

Acting in the Best Interest of Vulnerable Patients:  
The Role of Independent Parties in Off-Label  
Antipsychotic Prescribing for the Elderly in Nursing  
Homes and Children in Foster Care

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I. INTRODUCTION

Medical ethicists agree that physicians have an ethical obligation to place patients' welfare above their own self-interest and above obligations to other stakeholders in order to be proper advocates for their patients' well-being.<sup>1</sup> One of the biggest obstacles to patients receiving the best care from their physicians is the powerful and controversial relationship physicians have with pharmaceutical companies,<sup>2</sup> especially regarding off-label drugs.<sup>3</sup> Off-label use of drugs are those that are prescribed for a particular use that have not been formally approved by the Food and Drug Administration (FDA) and therefore, has not been tested for safety and efficacy for that use.<sup>4</sup> Off-label prescribing is a common practice in the medical industry.<sup>5</sup>

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1. COUNCIL ON ETHICAL & JUD. AFF., AM. MED. ASS'N, CEJA REP. 1-A-01, THE PATIENT-PHYSICIAN RELATIONSHIP, 3-4 (2001).

2. Victor E. Schwartz et. al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 333, 336 (2009) (discussing that pharmaceutical companies have the sole power to disseminate the information necessary for the FDA to decide what products should be available to the market and what information is necessary to provide physicians to make an "educated treatment decision").

3. See generally Gregory Conko, *Hidden Truth: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, 21 HEALTH MATRIX 149, 150 (2011) (stating that "[t]he agency bars nearly all speech promoting an off-label use regardless of its veracity, and vigorously enforces this restriction even when the information is not being broadcast to lay audiences but is provided directly to physicians with sophisticated medical training.").

4. Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 649-650 (2011).

While prescribing off-label drugs is not prohibited by law, there are substantial concerns for geriatric and pediatric populations because physicians are exercising excessive off-label prescribing of antipsychotic drugs without adequate scientific evidence of their efficacy.<sup>6</sup>

This article argues that independent parties need to be used as an appropriate safeguard to ensure that any off-label antipsychotic prescriptions are truly for the best interest of the patients. First, this article will briefly examine the general off-label practice and its prevalence among children in foster care and the elderly in nursing homes. Next, this article will address how caregivers' concerns can lead to off-label antipsychotic prescriptions, even with the knowledge of several concerns associated with prescribing. Lastly, this article will argue that an additional party, who is independent, should be used to act in the best interest of the patient instead of relying on physicians.

## II. GENERAL OFF-LABEL PRACTICE AND ITS PREVALENCE AMONG CHILDREN IN FOSTER CARE AND THE ELDERLY IN NURSING HOMES

Federal and state governments, as well as the United States Supreme Court, have all determined that physicians should have the freedom to pre-

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5. See Tim Mackey & Bryan A. Liang, *Off-Label Promotion Reform: A Legislative Proposal Addressing Vulnerable Patient Drug Access and Limiting Inappropriate Pharmaceutical Marketing*, 45 U. MICH. J.L. REFORM 1, 1-2 (2011) (finding that the prevalence of off-label prescribing has been estimated to be as high as 83 percent for certain kinds of drugs).

6. Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 476 (2009) (finding that a study examining prescribing practices for 169 commonly prescribed drugs found high rates of off-label use with little or no scientific support). However, even without proper scientific evidence there are times where physicians prescribing off-label antipsychotic drugs can be within the best interest of their patients. See generally O.I.G., OVERPRESCRIBED: THE HUMAN AND TAXPAYERS' COSTS OF ANTIPSYCHOTICS IN NURSING HOMES (2011) (statement of Daniel R. Levinson, Inspector General Department of Health & Human Services). Furthermore, David R. Levinson points out that most physicians have nursing home patients' best interest in mind when prescribing off-label antipsychotic drugs. *Id.* See also Scott Tillet, *Off-Label Prescribing of SSRIs to Children: Should Pediatric Testing Be Required, Or Are There Other Means to A Safer End for Children?*, 19 S. CAL. REV. L. & SOC. JUST. 447, 448 (2010) (finding that the American Academy of Pediatrics supports off-label prescribing because it can be the best available therapy for the pediatric patient).

scribe off-label with the belief that physicians will exercise this freedom responsibly.<sup>7</sup> For example, the Food, Drug, and Cosmetic Act (FDCA) specifically prohibits the FDA from interfering with a healthcare practitioner's ability to prescribe any legally marketed drug FDA approved drug for any condition or disease.<sup>8</sup> The notion behind this prohibition being that the FDA does not have the authority to interfere with a genuine healthcare practitioner-patient relationship.<sup>9</sup>

With the lack of federal restrictions to off-label prescribing, there is the belief that the FDCA has unintentionally made off-label prescribing a common practice for physicians finding that physicians no longer rely on the FDA for guidance on their prescription practices.<sup>10</sup> Off-label prescribing has especially been prevalent with the amount of antipsychotic drugs being prescribed by psychiatrist and non-psychiatrists greatly increasing in the last few years.<sup>11</sup> Antipsychotic drugs are FDA approved for patients with serious mental illnesses, but are increasingly being prescribed off-label to other populations and for other uses besides alleviating hallucinations and other severe behavioral symptoms.<sup>12</sup> As of 2010, one-quarter of nurs-

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7. See Dresser & Frader, *supra* note 6, at 476.

8. Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 69 (2008).

9. *Id.*

10. See, e.g., *id.* at 69-70 (determining that the "operation of the FDCA encourages the proliferation of off-label uses" and that "[t]he frequency and breadth of off-label prescribing. . . provide strong inferential evidence that doctors do not regard FDA approval as a necessary indicator of effectiveness. . . and perhaps even safety").

11. See Sandra G. Boodman, *Off-Label Use of Risky Antipsychotic Drugs Raises Concerns*, KAISER HEALTH NEWS, (Mar. 13, 2012), <http://www.kaiserhealthnews.org/Stories/2012/March/13/off-label-use-of-risky-antipsychotic-drugs.aspx> (finding that antipsychotic prescriptions doubled between 1995 and 2008, from 4.4 million to 9 million).

12. Duff Wilson, *Side Effects May Include Lawsuits*, N.Y. TIMES (Oct. 2, 2010), <http://www.nytimes.com/2010/10/03/business/03psych.html>. Important to note that the FDA has only approved antipsychotics for youth that have schizophrenia, bipolar disorder, or irritability associated with autism. Mehmet Burcu et al., *Atypical Antipsychotic Use Among Medicaid-Insured Children and Adolescents: Duration, Safety, and Monitoring Implications*, 24 J. OF CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 112 (2014). Furthermore, some antipsychotics that are approved for schizophrenia and bipolar purposes have not been approved for children and therefore are considered off-label prescriptions for any child regardless of his or her medical condition. Lara Salahi, *Antipsychotics for Foster Kids: Most*

ing home residents take antipsychotic drugs.<sup>13</sup> Furthermore, in 2012, a study by Rutgers University found that twelve to thirteen percent of children in foster care are prescribed antipsychotic drugs.<sup>14</sup>

Forty-two to sixty percent children in foster care determined to have emotional and behavioral problems,<sup>15</sup> and these problems are likely caused by awful family settings, the trauma from being placed into foster care, and separation from the biological parent.<sup>16</sup> Off-label antipsychotics may appear to be the only option in the current foster care system that needs to quickly control children with disruptive and violent behavior.<sup>17</sup> For elderly patients in nursing homes, a common reason that antipsychotic drugs are prescribed is for the treatment of dementia, specifically treatment of Alzheimer's disease.<sup>18</sup> There are many psychological symptoms that are associated with dementia, including but not limited to, delusions and hallucinations.<sup>19</sup> A list of behaviors, such as screaming, hitting agitation, and wandering, frequently coincide with these psychotic features.<sup>20</sup>

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*Commonly Prescribed Meds*, ABC NEWS (Dec. 1, 2011), <http://abcnews.go.com/Health/Wellness/foster-children-commonly-prescribed-antipsychotics/story?id=15056937>.

13. Wilson, *supra* note 12.

14. Lucette Lagnado, *Foster Kids Drugged Against Their Will Speak Out*, WALL ST. J. (FEB. 23, 2014), <http://online.wsj.com/news/articles/SB10001424052702303442704579361333470749104>.

15. Rick Naeurt, *Mental Health Needs of Foster Children*, PSYCH CENTRAL (Feb. 28, 2014), <http://psychcentral.com/news/2009/01/14/mental-health-needs-of-foster-children/3634.html>.

16. Michelle L. Mello, *Psychotropic Medication and Foster Care Children: A Prescription for State Oversight*, 85 S. CAL. L. REV. 395, 401 (2012).

17. Laurie E. Scudder, *Prescribing Antipsychotics in Children: Proceed With Caution*, MEDSCAPE (Apr 10, 2012), <http://www.medscape.com/viewarticle/761411>.

18. Artie Berns, *Dementia and Antipsychotics: A Prescription for Problems*, 33 J. LEGAL MED. 553, 555 (2012).

19. Kenneth Brummel-Smith, *It's Time To Require Written Informed Consent When Using Antipsychotics in Dementia*, 2 BRIT. J. MED. PRAC. 4, 4 (2008).

20. *Id.*

### III. CAREGIVER INFLUENCE THAT LEADS TO PRESCRIBING OFF-LABEL ANTIPSYCHOTIC DRUGS

Given the popularity of off-label antipsychotic prescriptions for vulnerable populations, supporters of this practice claim that the ethical justification for prescribing off-label drugs is that it provides the best available therapy for a particular patient.<sup>21</sup> As previously mentioned, the notion is that a physician will be able to prescribe for therapeutic purposes and for the best interest of a patient.<sup>22</sup> However, prescribing antipsychotic drugs to the elderly in nursing homes and children in foster care tend to be beneficial to the caretakers and fail to account for what should be done in the best interest of the patients.<sup>23</sup>

#### A. Elderly in Nursing Homes

For the elderly, nursing homes are the usual provider of care for those who no longer have the physical or mental abilities to care for themselves.<sup>24</sup> There are often disputes concerning what constitutes adequate care in this type of long-term care setting, especially in regards to patients with dementia.<sup>25</sup> In order to reduce the discomfort nursing home caregivers face, one of physicians' first reactions is to prescribe antipsychotic drugs that can possibly minimize the upsetting behaviors caused by dementia.<sup>26</sup> Further-

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21. Dresser & Frader, *supra* note 6, at 478-479.

22. *See Id.* at 478-479 (noting that guides for professional practice by a few medical organizations regarding policies on off-label prescribing for the patient's best interest).

23. *See* Edward Opton, *Can Antipsychotic Medications for Foster Children Be Better Regulated*, 31 YOUTH LAW NEWS, Apr. – Jun. 2012, available at [http://www.youthlaw.org/publications/yln/2012/apr\\_jun\\_2012/can\\_antipsychotic\\_medications\\_for\\_foster\\_children\\_be\\_better\\_regulated/](http://www.youthlaw.org/publications/yln/2012/apr_jun_2012/can_antipsychotic_medications_for_foster_children_be_better_regulated/) (finding that “[c]oncern that antipsychotic drugs in the foster care context often benefit caretakers at the expense of their foster children...”). *See* CAL. ADVOCS. FOR NURSING HOME REFORM, IN A STUPOR: WHAT CALIFORNIA'S ANTIPSYCHOTIC DRUG COLLABORATIVE REVEALS ABOUT ILLEGAL NURSING HOME DRUGGING 2 (2012), available at [http://www.canhr.org/reports/In\\_a\\_Stupor.pdf](http://www.canhr.org/reports/In_a_Stupor.pdf) (finding the misuse of antipsychotic drugs as a chemical restraint).

24. *See* David S. Douglas, David Feinberg, Robin Jacobsohn & Alice B. Stock, *Rx for the Elderly: Legal Rights (and Wrongs) Within the Health Care System*, 20 HARV. C.R.-C.L. L. REV. 425, 426 (1985).

25. *Id.*

26. *See* Brummel-Smith, *supra* note 19, at 4.

more, nursing homes have minimal staff with specialized training in psychology or behavior management to help understand and manage these types of behaviors.<sup>27</sup>

Nursing homes are prohibited from using physical restraints since the late 1990s, which has resulted in a significant decrease in their utilization.<sup>28</sup> Nursing home staff must attempt to manage difficult patients without physical restraints and therefore see medication as an effective alternative to decrease operation disruptions caused by behaviors associated with dementia.<sup>29</sup> This type of modern restraint is considered a chemical restraint in order to make patients' behavior more manageable.<sup>30</sup> The Centers for Medicaid and Medicare Services (CMS) attempted to mitigate unnecessary antipsychotic prescribing, such as when it used as a restraint, by establishing regulations.<sup>31</sup> However, these regulations do not specifically prohibit the use of antipsychotic medications for dementia patients, nor do they precisely define the unacceptable prescriptions for nursing home patients.<sup>32</sup>

### B. Children in Foster Care

For children in foster care, child welfare state agencies are accountable for supporting the health and mental health needs of children who are brought into their custody.<sup>33</sup> While a child is in foster care, the agency as-

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27. AM. SOC'Y OF CONSULTANT PHARMACISTS, USE OF ANTIPSYCHOTIC MEDICATIONS IN NURSING FACILITY RESIDENTS 3 (2001), <https://www.ascp.com/sites/default/files/ASCP-antipsychotics-statement.pdf>.

28. See Krista Maier, *Chemical Restraints and Off-Label Drug Use in Nursing Homes*, 16 MICH. ST. U. J. MED. & L. 243, 255 (2012) (stating that nursing homes only have to resort to using physical restraints 1.2% of the time).

29. *Id.* at 257. There is also no current drug that is actually available to inhibit behaviors caused by dementia. *Id.*

30. CAL. ADVOCS. FOR NURSING HOME REFORM, *supra* note 23, at 2. California has defined chemical restrict in its regulations as "a drug used to control behavior and used in a manner not required to treat the patient's medical symptoms." *Id.*

31. Maier, *supra* note 28, at 259-260.

32. *Id.* at 259-260.

33. Mello, *supra* note 16, at 398. For a majority of children, physicians can assume that parents will act in the best interest of the child. Anthony W. Austin, *Medical Decisions and Children: How Much Voice Should Children Have in Their Medical Care?*, 49 ARIZ. L. REV.

sumes the role of guardian over his health and wellness.<sup>34</sup> Although there are federal guidelines in place for the administration of health care to children in foster care, states usually have discretion in developing their programs and policies.<sup>35</sup>

Children with mental health conditions such as attention deficit hyperactivity disorder (ADHD) or depression can receive psychosocial therapy that assists in reducing symptoms and helping the child improve his or her functioning.<sup>36</sup> However, children in foster care fail to actually find this therapy available anywhere near them.<sup>37</sup> While state Medicaid programs are generally required to cover services and treatment outside of antipsychotic prescriptions, such as mental health screenings and treatment for identified conditions, state Medicaid administrators concede that it is difficult for foster children's physicians to find mental health specialists for appropriate referrals.<sup>38</sup> Instead, they resort to an easier and quicker solution – prescribing antipsychotic drugs.<sup>39</sup>

Critics have argued that off-labeling antipsychotic prescriptions are helping foster parents, schools, therapists, and caseworkers manage children that have serious behavioral issues but have not been diagnosed with a seri-

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143, 152 (2007).

34. Mello, *supra* note 16, at 398.

35. *Id.* Nearly all the children in foster care are enrolled in Medicaid health care coverage. *Id.*

36. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-15, CHILDREN'S MENTAL HEALTH: CONCERNS REMAIN ABOUT APPROPRIATE SERVICES FOR CHILDREN IN MEDICAID AND FOSTER CARE (2012).

37. *Id.* Furthermore, here is a story of one foster child, "Giovan Bazan was only six-years-old when he was first treated with medication for hyperactivity. Years later, while taking Ritalin at a double dosage, he was prescribed an antidepressant after another physician saw him "so mellowed out that he barely reacted." 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, a[nd] it seemed like every time there was a new drug to try me on." Mello, *supra* note 16, at 397.

38. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 36.

39. Tovin Lapan, *Legislation aims to curb over-medicated odyssey many foster children face*, LAS VEGAS SUN (Jun. 18, 2012), <http://www.lasvegassun.com/news/2012/jun/18/experts-worry-foster-kids-are-being-overmedicated/>.

ous mental illness.<sup>40</sup> This idea is supported by research that demonstrates that the largest group receiving these drugs in foster care are those with a disruptive-behavioral disorders and ADHD disorders.<sup>41</sup> When children in foster care are given antipsychotic drugs, the side effects can lead the children to be very passive and lethargic, leading children easier to manage than perhaps children not on antipsychotic medication who are very active and rebellious without any therapy treatment options.<sup>42</sup> While Congress enacted the Fostering Innovations and Improvement in Child Welfare Act in 2011 in order to require states to develop policies for oversight for all antipsychotic prescriptions for children in foster care, there is concern that state government cannot implement enough change by simply reviewing prescribing practices.<sup>43</sup>

#### IV. KNOWN RISKS OF PRESCRIBING OFF-LABEL ANTIPSYCHOTIC DRUGS

There are specific concerns that should lead physicians to contemplate if these drugs are in the best interest of vulnerable patients due to the lack of research and the possible safety risks.<sup>44</sup> Most clinical research protocol typically excludes children and the elderly.<sup>45</sup> These potential research subjects are more vulnerable to adverse drug reactions and therefore will respond differently than typical patients, resulting in their omission from the re-

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40. Jennifer Brown and Christopher Osher, *Colorado responds slowly to psychotropic drug use among foster kids*, DENVERPOST.COM, [http://www.denverpost.com/fostercare/ci\\_25555472/colorado-responds-slowly-psychotropic-drug-use-among-foster](http://www.denverpost.com/fostercare/ci_25555472/colorado-responds-slowly-psychotropic-drug-use-among-foster) (last visited May 4, 2014). About half of children enrolled in state and federal funded health insurance programs that take antipsychotics in Colorado have not been diagnosed with a serious mental illness that would lead to an FDA approved prescription of antipsychotics. *Id.*

41. Lagnado, *supra* note 14. Dr. Christoph Correll states that “the drugs generally work fast, which is often desired when kids are at risk of being suspended from school for their behaviors. . .having to wait for an appointment is not an option.” *Id.* See also Burcu, *supra* note 12 (finding that “Medicaid-insured youth diagnosed with externalizing behavioral disorders by far represented the largest group of youth receiving antipsychotic medications”).

42. Opton, *supra* note 23.

43. See Opton, *supra* note 23.

44. Mackley, *supra* note 5 at 22.

45. Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 655 (2013).



search pool.<sup>46</sup> Furthermore, once the FDA approves a drug, there is limited motivation for pharmaceutical companies to continue doing costly research to determine how their drugs affect vulnerable populations.<sup>47</sup>

Without clinical research for these populations, off-label antipsychotic prescriptions require significant monitoring and dosage adjustments by physicians.<sup>48</sup> This necessity is promoted through the issuance of the black box warning on labels for antipsychotic drugs, and it is the most serious labeling available for prescription medication.<sup>49</sup> Pharmaceutical companies are required to impose a black box warning to the label due to the potential severe adverse effects that have occurred with off-label antipsychotic prescribing for these populations.<sup>50</sup> However, the warning is not sufficient because evidence shows that it has not deterred physicians from off-label prescribing.<sup>51</sup>

Around 15,000 elderly people in nursing homes die each year from off-label use of antipsychotic medications.<sup>52</sup> Furthermore, children who are prescribed off-label antipsychotic medication have increased risk of suicidal ideation.<sup>53</sup> Off-label antipsychotic drugs are usually meant to treat severe mental illnesses such as bipolar and schizophrenia and are known to cause

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46. *Id.*

47. Johnson, *supra* note 8, at 81-82.

48. See Tillett, *supra* note 6, at 448 (finding also that these types of drugs also have serious restrictions for advertisements).

49. *Id.*

50. See Boodman, *supra* note 11 (finding that the black-box warning because the drugs increase the risk of death). See Salahi, *supra* note 12 (finding that Abilify received a black box warning label for inducing suicidal feelings in children).

51. See Mackley, *supra* note 5 at 23 (finding that Zyprexa black box warning specifically stated that research had shown an increase in mortality of elderly patients with dementia but physicians still inappropriately prescribed the drug). See also Tillett, *supra* note 6 at 447-448 (concluding that although the FDA determined in a study that certain antidepressants lead to increased suicidal behavior physicians continued to off-label prescribe these drugs).

52. Maier, *supra* note 28, at 243.

53. Tillett, *supra* note 6 at 447. A study consisted of a thorough review of published and unpublished controlled clinical trials of antidepressants, and involved nearly 4,400 children and adolescents. *Id.* The results of the study suggested that suicidal behavior and ideation was twice as likely in children with Major Depressive Disorder ("MDD") who were prescribed off-label antidepressants. *Id.*

severe side effects.<sup>54</sup> Children that receive improper dosages can experience severe side effects including, but not limited to, significant increases in cholesterol, rapid weight gain, development of diabetes, and irreversible movement disorders.<sup>55</sup> Nursing home patients have similar negative side effects, as well as possible life-threatening nervous system problems, neuroleptic malignant syndrome, diabetes, movement problems, seizures, and strokes.<sup>56</sup>

#### V. ENSURING ANTIPSYCHOTIC DRUG PRESCRIPTIONS ARE IN THE BEST INTEREST OF VULNERABLE PATIENTS

Most physicians want what is best for their patients.<sup>57</sup> However, based on the availability of reimbursement and caregivers directly benefiting from off-label antipsychotic drugs being prescribed, there should be an independent party involved in physicians' decisions to prescribe off-label drugs to ensure these vulnerable patients' needs and interests are properly met. These independent parties can be implemented as a consultant pharmacist in nursing homes and state court appointed individuals responsible for the psychiatric care of children in foster care.

##### A. Consultant Pharmacists in Nursing Homes

While nursing homes are already required to have a license pharmacist as a consultant, nursing homes should be required to employ consultant pharmacists that are independent from any incentives to promote off-label antipsychotic prescriptions for elderly patients.<sup>58</sup> Consultant pharmacists' main

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54. Boodman, *supra* note 11.

55. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 36.

56. O.I.G., *supra* note 6.

57. See generally Douglas Mossman, M.D. & Jill L. Steinberg, *Promoting, Prescribing, and Pushing Pills: Understanding the Lessons of Antipsychotic Drug Litigation*, 13 MICH. ST. U. J. MED. & L. 263, 266 (2009) ("[A] few doctors may be amoral, evil, or corrupt, but the vast majority—including the many physicians who have accepted meals, lecture fees, and other favors from drug companies—want to better the lives and health of their patients.").

58. See generally Dana Shilling, *Typically Atypical: Do Nursing Homes Misuse Atypi-*

purpose in nursing homes is to ensure that all medications are properly given and to protect the elderly from inappropriate use of antipsychotics.<sup>59</sup> These pharmacists review all residents' drug records on a monthly basis and educate nursing home staff and prescribing physicians on any concerns they have regarding unnecessary use, duration, or dosage amount of antipsychotic medication.<sup>60</sup> If truly independent, these consultant pharmacists are a valuable tool in ensuring medication is prescribed only in the best interest of the patient.<sup>61</sup>

Unfortunately, there have been many findings that consultant pharmacists currently do not have independence.<sup>62</sup> Therefore in 2011, CMS issued a Notice of Proposed Regulation, which would require nursing homes to only use consultant pharmacists who are unaffiliated with a long-term care pharmacy, pharmaceutical manufacturers, or distributors.<sup>63</sup> If such a proposed regulation was enacted, consultant pharmacists will have the ability to ensure that antipsychotic drugs are prescribed properly without any conflict of interest.<sup>64</sup> Unfortunately, in 2012, CMS released the final rule and

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*cal Antipsychotic Drugs?*, 251 Elder Law Advisory 1, 1 (Feb. 2012) (finding that nursing homes already are required to employ an consultant but the financial incentives of these consultants have been questioned).

59. See AM. SOC'Y OF CONSULTANT PHARMACISTS, *supra* note 27 at 3-4.

60. CAL. ADVOCS. FOR NURSING HOME REFORM, *supra* note 23 at 5.

61. *Antipsychotic Drugs*, CTR. FOR MEDICARE ADVOC., <http://www.medicareadvocacy.org/medicare-info/skilled-nursing-facility-snf-services/antipsychotic-drugs/> (last visited Mar. 31, 2014). See also CALIFORNIA ADVOCATES FOR NURSING HOME REFORM, *supra* note 23 at 5 (finding "[i]ndependence is critical to the effectiveness of consultant pharmacists").

62. See Wilson, *supra* note 12 (finding that Johnson & Johnson paid large kickbacks to Omnicare, the nation's largest long-term care pharmacy provider-Omnicare for Risperdal – an antipsychotic drug). Omnicare consultant pharmacists then made recommendations to nursing home physicians regarding which antipsychotic drugs to prescribe to those in long-term care. Maier, *supra* note 28, at 258.

63. Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities, 76 FR 63018-01 (proposed Oct. 11, 2011) (to be codified at 42 C.F.R. pt. 417, 422, 423, 483).

64. Stephen Barlas, *Medicare Wants Only 'Independent' Consultant Pharmacists in Nursing Homes*, 37 PHARMACY AND THERAPEUTICS (Jan. 2012), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278190/>.

removed any obligation for consultants to be independent.<sup>65</sup> Therefore until CMS again proposes mandatory pharmacy consultant independence, states should collaborate with American Society of Consultant Pharmacists to establish regulations that effectively promote pharmacy consultant independence for proper oversight of off-label antipsychotic prescriptions with a nursing.<sup>66</sup>

*B. Court Appointed Individual Responsible for Psychiatric Care of a Foster Child*

Because children in foster care are considered a state based issue, states should follow the lead of Nevada's recent law, enacted in 2011, that enables the state district court to appoint an individual who is legally responsible for all the decisions regarding a child's psychiatric care.<sup>67</sup> This legislation supports the idea that another party, besides the physician, should promote a child in foster care's best interest.<sup>68</sup> Pursuant to the law, a person who is legally responsible for the psychiatric care of a child will have the ability to approve or deny any physician recommendation for a foster child's prescription of antipsychotic drugs.<sup>69</sup> This appointed person must consider if

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65. Press Release, CMS, CMS Approves Program Changes for Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2013 (Apr. 4, 2012) (on file with author), available at <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2012-Fact-Sheets-Items/2012-04-02.html>.

66. See AM. SOC'Y OF CONSULTANT PHARMACISTS, STATEMENT ON SEPARATION OF CONSULTANT PHARMACISTS AND LONG-TERM CARE PHARMACY PROVIDERS (2001), <https://www.ascp.com/sites/default/files/ASCP-separation-statement.pdf> (finding that "because of the potential for conflicts of interest. . . recommends that consultant pharmacists who serve long-term care facilities should be independent of the long-term care pharmacy that provides medications to residents of the facility"). New Jersey already requires separation consulting pharmacist and any other party with ties to pharmaceutical companies. N.J. Admin. Code 8:39-29.1 (2014).

67. Lapan, *supra* note 39. See also Placement Resources, NEVADA DIVISION OF CHILD & FAM. SERVICES, [http://www.dcfs.state.nv.us/DCFS\\_PlaceRes.htm](http://www.dcfs.state.nv.us/DCFS_PlaceRes.htm) (last visited May 5, 2014).

68. See *Id.* (Author of the legislation stated "Instead of regulating doctors or pharmaceutical, we wanted to bring it to a personal level and have someone act in the role as parent for every foster kid.").

69. NEV. REV. STAT. § 432B.4687 (2013). Only in exceptional circumstances will a child be prescribed such drugs without consent from the legal representative. *Id.* at § 432B.4689. This includes when a physician or psychiatrist has determined that an emergen-

the benefits of each recommended antipsychotic drug for the child and the exact purpose of the drug, such as to control violent outbursts, outweigh any possible risks or likely side effects.<sup>70</sup> Furthermore, in order to fully safeguard against the unnecessary use of off-label antipsychotic drugs for children in foster care, an appointed person must have specific knowledge that the requested use of the drug has not been tested or approved by the FDA before authorizing the prescription for a child in foster care.<sup>71</sup>

## VI. CONCLUSION

A physician can act in the best interest of his or her patients when off-label prescribing antipsychotic drugs.<sup>72</sup> However, this ability to act in the best interest of the patient is questioned when drug benefits seems to only directly benefit the caregiver rather than the individual.<sup>73</sup> Even though these drugs are not approved for behavior modification purposes, these drugs are used as chemical restraints to control the upsetting behaviors of patients with dementia<sup>74</sup> or manage children that have serious behavioral issues but have not been diagnosed with a serious mental illness.<sup>75</sup> Any external benefit to the caregiver must be carefully weighed against the possibility of severe side effects to the patient. However, this evaluation of benefits to side effects has not occurred properly even with black box labels now on most antipsychotic medication that is prescribed to vulnerable populations.<sup>76</sup>

With little federal effective guidance on off-label antipsychotic prescriptions<sup>77</sup>, state government should instead enact independent parties to evaluate antipsychotic drug prescriptions for the elderly in nursing homes and

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cy situation exists. *Id.*

70. NEV. REV. STAT. § 432B.4687 (2013).

71. *Id.*

72. *See supra* note 22.

73. *See supra* Part III.

74. *See supra* note 19.

75. *See supra* note 40.

76. *See supra* note 51.

77. *See supra* note 7.

children in foster care. These individuals can be properly trained in clearly understand the purpose of the drugs as well as the possible side effects and complications.<sup>78</sup> Independent pharmacy consultants for elderly in nursing homes and court appointed individuals for children in foster care can be used as appropriate safeguards for ensuring that any off-label antipsychotic prescription are indeed prescribed in the best interest of the patient.

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78. See *supra* note 58 and 69.