, supra* note 9, at 32–33 (statement of Misty Stenslie).

35. David M. Rubin et al., *State Variation in Psychotropic Medication Use by Foster Care Children With Autism Spectrum Disorder*, 124 PEDIATRICS e305, e306 (2009). *See also* HALFON, ZEPEDA & INKELAS, *supra* note 31, at 1 (stating that children in foster care utilize 15–20 times the amount of mental health services than other children covered by Medicaid).

36. *Hearing, supra* note 9, at 9 (statement of Julie M. Zito, Professor of Pharmacy and Psychiatry, Pharm. Health Servs. Research, Univ. of Md., Balt.). A high prevalence of psychotropic medication use for foster care youth has been reported in many states, including California, Delaware, Maryland, Minnesota, and Pennsylvania. *Id.* *See also* Rubin et al., *supra* note 35, at e306 (suggesting that foster care youth use psychotropic medication at a rate of two to three times higher than other children in the community).

psychotropic medication while 41.3 percent received three or more.³⁷ Most polypharmacy,³⁸ however, is not adequately studied for safety or effectiveness in youth.³⁹ In fact, “pediatric research shows that increasing the number of concomitant medications increases the likelihood of adverse drug reactions.”⁴⁰

Finally, media attention to psychotropic medication use in the foster care system illustrates the growing public concern about this issue in particular.⁴¹ Indeed, “[t]he General Accounting Office . . . reported [in 2006] that nearly 1 in 3 states has identified the oversight of psychotropic medication use as 1 of the most pressing issues facing their child welfare systems in the next 5 years.”⁴² Because foster care youth seem to be medicated much more often than children in the general population, a Senate Panel asked the GAO to investigate such practices.⁴³

III. APPLICABLE FEDERAL LAW AND REGULATIONS

A. FDA NEW DRUG APPROVAL

The FDCA is the primary law regulating drug manufacturing and distribution,⁴⁴ and its “overriding purpose [is] to protect the public health.”⁴⁵ It requires that the FDA approve all new prescription drugs as safe and effective before they are placed on the market.⁴⁶ To obtain FDA approval, drug manufacturers engage in a multi-phase clinical trial process, focusing the first phase on safety and subsequent phases on effectiveness.⁴⁷

37. *Hearing, supra* note 9, at 12 (statement of Julie M. Zito).

38. “Variably called concomitant use, coprescription, or polypharmacy, this concept is most commonly operationalized in the literature as use of two or more concurrent psychotropic medications.” Ramesh Raghavan & J. Curtis McMillen, *Use of Multiple Psychotropic Medications Among Adolescents Aging Out of Foster Care*, 59 *PSYCHIATRIC SERVS.* 1052, 1052 (2008).

39. Gardiner Harris, *Proof is Scant on Psychiatric Drug Mix for Young*, *N.Y. TIMES*, Nov. 23, 2006, at A1.

40. *Hearing, supra* note 9, at 9 (statement of Julie M. Zito).

41. *See, e.g.*, Rubin et al., *supra* note 35, at e306; David Sessions, *Psychotropic Drug Abuse in Foster Care Costs Government Billions*, *POLITICS DAILY* (June 17, 2010), <http://www.politicsdaily.com/2010/06/17/psychotropic-drug-abuse-in-foster-care-costs-government-billions/>; Duff Wilson, *Child’s Ordeal Shows Risks of Psychosis Drugs for Young*, *N.Y. TIMES*, Sept. 1, 2010, available at <http://www.nytimes.com/2010/09/02/business/02kids.html>.

42. Rubin et al., *supra* note 35, at e306.

43. Wilson, *supra* note 41. *See also infra* Part V.C.

44. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361–62 (2002).

45. *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

46. 21 U.S.C. § 355 (2006).

47. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited Jan. 5, 2012).

Manufacturers first conduct clinical trials in controlled studies for the intended patient group.⁴⁸ They must then study how their proposed drug affects individuals using several drugs concurrently, and conduct further studies examining different populations and dosages.⁴⁹ Generally, the number of clinical trial subjects ranges anywhere from a few hundred to three thousand people.⁵⁰ The results of all such studies must then be formalized in a new drug application, which includes a description of how the drug was manufactured and processed, the proposed labeling, and “full reports of investigations.”⁵¹ A review team comprised of pharmacologists, doctors, scientists, and other experts then evaluates whether a drug is safe and effective for its proposed use based on the new drug application.⁵² Because no drug is conclusively safe, approval means only that the potential benefits of a drug sufficiently outweigh its risks.⁵³

The new drug application stage is especially critical because it requires manufacturers to provide data from all trials. An applicant cannot choose to include only favorable reports, as submission of all data bearing upon a drug’s safety and efficacy is required.⁵⁴ This transparency, however, does not always translate into practical use for clinicians actually prescribing the drug. When the FDA approves a drug for its proposed use, it also approves appropriate labeling for that product. Labels are included as inserts in the packaging of a drug and are generally written by drug companies rather than the FDA.⁵⁵ Although the FDA examines all available data implicating the risks and benefits of a drug in its approval review, much of this critical information neither appears on the label nor in pertinent articles regarding the drug. Further, because the existence of “reviewer uncertainty” is not included on labels, clinicians “cannot distinguish drugs that reviewers endorsed enthusiastically from those they viewed with great skepticism” based on the label alone.⁵⁶ Thus, even if a drug is approved for a certain use, the information that warranted that approval is often inaccessible and all of the drug’s risks are generally not available to the public.

[hereinafter *FDA Drug Review*].

48. *Id.*

49. *Id.*

50. *Id.*

51. 21 U.S.C. § 355(b)(1).

52. *FDA Drug Review*, *supra* note 47.

53. *Id.*

54. *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 410 (Ct. App. 1967).

55. Lisa M. Schwartz & Steven Woloshin, *Lost in Transmission—FDA Drug Information That Never Reaches Clinicians*, 361 NEW ENG. J. MED. 1717, 1717 (2009).

56. *Id.* at 1719.

The new drug approval process is imperfect in another—and arguably more pressing—way: the regulations somewhat limit access to FDA-approved pediatric products. If specific testing in a pediatric population is not completed in the clinical studies, a new drug approval will generally be available only for adult indications.

B. PEDIATRIC DRUG RESEARCH

Before the FDA's pediatric program began, only about 20 percent of approved drugs were labeled for pediatric use.⁵⁷ While new drug applications required manufacturers to conduct controlled trials, inclusion of youth subjects in those trials was never mandated. Experts blame this historical inadequacy on several factors. Primarily, the financial incentives to study the effect of drugs on children were trivial.⁵⁸ Only those drugs with a large market—vaccines, antibiotics, and cold medicines—were adequately studied in children.⁵⁹ Children also tend to be more difficult to examine.⁶⁰ Pediatric studies require “child-friendly environments in every sense, from age-appropriate equipment and medical techniques to pediatric specialists who are sensitive to a child's fear.”⁶¹ Finally, issues such as informed consent and the child's right to decide whether to enroll in a study presented complicated ethical dilemmas.⁶² Without any incentives or regulations mandating drug manufacturers to conduct clinical trials for pediatric populations, there were few compelling reasons to do so. As a result, most drugs prescribed for children before Congress stepped in were not tested for use in children.

Legislations in the late 1990s and early 2000s have created both voluntary and mandatory mechanisms—a “carrot-and-stick approach”⁶³—to conducting pediatric drug studies. More studies have been conducted in

57. *Drug Research and Children*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143565.htm> (last visited Jan. 5, 2012).

58. *Id.*

59. *Id.*

60. See Lisa Jerles, Note, *The Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act—Helping or Hurting America's Children?*, 6 *CARDOZO PUB. L. POL'Y & ETHICS J.* 515, 523–26 (2008) (noting that children also account for only 24.6 percent of the United States population).

61. *Drug Research and Children*, *supra* note 57 (internal quotation marks omitted).

62. *Id.* See also Jacinta OA Tan & Michael Koelch, *The Ethics of Psychopharmacological Research in Legal Minors*, *CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH* (Dec. 8, 2008), <http://www.capmh.com/content/2/1/39> (discussing ethical issues such as “the premise of research, consent and competence, dilemmas of inequalities of health care provision, the impact of research design and the requirement for ‘minimal risk’ and ‘benefit,’ and influences of commercial interests”).

63. *Drug Research and Children*, *supra* note 57.

children since the legislation passed than in the last thirty years, and pediatric data has been added to more than eighty drug labels.⁶⁴ For example, examination of the drug Luvox (fluvoxamine maleate), used to treat obsessive-compulsive disorder, revealed that while most adolescents should likely receive the recommended adult dose, girls ages eight to eleven may need a lower dose of the drug⁶⁵:

New discoveries have revealed underdosing, overdosing, ineffectiveness, and safety problems. . . . Even though the best and brightest pediatric minds have helped us establish dosages for children, we're finding out that the dose is different than we thought in some cases. And that probably came as a surprise to most of us.⁶⁶

The “carrot” of the FDA’s pediatric drug program is found in the Pediatric Exclusivity Provision of the Food and Drug Administration Modernization Act of 1997, reauthorized and extended through 2007 as the Best Pharmaceuticals for Children Act.⁶⁷ This provision allows six months of marketing exclusivity to those companies who conduct pediatric studies.⁶⁸ The additional market exclusivity is not only added to the single drug studied, but to any of the manufacturer’s other formulations with existing patent life containing the same active ingredients.⁶⁹ “Once the economic disincentive” to conducting pediatric drug studies was removed, “the dam broke completely open.”⁷⁰

While the FDA retained authority to offer incentives such as the voluntary pediatric exclusivity program, it could not require manufacturers to conduct pediatric clinical trials until President Bush signed the Pediatric Research Equity Act of 2003 (“PREA”) into law. Under the PREA, the FDA may oblige manufacturers to include the results of pediatric drug studies in their new drug applications if the product (1) “is likely to be used in a substantial number of pediatric patients,” or (2) “would provide a meaningful benefit to children over existing treatments.”⁷¹ The FDA also has authority to grant full waivers to this requirement under limited circumstances: (1) when studies are impossible or impracticable given, for

64. *Id.*

65. *Id.*

66. *Id.* (internal quotation marks omitted).

67. Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002) (codified as amended in scattered sections of 21 and 42 U.S.C.).

68. *Id.* sec. 10, § 355a(n), 115 Stat. at 1415 (codified as amended at 21 U.S.C. 355a(n)).

69. *Drug Research and Children*, supra note 57.

70. *Id.* (internal quotation marks omitted).

71. *Id.*

example, a small patient population; (2) when evidence suggests that the drug would be unsafe or ineffective for all pediatric ages; (3) when the drug would not meaningfully benefit children over existing treatments; or (4) when the drug is unlikely to be used by a substantial number of youth patients.⁷² Partial waivers may be granted for all of the same reasons or if reasonable attempts to produce a pediatric formulation have failed in the past.⁷³

Although this regulatory scheme has produced tangible and substantial benefits, some critics argue that Congress still has a long way to go in order to address critical pediatric health and safety concerns.⁷⁴ When the National Institutes of Health examined studies conducted pursuant to the pediatric exclusivity program, it found some troubling statistics: while labeling changes indicated that pediatric drug studies produced valuable and unique data, most articles are not published and nearly half of the published articles “focus their attention away from the crucial safety data.”⁷⁵ Another organization, the Alliance for Human Research Protection, argues that the true beneficiaries of the pediatric exclusivity program are not children but pharmaceutical companies.⁷⁶ Given the lack of oversight and regulations regarding how and where companies must conduct studies, it would seem that companies conduct studies however they like. Because it is “much cheaper, easier, and less time consuming to conduct research” offshore, it may come as no surprise that of 174 published trials indicating study location, 65 percent were conducted abroad and 11 percent did not include any sites in the United States.⁷⁷ Whether this conduct raises cause for concern is unknown, but “[t]he efficacy of a medication may depend on genetic background and access to health care resources, among other factors, which may differ across countries.”⁷⁸

72. 21 U.S.C. § 355c(a)(4)(A) (2006).

73. *Id.* § 355c(a)(4)(B).

74. See Joanna K. Sax, *Reforming FDA Policy for Pediatric Testing: Challenges and Changes in the Wake of Studies Using Anti-Depressant Drugs*, 4 *IND. HEALTH L. REV.* 61, 76 (2007) (recommending policy considerations including listing trials in public databases, changing the exclusivity provision and labeling methods, and implementing surveillance methods after new drug approval).

75. Daniel K. Benjamin Jr. et al., *Safety and Transparency of Pediatric Drug Trials*, 163 *ARCHIVES PEDIATRICS & ADOLESCENT MED.* 1080, 1080 (2009).

76. Vera Hassner Sharav, *Globalization of Pediatric Drug Trials—For Whose Benefit?*, *ALLIANCE FOR HUM. RES. PROT.* (Aug. 26, 2010), <http://www.ahrp.org/cms/content/view/721/70/>.

77. *Id.* (citing Sara K. Pasquali et al., *Globalization of Pediatric Research: Analysis of Clinical Trials Completed for Pediatric Exclusivity*, 126 *PEDIATRICS* e687, e687 (2010)).

78. *Id.*

C. OFF-LABEL PRESCRIBING

Drugs need not be approved by the FDA for every potential use for which they could be prescribed. Physicians may prescribe drugs for medical conditions whether or not that specific use is included on the label. Such “off-label” use of an approved drug is use for any purpose—any indication, condition, dosage, or population—not yet evaluated and approved by the FDA.⁷⁹

Off-label prescribing is rather prevalent in modern medical practice. Some experts estimate that nearly one-half of all drug prescriptions in the United States are for off-label uses.⁸⁰ The Supreme Court regards off-label prescribing as a “necessary corollary of the FDA’s mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine.”⁸¹ Indeed, neither Congress nor the FDA regulates the practice of medicine, and federal regulations recognize 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.”⁸² While health care professionals are free to prescribe products off label, they must still adhere to medical practice guidelines and a sound standard of care in making prescribing decisions. For example, off-label use has support from the American Medical Association when “such use is based on sound scientific evidence and sound medical opinion.”⁸³

Off-label uses harvest support from wide-ranging levels of evidence. Authorities recognize a certain “hierarchy”: “[t]ypically at the top are large randomized controlled trials (RCTs), followed by smaller RCTs, cohort studies, case-control studies, poorly controlled or uncontrolled studies, case reports, and expert opinion.”⁸⁴ An off-label use may originate from a

79. *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 182 (E.D. Pa. 2007). *See also* Tardy v. Eli Lilly & Co., No. CV-03-538, 2004 Me. Super. LEXIS 168, at *1 n.3 (Me. Super. Ct. Aug. 3, 2004) (citation omitted).

80. Kaspar J. Stoffelmayr, *Products Liability and “Off-Label” Uses of Prescription Drugs*, 63 U. CHI. L. REV. 275, 275 (1996). *See also* David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1021 (2006) (estimating a general off-label prescription rate of 21 percent, with some classes of drugs prescribed off-label at a rate of around 46 percent).

81. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001).

82. 21 U.S.C. § 396 (2006).

83. Judith G. Edersheim, *Off-Label Prescribing: Minimizing Risks and Liabilities*, PSYCHIATRIC TIMES, Apr. 2009, at 12, 14 (internal quotation marks omitted).

84. Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 479 (2009).

physiological link or similarity in condition or “therapeutic class” to an FDA-approved use.⁸⁵ Often, off-label prescriptions extend a labeled use to a related condition or broader population.⁸⁶ Resources such as medical compendia, peer-reviewed medical journals, and Continuing Medical Evaluation events enable practitioners to keep abreast of current information regarding off-label uses.⁸⁷

While such evidence validates some off-label treatments, critics contend that off-label medication use often occurs without strong scientific support.⁸⁸ Off-label uses are clearly not subject to the same rigorous standards that the FDA’s new drug approval process mandates. While approved drugs undergo a complex multiphase clinical trial review procedure to establish their safety and efficacy in the intended population, their off-label counterparts can technically be subject to much less scrutiny and require less evidentiary support. This can leave patients with no alternative but an inadequately tested medication, which could “undermine[] the public’s expectation that they will be given drugs with known safety and efficacy.”⁸⁹ When an off-label use lacks a “solid evidentiary basis,” the “potential for harm is greatest.”⁹⁰

Unfortunately, the regulatory scheme as of December 2011 provides little incentive for manufacturers to study off-label uses with the same rigorous scrutiny required for new drug approval. Given that off-label prescribing is legal and prevalent, seeking approval for new uses does not offer financial benefit and thus does not incentivize manufacturers to engage in the costly and time-consuming clinical trial and approval process. This limitation on rigorous testing is especially problematic for relatively small populations, like this nation’s youth. Moreover, although physicians may prescribe drugs for off-label uses, the federal regulatory system does not allow manufacturers to promote unapproved uses; drugs marketed as such are regarded as misbranded by the FDA.⁹¹ Thus, a doctor

85. *Id.*

86. Joshua Cohen, Andrew Wilson & Laura Faden, *Off-Label Use Reimbursement*, 64 FOOD & DRUG L.J. 391, 392 (2009).

87. Dresser & Frader, *supra* note 84, at 479; Ralph F. Hall & Tracy A. Braun, *Leaving No Child Behind? Abigail Alliance, Pediatric Products and Off-Label Use*, 8 HOUS. J. HEALTH L. & POL’Y 271, 296 (2008).

88. Radley, Finkelstein & Stafford, *supra* note 80, at 1021.

89. Edersheim, *supra* note 83, at 14.

90. Dresser & Frader, *supra* note 84, at 476.

91. *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, FDA (Jan. 2009), <http://www.fda.gov/oc/op/goodreprint.html>.

may prescribe a drug that is unapproved for one indication while a manufacturer may not promote the same drug for that use. Ultimately, manufacturers profit from off-label uses of drugs even if they have provided few if any studies regarding those uses.

Pediatric medication prescribing demonstrates some of the chief evidentiary uncertainties related to off-label prescribing. Given that so few drugs are approved by the FDA for use in children, experts estimate that approximately 50 to 75 percent of medications used in the pediatric population are prescribed off label.⁹² Thus, practitioners must base prescribing decisions on “extrapolation of efficacy, dosing, administration and side effect profiles from adult studies” or treatment evidence “based on anecdote, case reports or open studies of clinical experience.”⁹³ Yet children’s organs, immune systems, and body proportions mature at different rates throughout their development, which produces serious questions about whether the medical community can assess whether use of a drug is warranted based solely on data derived from adults.⁹⁴ Because of the scarcity of pediatric data, clinicians must often make prescribing decisions without much suitable guidance.

Examining the history of “pediatric pharmacology” produces a clear illustration of the seriousness of the risk of harm associated with the practice of off-label prescribing in the pediatric population.⁹⁵ For example, doctors stopped prescribing the antibacterial chloramphenicol to newborns after seeing a pattern of deaths; the antibiotic was promised to be more effective than any other available drug, but ended up inflicting “devastating and lethal” complications for infants.⁹⁶ Such “horror stories” suggest the

92. Julie M. Zito et al., *Off-Label Psychopharmacologic Prescribing for Children: History Supports Close Clinical Monitoring*, CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH (Sept. 15, 2008), <http://www.capmh.com/content/2/1/24>.

93. *Id.* Physicians have also been known to resort to “extemporaneous formulations” such as crushing tablets to mix with a child’s meal. Such formulations raise safety concerns because they may be “poorly or inconsistently bioavailable.” FOOD & DRUG ADMIN., THE PEDIATRIC EXCLUSIVITY PROGRAM: JANUARY 2001 STATUS REPORT TO CONGRESS 3 (2001), available at <http://www.fda.gov/downloads/drugs/developmentapprovalprocess/developmentresources/ucm049915.pdf>.

94. See Frank James, *Drugmakers, Bush Clash on Kid Trials*, CHI. TRIB., Feb. 5, 2003, at N8 (“If you simply scale down the dose by body weight, what it misses is the maturational changes in how the drug is removed from the body The baby’s capacity to remove the drug may be 2 or 3 percent of the capacity of an adult or an older child. A drug can quickly build up to toxic levels.” (internal quotation marks omitted)).

95. Zito et al., *supra* note 92.

96. *Id.* at 2; James, *supra* note 94 (noting further that pediatricians at a Tennessee hospital in 1999 saw seven infants develop digestive blocks requiring surgery after ingesting erythromycin for pertussis).

necessity of reassessing off-label prescribing practices for drug use in children. This is “particularly true for the treatment of emotional and behavior disorders” due to the expanded use of many drugs for “psychotherapeutic purposes,” the dearth of any guidelines with respect to both pediatrics and child psychiatry, the “absence of objective markers of emotional and behavioral conditions,” and the need to engage multiple parties in monitoring and regulating activities.⁹⁷

Although “horror stories” certainly expose the risks associated with off-label prescribing, the practice is well accepted from legal, medical, and policy standpoints. In fact, the American Academy of Pediatrics (“AAP”) endorses off-label prescribing as a necessary component to pediatric care. When “done . . . in the best interest of the patient” and “based on sound scientific evidence, expert medical judgment, or published literature,” off-label prescribing is often the best available therapy for pediatric patients.⁹⁸ Many experts agree that access to potentially beneficial treatments not yet endorsed by the FDA should not be delayed until that treatment receives formal approval.⁹⁹ In many cases, patient care could simply not progress without access to off-label uses.¹⁰⁰ With close monitoring and strong evidentiary support, the off-label use of medications will continue to be valuable in the treatment of mental health disorders.

D. LEGISLATION REGARDING HEALTH CARE FOR FOSTER CHILDREN

Federal legislation in recent years has attempted to address the oversight of psychotropic medication use in the foster care system. In 2008, Representative Jim McDermott (D-Wash.) introduced the Investment in Kids’ Instruction, Development, and Support Act (“Invest in KIDS Act”), which was devised to improve outcomes for foster youth by investing in families and building system accountability.¹⁰¹ McDermott, the only psychiatrist in Congress at the time,¹⁰² held a public hearing on the way atypical antipsychotics are prescribed to foster children without adequate oversight.¹⁰³ Though the Invest in KIDS Act ultimately died in committee,

97. Zito et al., *supra* note 92.

98. Am. Acad. of Pediatrics Comm. on Drugs, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS 181, 181–83 (2002).

99. Dresser & Frader, *supra* note 84, at 477.

100. *Id.* at 476.

101. H.R. 5466, 110th Cong. (2008).

102. Sessions, *supra* note 41.

103. Stephen Barlas, *Concern About Psychotropic Drugs and Foster Kids*, PSYCHIATRIC TIMES, July 2008, at 62.

it brought public attention to the rising concerns related to mental health care oversight throughout the foster care system.

The Fostering Connections to Success and Increasing Adoptions Act, signed into law by President Bush in October 2008, is a significant piece of federal legislation regarding children in the foster care system. Section 205 requires state welfare agencies to work with state Medicaid agencies to develop a health care plan—including mental health provisions—for children in foster care by outlining (1) a schedule for initial and follow-up health screens; (2) how needs identified in such screens will be monitored and treated; (3) how medical information will be updated and shared; (4) how to ensure continuity of care; (5) oversight of prescription medicines; and (6) how the state will consult with providers to ensure appropriate care.¹⁰⁴ Though the legislation does not mention psychotropic medication specifically, it does require states to ensure prescription medication oversight for children in foster care.¹⁰⁵

The Child and Family Services Improvement and Innovation Act, passed in September 2011, addresses this issue by explicitly requiring states to establish protocols for appropriate use of psychotropic drugs by foster children.¹⁰⁶ How completely and effectively states implement this legislation, however, remains to be seen.

IV. HEALTH CARE SPENDING AND THE MEDICAID PROGRAM

Medicaid is the primary health care funding source for children in state foster care.¹⁰⁷ Medicare and Medicaid programs comprise the largest single purchaser of health care in the world¹⁰⁸—no small feat considering national health care expenditures reached \$2.5 trillion and accounted for 17.6 percent of the gross domestic product in 2009.¹⁰⁹ In fact, Medicaid

104. Fostering Connections to Success and Increasing Adoptions Act of 2008, Pub. L. No. 110-351, sec. 205, § 622(b)(15), 122 Stat. 3949, 3961 [hereinafter *Fostering Connections Act*]. See also KAMALA ALLEN, CTR. FOR HEALTH CARE STRATEGIES, INC., HEALTH SCREENING AND ASSESSMENT FOR CHILDREN AND YOUTH ENTERING FOSTER CARE: STATE REQUIREMENTS AND OPPORTUNITIES 1 (2010), available at http://www.chcs.org/usr_doc/CHCS_CW_Foster_Care_Screening_and_Assessment_Issue_Brief_111910.pdf.

105. Fostering Connections Act, sec. 205, § 622(b)(15), 122 Stat. at 3961.

106. Child and Family Services Improvement and Innovation Act, Pub. L. No. 112-34, § 101(b)(2), 125 Stat. 369, 369 (2011) (to be codified in scattered sections of 42 U.S.C.).

107. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-26, FOSTER CARE: STATE PRACTICES FOR ASSESSING HEALTH NEEDS, FACILITATING SERVICE DELIVERY, AND MONITORING CHILDREN'S CARE 11 (2009).

108. JENNIFER STAMAN, CONG. RESEARCH SERV., HEALTH CARE FRAUD AND ABUSE LAWS COVERING MEDICARE AND MEDICAID: AN OVERVIEW 1 (2008).

109. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/>

spending constituted 15 percent of total national health expenditures at \$373.9 billion in 2009, and the Centers for Medicare & Medicaid Services expects that number to grow at an average rate of 7.9 percent per year until 2019.¹¹⁰ In 2004, Medicaid expenditures for children in the foster care system surpassed \$5 billion.¹¹¹

A. MEDICAID ELIGIBILITY FOR CHILDREN IN FOSTER CARE

The Medicaid program provides assistance to individuals and families with insufficient resources to obtain essential medical services. The states and federal government jointly finance the program, and although states are not required to participate, they must comply with federal regulatory requirements if they elect to do so.¹¹² State agencies thus administer relief and determine eligibility, payments, and qualifying services within “broad parameters” set by the federal government.¹¹³

In any state, certain requirements must be met in order to qualify for Medicaid coverage, and factors to be considered include age, disability, income, and citizenship status.¹¹⁴ Whether a child is eligible is determined by the child’s status; thus, a child can still qualify for Medicaid even if the adult with whom he or she lives does not.¹¹⁵ Although states have some discretion in selecting criteria for Medicaid program coverage, there are several mandatory eligibility groups. States that participate in the program are required to cover children who meet federal eligibility criteria for foster care under Title IV-E of the Social Security Act.¹¹⁶ The Urban Institute indicates that all states provide Medicaid coverage to children in the foster care system except “non-citizens, those with private health insurance, and children who leave foster care” while visiting their home of removal.¹¹⁷

NationalHealthExpendData/25_NHE_Fact_Sheet.asp#TopOfPage (last modified Jan. 6, 2012).

110. *Id.*

111. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 107, at 12.

112. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1326 (S.D. Fla. 2006).

113. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 107, at 11–12. *See also Edmonds*, 417 F. Supp. 2d at 1326 (“Actual Medicaid relief is administered through state agencies pursuant to a Medicaid plan that has been approved by the U.S. Department of Health and Human Services.”).

114. *Medicaid Eligibility Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/MedicaidEligibility/01_Overview.asp#TopOfPage (last modified Aug. 11, 2011).

115. *Id.*

116. *See* 42 U.S.C. § 1396a(a)(10)(A)(i)(I) (2006).

117. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 107, at 12 n.18. *See also* GEEN, SOMMERS & COHEN, *supra* note 16, at 1.

B. PRESCRIPTION DRUG COVERAGE UNDER MEDICAID

States that participate in the Medicaid program must make statutorily mandatory services available to all eligible individuals and may also elect to cover optional services, such as coverage for outpatient prescription drugs.¹¹⁸ Once a state chooses to provide an optional service such as coverage of outpatient prescription drugs, that service is subject to federal requirements and becomes part of the state Medicaid plan.¹¹⁹ All states presently offer prescription drug benefits through Medicaid; such drugs accounted for over \$23 billion of Medicaid outlays in 2008.¹²⁰

The procedure for Medicaid reimbursement for prescription drugs involves several parties, including drug manufacturers, Medicaid providers, state agencies, and the federal government. In order for a prescription drug to be eligible for reimbursement under Medicaid, its manufacturer must first enter into a rebate agreement with Medicaid.¹²¹ Medicaid providers—such as physicians and pharmacists—may pay the manufacturer directly for a drug and then submit a reimbursement claim to its state Medicaid agency.¹²² While these claims are pending, the federal government reimburses state agencies for a significant amount of the funds.¹²³

Medicaid provides reimbursement for “covered outpatient drugs,”¹²⁴ not including those “used for a medical indication which is not a medically accepted indication.”¹²⁵ A medically accepted indication is one either approved under the FDCA or “supported by one or more citations included or approved for inclusion”¹²⁶ in three specified drug compendia—the American Hospital Formulary Service Drug Information (“AHFS”), United States Pharmacopeia-Drug Information (“USP”) or its successor publications, and the DRUGDEX Information System (“DRUGDEX”).¹²⁷ Further, states may subject a covered outpatient drug to prior authorization

118. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1326 (S.D. Fla. 2006).

119. *Id.*

120. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-957, MEDICAID: FRAUD AND ABUSE RELATED TO CONTROLLED SUBSTANCES IDENTIFIED IN SELECTED STATES 1 (2009).

121. 42 U.S.C. § 1396r-8(a)(1) (2006).

122. *Id.* § 1396a(a)(23), (32).

123. *Id.* § 1396b.

124. *Id.* § 1396r-8(a)(3) (authorizing payment for other drugs if the State has determined that “availability of the drug is essential to the health of beneficiaries,” the drug was given an FDA rating of “1-A,” and either the physician obtained approval through prior authorization or the Secretary “reviewed and approved the State’s determination” or concluded that “there were extenuating circumstances” to dispense the drug).

125. *Id.* § 1396r-8(k)(3).

126. *Id.* § 1396r-8(k)(6).

127. *Id.* § 1396r-8(g)(1)(B)(i).

or “exclude or otherwise restrict coverage of a covered outpatient drug” if the prescription is for a use other than a medically accepted indication or if the drug is listed as restricted, subject to a restriction pursuant to an agreement between the state and drug manufacturer, or excluded by a state-established formulary.¹²⁸

V. PSYCHOTROPIC MEDICATION AND MEDICAID FRAUD

The growing cost of health care in the United States is partially exacerbated by the prevalence of health care industry fraud and abuse. Federal and state agencies are paying critical attention to prosecuting such fraud given the heavy financial burden it causes taxpayers. While some experts estimate that around \$68 billion of the nation’s health care spending is lost to fraud each year, others calculate the yearly loss at closer to \$226 billion.¹²⁹ The Medicaid fraud dilemma has not only produced financial losses but also has exploited individuals while subjecting them to unnecessary or unsafe treatment.¹³⁰

Alaska-based nonprofit PsychRights commenced in 2009 a Medicaid Fraud Initiative against the psychiatric drugging of children in the United States. It proposed that the practice of overprescribing psychotropic drugs to children would cease once providers were financially exposed. In a similar vein, the GAO released a report in December 2011 that examines whether children in state care are being prescribed psychotropic medication outside of federal regulations and medical standards of practice.

A. HEALTH CARE FRAUD AND THE FALSE CLAIMS ACT

The vast “majority of health care fraud is committed by a very small minority of dishonest health care providers. “Sadly, the actions of these deceitful few ultimately serve to sully the reputation of perhaps the most trusted and respected members of our society—our physicians.”¹³¹ Prevalent types of health care fraud include falsely billing for services never rendered or more expensive procedures, performing “medically unnecessary services” or “misrepresenting non-covered treatments as

128. *Id.* § 1396r-8(d)(1)(A)–(B).

129. *Health Care Fraud*, IDAHO FRAUD AWARENESS COAL., <http://www.fightfraudidaho.com/individuals/health-care-fraud/> (last visited Jan. 18, 2012).

130. *The Problem of Health Care Fraud*, NAT’L HEALTH CARE ANTI-FRAUD ASS’N, http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_cent&wpscode=TheProblemOfHCFraud (last visited Jan. 6, 2012).

131. *Id.*

medically necessary” in order to compel insurance payments, and creating false diagnoses.¹³² Common fraudulent activity also includes accepting “kickbacks” for referrals, “unbundling” by billing single components of a procedure separately, and overbilling insurance carriers.¹³³

Among the most valuable tools available to combat health care fraud at the federal level is the False Claims Act (“FCA”); the government has recovered more than \$15 billion from FCA actions since Congress amended it in 1986.¹³⁴ The FCA imposes civil liability on persons who knowingly present or cause the presentation of false claims in order to obtain government recompense.¹³⁵ Under the FCA, it is a false claim to knowingly present a false or fraudulent claim for payment or approval, or to make or use, a false record or statement material to a false or fraudulent claim.¹³⁶ “Knowingly” is defined as actual knowledge; deliberate ignorance of the truth or falsity; or reckless disregard of the truth or falsity, and proof of specific intent to defraud is not required.¹³⁷ Several courts, including the Supreme Court, have delineated the meaning of the knowledge requirement as it applies to claims for Medicaid and other public funds. In general, every Medicaid provider “ha[s] a duty to familiarize itself with the legal requirements for cost reimbursement”¹³⁸ and claims of ignorance are an “untenable basis”¹³⁹ for failing to be aware of the duty to submit only truthful claims. Finally, claims submitted to Medicaid state agencies are considered claims presented to the federal government because, as discussed above, the federal government reimburses states for a substantial portion of funding.¹⁴⁰ As such, any false claim presented may give rise to liability under the FCA.

B. PSYCHRIGHTS’S MEDICAID FRAUD INITIATIVE AGAINST PSYCHIATRIC DRUGGING OF CHILDREN & YOUTH

Alaska-based nonprofit PsychRights commenced in 2009 a Medicaid Fraud Initiative in an effort to put an end to the “massive psychiatric

132. *Id.*

133. *Id.*

134. Matthew S. Brockmeier, *Pulling the Plug on Health Care Fraud: The False Claims Act After Rockwell and Allison Engine*, 12 DEPAUL J. HEALTH CARE L. 277, 278 (2009).

135. 31 U.S.C. § 3729(a) (2006).

136. *Id.* § 3729(a)(1).

137. *Id.* § 3729(b)(1).

138. *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 63–64 (1984).

139. *United States v. Nazon*, 940 F.2d 255, 260 (7th Cir. 1991).

140. *See supra* text accompanying notes 119–21.

drugging of children.”¹⁴¹ It seeks damages and penalties under the FCA against prescribers and pharmacies for presenting or causing to be presented claims under Alaska’s Medicaid and Children’s Health Insurance Programs that PsychRights contends are not covered under federal law.¹⁴² The initiative is operated through the FCA’s qui tam actions,¹⁴³ which allow private parties to sue on behalf of the United States government and share in the recovery if successful. Relying on information provided by the FDA and DRUGDEX, PsychRights created a list of drugs commonly prescribed to children, highlighting drugs with a medically accepted condition, drugs not supported by DRUGDEX but maintaining at least one citation for a pediatric indication, and drugs with neither FDA approval nor a citation in DRUGDEX.¹⁴⁴ PsychRights found that at least six drugs commonly prescribed to children—Symbyax (Zyprexa and Prozac together), Cymbalta, Geodon, Paxil, Invega, and Trazodone—have no medically accepted indications for pediatric populations.¹⁴⁵

PsychRights’s case rests on the notion that Medicaid is only permitted by Congress to reimburse states for outpatient drugs used for “medically accepted indications,” defined as indications approved by the FDA or “supported” by a citation in one of the compendia.¹⁴⁶ Defendants assert, however, that PsychRights’s interpretation of the statute is erroneous and that the Medicaid Act does not limit coverage to just those indications approved by the FDA or supported by the compendia.¹⁴⁷ In other words, such provisions “establish a ‘floor’ for reimbursements of medications by Medicaid programs, not a ‘ceiling’ as PsychRights claims.”¹⁴⁸ While

141. *PsychRights Initiative*, *supra* note 17.

142. *Id.*

143. Before a plaintiff, or “relator,” brings a qui tam action, he or she must provide the government with a copy of the complaint and disclose all substantially material evidence. *United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, 12 (D. Mass 2006), *vacated and remanded*, 507 F.3d 720 (1st Cir. 2007). This allows the government to investigate the claim on its own and decide whether to take over prosecution. *Id.* The complaint must remain under seal throughout this time. *Id.* at 12–13.

144. *PsychRights Initiative*, *supra* note 17.

145. James B. Gottstein, *PsychRights’ Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth*, PSYCHRIGHTS (May 17, 2010), <http://psychrights.org/education/ModelQuiTam/ModelQuiTamPowerPoint.pdf>. PsychRights also contends that virtually all polypharmacy constitutes a pediatric nonmedically accepted indication. *Id.*

146. Opposition to Motion to Dismiss Under Rule 12(b)(6) at 2, *United States ex rel. Law Project for Psychiatric Rights v. Matsutani*, No. 3:09-CV-00080-TMB (D. Alaska May 7, 2010) [hereinafter *Opposition to Motion to Dismiss*].

147. Memorandum in Support of Motion to Dismiss Under Rule 12(b)(6) at 2, *United States ex rel. Law Project for Psychiatric Rights v. Matsutani*, No. 3:09-CV-00080-TMB (D. Alaska Apr. 5, 2010).

148. *Id.*

Medicaid is required to pay for “covered outpatient drugs,” it is allowed to cover more.¹⁴⁹ Accordingly, defendants argue that no false claims were ever made and PsychRights failed to allege a violation of the FCA.¹⁵⁰

In contesting PsychRights’s interpretation, defendants argue that the statute implies that Medicaid must cover more than just “medically accepted indications” because otherwise it would render the provision allowing states to restrict or exclude coverage to medically accepted indications meaningless.¹⁵¹ Defendants support this by citing to *United States ex rel. Franklin v. Parke-Davis*, in which the relator argued that off-label claims of Neurontin were false because they were not for a “medically accepted indication” and therefore not reimbursable.¹⁵² The District Court of Massachusetts expressed skepticism about that interpretation¹⁵³ but ultimately did not rule on the issue.¹⁵⁴ In fact, the court stated that “[i]t is not clear which side gets the better of the statutory-tail-chases-cat debate” and requested an amicus brief from federal officials describing “the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions.”¹⁵⁵ PsychRights cites several cases in support of its interpretation of the Medicaid provisions at issue. For example, the same federal district court of Massachusetts acknowledged in a later decision that “Medicaid can only pay for drugs that are used for a medically accepted indication, meaning one that is either approved by the FDA or supported by citations in one of the three compendia.”¹⁵⁶

149. *Id.*

150. *Id.*

151. *Id.* at 6–8. “A state may exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication.” 42 U.S.C. § 1396r-8(d)(1)(B)(i) (2006).

152. *United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754, at *7–8 (D. Mass. Aug. 22, 2003).

153. “Thus, in Relator’s view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation.” *Id.* at *8.

154. *Id.*

155. *Id.* at *8–9.

156. *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 13–14 (D. Mass. 2008) (internal quotation marks omitted). *See also* *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44–45 (D. Mass. 2001) (“Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.”); *United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03-C-8239, 2007 U.S. Dist. LEXIS 52666, at *7–8 (N.D. Ill. July 20, 2007) (“Medicaid generally reimburses providers only for ‘covered outpatient drugs’ . . . [which] do not include drugs used for a medical indication which is not a medically accepted indication.” (internal quotation marks omitted)).

While the Department of Justice (“DOJ”) has not articulated an official position as to which interpretation is correct, several of its assertions indicate agreement with PsychRights. A DOJ news release publicizing a \$2.3 billion settlement with Pfizer in September 2009 stated that the company “caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs.”¹⁵⁷ Even more analogous is the Government’s Complaint in Intervention in *United States ex rel. Gobble v. Forest Laboratories*, in which it argued that “prescriptions caused to be presented to Medicaid that are not for medically accepted indications are false claims,” and that “Celexa (citalopram) and Lexapro (escitalopram) have no medically accepted indications for children and youth.”¹⁵⁸ As a result, “claims presented to Medicaid as a result of prescriptions of Celexa and Lexapro by physicians for use in children and youth are false or fraudulent for that reason.”¹⁵⁹

As of December 2011, the majority of state Medicaid programs, including Alaska, permits reimbursement for off-label uses regardless of whether such uses are supported by any of the compendia.¹⁶⁰ While defendants argue that this means reimbursements are authorized, PsychRights contends “[t]his is a reason for granting a preliminary injunction against the practice rather than shedding any light on whether the practice is permitted under Medicaid.”¹⁶¹ Regardless, in the eight states that do prohibit reimbursement for off-label prescriptions not supported by the compendia, a “Medicaid-reimbursement request for an off-label, non-compendium prescription constitutes a false claim.”¹⁶²

Although the District Court of Alaska granted defendant’s motion to dismiss PsychRights’s case, it did not determine whether PsychRights successfully asserted the existence of a false claim. Rather, the court concluded that it lacked subject matter jurisdiction to hear the actions under the FCA.¹⁶³ The Ninth Circuit affirmed the dismissal on October 25,

157. News Release, Dep’t of Health & Human Servs., Justice Department Announces Largest Health Care Fraud Settlement in its History (Sept. 2, 2009), <http://www.hhs.gov/news/press/2009pres/09/20090902a.html>.

158. Opposition to Motion to Dismiss, *supra* note 146, at 7.

159. *Id.* at 7–8.

160. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *7–8.

161. Opposition to Motion to Dismiss, *supra* note 146, at 11.

162. *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at *9–10.

163. Order Granting Defendant’s Motion to Dismiss Under Rule 12(b)(1) at 2, *United States ex rel. Law Project for Psychiatric Rights v. Matsutani*, No. 3:09-CV-00080-TMB (D. Alaska Sept. 24,

2011.¹⁶⁴

C. GOVERNMENT ACCOUNTABILITY OFFICE INVESTIGATION

The United States Senate Subcommittee on Federal Financial Management is similarly examining potential abuse of psychotropic medication in the foster care youth population. In November 2010, it asked the GAO to investigate this very issue:

At the request of Congress, the GAO is seeking information regarding cases in which state foster children have been prescribed psychotropic medication outside of federal regulations or accepted medical standards of practice. These may include very young foster children prescribed certain kinds of psychotropic drugs, children prescribed psychotropic drugs in dosages that exceed accepted standards, children prescribed psychotropic drugs in dosages for purposes other than a medically accepted indication, or children taking numerous psychotropic drugs concurrently.¹⁶⁵

The GAO collected data from Florida, Maryland, Massachusetts, Michigan, Oregon, and Texas and focused its investigation on antidepressants, often prescribed off label for uses not approved by the FDA.¹⁶⁶ Its experts found that certain prescribing practices “carry increased levels of risk for children,” including “concomitant prescriptions of five or more medications, doses exceeding maximum levels in FDA-approved drug labels, and prescriptions for infants.”¹⁶⁷ The GAO suggested that the risk imposed by such practices relates to a lack in research and evidentiary support.¹⁶⁸ Indeed, “no evidence supports the use of five or more psychotropic drugs” and “only limited evidence supports the use of even two drugs concomitantly in children.”¹⁶⁹ Research “demonstrating that high dosages are more effective” is lacking, and “there are no established mental health indications for the use of psychotropic drugs in infants.”¹⁷⁰ Although its report ultimately did not scrutinize the relationship between psychotropic medication and potential Medicaid fraud, the GAO did find

2010).

164. Law Project for Psychiatric Rights v. Matsutani, No. 10-35887, 2011 U.S. App. LEXIS 21722 (9th Cir. Oct. 25, 2011).

165. *GAO Seeks Information On Off Label Drugging of Foster Children*, UNITE FOR LIFE BLOG (Nov. 22, 2010, 3:08 PM), <http://uniteforlife.wordpress.com/category/foster-care/>.

166. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 18, at 1–2.

167. *Id.* at 12.

168. *See id.* at 14.

169. *Id.*

170. *Id.* at 15.

that the selected states' monitoring programs fell short of guidelines established by the American Academy of Child and Adolescent Psychiatry ("AACAP").¹⁷¹

VI. RECOMMENDATIONS

Psychiatric disorders in children can have harmful short-term and permanent consequences without suitable evaluation and treatment. Although psychotropic drugs are a significant element of treatment, the increased use of these drugs has "led to concerns that some children and adolescents are being overdiagnosed with psychiatric disorders and are being treated with medication/s that are not appropriate for them."¹⁷² It is clear that all states should develop a framework for the oversight of psychotropic medication to youth in foster care.¹⁷³ Given the plethora of approaches, there is not a single identified "best practice," but "what does appear to be true . . . is that any attention that is paid to this issue seems to make a positive difference."¹⁷⁴ Although no studies providing national data and recommendations yet exist, several states as well as professional organizations such as the AACAP and AAP have examined the research literature to develop practice guidelines for psychotropic medication prescriptions.¹⁷⁵ State agencies are thus well equipped with comparative information to improve programming in this area, although they must

171. *Id.* at 18.

172. AACAP, *Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents*, 48 AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 961, 962 (2009).

173. See Rubin et al., *supra* note 35, at e311 ("The observation of excessive variation across the United States in the use of psychotropic medications among children in foster care substantiates concerns for oversight of such use . . .").

174. KAREN WORTHINGTON, GA. SUPREME COURT COMM. ON JUSTICE FOR CHILDREN, *PSYCHOTROPIC MEDS FOR GEORGIA YOUTH IN FOSTER CARE: WHO DECIDES?* 16 (2011), [http://w2.georgiacourts.org/cj4c/files/Psych_meds_paper%20\(2\).pdf](http://w2.georgiacourts.org/cj4c/files/Psych_meds_paper%20(2).pdf). *Accord* TEX. HEALTH & HUMAN SERVS. COMM., *UPDATE ON THE USE OF PSYCHOACTIVE MEDICATIONS IN TEXAS FOSTER CHILDREN FISCAL YEARS 2002–2011*, 1 (2011), *available at* <http://www.hhsc.state.tx.us/medicaid/OCC/Psych-Medications.pdf> (noting a decline in psychotropic medication after implementation of voluntary standards for medication oversight).

175. *E.g.*, CONN. DEP'T OF CHILDREN & FAMILIES, *GUIDELINES FOR PSYCHOTROPIC MEDICATION USE IN CHILDREN AND ADOLESCENTS* (2010), *available at* http://www.ct.gov/dcf/lib/dcf/behavioral_health_medicine/pdf/guidelines_psychotropic_medication.pdf; ILL. DEP'T OF CHILDREN & FAMILY SERVS., *GUIDELINES FOR THE UTILIZATION OF PSYCHOTROPIC MEDICATIONS FOR CHILDREN IN FOSTER CARE*, *available at* <http://www.psych.uic.edu/csp/physicians/Medication%20Guidelines.pdf>; N.J. DEP'T OF CHILDREN & FAMILIES, *PSYCHOTROPIC MEDICATION POLICY* (2011), *available at* <http://www.state.nj.us/dcf/behavioral/providers/PsychotropicMeds.pdf>; TENN. DEP'T OF CHILDREN'S SERVS., *PSYCHOTROPIC MEDICATION UTILIZATION PARAMETERS FOR CHILDREN IN STATE CUSTODY*, *available at* <http://www.tn.gov/youth/dcsguide/policies/chap20/PsychoMedUtilGuide.pdf>.

consider several competing concerns.

As a society, we push for “quick fixes.” The reimbursement structure of our health care system offers incentives for brief medication visits, instead of comprehensive, collaborative, and interdisciplinary mental health treatment approaches. Despite research that suggests comprehensive treatment approaches are more effective in treating many mental health problems commonly seen in youth, the reimbursement structure of our health care system tends to impede this treatment strategy.¹⁷⁶

Consequently, this Note proposes that states develop a framework for prescribing, administering, and monitoring psychotropic medication use for children in foster care that accounts for Medicaid’s reimbursement structure and is guided by safety concerns raised by off-label prescribing and inconsistent mental health assessment. First, states should mandate timely mental health assessments to evaluate the appropriateness of treatment for children in their care. Second, states would be well served to evaluate standards for Medicaid reimbursement of off-label prescriptions to develop guidelines for how such medications are best prescribed. Finally, states should consider taking advantage of Medicaid rules to develop a series of “red flag” indicators that will prompt additional oversight for prescriptions indicating both salient safety concerns and potential Medicaid fraud.

A. MANDATORY MENTAL HEALTH SCREENINGS FOR CHILDREN IN FOSTER CARE

Federal regulations require state child welfare agencies to implement “a schedule for initial and follow-up health screenings that meet reasonable standards of medical practice.”¹⁷⁷ Notably, the law lacks any requirement regarding mental health screenings specifically or a timeframe within which any type of health assessment must be made. A fifty-state survey conducted in 2010 found that only thirty-eight states require a behavioral health screening for children removed from their homes.¹⁷⁸ Four states require such screening within twenty-four hours, while eleven states extend the deadline to thirty days after removal.¹⁷⁹

176. LESLIE ET AL., *supra* note 13, at 20.

177. Fostering Connections to Success and Increasing Adoptions Act of 2008, Pub. L. No. 110-351, sec. 205, § 622(b)(15), 122 Stat. 3949, 3961.

178. ALLEN, *supra* note 104, at 3.

179. *Id.*

This particular population of children is in critical need of early assessment and intervention for behavioral and mental health needs.¹⁸⁰ Indeed, the AAP recommends a comprehensive mental health evaluation within thirty days of foster care placement.¹⁸¹ “[E]arly identification of unmet and pre-existing conditions” can “resolve acute health issues and better manage chronic conditions.”¹⁸² Further, a child’s education, employment, and financial prospects may be negatively impacted without effective early identification and intervention.¹⁸³ Although federal regulations mandate some form of health assessment, it is currently up to the states to determine the extent of their involvement in a child’s mental health outcome. Given that an estimated 50 percent of foster care youth have significant behavioral health challenges, timely assessments and evaluations should be a mandatory component of every state’s foster care protocol.¹⁸⁴

With mandatory mental health screenings—both after entry into the foster care system and at consistent points throughout a child’s stay—states may also be better able to keep abreast of the types of treatment children receive. The GAO’s investigation focused on certain types of cases that could easily be caught and prevented with such mental health screenings—cases in which children are prescribed psychotropic drugs at inappropriate ages and dosage levels. By mandating mental health screenings in a formal oversight framework, states can avoid potentially fraudulent prescriptions of psychotropic drugs and improve the health and safety of children in their care.

B. EVALUATION OF EVIDENCE FOR OFF-LABEL PRESCRIBING

States would be well served to partner with their Medicaid provider systems to reevaluate prescription and reimbursement guidelines and develop a consistent framework to guide how medication is to be prescribed off label. While children certainly need access to off-label medication, the medical community is responsible for ensuring that treatment decisions are supported by solid evidence. Indeed, “[a]s long as

180. See *supra* text accompanying notes 31–43.

181. Allen, *supra* note 104, at 2. See also HALFON, ZEPEDA & INKELAS, *supra* note 31, at 1 (noting similar recommendations made by the Child Welfare League of America, the AAP, and the AACAP).

182. Allen, *supra* note 104, at 1.

183. *Facts on Children’s Mental Health*, *supra* note 12.

184. Allen, *supra* note 104, at 1.

the regulatory system gives physicians the freedom to prescribe off label, patients will depend on the medical profession to exercise this freedom responsibly.”¹⁸⁵

Congress plainly allows Medicaid reimbursement for uses either approved by the FDA or supported by citation in one of the compendia. The Medicaid Act, however, does not provide a “definitive policy”¹⁸⁶ regarding whether federal regulations actually permit states to provide reimbursement for off-label, non-compendium drug prescriptions. Regardless of whether such prescribing is even permitted under federal regulations, the question of whether states should provide reimbursement for off-label drug prescriptions not supported by a medical compendium inevitably arises. Further, given the attention to Medicaid fraud over the last five years with respect to psychotropic drugs, states may be wary to permit the reimbursements under question until federal requirements are clarified.

Even uses supported by citation in the compendia are difficult to identify under the current federal regulations. For example, “support” is not clearly defined and none of the compendia has a section designated “Uses Supported by Citation.”¹⁸⁷ Thus, whether any of the compendia ever sufficiently support coverage is not always clear. The United States shared its definition of “support” in *Rost v. Pfizer*:

Whether a particular use is “supported by” a compendium citation may depend on a variety of factors, including the type of drug and indication at issue, the compendium’s assessment of the drug’s efficacy in treating the indication, the content of the compendium citation, and the scope and outcome of the studies as described in the compendium.¹⁸⁸

Given the great variance among the compendia in organization and comprehensiveness, states should develop appropriate guidelines for determining whether off-label uses have sufficient evidentiary support. For example, although each of the compendia includes sections for “uses,” they vary in the amount of research supporting such uses. Of the three

185. Dresser & Frader, *supra* note 84, at 483.

186. Reply to Defendants/Appellees’ Response to Request for Judicial Notice of U.S. Statement of Interest in *Polansky* at 4, United States *ex rel.* Law Project for Psychiatric Rights v. Matsutani, No. 10-35887 (9th Cir. Mar. 25, 2011).

187. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1332 (S.D. Fla. 2006).

188. United States’ Statement of Interest in Response to Defendant’s Motion to Dismiss Plaintiff’s First Amended Complaint at 6, United States *ex rel.* *Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6 (D. Mass 2006), *vacated and remanded*, 507 F.3d 720 (1st Cir. 2007) (No. 1:03-cv-11084).

compendia, DRUGDEX is the most comprehensive¹⁸⁹ and authorizes around twice as many off-label uses as the other two directories;¹⁹⁰ of the dozen top-selling drugs in the United States, USP carries nine off-label uses, AHFS sixty-eight, and DRUGDEX 203.¹⁹¹ Thus, it “effectively sets the standards” for Medicaid reimbursement.¹⁹² DRUGDEX lists both approved and off-label uses in a section titled “Therapeutic Uses,” where each off-label use is given an efficacy rating of either “possibly effective” or “ineffective.”¹⁹³ Support ranges from a “single case study” to “randomized placebo-controlled double-blind clinical studies,” and although it cites articles to support its listings, such articles are not required to meet any specific scientific criteria.¹⁹⁴ Likewise, AHFS lists all approved and off-label uses in a “Uses” section, which “discusses the effectiveness of a drug for the listed uses but does not rate the efficacy of the off-label uses, mention documentation, or refer to the literature that the AHFS editors reviewed.”¹⁹⁵

If prescribers are to make safe and effective off-label treatment decisions, they must be able to assess the quality of evidence supporting such uses. Resources such as the compendia “can be useful, but offer clear guidance only after high-quality research has evaluated a particular off-label use.”¹⁹⁶ Of course, off-label uses may not be subject to the most rigorous research like that required by the FDA’s new drug approval process, but the “justification for off-label prescribing is strongest when rigorous research”¹⁹⁷ and other forms of evidence support its practice. By creating comprehensive and clear guidelines for how drugs are to be

189. JANE PERKINS, NAT’L HEALTH LAW PROGRAM, Q&A: MEDICAID COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS 4 (2007). DRUGDEX publisher Thomson Corporation is not only a multibillion dollar firm but also the only private company to own any of the directories. Accordingly, one critic has noted that “[o]ne of the least-known but biggest gifts Congress gave big pharma was to authorize an industry-supported private company to decide whether Medicaid would pay for off-label uses of prescription drugs.” MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 204 (2004).

190. ANGELL, *supra* note 189, at 205.

191. David Armstrong, *How Drug Directory Helps Raise Tab for Medicaid and Insurers: They Pay for “Off-Label” Uses If Listed—And Drugdex Lists Great Many of Them*, WALL. ST. J., Oct. 23, 2003, at A1.

192. ANGELL, *supra* note 189, at 205.

193. *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1333 (S.D. Fla. 2006); Perkins, *supra* note 189, at 4–5.

194. *Edmonds*, 417 F. Supp. 2d at 1333; Perkins, *supra* note 189, at 4–5.

195. Perkins, *supra* note 189, at 4.

196. Dresser & Frader, *supra* note 84, at 479.

197. *Id.* at 480.

prescribed off label and which uses are adequately supported by the compendia, states may improve mental health outcomes for children in foster care while ensuring that only those prescriptions authorized by the tenuous federal regulations are permitted Medicaid reimbursement.

C. DEVELOPMENT OF “RED FLAG” INDICATORS TO PROMPT ADDITIONAL OVERSIGHT

Many states that have analyzed psychotropic medication use for children in foster care have developed “medication guidelines” or “utilization parameters” to inform prescribing practices.¹⁹⁸ Several states use “red flag” indicators to identify the most salient problems with safety and quality of care in psychotropic medication prescriptions. Many of the red flags identified thus far by states implicate the same concerns raised by the Medicaid fraud literature. States may limit potential Medicaid fraud by creating a framework of red flag indicators to guide prescribing practices and prompt additional oversight. States may take careful advantage of Medicaid rules to institute control over alarming psychotropic medication prescriptions indicated by identified red flag markers.

While every state should identify the red flags most pertinent to the children in their care, some red flag indicators relevant to potential Medicaid fraud include the following: (1) when psychotropic drugs are prescribed to very young children; (2) when polypharmacy is used before monopharmacy or multiple psychotropic medications are used at the same time; (3) when prescribed dosages exceed maximum recommendations; and (4) when the risks and benefits of a drug are not adequately documented or available.¹⁹⁹ States may partner with their Medicaid provider systems to initiate additional review and oversight when a child is prescribed medication that raises one of these red flags.²⁰⁰ Thus, “prescriptions that are outside established guidelines [can] trigger some kind of response when they are entered into the Medicaid system for

198. See, e.g., WORTHINGTON, *supra* note 174, at 18.

199. LESLIE ET AL., *supra* note 13, at 7. Other red flag markers include the use of non-approved medications over those that are FDA approved, the use of several medications within the same “class” such as antidepressants, antipsychotics, and mood stabilizers, and the extended use of medication for children not diagnosed with Bipolar Disorder, Psychosis, or Schizophrenia. *Id.*

200. WORTHINGTON, *supra* note 174, at 30–31. See also LESLIE ET AL., *supra* note 13, at 7 (“These ‘red flags’ served multiple purposes, including: prompting case reviews; ordering lab work when indicated for specific medications; initiating the prior authorization process from Medicaid for select medications; conducting internal quality assurance initiatives; and identifying ‘outliers’ (i.e., individual prescribers whose prescribing patterns fall outside of normal trends).”).

payment.”²⁰¹

One such response is prior approval as a condition for Medicaid coverage and payment for prescriptions that raise red flags.²⁰² States are authorized by federal law to establish a prior approval authorization program,²⁰³ but only if it meets specific requirements.²⁰⁴ For example, the system providing for approval must respond to any request for prior authorization within twenty-four hours and provide for the dispensing of a seventy-two hour supply of a covered prescription drug during emergency situations.²⁰⁵ Concern about mental health drugs has prompted several states to require prior approval for prescribing certain classes of drugs to young children.²⁰⁶ In Illinois, for example, prior approval is required for all ADHD medication prescribed to anyone under the age of six and all Atypical Antipsychotics medication for children under the age of eight.²⁰⁷ In Florida, any prescription of an antipsychotic medication for a child under the age of six will not be approved until another medical assessment is performed.²⁰⁸ Prior approval programs have shown a decline in Medicaid claims for antipsychotic medications for young children, greater consistency in prescribing practices, and a decrease in proposed dosages.²⁰⁹ Prior approval programs must be carefully tailored, however, to ensure that access to appropriate care is not overly restricted.²¹⁰

201. WORTHINGTON, *supra* note 174, at 30.

202. 42 U.S.C. § 1396r-8(d)(5) (2006). Prior approval programs are meant to provide support to physicians, ensure that children receive suitable dosages, and reduce inappropriate use of particular psychotropic medications. *See* ILL. DEP’T OF CHILDREN & FAMILY SERVS., *supra* note 175.

203. *See supra* text accompanying note 128.

204. 42 U.S.C. § 1396r-8(d)(5).

205. *Id.*

206. Informational Notice, Ill. Dep’t of Healthcare & Family Servs., Prior Approval for Atypical Antipsychotics and ADHD Medications for Young Children (Aug. 3, 2009), <http://www.hfs.illinois.gov/html/080309n1.html>. *See also* Wilson, *supra* note 41 (noting prior approval programs in California and Florida).

207. Informational Notice, *supra* note 206.

208. WORTHINGTON, *supra* note 174, at 30–31.

209. *Id.* at 31.

210. *See* Chris Koyanagi, Sandra Forquer & Elaine Alfano, *Medicaid Policies to Contain Psychiatric Drug Costs*, 24 HEALTH AFF. 536, 536–37 (2005); Christine Y. Lu et al., *Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medication for Bipolar Illness*, 48 MED. CARE 4, 4, 9 (2010) (finding that more research should be done to assess whether “specific seriously mentally ill populations or drug classes should be exempted from [prior authorization] policies”); Yuting Zhang et al., *Effects of Prior Authorization on Medication Discontinuation Among Medicaid Beneficiaries with Bipolar Disorder*, 60 PSYCHIATRIC SERVS. 520, 520 (2009) (concluding that a prior-authorization policy for second-generation antipsychotic and anticonvulsant medication in Maine may have increased patient risk without a corresponding benefit in cost savings to the state).

A second response takes the form of systemic oversight of the prescribing practices of specific providers who consistently raise red flags. States may

look for such things as which providers vary the most from mandatory or recommended guidelines, whether there is a nexus between medications prescribed and free samples or other incentives from pharmaceutical representatives, and whether the use of psychotropic medications is higher at particular facilities or for particular subgroups in foster care.²¹¹

With a framework that flags potentially inappropriate prescribing practices, states may be better able to exert productive control over particular providers to improve the mental health outcomes of children in state foster care.

VII. CONCLUSION

As the use of psychotropic medications in the foster care system rises, so should states' responsibility for providing safe and effective oversight. National regulations leave states with wide discretion to develop their own systems, but states cannot choose to ignore the opportunity to promote improved mental health outcomes for some of the population's most vulnerable youth. By creating a framework for prescribing, administering, and monitoring psychotropic medication use that is guided by Medicaid's reimbursement structure and safety concerns raised by off-label prescribing and inconsistent mental health assessments, states can create a system that prevents potential Medicaid abuses while encouraging appropriate mental health services for children in foster care.

211. WORTHINGTON, *supra* note 174, at 31.

