

**DRUGGING GRANDMA: THE SEVERE  
DANGERS OF CHEMICALLY RESTRAINING  
NURSING HOME RESIDENTS WITH  
POTENT ANTIPSYCHOTIC AND  
PSYCHOTROPIC PHARMACEUTICALS**

*Breanna M. Taylor*

*Legislation was implemented to heighten the quality of life in nursing home facilities. Decreasing the use of physical restraint in nursing homes was the main concern. Due to the laws implemented and the initiative of advocacy organizations, the prevalence of the use of physical restraint in nursing home facilities has decreased. However, in the midst of minimizing physical restraint, the use of chemical restraint has increased.*

*To improve the quality of life for nursing home residents, the use of chemical restraint must be minimized. Monitoring and supervising the use of certain medications, when needed, will lessen the overuse and misuse of chemical restraints. Also, requiring informed consent from patients prior to distributing the drug will decrease chemical restraint use. To ensure that facilities diminish their use of chemical restraint, Medicaid and Medicare sanctions should be imposed upon facilities for noncompliance. Nearly 7.6 billion dollars was spent in 2011 on unnecessary medications. Minimizing the use of chemical restraint would not only improve the life of nursing home residents, but would also improve the nursing facilities' budget.*

---

Breanna M. Taylor is an Associate Editor 2015-2016, Member 2014-2015, *The Elder Law Journal*; J.D. 2016, University of Illinois, Urbana-Champaign; B.A. 2012, University of Michigan. The author would like to dedicate this Note to her parents, Michael and Sherryl, her brother, Michael, all influential past and present elders, and especially her Nana, who has taught her the meaning of life: "Everyday is a holiday."

## I. Introduction

Alexander Zaiko, age eighty-five, entered the Kern Valley Healthcare skilled nursing facility on September 12, 2006 and died from Zyprexa and Depakote injections eight days later.<sup>1</sup> Fannie Mae Brinkley, age ninety-one, declined to eat her supper in the Kern Valley dining room and was injected with a toxic amount of Depakote.<sup>2</sup> She passed away six days later on December 23, 2006.<sup>3</sup> Over the period of a month, Joseph Shepter, age seventy-four, was administered a concoction of three antipsychotic drugs at Kern Valley, including Depakote, accelerating his death on January 14, 2007.<sup>4</sup>

Twenty additional residents at this skilled nursing facility in southern California were administered an unjustifiable amount of psychotropic medications, causing them severe adverse reactions and endangering their physical and mental health.<sup>5</sup> Following an investigation in 2007 by the Justice Department's Bureau of Medical Fraud and Elder Abuse (BMFEA) and the California Department of Public Health (CDPH), the Department of Justice charged the three alleged abusers with three counts of elder or dependent adult abuse resulting in death; one count of elder or dependent adult abuse with infliction of injury; four counts of elder or dependent adult abuse; and two counts of assault with a deadly weapon.<sup>6</sup>

Despite each of the three abusers contributing significantly towards the accelerated deaths of Alexander, Fannie, and Joseph, as well as the physical pain and mental suffering of another twenty residents, only one abuser, Gwen Hughes, the former Director of Nurs-

---

1. Steve Chawkins, *3 Arrested in Nursing Home Deaths in Lake Isabella*, LA TIMES (Feb. 20, 2009), <http://articles.latimes.com/2009/feb/20/local/me-nursing-home-deaths20>.

2. *Id.*

3. Chawkins, *supra* note 1; Stacey Shepard & James Burger, *Reports Detail Fatal Druggings at Nursing Facility*, THE BAKERSFIELD CALIFORNIAN (Feb. 18, 2009), <http://www.bakersfieldcalifornian.com/news/2009/02/19/reports-detail-fatal-druggings-at-nursing-facility.html>; Vera Sharay, *Deaths, A Consequence of Forced Psychotropic Drugs*, ALL FOR HUMAN RESEARCH PROT. (Feb. 19, 2009), <http://www.ahrp.org/cms/content/view/517/56/>.

4. Chawkins, *supra* note 1; Shepard & Burger, *supra* note 3.

5. Press Release, State of Cal. Dep't of Justice Office of the Attorney General, Attorney General Kamala D. Harris Announces Nurse Sentenced to 3 Years in Prison for "Convenience Drugging" Elder Patients (Jan. 9, 2013), <http://oag.ca.gov/news/press-releases/attorney-general-kamala-d-harris-announces-nurse-sentenced-3-years-prison->

6. Complaint, People of the State of California v. Gwen D. Hughes et al., (2007), [https://oag.ca.gov/system/files/attachments/press\\_releases/n1682\\_2-4-09\\_-\\_felony\\_complaint.pdf](https://oag.ca.gov/system/files/attachments/press_releases/n1682_2-4-09_-_felony_complaint.pdf).

ing, was sentenced to three years in state prison.<sup>7</sup> The other two abusers, Dr. Hoshang M. Pormir, the former Medical Director, and Pamela Ott, the former Chief Executive Officer, were both sentenced to 300 hours of volunteer service in addition to individualized probation schedules.<sup>8</sup> The respective sentences of the three abusers pale in comparison to the devastation and trauma they caused and the distrust they awakened in their community.<sup>9</sup>

Over the past two decades, nursing home occupancy in the United States has fluctuated between 1.3 and 1.4 million residents.<sup>10</sup> However, the United States Census Bureau anticipates that the population aged sixty-five and over will double by 2050.<sup>11</sup> As of 2012, the average life expectancy for females is 81.2 years and for males is 76.4 years.<sup>12</sup> Thus, the average life expectancy for a sixty-five year old person is another 19.3 years.<sup>13</sup> As this population increases, so do the realities of senior care—specifically the quality of care that the elderly can expect to receive in their futures.<sup>14</sup>

When federal government programs like Medicare and Medicaid currently assess the quality of care available in nursing home facilities, the use of restraints remains one of the most divisive features.<sup>15</sup> However, restraint use was not always a standard consideration. In 1987, Congress enacted legislation to protect residents of nursing home facilities from the use of restraint, believing use to have a signif-

---

7. Press Release, *supra* note 5.

8. *Id.*

9. *Id.*

10. NAT'L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH, UNITED STATES, 2013 WITH SPECIAL FEATURE ON PRESCRIPTION DRUGS 324-25 (2014), <http://www.cdc.gov/nchs/data/hus/hus13.pdf#110> (reporting nursing home beds, residents, and occupancy rates, by state between 1995 and 2012).

11. JENNIFER M. ORTMAN, VICTORIA A. VELKOFF & HOWARD HOGAN, U.S. CENSUS BUREAU, AN AGING NATION: THE OLDER POPULATION IN THE UNITED STATES 2 (May 2014), <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p25-1140.pdf>.

12. Larry Copeland, *Life Expectancy in the USA Hits a Record High*, USA TODAY (Oct. 9, 2014, 3:54 AM), <http://www.usatoday.com/story/news/nation/2014/10/08/us-life-expectancy-hits-record-high/16874039/>.

13. *Id.*

14. CONG. BUDGET OFFICE, RISING DEMAND FOR LONG-TERM SERVICES AND SUPPORT FOR ELDERLY PEOPLE 1, 7 (June 26, 2013), <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44363-LTC.pdf>.

15. See C. Gastmans & K. Milisen, *Use of Physical Restraint in Nursing Homes: Clinical-Ethical Considerations*, 32 J. MED. ETHICS 148, 148 (2006), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2564468/pdf/148.pdf>.

icantly detrimental effect on a resident's quality of life.<sup>16</sup> This protection is known as the Federal Nursing Home Reform Act (NHRA)<sup>17</sup> and was enacted as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA).<sup>18</sup> The federal government created national standards and accompanying compliance systems for nursing home facilities, including restrictions on inappropriate restraint use.<sup>19</sup> The NHRA was the first legislation enacted that confronted nursing home safety and created necessary protections.<sup>20</sup>

While this legislation was designed to heighten the quality of life available in a nursing home facility,<sup>21</sup> monitoring through persistent advocacy organizations was found necessary to guarantee that the initiatives were implemented and subsequently maintained as intended by Congress.<sup>22</sup> A strong and determined movement was successful in decreasing the reliance on and prevalence of physical restraint use in nursing home facilities.<sup>23</sup> However, the use of chemical restraints have severely escalated in the midst of statutory provisions, monitoring initiatives, and greater social awareness that brought the use of physical restraints to a minimum.<sup>24</sup>

This Note seeks to evaluate the transition from a decrease in the use of physical restraint to an increased use of chemical restraints. This Note will then recommend a change in existing legal approaches that will mitigate this threatening issue. Part I will summarize the history of restraint use regulations, as well as provide a general overview of physical and chemical restraints. Part II will explore the gray area of medical necessity with regard to potent psychotropic and antipsychotic medications as well as highlight occurrences of misuse and overuse of these drugs. Additionally, Part II will discuss the federal

---

16. LAWRENCE A. FROLIK & RICHARD L. KAPLAN, *ELDER LAW IN A NUTSHELL* 167-68 (6th ed. 2014).

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Safety Without Restraints A New Practice Standard for Safe Care*, MINN. DEP'T OF HEALTH, <http://www.health.state.mn.us/divs/fpc/safety.htm> (last updated Dec. 2001).

24. See generally R. Tamara Konetzka, Ph.D., et al., *The Effects of Public Reporting on Physical Restraints and Antipsychotic Use in Nursing Home Residents with Severe Cognitive Impairment*, 62 J. OF AM. GERIATRICS SOC. 454-61 (2014) (reporting a study that claims that public reporting of nursing home usage of physical restraints decreased such uses, but led to an increased use of chemical restraints).

government's oversight and mishandling of this problem, as well as the corresponding results of such an omission. Lastly, this Part will present logical incentives, which ought to propel psychotropic and antipsychotic restriction while admitting the risks associated with potential limits towards medicinal administration. Part III will offer three strategies that would lessen the prevalence of chemical restraint use and subsequently increase the quality of life for nursing home residents. Ignorance and blindness toward chemical-restraint use is no longer acceptable, and Part IV concludes that actions must be taken in the present to protect and provide quality nursing home care for the future.

## II. Background of Restraint Use

### A. The Development of the Nursing Home Reform Act

In the late eighties, a growing public concern emerged regarding the inadequate level of care being provided by United States nursing home facilities.<sup>25</sup> In response, Congress initiated a thorough investigation to isolate the chief causes of inadequate nursing home care and propose viable solutions.<sup>26</sup> To execute this mission, Congress requested that the Institute of Medicine (IOM) evaluate the level of care in Medicaid and Medicare-qualified nursing homes to determine how such care could be better provided.<sup>27</sup> IOM delineated its findings and recommendations in its 1986 report entitled *Improving the Quality of Care in Nursing Homes*.<sup>28</sup> An expert panel reasoned that a stronger federal role was necessary to improve the quality of care, and articulated that improvements focused in the areas of performance standards, staff training protocol, and resident-needs assessments would help advance care improvement goals.<sup>29</sup>

---

25. *Nursing Home Reform Act*, NURSING HOME ABUSE GUIDE, <http://nursinghomeabuseguide.com/resources/nursing-home-reform-act/> (last visited Mar. 5, 2016).

26. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, NURSING HOME SURVEY AND CERTIFICATION: OVERALL CAPACITY 1 (Mar. 1999), <https://oig.hhs.gov/oei/reports/oei-02-98-00330.pdf>.

27. *Nursing Home Reform Act*, *supra* note 25.

28. INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES (Jan. 1, 1986), <http://www.iom.edu/Reports/1986/Improving-the-Quality-of-Care-in-Nursing-Homes.aspx>.

29. Hollis Turnham, *Federal Nursing Home Reform Act from the Omnibus Budget Reconciliation Act of 1987*, <http://www.ncmust.com/doclib/OBRA87summary.pdf> (last visited Mar. 5, 2016).

With this recommendation, the National Citizens Coalition for Nursing Home Reform (NCCNHR) organized a "Campaign for Quality Care" to support Congress' attempts towards reform.<sup>30</sup> NCCNHR gained sponsorship from other national organizations, nursing homes, and health care professionals to force the implementation of the federal law, now known as NHRA.<sup>31</sup> NHRA was a part of the compilation ORBA signed into law by President Ronald Reagan.<sup>32</sup> The regulations were promulgated by the Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration, a federal agency within the United States Department of Health and Human Services.<sup>33</sup> The regulations establish "specific rights and services a nursing home must supply in order to be eligible to participate in Medicare and Medicaid programs."<sup>34</sup>

Supporting NHRA's primary objective, ensuring that nursing home residents receive quality care that will result in achieving or maintaining their "highest practicable" physical, mental, and psychosocial well-being, was required for any nursing home facility to remain eligible for Medicare and Medicaid payments.<sup>35</sup> The facilities could attain this standard through incorporating and upholding NHRA's Resident Bill of Rights.<sup>36</sup> The Bill of Rights sought to protect nursing home residents' privacy, individuality, and dignity.<sup>37</sup> Specifically, the Bill of Rights ensures a standard of care free from "mistreatment, abuse, and neglect" and the right to "be free from . . . physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical

---

30. *Id.* The National Citizens' Coalition for Nursing Home Reform (NCCNHR) is now known as The National Consumer Voice for Quality Long-Term Care and remains a non-profit organization concentrated on substandard care in United States nursing homes.

31. *Id.*

32. *Id.*

33. *Id.*

34. See generally Charles Grassley, *The Resurrection of Nursing Home Reform: A Historical Account of the Recent Revival of the Quality of Care Standards for Long-Term Care Facilities Established in the Omnibus Reconciliation Act of 1987*, 7 *ELDER L. J.* 267, 268 (1999).

35. 42 C.F.R. § 483.25 (2005).

36. See Martin Klauber, *The 1987 Nursing Home Reform Act*, AARP (Feb. 2001), [http://www.aarp.org/home-garden/livable-communities/info-2001/the\\_1987\\_nursing\\_home\\_reform\\_act.html#RESIDENTS](http://www.aarp.org/home-garden/livable-communities/info-2001/the_1987_nursing_home_reform_act.html#RESIDENTS) (listing the Residents' Bill of Rights established in The Nursing Home Reform Act).

37. *Id.*

symptoms.”<sup>38</sup> These federal rights were intended to be a baseline for states to use in developing their own protocols.<sup>39</sup>

## B. Enforcing the Nursing Home Reform Act

It was not until the early 1990s that CMS created two national systems to monitor this initiative and routinely collect information data on nursing home quality.<sup>40</sup> The Minimum Data Set (MDS) and the Online Survey Certification and Reporting systems (OSCAR) filled this void.<sup>41</sup> The information collected by the systems is drawn from two different perspectives: MDS from the resident,<sup>42</sup> and OSCAR from the facility.<sup>43</sup>

MDS uses surveyor agents to ascertain a comprehensive assessment of each individual resident’s functional capabilities using seventeen categories, the sixteenth category being “restraints.”<sup>44</sup> CMS provides MDS agents with an assessment manual to be used during their monitoring visits.<sup>45</sup> Section ‘P’ of the manual addresses restraints.<sup>46</sup> This section of the manual provides a seven-step process which agents are expected to use to perform the physical restraint assessment using a seven-day look-back period.<sup>47</sup> The multi-step assessment procedure includes a medical record review, discussions with several members of the nursing staff, and a thorough visual evaluation of any device,

---

38. *Medicare State Operations Manual Provider Certification*, DEP’T OF HEALTH & HUMAN SERVS. (Sept. 7, 2000), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R20SOM.pdf>.

39. See generally Turnham, *supra* note 29.

40. Ning Jackie Zhang, *National Quality Measurement Systems for Assessment of Nursing Home Care*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (Sept. 14, 2009), <http://www.qualitymeasures.ahrq.gov/expert/expert-commentary.aspx?id=16456>.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Minimum Data Set Evaluation Form*, CTR. FOR MEDICARE & MEDICAID SERVS. (July 31, 2006), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30Draft.pdf> (delineating the seventeen categories used by the DMS to determine a resident’s functional capacity: (a) demographics; (b) hearing, speech, and vision; (c) cognitive patterns; (d) mood; (e) behavior; (f) preference for customary routine, activities, community setting; (g) functional status; (h) bladder and bowel; (i) active disease diagnosis; (j) health condition; (k) swallowing/nutritional status; (l) oral and dental status; (m) skin conditions; (n) medications; (o) special treatments and procedures; (p) restraints; and (q) participation in assessment and goal setting).

45. See generally *id.*

46. *Id.* at 30.

47. *Section P: Restraints*, CMS’S RAI VERSION 3.0 MANUAL 4 (May 2010), [http://www.ahcancal.org/facility\\_operations/Documents/RAI\\_3.0/MDS%203.0%20Chapter%203%20Section%20P%20V1.02%20May%202010.pdf](http://www.ahcancal.org/facility_operations/Documents/RAI_3.0/MDS%203.0%20Chapter%203%20Section%20P%20V1.02%20May%202010.pdf).

material, or equipment suspected by the agent to have been used as a restraint.<sup>48</sup> This system ultimately relies on judgment calls by MDS agents.<sup>49</sup> In addition to the manual, the agents use a coding form to account for their findings.<sup>50</sup> The information acquired is then electronically submitted by nursing homes to their respective state's MDS database.<sup>51</sup> Finally, state data is consolidated and transmitted to the national MDS database.<sup>52</sup>

The other monitoring system, OSCAR, is "a compilation of all the data elements collected by surveyors during [an] inspection survey conducted at nursing facilities for the purpose of certification for participation in the Medicare and Medicaid programs."<sup>53</sup> OSCAR requires state survey agents to conduct irregular and unannounced evaluations every fifteen months at all Medicare and Medicaid certified nursing homes.<sup>54</sup> To evaluate a facility's compliance with NHRA, and subsequently its eligibility for Medicare and Medicaid funding, five different forms are used to gather information regarding the facility's operational characteristics,<sup>55</sup> patient characteristics,<sup>56</sup> and health and life safety deficiencies.<sup>57</sup> Data collected by the agents is then stored in the OSCAR database.<sup>58</sup>

If non-compliance is discovered by an OSCAR survey agent, any or all of the following sanctions could be imposed: "directed in-service training of staff; directed plan of correction; state monitoring; civil monetary penalties; denial of payment for all new Medicare or Medi-

---

48. *Id.*

49. *See generally id.* at 3.

50. *See id.* at 2.

51. *Minimum Data Set (MDS) Resources*, AM. SOC'Y OF CONSULTANT PHARMACISTS, <https://www.ascp.com/articles/minimum-data-set-mds-resources> (last visited Mar. 5, 2016).

52. *Minimum Data Set (MDS) Resources*, *supra* note 51; *Section P: Restraints*, *supra* note 47.

53. *What is OSCAR Data?*, AM. HEALTH CARE ASS'N, [http://www.ahcancal.org/research\\_data/oscar\\_data/pages/whatisoscardata.aspx](http://www.ahcancal.org/research_data/oscar_data/pages/whatisoscardata.aspx) (last visited Mar. 5, 2016).

54. *Long-term Care: Facts on Care in the US*, BROWN SCH. OF PUB. HEALTH, <http://ltcfocus.org/1/about-us> (last visited Mar. 5, 2016).

55. Ctr. for Medicare and Medicaid Serv. Form 671, <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS671.pdf> (last visited Mar. 5, 2016).

56. Ctr. for Medicare and Medicaid Serv. Form 672, <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS672.pdf> (last visited Mar. 5, 2016).

57. Ctr. for Medicare and Medicaid Serv. Form 2567, <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms2567.pdf> (last visited Mar. 5, 2016).

58. AM. HEALTH CARE ASS'N, *supra* note 53.



caid admissions; denial of payment for all Medicaid or Medicare patients; temporary management; and or termination of the provider agreement.”<sup>59</sup> As of July 2012, the OSCAR program was replaced with a bifurcated system: the Certification and Survey Provider Enhanced Reporting system (CASPER) and the Quality Improvement Evaluation System (QIES).<sup>60</sup>

The new CASPER system monitored the use of antipsychotics in nursing homes by separating the data collected by long-stay and short-stay residents.<sup>61</sup> However, in 2013, CMS eliminated this data collection from CASPER’s responsibility and redirected this quality measure to Nursing Home Compare (NHC), a federal website established to assist families and caregivers in comparing facilities nationwide and in their local neighborhoods.<sup>62</sup> NHC uses a one to five-star ranking system and accounts for criteria such as health standards, staffing, and a variety of physical and clinical measures including the frequency of antipsychotic use.<sup>63</sup> In essence, this highly valuable health information data is processed through a complex algorithm created by CMS to return a corresponding star ranking for the nursing home facilities.<sup>64</sup>

Although CMS has at least three systems in place that have the means to adequately account for antipsychotic and psychotropic drug use,<sup>65</sup> none utilizes an established and successful method to adequately

---

59. Martin Klauber, *The 1987 Nursing Home Reform Act*, AM. ASS’N OF RETIRED PERSONS (Feb. 2001), [http://www.aarp.org/home-garden/livable-communities/info-2001/the\\_1987\\_nursing\\_home\\_reform\\_act.html](http://www.aarp.org/home-garden/livable-communities/info-2001/the_1987_nursing_home_reform_act.html).

60. Cowles Research Group, *Long Term Care Info, Survey Data*, LONG TERM CARE INFO, [http://www.longtermcareinfo.com/about\\_oscar.html](http://www.longtermcareinfo.com/about_oscar.html) (last visited Mar. 5, 2016).

61. *CMS Makes Changes to Antipsychotic Measures on CASPER Reports*, LEADINGAGE NEW YORK, <http://www.leadingageny.org/providers/nursing-homes/survey-clinical-and-quality/cms-makes-changes-to-antipsychotic-measures-on-casper-reports/> (last visited Mar. 5, 2016).

62. *CMS Makes Changes*, *supra* note 61; *Five-Star Quality Ranking System*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/FSQRS.html> (last modified Oct. 15, 2015).

63. *Five-Star Quality Ranking System*, *supra* note 62.

64. *Id.*

65. *Description of Antipsychotic Medication Quality Measures on Nursing Home Compare*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/AntipsychoticMedicationQM.pdf> (last visited Mar. 5, 2016); *see generally* DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, *PSYCHOTROPIC DRUG USE IN NURSING HOMES* (Nov. 2001), <http://oig.hhs.gov/oei/reports/oei-02-00-00490.pdf>.

ly review or account for unwarranted chemical restraint use despite its express exclusion in the Code.<sup>66</sup>

### C. Physical Restraints

Physical restraint is typically defined as “any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily, which restricts freedom of movement or normal access to one’s body.”<sup>67</sup> Devices used by nursing homes that constitute physical restraints include, but are not limited to, leg or arm restraints, soft ties, restrictive vests, hand mitts, and wheelchair lap cushions or trays that prevent a resident from rising.<sup>68</sup> The use of tight-tucking or velcroing of sheets, side rails, or the use of any gate device that a resident cannot reach nor operate are examples of nursing home practices that satisfy the definition of physical restraint.<sup>69</sup> Traditionally, these devices and practices were used as safety measures to prevent the unsteady and frail from falling,<sup>70</sup> to prevent the agitated from pulling on an intravenous line,<sup>71</sup> or to prevent the breaking open of a suture.<sup>72</sup> Another out-of-date justification for restraint use was to prevent wandering residents from making any unaccompanied trips.<sup>73</sup> The rationale for resident restraint would generally fit into one of two categories: either the resident was a danger to himself or to someone else.<sup>74</sup>

---

66. THOMAS T.H. WAN ET AL., *IMPROVING THE QUALITY OF CARE IN NURSING HOMES: AN EVIDENCE-BASED APPROACH* 29-30 (The Johns Hopkins University Press 2010).

67. Memorandum from Director Survey & Certification Group to State Survey Agency Directors (Jun. 22, 2007), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-22.pdf>.

68. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, *MINIMIZING RESTRAINTS IN NURSING HOMES: A GUIDE TO ACTION 1*, <https://oig.hhs.gov/oei/reports/oei-01-91-00840.pdf> (last visited Mar. 5, 2016).

69. BARBARA HEGNER ET AL., *NURSING ASSISTANT: A NURSING PROCESS APPROACH* 39-40 (10th ed. 2007).

70. Jill A. Blakeslee, *Speaking Out: Untie the Elderly*, 88 AM. J. NURSING 833, 833-34 (1988).

71. Valerie T. Cotter & Lois K. Evans, *Avoiding Restraints in Hospitalized Older Adults with Dementia*, ALZHEIMER’S ASS’N (2012), <https://consultgeri.org/try-this/dementia/issue-d1.pdf>; see Terry Terpstra et al., *Reducing Restraints: Where to Start*, 29 J. CONTINUING EDUC. NURSING 10, Tbl. 1 (1998).

72. Terpstra et al., *supra* note 71.

73. Blakeslee, *supra* note 70.

74. Denise Handlon, *Commitment Process: When a Person is a Danger to Self or Others*, HUBPAGES (Dec. 5, 2015), <http://hubpages.com/health/Danger-to-self-or-others>; see generally Blakeslee, *supra* note 70.

However, the Association of Rehabilitation Nurses has shown that use of physical restraint in nursing home facilities heightens an elderly resident's risk of emotional, mental, or physical injury.<sup>75</sup> These injuries may manifest through depression, confusion, agitation, anxiety, social isolation, functional decline, decreased circulation, deteriorated muscle mass, nerve damage, ulcers, incontinence, asphyxiation, or death.<sup>76</sup> While legislation tolerates the physical restraint in nursing homes when necessary to treat the patient's medical symptoms, it is hard to discern when such a measure has been overdone in its necessity or severity.<sup>77</sup> Research has shown a gradual reduction in the use of physical restraints;<sup>78</sup> yet, concerns linger as recent studies correlate the decline of physical restraint use with a simultaneous increase in chemical drug use as its newfound substitute.<sup>79</sup>

#### D. Chemical Restraints

##### I. CHEMICAL RESTRAINTS AS DEFINED BY REGULATION

Federal regulations define chemical restraint as "any drug that is used for discipline or convenience and not required to treat medical symptoms."<sup>80</sup> Thus, each resident's medicinal regimen must be free from unnecessary drugs.<sup>81</sup> This definition also provided that:

---

75. *Elderly Restraints*, NURSING HOME ABUSE GUIDE, <http://nursinghomeabuseguide.com/abuse-injuries/elderly-restraints/> (last visited Mar. 5, 2016).

76. *Id.*

77. See *Recognizing and Treating Resident Depression*, ILL. COUNCIL ON LONG-TERM CARE, [http://www.nursinghome.org/fam/fam\\_005.html](http://www.nursinghome.org/fam/fam_005.html) (last visited Mar. 5, 2016); see also *Negative Impact of Restraints*, NURSING HOME ABUSE GUIDE, <http://nursinghomeabuseguide.com/abuse-injuries/elderly-restraints/physical/> (last visited Mar. 5, 2016). See generally 42 C.F.R. § 483.13 (2015).

78. Memorandum from Director of Survey & Certification Group to State Survey Agency Directors (Nov. 7, 2008), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-11.pdf> (evaluating the efforts to reduce the use of physical restraints after the passage of NHRA).

79. See generally Konetzka et al., *supra* note 24 (reporting a study that claims that public reporting of nursing home physical restraint use decreased use of physical restraints, but led to an increased use of chemical restraints).

80. 42 C.F.R. § 483.13(a); see Julie A. Braun & Lawrence A. Frolik, *Legal Aspects of Chemical Restraint Use in Nursing Homes*, 2 MARQ. ELDER'S ADVISOR 21, 21 (2000), <http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1232&context=elders>.

81. *Provider Education Article: Psychotropic Drug Use in Skilled Nursing Facilities (SNF)*, DEP'T OF HEALTH & HUMAN SERVS. CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 25, 2002), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/ab02143.pdf>.

an unnecessary drug is any drug when used: (i) in excessive dose; or (ii) for excessive duration; or (iii) without adequate monitoring; or (iv) without adequate indications for its use; or (v) in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or (vi) any combination of the reasons above.<sup>82</sup>

Additionally, regulations express that residents who have not previously been prescribed antipsychotic drugs should not have them prescribed unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in their clinical record.<sup>83</sup>

## II. TYPES OF CHEMICAL RESTRAINTS

Medications most commonly used by nursing facilities as chemical restraints include sedatives, psychotropic, and antipsychotic drugs, all administered to control behavior by inducing sleep, stabilizing moods, or lessening anxiety or agitation.<sup>84</sup> Undoubtedly, there are many appropriate and valuable uses for drug treatment.<sup>85</sup> However, the United States Food and Drug Administration has not currently issued approval for any drug to be used as a chemical restraint.<sup>86</sup>

## III. SIDE EFFECTS OF NEEDLESS CHEMICAL RESTRAINT DRUGS

Abuse of these medications presents equally damaging side effects as those connected to physical restraints, including, but not limited to, overdose, malnutrition, dehydration, pain desensitization, brain injury, bedsores, chemical dependence, asphyxiation, or death.<sup>87</sup> Even if the unnecessary chemical medication does not produce a dangerous or severe side effect, unnecessarily sedating or subduing a resident's behavior deprives them of their ability to communicate their concerns, needs, or desires, provide appropriate responses to their

---

82. 42 C.F.R. § 483.25(l)(1)(i)-(vi) (2015).

83. 42 C.F.R. § 483.25(l)(2)(i)-(ii) (2015).

84. Braun & Frolik, *supra* note 80.

85. See *Mental Health Medications: Overview*, NAT'L INST. OF MENTAL HEALTH (2015), <http://www.nimh.nih.gov/health/publications/mental-health-medications/index.shtml> (discussing uses for medications for the treatment of mental disorder symptoms).

86. *Chemical Restraints on Elderly*, NURSING HOME ABUSE GUIDE, <http://nursinghomeabuseguide.com/abuse-injuries/elderly-restraints/chemical/> (last visited Mar. 5, 2016).

87. Nadia Chivers, *The Illegal Use of Chemical Restraints in Illinois Nursing Homes*, CHI. BRIDGE (Apr. 21, 2010), <http://www.thechicagobridge.org/the-illegal-use-of-chemical-restraints-in-illinois-nursing-homes/>.

caretakers, and to obtain the quality of care they deserve.<sup>88</sup> With a diminished ability to think clearly, these residents suffer a loss of autonomy and dignity and can develop strong feelings of humiliation and shame.<sup>89</sup>

### III. Analysis

#### A. The Gray Area of Medical Necessity

There is good reason to worry about chemical-restraint misuse in nursing home facilities.<sup>90</sup> However, monitored and supervised use of antipsychotic and psychotropic medications when needed for a mental health condition is universally favored.<sup>91</sup> While many support chemical restraint use from a medical necessity standpoint, some experts remain suspicious, finding this rationale a severely unsettling issue.<sup>92</sup>

These outspoken experts favor a strong proposal.<sup>93</sup> Evaluations of psychiatric and behavioral experts show discontentment and disagreement with the definition of chemical restraint.<sup>94</sup> When surveyed by the Expert Consensus Guidelines on Behavioral Emergencies, a majority of respondents indicated a desired refocus of medications used in the treatment of psychiatric diagnoses to be viewed as a *treatment* rather than a *restraint*.<sup>95</sup> Nevertheless, even when monitoring a prescribed medication's regulated purpose, recommended dosage, and duration of treatment plan, in addition to supervising the patient's progress overall, this proposed differentiation does little to resolve the fine line between essential treatment and avoidable restraint, and merely disguises a chemical restraint as a treatment plan.<sup>96</sup>

The risk of prescribing any medication, but specifically an unnecessary antipsychotic or psychotropic medication, to an elderly pa-

---

88. *Id.*

89. Edna Evergreen Scenario, *Providing a Quality Life While Avoiding Restraint Usage*, OFFICE OF QUALITY ASSURANCE (1999).

90. *Chemical Restraints on Elderly*, *supra* note 86.

91. *See generally* Konetzka et al., *supra* note 24, at 454.

92. *Id.*

93. *White Paper for Chemical Restraint Use for The California Department of Public Health*, HEALTH SERVS. ADVISORY GRP., INC. 1-1 (July 2012), <http://www.cdph.ca.gov/programs/LnC/Documents/CAHPS-HSAG-White-Paper-Chemical-Restraint-Use-Final.pdf>.

94. *Id.*

95. *Id.*

96. *See generally id.*

tient is heightened due to this particular cohort's health sensitivity.<sup>97</sup> It is necessary to monitor a drug's response to a patient's body and the body's reaction to a drug, a practice known as pharmacodynamics.<sup>98</sup> Numerous studies have confirmed that older adults are highly susceptible to the adverse side effects that accompany antipsychotic and psychotropic medications.<sup>99</sup> On average, elderly men and women in their eighties take approximately fifteen medications each day.<sup>100</sup> Combining such a large quantity and variety of medications with an antipsychotic or psychotropic drug further exacerbates the risks and adverse reactions these chemical restraint drugs present to elderly patients.<sup>101</sup>

While the effects of polypharmacy, or taking four or more medications concurrently,<sup>102</sup> is not within the scope of this Note, management of the risks associated with the misuse of psychoactive medications in nursing homes remains one of the most dangerous quality of care issues for institutionalized elderly.<sup>103</sup>

## B. Psychotropic Misuse—A Longstanding, Persistent National

---

97. See Gerald A. Maguire, *Impact of Antipsychotics on Geriatric Patients: Efficacy, Dosing, and Compliance*, 2 PRIMARY CARE COMPANION J. OF CLINICAL PSYCHIATRY 165, 171 (2000); H. Uchida et al., *Increased Antipsychotic Sensitivity in Elderly Patients: Evidence and Mechanisms*, 70 J. CLINICAL PSYCHIATRY 397 (2009); P. Gareri et al., *Adverse Effects of Atypical Antipsychotics in the Elderly: A Review*, 23 DRUGS AGING 937 (2006).

98. J. Mark Ruscin & Sunny A. Linnebur, *The Merck Manual Professional Edition Drug Therapy in the Elderly*, PHARMACODYNAMICS IN THE ELDERLY (June 2014), [http://www.merckmanuals.com/professional/geriatrics/drug\\_therapy\\_in\\_the\\_elderly/pharmacodynamics\\_in\\_the\\_elderly.html](http://www.merckmanuals.com/professional/geriatrics/drug_therapy_in_the_elderly/pharmacodynamics_in_the_elderly.html).

99. See generally Pamela L. Lindsey, *Psychotropic Medication Use Among Older Adults: What All Nurses Need to Know*, 35 J. GERONTOLOGICAL NURSING 28 (2009) (citing four studies that evaluated psychotropic medication on older adult subject groups and consistently document the sensitivity of this cohort: Bulat, Castle, Rutledge & Quigley, 2008; Carr, 2005; Grasso, Bates & Shore, 2007; Mott, Poole & Kenrick, 2005).

100. See generally Barbara Farrell, *Drug-related Problems in the Frail Elderly*, 57 CAN. FAM. PHYSICIAN 168, 168-69 (2011) (citing a study that found that patients with an average age of eighty-one, were taking an average of fifteen medications each, with a distribution of 6-28); *ASCP Fact Sheet*, AM. SOC'Y OF CONSULTANT PHARMACISTS (2014), <https://www.ascp.com/articles/about-ascp/ascp-fact-sheet> (on average individuals aged eighty to eighty-four take an average of eighteen prescriptions per year).

101. John O. Brooks & Jennifer C. Hoblyn, *Neurocognitive Costs and Benefits of Psychotropic Medications in Older Adults*, 20 J. OF GERIATRIC PSYCHIATRY & NEUROLOGY 199, 214 (2007).

102. Emily R. Hajjar et al., *Polypharmacy in Elderly Patients*, 5 AM. J. OF GERIATRIC PHARMACOTHERAPY 345 (2007).

103. Cory W. Brooks, Essay, *Skilled Nursing Homes: Replacing Patient Restraints with Patient Rights*, 45 S.D. L. REV. 606, 619 (1999-2000) (citing testimony given by Dr. Mark H. Beers, a professor of geriatric medicine at the University of California, Los Angeles at the House Ways and Means Subcommittee on Health in 1989).

### Problem

The danger of antipsychotic and psychotropic drugs in elderly institutions is not a new discovery. In 1989, in the wake of the government's NHRA regulations and policy reforms, Dr. Beers, a professor of geriatric medicine at the University of California, Los Angeles, sought to reveal the continuing prevalence of psychotropic drug use in nursing home facilities.<sup>104</sup> Dr. Beers' study used twelve Boston-area nursing home facilities and 850 patients as its sample group.<sup>105</sup> The results of the study indicated that two-thirds of the nursing home residents had orders for at least one psychotropic drug and more than twenty-five percent were prescribed antipsychotic medications, whereas only thirteen percent had a diagnosis that could uncover latent psychotic behavior.<sup>106</sup> More unsettling about his research was the frequency of orders written as "as needed"<sup>107</sup> or the abbreviation "PRN."<sup>108</sup> This notation allows nursing staff to administer medications according to their perceived understanding of what the patient needs.<sup>109</sup>

This study demonstrates that overuse and misuse of pharmaceutical medications has been an enduring problem affecting nursing home communities for decades.<sup>110</sup> Failure to address such a persistent issue falls on the shoulders of several organizational powers, most significantly on the federal government.<sup>111</sup>

### C. Oversight by the Federal Government

When developing NHRA certification programs, regulations were developed expressly prohibiting both physical and chemical restraint use.<sup>112</sup> However, due to the greater prevalence of physical restraint use in the 1980s, these measures were considered a primary in-

---

104. State of Cal., Little Hoover Commission, *Skilled Nursing Homes: Care Without Dignity*, Report # 109, at 16 (Apr. 1991), <http://www.lhc.ca.gov/earlyreports/109rp.html>.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Medical Dictionary*, MEDLINE PLUS, <http://www.merriam-webster.com/medlineplus/PRN> (last visited Mar. 5, 2016) (defining PRN as needed; as the circumstances require—used in writing prescriptions).

109. State of Cal., *supra* note 104.

110. *Id.*

111. *See id.*

112. Konezka et al., *supra* note 24.

indicator for poor quality of care in nursing home facilities.<sup>113</sup> A sharpened focus on the physical form of restraint minimized federal attention paid to chemical restraint abuse.<sup>114</sup> Reporting of chemical restraint use was neither required nor included in compliance reports until the shift from the CASPER system in 2012 and then the NHC website in 2013.<sup>115</sup> A growing awareness of the risk of chemical restraints at the turn of the millennium finally led to this decade-later reevaluation of the overuse of antipsychotics, psychotropics, and similar medications.<sup>116</sup>

#### D. Results of the Federal Government's Mishandling of Chemical Restraint Use

CMS neglected to properly monitor the expensive funding for this overuse and misuse of antipsychotic and psychotropic drugs.<sup>117</sup> In 2007, *The Wall Street Journal* re-published statistics formulated by CMS regarding Medicaid's spending on atypical antipsychotic drugs<sup>118</sup> between the years 2000 and 2005.<sup>119</sup> The federal program's spending increased from \$2.14 billion to \$5.4 billion on these medications.<sup>120</sup> These atypical antipsychotic drugs, or "second generation antipsychotic medications," are a variety of medications used to treat psychiatric conditions, some of which are approved to treat bipolar disorder, schizophrenia, bipolar mania, acute mania, and other mental illness conditions.<sup>121</sup> Notably, the article also reported that nearly twenty-one percent of nursing home patients who receive these atypical antipsychotic medications have not been diagnosed as having a psychiatric or

---

113. *Id.*

114. *Id.*

115. *Id.*

116. See generally *Mental Health Medications*, NAT'L ALL. ON MENTAL ILLNESS, <http://www.nami.org/Learn-More/Treatment/Mental-Health-Medications> (last visited Mar. 5, 2016).

117. Jan Goodwin, *Antipsychotics in Nursing Homes*, AARP (July/Aug. 2014), <http://www.aarp.org/health/drugs-supplements/info-2014/antipsychotics-overprescribed.html>.

118. Brand names for atypical antipsychotic drugs include Clozaril, Zyprexa, Seroquel, Risperdal, Invega, Abilify, and Geodon, among others. *Mental Health Medications*, *supra* note 116.

119. Joe Mantone, *Antipsychotic Drugs Abused as Chemical Restraints for Elderly*, WALL ST. J. (Dec. 4, 2007, 7:17 AM), <http://blogs.wsj.com/health/2007/12/04/antipsychotic-drugs-abused-as-chemical-restraints-for-elderly/>.

120. *Id.* (showing diagram from Centers for Medicare & Medicaid Services, tabulation of Medicaid Drug Rebate Data).

121. *Mental Health Medications*, *supra* note 116.



mental illness condition.<sup>122</sup> Although the article claims that CMS “said they are increasing vigilance of prescription abuse during nursing-home inspections,” data from the consecutive years appear otherwise.<sup>123</sup>

In 2009, when CMS classified Massachusetts as a state with one of the highest percentages<sup>124</sup> of antipsychotic drug abuse in nursing homes, The Boston Globe responded by executing an independent study.<sup>125</sup> The Globe’s findings corroborated CMS’ statistics for the state of Massachusetts and added valuable data to CMS’ national investigation as well.<sup>126</sup> The news outlet and CMS both reported that twenty-eight percent of Massachusetts’ nursing home residents received antipsychotic medication, and of that twenty-eight percent, twenty-two percent were receiving medication without a medical diagnosis requiring use of any antipsychotics.<sup>127</sup> Even for those that were receiving antipsychotic medications for a diagnosed condition, Paul Raia, the Vice President of Clinical Services for the Massachusetts and New Hampshire Alzheimer’s Association, asserted that nursing homes do not “regularly reevaluate patients’ medications to determine whether the antipsychotics are, in fact, effective and whether the dose can be lowered or eliminated.”<sup>128</sup> For those that are administered antipsychotic medications without a diagnosis, Robert A. Stern, an Alzheimer’s specialist and brain researcher at Boston University School of Medicine, believes that these residents are treated with antipsychotics for sedation or control when their behavior is too hard for the staff to manage.<sup>129</sup>

CMS Nursing Home Data Compendium for 2013 further supports this increased use.<sup>130</sup> While the use of physical restraint has become rare, with only 1.7 percent of residents on average reporting physical restraint in the past seven days, 24.2 percent of residents state

---

122. Mantone, *supra* note 119.

123. *Id.*

124. Kay Lazar, *Nursing Home Drug Use Puts Many at Risk*, THE BOSTON GLOBE (Mar. 8, 2010), [http://www.boston.com/news/local/massachusetts/articles/2010/03/08/antipsychotic\\_drug\\_use\\_for\\_dementia\\_patients\\_is\\_questioned/](http://www.boston.com/news/local/massachusetts/articles/2010/03/08/antipsychotic_drug_use_for_dementia_patients_is_questioned/).

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. See *Nursing Home Data Compendium 2013 Edition*, CTR. FOR MEDICARE & MEDICAID SERVS., DEP’T. OF HEALTH & HUMAN SERVS. 1, [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/nursinghomedatacompendium\\_508.pdf](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/nursinghomedatacompendium_508.pdf) (last visited Mar. 5, 2016).

that they received antipsychotic medication at least once in the past seven days.<sup>131</sup> The Data Compendium also presents the percentage of nursing home residents taking antipsychotic medications in each of the fifty states.<sup>132</sup> The results collected from 2012 reveal overwhelming findings regarding the use of antipsychotic drugs: 12.3 to 21.2 percent in sixteen states;<sup>133</sup> 21.3 to 23.1 percent in thirteen states;<sup>134</sup> 23.2 to 24.6 percent in six states;<sup>135</sup> 24.7 to 27.7 percent in eleven states;<sup>136</sup> and 27.8 to 34.1 percent in five states.<sup>137</sup> Thus, in thirty-five states, more than twenty percent of nursing home residents are being medicated with antipsychotics.<sup>138</sup>

### E. Litigation Against Drug Companies

While CMS has vocalized their intention of decreasing the use of antipsychotic drugs in nursing homes and has launched initiatives in an attempt to execute its goal,<sup>139</sup> the marketing and promoting of off-label drug use, or a use for which the FDA has not approved, is a practice that nursing homes have been found to engage in and has been significantly misaddressed by government agencies.<sup>140</sup> Off-label promotion is attractive to pharmaceutical companies as it acts to enhance their market penetration.<sup>141</sup> This practice is done, however, at the risk of simultaneously endangering unintended users.<sup>142</sup> In 2007,

---

131. *Id.* at 160.

132. *Id.* at 164.

133. *Id.* at 164. The sixteen states include Alaska, Colorado, Hawaii, Iowa, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, North Carolina, North Dakota, Oregon, South Carolina, Wisconsin, and Wyoming.

134. *Id.* The thirteen states include Arizona, Delaware, District of Columbia, Idaho, Indiana, New Mexico, New York, Pennsylvania, Rhode Island, South Dakota, Virginia, Washington, and West Virginia.

135. *Id.* The six states include California, Florida, Kentucky, Maine, Nebraska, and Vermont.

136. *Id.* The eleven states include Alabama, Arkansas, Connecticut, Georgia, Kansas, Massachusetts, New Hampshire, Ohio, Oklahoma, Tennessee, and Utah.

137. *Id.* The five states include Illinois, Louisiana, Mississippi, Missouri, and Texas.

138. *Id.*

139. Daniel Butler & Richard Mollot, *Federal Requirements & Regulatory Provisions Relevant to Dementia Care & the Use of Antipsychotic Drugs*, LONG TERM CARE CMTY. COAL. 1, 4, <http://www.ltccc.org/publications/documents/ltccc-antipsychotic-drugs-oversight-ftags-mar2013.pdf> (last updated March 2013).

140. "Off-Label" and Investigational Use of Marketed Drugs, *Biologics, and Medical Devices-Information Sheet*, FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last updated Jan. 25, 2016).

141. Alexander T. Tabarrok, *Assessing the FDA Via the Anomaly of Off-Label Drug Prescribing*, 5 INDEP. REV. 25, 26-29 (2000).

142. *Id.*

when the Food and Drug Administration (FDA) evaluated six months of Medicare medical records for a CMS standards review, it realized that eighty-three percent of atypical antipsychotic drugs in nursing home facilities were being used to treat off-label conditions and eighty-eight percent were associated with an FDA black box warning.<sup>143</sup> Pharmaceutical companies are required to include these box warnings for the sole purposes of protecting the public and providing necessary health literature on the proper and intended use of pharmaceutical medications.<sup>144</sup> Thus, the promotion of an off-label use counteracts the entire purpose of these government regulations.<sup>145</sup>

Pharmaceutical companies are proportionally accountable for an increased use of antipsychotic and psychotropic drugs on institutionalized elderly with their rampant promotion of unintended drug use in nursing home facilities nationwide.<sup>146</sup> Janssen-Cilag, a subsidiary of the popular Johnson & Johnson Company, manufactures Risperdal, an antipsychotic drug most commonly used to treat schizophrenia and bipolar disorder.<sup>147</sup> The FDA approved Risperdal in 1993 and it has been on the market ever since.<sup>148</sup> In *United States of America v. Janssen Pharmaceuticals, Inc.*, Janssen-Cilag was charged with illegally marketing Risperdal to nursing home facilities as a means to control their residents' undesirable behavior.<sup>149</sup> Janssen-Cilag was aware that the drug was linked to higher incidences of death and stroke, yet still incentivized physicians and pharmacists through kickbacks to prescribe the drug to patients without a condition that required such a strong medication.<sup>150</sup> Janssen-Cilag settled with more than \$2.2 billion in criminal and civil fines, making this case the third-largest pharmaceutical set-

---

143. Daniel R. Levinson, *Medicate Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, U.S. DEPT OF HEALTH & HUMAN SERVS. 1, 4 (May 2011), <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>.

144. *Id.*

145. *See id.* at 3.

146. Chuck Bartels, *Johnson & Johnson Subsidiary Hid Risks Associated With Risperdal, Drug That Made Company Billions*, HUFFINGTON POST (Apr. 11, 2012), [http://www.huffingtonpost.com/2012/04/11/johnson-johnson-risperdal-risks\\_n\\_1417999.html](http://www.huffingtonpost.com/2012/04/11/johnson-johnson-risperdal-risks_n_1417999.html).

147. *Id.*

148. *United States v. Janssen Pharmaceuticals, Inc.*, cr-13-605 (2013), [http://www.justice.gov/sites/default/files/usao-edpa/legacy/2014/02/11/JanssenPharma\\_information.pdf](http://www.justice.gov/sites/default/files/usao-edpa/legacy/2014/02/11/JanssenPharma_information.pdf) (settlement agreement filed with the United States District Court for the Eastern District of Pennsylvania).

149. *Id.* at 21.

150. James W. Slater, *Overmedication of Nursing Home Patients*, AKRON BEACON J. (Nov. 13, 2014), <http://www.ohio.com/blogs/legal-news/legal-news-1.513148/over-medication-of-nursing-home-patients-1.540585>; Bartels, *supra* note 146.

tlement in United States history.<sup>151</sup> In response to this lawsuit, Janssen-Cilag released a statement that reiterated Risperdal's warnings and precautions and highlighted the lack of FDA approval for treatment in the elderly.<sup>152</sup>

This lawsuit against Janssen-Cilag did not deter other pharmaceutical companies from engaging in the marketing of off-label anti-psychotic and psychotropic drugs to nursing home facilities. Unsurprisingly, all subsequent lawsuits as a result unanimously ended in a settlement.<sup>153</sup>

Eli Lilly was charged with marketing its pharmaceutical Zyprexa to nursing home facilities and settled with the government for \$1.45 billion.<sup>154</sup> The FDA has approved Zyprexa to treat schizophrenia and bipolar disorder.<sup>155</sup> Bristol-Myers Squidd settled a suit for \$515 million against claims charging the company with marketing its antipsychotic drug, Abilify, to nursing homes facilities.<sup>156</sup> The FDA has also approved Abilify to treat schizophrenia, especially in cases of mental illness relapse prevention.<sup>157</sup> Pfizer settled their antipsychotic off-label marketing scheme for \$301 million involving its drug, Geodon, which was approved for the treatment of acute mania and schizophrenia.<sup>158</sup> Astra Zeneca utilized assertive sales and promotional strategies to market its antipsychotic drug, Seroquel, ultimately costing the company \$520 million to settle.<sup>159</sup>

---

151. Katie Thomas, *J.&J. to Pay \$2.2 Billion in Risperdal Settlement*, N.Y. TIMES (Nov. 4, 2013), [http://www.nytimes.com/2013/11/05/business/johnson-johnson-to-settle-risperdal-improper-marketing-case.html?\\_r=0](http://www.nytimes.com/2013/11/05/business/johnson-johnson-to-settle-risperdal-improper-marketing-case.html?_r=0).

152. *Highlight of Prescribing Information*, FOOD & DRUG ADMIN., [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/020272s065,020588s053,021444s0411bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020272s065,020588s053,021444s0411bl.pdf) (last visited Mar. 5, 2016).

153. Slater, *supra* note 150; Duff Wilson, *Side Effects May Include Lawsuits*, N.Y. TIMES (Oct. 2, 2010), [http://www.nytimes.com/2010/10/03/business/03psych.html?page\\_wanted=all](http://www.nytimes.com/2010/10/03/business/03psych.html?page_wanted=all).

154. *Eli Lilly and Company Agrees to Pay \$1.45 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa*, U.S. DEP'T OF JUSTICE (Jan. 15, 2009), <http://www.justice.gov/archive/opa/pr/2009/January/09-civ-038.html>.

155. News Release, Food & Drug Admin, FDA approves first generic olanzapine to treat schizophrenia, bipolar disorder (Oct. 24, 2011), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm277022.htm>.

156. Wilson, *supra* note 153.

157. *Highlights of Prescribing Information*, FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM191607.pdf> (last visited Mar. 5, 2016).

158. Wilson, *supra* note 153.

159. Duff Wilson, *For \$520 Million, AstraZeneca Will Settle Over Marketing of a Drug*, N.Y. TIMES (Apr. 26, 2010), <http://www.nytimes.com/2010/04/27/business/27drug.html>.

These recent lawsuits confirm that some pharmaceutical companies have devised a way to promote off-label drug use to capitalize on vulnerable sectors of the American public, persuading several nursing home facilities and licensed physicians with their illegitimate offers.<sup>160</sup> These industries are entrusted with incredible gatekeeping powers, and failure to handle their authority properly causes a supreme reduction of trust and safety.<sup>161</sup>

#### F. Incentives in Restricting Drug Use in Nursing Homes

CMS has a genuine financial interest in decreasing the use of unnecessary pharmaceuticals in nursing home facilities.<sup>162</sup> Expense reports in 2011 for Medicare Part D<sup>163</sup> spending on antipsychotic drugs yielded \$7.6 billion.<sup>164</sup> Eliminating the portion of this \$7.6 billion spent on unnecessary medications would amass additional savings that could be redistributed within the facilities' budget. In 2013, the Department of Health and Human Services (DHHS) proposed new federal standards with regard to the amount of hourly care that residents should receive daily—the minimum being two hours.<sup>165</sup> Fifty-four percent of nursing homes fail to meet these standards.<sup>166</sup> Furthermore,

---

160. See generally James McNair, *The Kickback, Fraud, and Drug Switch Claims That Ail a Louisville Pharmacy Company*, KY. CTR. FOR INVESTIGATIVE REPORTING (May 21, 2015), <http://kycir.org/2015/05/21/the-kickback-fraud-and-drug-switch-claims-that-ail-a-louisville-pharmacy-company/> (discussing the strategy of how kickbacks are becoming a standard pharmaceutical industry practice to get generic drugs into nursing facilities).

161. See Mark Kessel, *Restoring the pharmaceutical industry's reputation*, NATURE BIOTECHNOLOGY (Oct. 9, 2014), <http://www.nature.com/nbt/journal/v32/n10/full/nbt.3036.html> (discussing the damage to the Pharmaceutical Industries reputation on account of unethical behavior).

162. See Jena Grady, *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*, 23 ANNALS OF HEALTH L. 113 (2014) (addressing CMS's attempts "to mitigate unnecessary anti-psychotic prescribing, such as when it is used as a restraint, by establishing regulations."); see also Dan Mendelson et al., *Prescription Drugs in Nursing Homes: Managing Costs and Quality in a Complex Environment*, NAT'L HEALTH POLICY FORUM (Nov. 12, 2002), [http://www.nhpf.org/library/issue-briefs/IB784\\_RxDrugs&NursHomes\\_11-12-02.pdf](http://www.nhpf.org/library/issue-briefs/IB784_RxDrugs&NursHomes_11-12-02.pdf) (discussing financial burden of medications).

163. See Medicare.gov for more information regarding Medicare Part D, the federal government program, which subsidizes prescription drug costs and insurance premiums for Medicare beneficiaries.

164. Press Release, Ctrs. for Medicare & Medicaid Servs., National Partnership to Improve Dementia Care exceeds goal to reduce use of antipsychotic medications in nursing homes: CMS announces new goal (Sept. 19, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-09-19.html>.

165. *Report: Understaffed Nursing Homes Endanger Patients*, ABC NEWS (July, 23, 2013), <http://abcnews.go.com/US/story?id=96416>.

166. *Id.*

thirty-four states<sup>167</sup> implemented regulations for daily direct care—and the standards which were chosen drastically vary; some states set their requirements much lower than DHHS' two hour proposal—only .44 hours required in Arizona<sup>168</sup>—and some states almost doubled the proposal—3.9 hours per resident in Florida.<sup>169</sup> Despite state regulations, 700 facilities fell short of their required daily direct care per patient, 250 facilities of which were located in Illinois.<sup>170</sup>

These insufficient daily direct care hours are likely correlative to understaffing in nursing home facilities. Studies have demonstrated that nursing homes with the highest percentage of residents who receive unnecessary antipsychotics tend to have the least amount of staff accessible on site.<sup>171</sup> Furthermore, these low-staffed nursing homes often receive more payments from Medicaid, which subsequently compensates facilities at a lower rate than private insurance plans.<sup>172</sup> Lower intake from Medicaid services decreases nursing home profit and expendable revenue, which reduces the ability of a facility to hire more employees.<sup>173</sup> Siphoning money saved from unnecessary antipsychotic medication expenses into staffing, hiring, and training protocol would be mutually beneficial for CMS, nursing home facilities, and residents alike.<sup>174</sup>

---

167. This figure of thirty-four includes Washington, D.C.

168. Jeff Kelly Lowenstein, *Nursing Home Care Levels May Be Much Lower Than Families Think*, CTR. FOR PUB. INTEGRITY, NBC NEWS (Nov. 12, 2014), <http://www.nbcnews.com/news/investigations/nursing-home-care-levels-may-be-much-lower-families-think-n246431> (citing survey data collected by Charlene Harrington, an emeritus professor of nursing at the University of California, San Francisco. For more information on Charlene Harrington's research, see <http://nursing.ucsf.edu/faculty/charlene-harrington>).

169. *Id.*

170. *Id.*

171. Kay Lazar, *Finding Alternatives to Potent Sedatives*, BOSTON GLOBE (Apr. 30, 2012), <http://www.bostonglobe.com/metro/2012/04/29/finding-alternatives-potent-sedatives/0S3EaKlyAtTCIGC9MewB0N/story.html> (“Those [nursing homes] with the highest percentage of residents who receive antipsychotics contrary to nursing home regulators' recommendations also tend to have the lowest numbers of registered nurses and nurses aides.”)

172. *Id.* (“These homes also typically have more residents on Medicaid, a government insurance program that reimburses nursing homes at a far lower rate for patient care than private insurers do, so the homes would have less money to hire staff.”)

173. *Id.*

174. See generally Press Release, *supra* note 164 (discussing how reducing the use of unnecessary antipsychotics would be helpful to patients); Mantone, *supra* note 119 (discussing how nearly twenty-one percent of nursing home patients who receive these drugs do not have a psychosis diagnosis and Medicaid spent \$5.4 billion on atypical antipsychotic drugs in 2005).

### G. Risks Associated with Banning or Restricting Psychotropic and Antipsychotic Drugs in Nursing Home Facilities

Enforcing limits or forbidding the administration of certain pharmaceuticals in nursing home facilities could jeopardize elder accessibility to care in at least two ways.<sup>175</sup> First, gaining admission to a nursing home facility may become increasingly difficult and subjective.<sup>176</sup> Second, barring access to particular drugs is unfair for patients whose diagnoses require these restricted drugs.<sup>177</sup>

Nursing homes have complete authorization for approving or refusing admission or for discharging an applicant.<sup>178</sup> These decisions do not require justification or explanation to the applicant or their family.<sup>179</sup> If a nursing home has concerns about an applicant's agitation levels or combative nature, they will likely engage in prescreening to determine whether admission should be allowed.<sup>180</sup> Alternatively, patients who seek admission with an existing prescription of antipsychotic medications would be refused entry and those who receive prescription while a resident would be at risk of discharge or deprivation of medicinal access.<sup>181</sup>

---

175. See *Mental Health Medications*, NAT'L INST. OF MENTAL HEALTH (Apr. 2015), <http://www.nimh.nih.gov/health/topics/mental-health-medications/mental-health-medications.shtml> (discussing how psychotropic and psychotherapeutic medications help people with mental disorders to avoid serious and disabling symptoms of their diseases); see also Braun & Frolik, *supra* note 80 (discussing how psychotropic drugs can be an important treatment therapy when used properly). See generally *Admission to a Nursing Home*, NURSINGHOMEFAMILIES.COM, [http://www.nursinghomefamilies.com/NH\\_web/Admission\\_to\\_a\\_Nursing\\_Home.html](http://www.nursinghomefamilies.com/NH_web/Admission_to_a_Nursing_Home.html) (last visited Mar. 5, 2016).

176. See generally *Admission to a Nursing Home*, *supra* note 175 (discussing how nursing homes can refuse admission without reason); see also Steve Yoder, *The Coming Nursing Home Shortage*, FISCAL TIMES (Jan. 26, 2012), <http://khn.org/news/fiscal-times-nursing-home-shortage/> (discussing a likely nursing home shortage in coming years).

177. See NAT'L INST. OF MENTAL HEALTH, *supra* note 175 (discussing how psychotropic and psychotherapeutic medications help people with mental disorders to avoid serious and disabling symptoms of their disease); see also Braun & Frolik, *supra* note 80 (discussing how psychotropic drugs can be an important treatment therapy when used properly).

178. *Admission to a Nursing Home*, *supra* note 175.

179. *Id.*

180. See generally *Preadmission Screening and Resident Review (PASRR)*, MEDIC AID.GOV, <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Institutional-Care/Preadmission-Screening-and-Resident-Review-PASRR.html> (last visited Mar. 5, 2016) (discussing pre-admissions screening as a federal requirement that all applicants for a "Medicaid-certified nursing facility be evaluated for mental illness and/or intellectual disability" and "be offered the most appropriate setting for their needs").

181. See generally Lazar, *supra* note 171; see also Yoder, *supra* note 176 (discussing how in the near future older people who need full time care will not all be able to obtain it due to a coming nursing home shortage).

Implementing a complete ban on psychotropic and antipsychotic medications creates accessibility problems in exchange for the elimination of overuse and misuse of such drugs.<sup>182</sup> However, this trade-off creates avoidable and preventable risks.<sup>183</sup> Frustrating access to nursing homes altogether is not suitable, nor is preventing residents from receiving necessary medications. Thus, alternative resolutions must be considered.

#### IV. Recommendation

There is no easy or straightforward resolution for the very complicated problem of caring for the aging. While attributing blame is the automatic and expected reaction, it is essential to keep the overall well-being of nursing home residents at the forefront of this healthcare battle. Nevertheless, despite the difficult terrain, advocating for change must not be precluded.

##### A. Finding Alternatives to the Use of Psychotropic and Antipsychotic Medications

Alternatives exist with almost any treatment. The unnecessary administration of antipsychotic and psychotropic medications presents no exception. Life Care Center of Nashoba Valley, a nursing home located in Littleton, Massachusetts has embraced a practicable, alternative approach to combat the industry's sedation trend.<sup>184</sup> The facility trains its staff to spend increased amounts of time with each patient, encourages relationship development between staff and residents, and aims to provide customized care to each resident.<sup>185</sup>

As the medical director for two Virginia nursing homes, Dr. Jonathan Evans has openly stated that it is never too late for a skilled

---

182. See generally Lazar, *supra* note 171; see also Brooks, *supra* note 103 (discussing how chemical restraints can be "used in acute and long-term care settings with the goal to prevent injury and protect patients"); see also *Admission to a Nursing Home*, *supra* note 175 (discussing breadth of discretion that nursing homes have in deciding whether to admit individuals).

183. Lazar, *supra* note 171.

184. *Id.*

185. *Id.* (detailing how staff members at Nashoba engage residents in hobbies and activities that they are passionate about, for instance, Margie enjoys dancing. The administration also encourages staff members to cater to resident's personalities, which resulted in a staff member bringing a retired electrician, Richard, a toolbox full of tools).



nursing facility to implement alternative treatment.<sup>186</sup> Dr. Evans realized that the amount of antipsychotic medications he was allowing to be administered to residents at his two Virginia facilities on behalf of overwhelmed staff was unacceptable.<sup>187</sup> “We are trained as physicians to think that every problem has a potential solution, and the most widely used solution is a medication, but that doesn’t work for every problem.”<sup>188</sup> Dr. Evans refocused his two facilities’ attentions on providing heightened care and has implemented educational programs for caregivers that encounter challenging situations with agitated patients.<sup>189</sup>

Building improvement from the inside and engaging in self-assessment should become an initiative of every skilled nursing facility. Developing acceptable alternatives to chemical restraints and training nursing staff on these appropriate measures would facilitate better care.

## B. Securing Informed Consent for Prescriptions

Informed consent is an invaluable concept of American healthcare,<sup>190</sup> and nursing home residents should not be exempt from this standard. Yet, facilities in many states fail to obtain informed consent before administering medications to residents.<sup>191</sup> Failure to secure consent in many states is not a noncompliance issue as much as it is a lack of requirement and regulation issue.<sup>192</sup> California, like most states, requires informed consent for surgical procedures and medical treatments, but it does not compel a nursing facility to secure a resident’s consent for antipsychotic drug prescriptions.<sup>193</sup> Massachusetts

---

186. *See id.* (discussing how Dr. Evans said that he would dedicate his presidency of the American Medical Directors Association to educating caregivers that challenging behaviors from dementia might be due to pain or fear).

187. *Id.*

188. *Id.*

189. Lazar, *supra* note 171.

190. William Heisel, *No signature required to give nursing home residents antipsychotics*, REPORTING ON HEALTH (Sept. 16, 2014), <http://www.reportingonhealth.org/2014/09/15/no-signature-required-give-nursing-home-residents-antipsychotics>.

191. *Id.*

192. Heisel, *supra* note 190; *see* William C. Wilson, *Informed Prescribers Should Obtain Informed Consent*, SOC’Y FOR POST-ACUTE & LONG-TERM CARE MED. (2013), [http://www.caringfortheages.com/article/S1526-4114\(13\)00436-8/pdf](http://www.caringfortheages.com/article/S1526-4114(13)00436-8/pdf); *see also* Kay Lazar & Matt Carroll, *A rampant prescription, a hidden peril*, BOSTON.COM (Apr. 29, 2012), [http://www.boston.com/lifestyle/health/articles/2012/04/29/nursing\\_home\\_residents\\_with\\_dementia\\_often\\_given\\_antipsychotics\\_despite\\_health\\_warnings/?page=1](http://www.boston.com/lifestyle/health/articles/2012/04/29/nursing_home_residents_with_dementia_often_given_antipsychotics_despite_health_warnings/?page=1).

193. Heisel, *supra* note 190.

and Wisconsin are among the states that have recently implemented informed consent requirements for any antipsychotic or psychotropic drugs.<sup>194</sup>

Nevertheless, obtaining informed consent is not as simple as having paperwork signed by the patient.<sup>195</sup> In California, nursing home staff are not authorized nor licensed to obtain these documents.<sup>196</sup> Instead, a physician, nurse practitioner, or physician's assistant must secure informed consent paperwork for it to be legally valid.<sup>197</sup> Yet, state surveyors do not regulate these licensing parameters or keep them in consideration when reviewing informed consent documentation for pharmaceutical administration.<sup>198</sup>

Seeking consent from nursing home residents, or an appropriate surrogate, would reduce unnecessary uses of antipsychotic drugs in nursing home facilities. Ideally, physicians and nursing home staff would better collaborate to ensure proper consent before dispensing pharmaceuticals to residents.<sup>199</sup> Monitoring this collaboration should become a high priority of state surveyors. Nevertheless, legislators have neglected to require state surveyors, or medical personnel, to fulfill this essential tenet of American health care.

In September 2012, three U.S. Senators, Blumenthal, Kohl, and Grassley, presented a bipartisan bill to Congress specifically addressing the overuse of antipsychotic medications in nursing home facilities.<sup>200</sup> Senator Richard Blumenthal declared:

Excessive prescription of antipsychotic drugs in nursing homes is elder abuse—plain and simple. It is chemical restraint, as pernicious and predatory as unnecessary physical restraint . . . . We must do more to protect consumers from this blatant misuse and encourage responsible use of antipsychotic drugs . . . . Despite the black box warnings and numerous multi-billion dollar settlements levied against pharmaceutical manufacturers for illegal off-label marketing, we continue to see an alarming number of dementia patients in nursing home and assisted living facilities being prescribed antipsychotics off-label to deal with agitation or other behavioral issues . . . . Our legislation provides some straight forward and commonsense steps that will help decrease the

---

194. *Id.*

195. *See* Wilson, *supra* note 192.

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.*

200. Press Release, Chuck Grassley, Kohl, Grassley, and Blumenthal Seek to Cut Misuse of Antipsychotics (May 22, 2012), <http://www.grassley.senate.gov/news/news-releases/kohl-grassley-and-blumenthal-seek-cut-misuse-antipsychotics>.

improper, dangerous, and costly use of antipsychotics and accelerate the shift toward the broader use of safer alternatives.<sup>201</sup>

The bill, titled Improving Dementia Care Treatment in Older Adults Act of 2012, sought to implement educational programs and to establish requirements for individuals responsible for administering antipsychotics to skilled nursing home residents.<sup>202</sup> Section Five of the Bill focused exclusively on standardizing procedures for securing informed consent before prescribing antipsychotic medications in both nursing facilities and skilled nursing facilities.<sup>203</sup> It sets out protocol, requirements, timing, and compliance expectations for care facilities.<sup>204</sup> Congress redirected this legislation to the Committee on Finance.<sup>205</sup> It has yet to be attended.<sup>206</sup> Nevertheless, it should be readdressed to enrich the quality of care available to United States' seniors and reaffirm the significance of securing medical informed consent regardless of residency placement in a nursing home facility.

### C. Repairing Staffing Shortages

A common thread throughout many quality care issues plaguing nursing home residents nationwide is the strain and exhaustion experienced by care facilities' staff.<sup>207</sup> The crisis of staff shortages mixed with an imminent increase in facility need is an issue a majority of adults will face whether through their own care or through the care of their loved ones.<sup>208</sup> With nursing home budgets experiencing financial cuts from Medicare and Medicaid reimbursements, the ability to fairly

---

201. Press Release, Richard Blumenthal, United States Senator, Senators Blumenthal, Kohl, Grassley Seek to Protect The Elderly And Taxpayers From Abusive Overprescribing of Antipsychotics (Sept. 21, 2012), <http://www.blumenthal.senate.gov/newsroom/press/release/senators-blumenthal-kohl-grassley-seek-to-protect-the-elderly-and-taxpayers-from-abusive-overprescribing-of-antipsychotics>; *Improving Dementia Care Treatment in Older Adults Act (S.3604)*, HEALTHCARE ACADEMY BLOG (Oct. 1, 2012), <https://www.healthcareacademy.com/2012/10/improving-dementia-care-treatment-in-older-adults-act-s-3604/>.

202. *Improving Dementia Care Treatment for Older Adults Act of 2012*, OPEN CONG., [https://www.opencongress.org/bill/s3604-112/actions\\_votes](https://www.opencongress.org/bill/s3604-112/actions_votes) (last updated March 19, 2015).

203. *Improving Dementia Care Treatment for Older Adults Act*, S. 3604, 112th Cong. § 5 (2012).

204. *Id.*

205. *Improving Dementia Care*, *supra* note 202.

206. *See generally id.*

207. *See James R. Hagerty, As America Ages, Shortage of Help Hits Nursing Homes*, WALL ST. J. (April 14, 2013, 10:32 PM), <http://www.wsj.com/articles/SB10001424127887324392804578360712470799082>.

208. *Id.*

compensate employees has become more limited.<sup>209</sup> In 2013, *The Wall Street Journal* made note of the staff shortage affecting American nursing homes, citing low pay, the prospective chance of occupational injury, unpleasant day-to-day responsibilities, and physically draining work to be among the reasons for this deficiency.<sup>210</sup> Elderly care facilities cannot afford to have this reputation attached to the profession of nursing home aides because of the future need for these facilities. According to Charlene Harrington, a professor emeritus at the University of California San Francisco, nursing homes in the U.S. have on average one nursing aide on duty for every ten residents;<sup>211</sup> whereas the ratio should reflect a one-to-seven distribution.<sup>212</sup>

CMS should consider recommending a national resident to nursing aide ratio to prevent facilities from immediately cutting those expenses that are essential for the success and existence of the facilities all together. A more radical approach would involve a pay-rate schedule in addition to a reasonable resident-to-staff ratio that would promote a balance of adequate care and just compensation.

If staff shortages continue to progress, nursing home facilities will become increasingly less successful in their ability to deliver quality care, fulfill Medicare and Medicaid standards, maintain high residency occupancy, and/or preserve positive reputations in their local communities. Although budget cuts and a greater need for financial planning are exceedingly serious problems for nursing homes nationwide, cutting staff and decreasing compensation only stands to exacerbate problems of strain and exhaustion.

#### **D. Creation of a Program to Implement Sanctions and Withhold Medicare Payments for Care**

Sanctions were successful in reducing physical restraint use throughout American nursing home facilities.<sup>213</sup> The systems implemented, regulated, and monitored have kept a recurrence of physical restraint minimal.<sup>214</sup> Since sanctions are used to regulate the compliance programs with regard to physical restraints in Medicare and

---

209. Yoder, *supra* note 176.

210. Hagerty, *supra* note 207.

211. *Id.*

212. *Id.*

213. Memorandum, *supra* note 78, at 1.

214. *Id.*

Medicaid facilities,<sup>215</sup> a similar program could conceivably be used to phase out unnecessary chemical restraint use. CMS should mimic the approach used to combat physical restraint use in the early 1990s. Currently, CMS considers the frequency and prevalence of physical restraints in a given nursing home to denote a one out of five star ranking on the NHC website.<sup>216</sup> The complex algorithm used for this ranking system is not a strong enough deterrent for facilities to alter use of potent antipsychotic and psychotropic drugs to control some residents' behavior. Following the physical restraint approach from the 1990s would involve the creation a national system that would monitor initiatives and routinely collect information data on nursing home pharmaceutical expenditures, at both facility and patient levels. Data can be collected by state surveyors, amassed into a national database, and used to determine and regulate payments by Medicare and Medicaid programs. Sanctions for noncompliance could remain the same, including guided facility training, mandated correction plans, refusal or withholding of payment by Medicare or Medicaid, monetary penalties, temporary in-facility supervision, and/or termination of the provider agreement based on the severity of the drug use.<sup>217</sup>

Recycling the course of action taken to diminish physical restraints in nursing home facilities may bring a similar success to the issue of chemical restraints. Yet, the effectiveness of a 'new' system will depend on advocacy efforts and sponsorship from other national organizations, nursing homes, and health care professionals to force implementation of compliance measures. Such a plan would have a positive impact on current residents' quality of life, and would restore comfort and optimism in Americans for the future of nursing home care.

---

215. *Id.* at 8.

216. *Five-Star Quality Ranking System*, *supra* note 62.

217. *See id.*

## V. Conclusion

Alison Weingartner did her best to perform due diligence when researching and ultimately selecting a nursing home for her mother, Rosanne Murphy, age eighty.<sup>218</sup> When Rosanne's memory loss symptoms were occurring more frequently, Alison began her search for an appropriate skilled nursing facility that she felt could accommodate her mother's needs.<sup>219</sup> In pursuit of safe, high-quality care, Alison visited ten facilities, eventually choosing Ledgewood Rehabilitation and Skilled Nursing Center to become Rosanne's new home.<sup>220</sup> This facility was nestled in the quiet neighborhood of Beverly, Massachusetts, twenty-six miles outside of Boston, and in close vicinity to Alison's home.<sup>221</sup> Alison willingly chose Ledgewood because it offered a special care unit for Alzheimer patients that was allegedly better trained to meet the needs of residents with diminishing mental capacity.<sup>222</sup> It was not long after Rosanne moved in to Ledgewood that she received unnecessary antipsychotic medications.<sup>223</sup> Rosanne became part of an alarming statistic; nineteen percent of the Ledgewood's residents were receiving antipsychotic drugs without diagnoses that prompted such medications.<sup>224</sup> Fortunately, Alison was attentive and grew concerned with the care her mother was receiving at Ledgewood.<sup>225</sup> This led to an early termination of the facility's care, requested discharge, and new facility selection, potentially saving Rosanne from meeting a fate similar to Alexander Zaiko, Fannie Mae Brinkley, and Joseph Shepter at Kern Valley Healthcare.<sup>226</sup>

As our population ages, it is important to monitor the availability of quality care for Americans in nursing home facilities. Through persistent efforts, enforced legislation, and influential advocacy groups, a reduction in the use of physical restraints has been achieved.<sup>227</sup> The focus must now shift to chemical restraints, an equally harmful and malicious form of control. Pharmaceuticals have an important function when properly prescribed, consented to, and ad-

---

218. Lazar & Carroll, *supra* note 192.

219. *Id.*

220. *Id.*

221. *Id.*

222. *Id.*

223. *Id.*

224. *Id.*

225. *Id.*

226. Lazar & Carroll, *supra* note 192; Chawkins, *supra* note 1.

227. Memorandum, *supra* note 78, at 1.

ministered with proper monitoring; however, those used out of convenience or for off-label purposes must be reduced to extinction. While the overuse and misuse of antipsychotic and psychotropic drugs has been acknowledged, failure to seek alternative treatments, implement sanctions, or withhold Medicare payment diminishes justice and trust within the legal field and healthcare market. With a healthcare dependent population aging faster than ever, these are qualities of care we cannot risk compromising.