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## Lifting the Fog: The Problem of Antipsychotic Drug Use in Nursing Facilities

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# Lifting the Fog:

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The Problem of  
Antipsychotic Drug  
Use in Nursing  
Facilities

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Class of 2012

April 2011

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\*This paper is submitted in satisfaction of the Food and Drug Law course requirement.

## **Abstract**

With the rapid increase in the elder population nationwide, the problem of excessive dependence on risky antipsychotic drug treatment for dementia-related behavioral problems in nursing facilities must be addressed. At the federal level, the over-prescription of antipsychotics to the elderly in nursing homes is addressed first by regulation specific to nursing facilities, such as the Federal Nursing Home Reform Amendments (FNHRA), a part of the Ombudsman Budget Reconciliation Act of 1987 (OBRA '87) as well as through the Centers for Medicare and Medicaid Services (CMS) guidelines. Secondly, the Food and Drug Administration (FDA) has authority to issue black box warnings and regulation pertaining to off-label drug use for antipsychotics used to treat behavioral problems associated with dementia, a use that has not been approved by the FDA. Additionally, under state common law, these problems are addressed under the informed consent and right to refuse treatment doctrines. Despite the extensive multi-tiered body of law addressing this issue, no coherent and effective system has yet been devised to effectively protect patient rights. This paper suggests solutions to system failures via multi-faceted changes at federal and state levels in order to make the available framework more coherent and facilitate a shift to a nonpharmacologic treatment emphasis in the future.

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## I. Introduction

By 2030, 70 million Americans will be over the age of 65, comprising more than 20% of the American population.<sup>1</sup> The number of residents in long term care services like nursing homes will increase from 8 million in 2000 to 19 million in 2050.<sup>2</sup> Mental disorders are present in a large percentage of the nursing home population.<sup>3</sup> Antipsychotics,<sup>4</sup> benzodiazepines, and antidepressants are among the medications most commonly used to manage problem behaviors.<sup>5</sup> Historically, antipsychotics have been used excessively and without appropriate diagnosis or monitoring for side effects in nursing home residents, often solely for the convenience of staff.<sup>6</sup>

With the rapid increase in the elder population nationwide, problems specific to this age group have come to light and must be addressed. Despite the multiplicity of strategies devised to address these issues, no approach has yet adequately resolved the situation. At the federal level, the over-prescription of antipsychotics to the elderly in nursing homes is addressed first by regulation specific to nursing facilities, such as the Federal Nursing Home Reform Amendments (FNHRA), a part of the Ombudsman Budget Reconciliation Act of 1987 (OBRA '87) as well as

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<sup>1</sup> See Gregory Spencer, U.S. Dep't of Commerce, Pub. No. P25-1130, *Population Projections of the United States by Age, Sex, Race, and Hispanic Origin: 1995-2050*, U.S. Bureau of the Census Consumer Population Reports 1, 10 tbl.G (1996) available at <http://www.census.gov/prod/1/pop/p25-1130.pdf>. As of 2006, there were 37 million Americans over the age of sixty-five. Fed. Interagency Forum on Aging-Related Statistics, *Older Americans 2008: Key Indicators of Well-Being 2* (2008), available at [http://agingstats.gov/agingstatsdotnet/Main\\_Site/Data/2008\\_Douments/OA\\_2008.pdf](http://agingstats.gov/agingstatsdotnet/Main_Site/Data/2008_Douments/OA_2008.pdf).

<sup>2</sup> See Office of Assistant Sec'y for Planning & Evaluation, Dep't of Health & Human Servs. et al., *The Future Supply Long-Term Care Workers in Relation to the Aging Baby Boom Generation: Report to Congress 3* (2003), available at <http://aspe.hhs.gov/daltcp/reports/ltcwork.pdf>.

<sup>3</sup> See Pravin Kamble et al., *Use of Antipsychotics Among Elderly Nursing Home Residents with Dementia in the US: An Analysis of National Survey Data*, 26 DRUGS & AGING 483-492 (2009).

<sup>4</sup> Antipsychotic drugs, commonly referred to as psychotropic or neuroleptic, are often used for the treatment of severe mental disorders. See *Riese v. St. Mary's Hosp. & Med. Ctr.*, 209 Cal. App. 3d 1303, 1310 (1987) (defining antipsychotic drugs).

<sup>5</sup> See Peter P. De Deyn, *Risperidone for the Treatment of Neuropsychiatric Features in Dementia*, 11 DRUGS & AGING 887-896 (2006).

<sup>6</sup> See Marcel G.M. Rikkert, *Antipsychotics for Behavioural and Psychological Problems in Elderly People with Dementia: A Systematic Review of Adverse Events*, 22 DRUGS & AGING 845-858(2005).

through the Centers for Medicare and Medicaid Services (CMS)<sup>7</sup> guidelines. Secondly, the Food and Drug Administration (FDA) has authority to issue black box warnings and regulation pertaining to off-label drug use for antipsychotics used to treat behavioral problems associated with dementia, a use that has not been approved by the FDA. Although this authority has been used primarily to target drug manufacturers, black box warnings and off-label drug use regulation could also be used to regulate further downstream in nursing facilities to stem the over-prescription of antipsychotics. Additionally, under state common law, these problems are addressed under the informed consent and right to refuse treatment doctrines, which include resident competence, knowledge, and voluntariness of medical treatment. Despite this extensive multi-tiered body of law and the risky nature of this treatment option, no coherent and effective system has yet been devised to effectively protect patient rights.

This paper will attempt to offer a way in which legislative, judicial, and policy considerations may work in tandem in order to create meaningful private rights of action for nursing home patients who have been overmedicated with antipsychotic drugs as an alternative to personal care. Part II addresses the complex medical issues of treating elderly nursing home residents with antipsychotic drugs for the symptoms of dementia in order to clarify the issue and create a background against which legal reform should be considered. Part III summarizes current federal legislation addressing nursing home resident rights and the strengths and weaknesses of CMS guidelines and federal reform. FDA regulation of off-label drugs and the issuance of black-box warnings will also be addressed, along with their relative success in litigation against pharmaceutical companies advertising antipsychotics for off-label use in nursing homes for dementia patients and the ways in which this mode of action may be channeled to regulate the actions of nursing home facilities as well. Part IV addresses state common law doctrines of

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<sup>7</sup> Formerly known as the Health Care Financing Administration (HCFA).

informed consent and the right to refuse treatment in several states, as well as the strengths and weaknesses of this system in relation to elderly nursing home residents. Part V will suggest solutions to system failures via multi-faceted changes at federal and state levels in order to make the available framework more effective and coherent, as well as broader policy adjustments going forward in the future. Part VI concludes.

## II. Medical Issues

Antipsychotic drug treatment for behavioral problems related to cognitive impairment in the elderly has become a pressing issue because of the prevalence of these symptoms in nursing facility residents. More than 50 percent of residents in assisted living and nursing homes have some form of dementia or cognitive impairment, including Alzheimer's disease.<sup>8</sup> Almost all patients with Alzheimer's experience some degree of behavioral disturbance during the course of their disease, including depression, anxiety, apathy, psychosis and agitation.<sup>9</sup> These symptoms vary in frequency and severity and can present challenges for patients and caregivers.

Traditionally, typical antipsychotics have been used to treat agitation and psychosis related to Alzheimer's disease<sup>10</sup>. Although effective, these drugs cause increased risk of death and cardiovascular events, worsening of cognitive function, increased Parkinsonism,<sup>11</sup> metabolic disease, and falls.<sup>12</sup> Due to the changes occurring with age, prescribing drugs for the elderly is very different from prescribing for other members of society.<sup>13</sup> In addition to other mental

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<sup>8</sup> See Alzheimer's Association, *Alzheimer's Association Releases Dementia Care Practice Recommendations for End-of-Life Care*, available at [http://www.alz.org/national/documents/release\\_082807\\_dc recommends.pdf](http://www.alz.org/national/documents/release_082807_dc recommends.pdf) (last updated Aug. 28, 2007).

<sup>9</sup> See Sergio E. Starkstein et al., *Apathy Predicts More Severe Parkinsonism in Alzheimer's Disease*, 17 AM. J. GERIAT. PSYCHIATRY 291, 292 (2009).

<sup>10</sup> See Gordon K. Wilcock, *Treatment for Alzheimer's Disease*, 15 INT. J. GERIAT. PSYCHIATRY 562, 562 (2000).

<sup>11</sup> Symptoms similar to those exhibited with Parkinson's disease, including tremor of resting muscles, rigidity, slowness of movement, impaired balance, and a shuffling gait. See Starkstein, *supra* note 9.

<sup>12</sup> See Clive Ballard et al., *A Randomised, Blinded, Placebo-Controlled Trial in Dementia Patients Continuing or stopping Neuroleptics (The DART-AD Trial)*, 5 PLOS MEDICINE 587, 587 (2008).

<sup>13</sup> See James A. Jernigan, *Update on Drugs and the Elderly*, 29 AM. FAM. PHYSICIAN 238, 238 (1984).

problems, depression is often attributable to elderly patients taking multiple drugs (polymedication) which complicate and worsen their conditions.<sup>14</sup> Prescribed judiciously, antipsychotic drugs can enhance the physical and psychological well-being of the elderly. However, altered drug disposition makes this age group particularly sensitive to the undesirable side effects discussed above, which can lead to a decline in medical and functional status of the patient and an increased risk of drug interactions.<sup>15</sup> Because of the many deleterious side effects of these drugs, the American Academy of Family Physicians recommends that antipsychotics only be used as a last resort in the management of behavioral problems in the elderly.<sup>16</sup>

The problem of overmedication and excessive use of antipsychotics in nursing facilities continues today despite the myriad legislative measures in the past two decades. In 2009, an investigative report by the Chicago Tribune reviewing more than 40,000 federal and state inspection reports for Illinois' 742 nursing facilities identified 1200 violations involving antipsychotic medications and affecting 1900 residents since 2001.<sup>17</sup> The report identified 12 resident deaths and dozens of incidents where residents broke bones after falling while they were medicated.<sup>18</sup> The recorded reasons for medication were tenuous: one resident was “yelling out” and “easily annoyed;” another resident was “teasing another resident and generally being ‘nasty.’”<sup>19</sup> Similarly, the Boston Globe reported that nearly 28% of all Massachusetts nursing

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<sup>14</sup> See Tina M. Champion, *The Elderly Suing Doctors: Reasons and Recovery*, 12 ALB. L.J. SCI. & TECH. 895, 900 (2002).

<sup>15</sup> See Kiran Rabheru, *Alternatives to Atypical Antipsychotics for the Management of Dementia-Related Agitation*, 25 DRUGS & AGING 381, 383 (2008).

<sup>16</sup> See Ann M. Hamer and John Muench, *Adverse Effects of Antipsychotic Medications*, 81 AM. FAMILY PHYSICIAN 617, 621 (2010).

<sup>17</sup> See Sam Roe, *Compromised Care: Psychotropic Drugs Given to Nursing Home Patients Without Cause*. CHI. TRIB. (Oct. 27, 2009).

<sup>18</sup> See *id.*

<sup>19</sup> See *id.*



home residents were given antipsychotic drugs in 2009 and that 22% of them (2483 residents) did not have a medical condition supporting use of the drug.<sup>20</sup>

Misuse of antipsychotic medications in the treatment or control of nursing home residents is still pervasive, despite the development of suitable alternatives to the use of chemical and physical restraints.<sup>21</sup> In fact, studies performed in the early 1990s indicated that lower rates of restraint use appear to have been achieved with no increase in serious resident injuries, economic costs, or legal liability exposure for the nursing facility.<sup>22</sup> When restraints have been removed and independence and rehabilitation are encouraged as an alternative, the ability of residents to perform daily activities improves.<sup>23</sup> Despite these findings, in 2009, 26.1% of the nation's 1,359,787 nursing home residents still received antipsychotic drugs,<sup>24</sup> frequently for reasons not approved by the FDA.<sup>25</sup>

### III. Federal Legislation

#### A. OBRA '87

Congress devised several solutions to the problem of overmedication with antipsychotic drugs in nursing facilities in the past, beginning with an amendment to the Older Americans Act

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<sup>20</sup> See Kay Lazar, *Nursing Home Drug Use Puts Many at Risk*, BOSTON GLOBE, Mar. 8, 2010.

<sup>21</sup> See Joan M. Dunbar et al., *Don't Restrain: The Education Intervention of the National Nursing Home Restraint Removal Project*, 36 GERONTOLOGIST 539 (1996); Perla Werner et al., *Individualized Care Alternatives Used in the Process of Removing Physical Restraints in the Nursing Home*, 42 J. AM. GERIATRICS SOC'Y 321 (1994).

<sup>22</sup> See e.g., Mary E. Tinetti et al., *Mechanical Restraint Use and Fall-related Injuries among Residents of Skilled Nursing Facilities*, 116 ANNALS INTERN. MED. 369 (1992); Charles D. Phillips et al., *Reducing the Use of Physical Restraints in Nursing Homes: Will It Increase Costs?* 83 AM. J. PUB. HEALTH 342 (1993); Marshall B. Kapp, *Restraint Reduction and Legal Risk Management*, 47 J. AM. GERIATRICS SOC'Y 375 (1999).

<sup>23</sup> See, e.g., Richard R. Neufeld & Joan M. Dunbar, *Restraint Reduction: Where Are We Now?* NURSING HOME ECON., May-June 1997, at 11, 12 (arguing that the ability of residents to participate in daily activities improves when restraints are removed).

<sup>24</sup> See CMS, *MDS Active Resident Information Report: Fourth Quarter 2009, Medications- Days Received the Following Medication – Antipsychotic*, available at [http://www.cms.gov/MDSPubQandResRep/04\\_activeresreport.asp?isSubmitted=res3&var=O4a&date=29](http://www.cms.gov/MDSPubQandResRep/04_activeresreport.asp?isSubmitted=res3&var=O4a&date=29) (last visited Mar. 30, 2011).

<sup>25</sup> See Center for Medicare Advocacy, Inc., *Off-Label Drug Use Is Common and Hurts Nursing Home Residents*, available at <http://www.medicareadvocacy.org/2010/03/off-label-drug-use-is-common-and-hurts-nursing-home-residents/> (last visit Mar. 30, 2011).

of 1965 which made state receipt of federal funds under Title III of the Act contingent upon the state's establishment and adherence to a comprehensive plan in compliance with the Act.<sup>26</sup> Most significantly, Congress incorporated another solution in the Omnibus Budget Reconciliation Act of 1987 (OBRA '87).<sup>27</sup> OBRA '87 included extensive revisions to the statutory Medicare and Medicaid requirements for long-term care facilities, including limiting the use of antipsychotic medications for residents.

The final rules for the application of OBRA '87 promulgated by the Department of Health and Human Services (HHS) in 1991 raised expectations of sweeping reform in the nursing home industry. These rules included implementation of Congressional intent to protect the rights of nursing home residents to freedom from "any physical or chemical restraints imposed for purposes of discipline or convenience."<sup>28</sup> The regulations clarify that freedom from restraint also encompasses the resident's right to refuse treatment.<sup>29</sup> Restraints may only be imposed under a physician's order to treat the resident's medical problems after less restrictive or intrusive interventions have been considered and attempted unsuccessfully, rather than for the purpose of discipline or staff convenience.<sup>30</sup> Similar provisions restricting the permissible scope of physical and chemical restraints appear in the "Resident Bill of Rights" adopted by each state.<sup>31</sup> Although one section of the act sets out minimum "quality of life" standards, requiring that each facility "must provide a safe, clean, comfortable and homelike environment,"<sup>32</sup> these standards fail to cover the decrease in quality of life caused by overmedication and lower functioning associated with antipsychotic drugs.

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<sup>26</sup> See 42 U.S.C. § 3021(c) (1990).

<sup>27</sup> See The Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, 101 Stat. 1330-275.

<sup>28</sup> 42 U.S.C. §1395i-3(c)(1)(A)(ii)(2000).

<sup>29</sup> 42 C.F.R. §483.10(b)(4)(2003).

<sup>30</sup> 42 C.F.R. §483.13(a)(2000); 42 U.S.C.A. §1395i-3(c)(1)(A)(ii); 1396r(c)(1)(A)(ii).

<sup>31</sup> See *Don't Make Them Leave Their Rights at the Door: A Recommended Model State Statute to Protect the rights of the Elderly in Nursing Homes*, 4 CONTEMP. HEALTH L. & POL'Y 321, 322 (1988).

<sup>32</sup> See 42 C.F.R. §483.15(b)(1)(2003).

Although the Federal Nursing Home Reform Amendments (FNHRA), attached to OBRA '87, do not explicitly give a private right of action, such a right is essential to the effectiveness of the statute. Although CMS performs annual inspections of facilities receiving Medicare or Medicaid funding,<sup>33</sup> these visits are insufficient to capture an accurate account of the more subtle issues of overmedication.<sup>34</sup> However, a private right of action would allow patients and their families, parties better situated than CMS to observe negligent and purposeful overuse of antipsychotics, to bring suit and hold nursing facilities liable. The Third Circuit has ruled that the Act does in fact implicitly give nursing home residents the right to bring claims to challenge the quality of their treatment, although other jurisdictions have yet to follow the Court's lead.<sup>35</sup> In *Grammer v. John J. Kane Regional Centers- Glen Hazel*, the Third Circuit held that "language used throughout the FNHRA is explicitly and unambiguously rights-creating."<sup>36</sup> The Court reasoned that federal laws that do not explicitly authorize private causes of action may do so implicitly and furthermore, actions for violations of federal law under 42 U.S.C. § 1983 are "presumptively available" against individuals acting under color of state law.<sup>37</sup> Congress should codify this judicially created private right of action as an amendment to the Act in order to give

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<sup>33</sup> "CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures." 42 C.F.R. §488.9.

<sup>34</sup> U.S. Government Accountability Office (GAO) identified procedural weaknesses and predictable timing of state surveys of nursing homes as leading to understatements of the extent of serious care problems by state surveyors. *Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight*. Report to Congressional Requesters (statement of William J. Scanlon, Director, Health Financing and Public Issues, Health, Education and Human Services Division) (published as GAO-03-561) available at <http://www.google.com/url?sa=t&source=web&cd=1&sqi=2&ved=0CBgQFjAA&url=http%3A%2F%2Fwww.gao.gov%2Fnew.items%2F03561.pdf&rct=j&q=gao%20nursing%20home%20quality&ei=eF-XTc3-HsmE0QHF--j1Cw&usg=AFQjCNGI7yQGM9M0dxaATWlf-Dt6ON4qww&sig2=ueNYxle5n59X99uwGkD5dQ>.

<sup>35</sup> See, e.g., *Duncan v. Johnson-Mathers Health Care, Inc.*, 2010 WL 3000718 (E.D. Ky Jul. 28, 2010) (NO. 5:09-CV-00417-KKC) (holding that the statute's focus is on nursing homes, not the nursing home residents, and therefore an implicit private right of action should not be construed in the statutory language).

<sup>36</sup> 570 F.3d 520, 532 (3<sup>rd</sup> Cir. 2009).

<sup>37</sup> See *id.* (citing *Livadas v. Bradshaw*, 512 U.S. 107 (1994)).

all nursing home residents and their families the ability to make full use of this act in preventing the unnecessary prescription of risky antipsychotics.

## **B. CMS Guidelines**

The Centers for Medicare and Medicare Services (CMS), the agency responsible for regulating nursing homes participating in the Medicare and Medicaid programs, developed interpretive guidelines for fulfilling OBRA requirements which were implemented nationally in 1990.<sup>38</sup> All antipsychotic drugs are subject to the “unnecessary drug” regulation of OBRA. According to the CMS guidelines, “residents must be free of unnecessary drugs” which are defined as those that are “duplicative, excessive in dose or duration, or used in the presence of adverse effects or without adequate monitoring or indication.”<sup>39</sup> Medical, environmental and psychosocial causes of behavioral problems must be ruled out, and nonpharmacologic management must be attempted before antipsychotic drugs are prescribed to nursing home residents.<sup>40</sup> Because treatment with antipsychotic medications is indicated only to maintain or improve functional status, diagnoses and specific target symptoms or behaviors must be documented and the effectiveness of drug therapy must be monitored.<sup>41</sup>

Each nursing home is surveyed annually to ascertain compliance with OBRA and CMS guidelines.<sup>42</sup> Because facilities that do not meet CMS’s legislated requirements may be denied Medicare reimbursement, physicians who prescribe medications for nursing home residents must document the medical necessity of noncompliance with regulations.<sup>43</sup> As a resource for physicians and facilities, a local consultant pharmacist reviews all charts monthly and assists

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<sup>38</sup> See Health Care Financing Administration. *Survey procedures and interpretive guidelines for skilled nursing facilities and intermediate care facilities*. Baltimore: U.S. Dept. of Health and Human Services, 1990.

<sup>39</sup> 42 C.F.R. §483.25.

<sup>40</sup> See *id.*

<sup>41</sup> See *id.*

<sup>42</sup> See *id.*

<sup>43</sup> See *id.*

with compliance.<sup>44</sup> According to the OBRA strategy, the long-term care facility, rather than the prescribing physician, is accountable for monitoring drug use. This approach reflects the realities of nursing home practice, because the prescribing physician only visits the facility occasionally.<sup>45</sup> Despite CMS and state survey activities, weaknesses persist in identifying nursing facility quality-of-care issues. Poor investigation and documentation of deficiencies, limited quality assurance systems, and large number of inexperienced surveyors, as well as predictable survey timing allow nursing facilities to conceal problems from surveyors.<sup>46</sup> Although CMS is working to improve state survey review, federal and state reforms are still poorly balanced and violations by nursing homes continue. More legislative fine-tuning must be undertaken if the elderly in resident care are to be guaranteed protection of their rights.

## C. FDA Regulation

### 1. Off-Label Use

Along with CMS regulation of resident patient care in nursing facilities, the Food and Drug Administration (FDA) also plays a role in regulating antipsychotic treatment. Under the heading of “off-label use,” the FDA allows physicians to use available drugs for indications that are not included in approved labeling without submission of a new drug application.<sup>47</sup> Off-label

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<sup>44</sup> See *id.*

<sup>45</sup> See Rebecca Dresser, *The Curious Case of Off-Label Use*, 37 HASTINGS CTR. REP. 9, 9 (2007).

<sup>46</sup> See *Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight*. Report to Congressional Requesters (statement of William J. Scanlon, Director, Health Financing and Public Issues, Health, Education and Human Services Division) (published as GAO-03-561) available at

<http://www.google.com/url?sa=t&source=web&cd=1&sqi=2&ved=0CBgQFjAA&url=http%3A%2F%2Fwww.gao.gov%2Fnew.items%2Fd03561.pdf&rct=j&q=gao%20nursing%20home%20quality&ei=eF-XTc3-HsmE0QHF--j1Cw&usq=AFQjCNGI7yQGM9M0dxaATWIf-Dt6ON4qww&sig2=ueNYxle5n59X99uwGkD5dQ>.

<sup>47</sup> As long as the physician is well informed about the product and bases the use on firm scientific rationale and sound medical evidence when the intent is the “practice of medicine” without submission of an Investigational New Drug Application (IND), Investigation Device Exemption (IDE) or review by an Institutional Review Board (IRB). See U.S. Food and Drug Administration, “*Off-Label*” and *Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last updated Oct. 18, 2010).

prescriptions are widely used, and comprise approximately 21% of drug use overall.<sup>48</sup> There are three primary types of off-label use: (1) using a drug to treat a condition for which it is not indicated, (2) treating an indicated condition with different doses than those specified on the label, and (3) prescribing a drug for a different patient population than that indicated.<sup>49</sup> Off-label uses of approved medications have not been subjected to the baseline FDA scrutiny required for on-label indications, and are therefore considered riskier.<sup>50</sup> FDA approved primary indicated uses for antipsychotic drugs include treatment of schizophrenia and bipolar disorder.<sup>51</sup> Treatment for dementia in the elderly is one common off-label use of antipsychotics.<sup>52</sup>

Under the Food, Drug, and Cosmetic Act, a drug is misbranded when its labeling does not contain “adequate directions for use.”<sup>53</sup> The FDA cannot approve adequate directions for use until the drug is approved for a particular use or indication based on the FDA’s finding that the drug is safe and effective.<sup>54</sup> A drug that is promoted for an unapproved (off-label) indication or use does not contain “adequate directions for use” because the off-label indication or use is not included in the FDA-approved labeling for the drug. Thus a manufacturer’s promotion of a drug for an off-label use constitutes misbranding of the drug.<sup>55</sup> Although it is improper for a drug company to affirmatively merchandize a drug for an off-label use, doctors may voluntarily

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<sup>48</sup> Anna Wilde Mathews & Avery Johnson, *FDA to Propose Guidelines for ‘Off-Label’ Drug Use*, WALL ST. J. (Feb. 15, 2008).

<sup>49</sup> See U.S. Food and Drug Administration, “*Off-Label*” and *Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last updated Oct. 18, 2010).

<sup>50</sup> See *id.*

<sup>51</sup> See e.g., Label approved on Mar. 1, 2011 for Haldol, NDA no. 015923. U.S. Food and Drug Administration, *FDA Approved Drug Products: Label and Approval History*, available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/015923s086,018701s063lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/015923s086,018701s063lbl.pdf) (last visited Mar. 30, 2011).

<sup>52</sup> Other off-label uses for antipsychotics included treatment of symptoms related to agitation, anxiety, psychotic episodes, obsessive behavior, and behaviors related to dementia and depression. See Marisa E Domino & Marvin S. Swartz, *Who Are the New Users of Antipsychotic Medications?* 59 PSYCHIATR SERV 507, 511 (2008).

<sup>53</sup> 21 U.S.C. §352(f)(1).

<sup>54</sup> 21 U.S.C. §§352,355(a),(d).

<sup>55</sup> See *In re Zyprexa Products Liability Litigation*, 671 F.Supp.2d 397, 414-5 (E.D.N.Y. 2009).

prescribe FDA approved medicines for approved and unapproved uses as they deem appropriate in their professional judgment.<sup>56</sup>

## 2. Black Box Warnings

In addition to its authority to prosecute the misbranding of drugs, the FDA was also given the authority to mandate drug warnings by the Food and Drug Administration Amendments Act (FDAAA) of 2007.<sup>57</sup> Previously, the FDA could only request, but not require that the manufacturer comply with suggested drug warning labeling.<sup>58</sup> An FDA black box warning is ordinarily issued to highlight that there is an adverse reaction<sup>59</sup> sufficiently serious in proportion to the potential benefit from the drug such that it is essential to be considered in assessing the risks and benefits of using that drug.<sup>60</sup> Such warning has been issued for all antipsychotics used to treat the elderly in nursing facilities.<sup>61</sup> No antipsychotics have been approved by the FDA for treating psychosis or agitation in elderly patients with dementia<sup>62</sup>. However, the black-box warning is not a contraindication and clinicians still have the option of using these drugs for dementia patients at their discretion.<sup>63</sup> The focus of the warning was to make physicians aware of the risks of treatment in order to sufficiently inform patients and caregivers of the risks.<sup>64</sup>

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<sup>56</sup> *See id.*

<sup>57</sup> *See* Food and Drug Administration Amendments Act of 2007, Pub.L. 110-85, §1, Sept. 7, 2007, 121 Stat. 823.

<sup>58</sup> *See id.*

<sup>59</sup> The FDA defines serious adverse reaction as fatal, life-threatening or permanently disabling. Food and Drug Administration, *Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075096.pdf> (last updated Jan. 17, 2006).

<sup>60</sup> *See id.*

<sup>61</sup> *See* Food and Drug Administration, *FDA Requests Boxed Warnings on Older Class of Antipsychotic Drugs*, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116912.htm> (last updated June 16, 2008).

<sup>62</sup> *See id.*

<sup>63</sup> *See* Jun Yan, *FDA Extends Black-Box Warning to All Antipsychotics*, 43 PSYCHIATRIC NEWS 1, 1 (2008).

<sup>64</sup> *See* Jane Akre, *FDA Mandates Black Box Warning On Older Antipsychotics*, INJURY BOARD NATIONAL NEWS DESK (June 17, 2008) available at <http://news.injuryboard.com/fda-mandates-black-box-warning-on-older-antipsychotics.aspx?googleid=241940>.



The FDA issued the black box warnings for antipsychotics in response to approximately 15,000 elderly nursing home residents dying each year from the off-label use of antipsychotic drugs for “an indication [for which] FDA knows the drug doesn't work.”<sup>65</sup> A retrospective analysis of the use of anti-psychotic drugs by Medicare beneficiaries in nursing homes in 2000-2001 found the highest rate of antipsychotic drug use in more than a decade.<sup>66</sup> More than a quarter of residents received at least one prescription for antipsychotic drugs and of those, more than half took doses exceeding maximum levels, received duplicative therapy, or had inappropriate indications according to guideline requirements.<sup>67</sup> The atypical antipsychotic drugs were inappropriately used for residents with depression, dementia, and nonaggressive behavior problems. Resident outcomes did not improve with use of the atypical antipsychotics.<sup>68</sup>

In response to these statistics, in 2005, the FDA first issued black box warnings against prescribing atypical antipsychotic drugs for patients with dementia which indicated that the drugs increased dementia patient mortality.<sup>69</sup> In June 2008, the FDA extended its warning to all categories of antipsychotic drugs and explicitly advised health care professionals that “[a]ntipsychotics are not indicated for the treatment of dementia-related psychosis.”<sup>70</sup> Although the FDA's black box warning led to some decrease in the use of antipsychotics for elderly

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<sup>65</sup> See Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply*, 110<sup>th</sup> Cong., First Sess. (March 13, 2007), Serial No. 110-5, page 66 available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_house\\_hearings&docid=f:35502.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_house_hearings&docid=f:35502.pdf).

<sup>66</sup> See Becky A. Briesacher et al., *The Quality of Antipsychotic Drug Prescribing in Nursing Homes*, 165 ARCH INTERN MED. 1280, 1280 (2005),

<sup>67</sup> See *id.*

<sup>68</sup> See *id.*

<sup>69</sup> U.S. Food and Drug Administration, *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances* (April 5, 2005) available at <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm>.

<sup>70</sup> U.S. Food and Drug Administration, *Information for Healthcare Professionals: Conventional Antipsychotics*, FDA Alert (June 16, 2008), available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>.



patients with dementia,<sup>71</sup> more than 29% of newly-admitted residents nursing home residents who were admitted in 2006, after the first black box warning was issued, still received at least one antipsychotic medication that year, more than a third of whom had no identified clinical indication for antipsychotic drug therapy.<sup>72</sup> The percentage of nursing home residents who continue to be treated with antipsychotics off-label indicates that black box warnings standing alone are insufficient to address the problem of over-prescription.

### 3. Pharmaceutical Company Litigation

The extensive use of atypical antipsychotic drugs for nursing home residents may in part be attributed to drug companies' marketing of such off-label uses for residents, as reflected in recent litigation by the United States against drug companies for misbranding antipsychotic drugs. Litigation centered on the atypical antipsychotic drug Zyprexa,<sup>73</sup> manufactured by Eli Lilly and indicated for use in patients with schizophrenia and bipolar disorder.<sup>74</sup> The FDA has never approved Zyprexa for treatment of dementia in the elderly. Zyprexa's current label bears an FDA-mandated black box warning that "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Zyprexa is not approved for the treatment of patients with dementia-related psychosis."<sup>75</sup> Between September 1999 and November 2003, Eli Lilly's long-term care sales force promoted Zyprexa for the treatment of dementia, depression, anxiety, and sleep problems in nursing home residents, despite the lack of

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<sup>71</sup> E. Ray Dorsey et al., *Impact of FDA Black Box Advisory on Antipsychotic Medication Use*, 170 ARCH INTERNAL MED. 96, 97 (2010).

<sup>72</sup> Yong Chen et al., *Unexplained Variation Across US Nursing Homes in Antipsychotic Prescribing Rates*, 170 ARCH INTERNAL MED. 89, 91 (2010).

<sup>73</sup> Generic name Olanzapine, an atypical antipsychotic drug approved for use in the treatment of schizophrenia and bipolar disorder. See PubMed Health, *Drugs and Supplements*, available at <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000161/> (last updated Mar. 16, 2011).

<sup>74</sup> See Label approved on Dec. 1, 2010 for Zyprexa, NDA no. 020592. U.S. Food and Drug Administration, *FDA Approved Drug Products: Label and Approval History*, available at [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory) (last visited Mar. 30, 2011).

<sup>75</sup> See *id.*

FDA approval for those uses.<sup>76</sup> In January 2009, Eli Lilly pleaded guilty to a charge that it illegally marketed the anti-psychotic drug Zyprexa for an unapproved use and agreed to pay \$1.42 billion to settle civil suits and end the criminal investigation.<sup>77</sup>

Eli Lilly's promotion of Zyprexa for these additional intended uses violated 21 U.S.C. §352(f)(1) because Zyprexa's labeling did not bear adequate directions for each of the drug's intended uses.<sup>78</sup> In addition to the government charges for misbranding, over 30,000 cases were brought against Eli Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with Zyprexa.<sup>79</sup> These plaintiffs alleged that they suffered deleterious side effects and that Eli Lilly misled them and their physicians about the likelihood of these side effects which prevented them from making an informed decision about their treatment.<sup>80</sup> Despite the incredibly large criminal and civil penalties accrued by Eli Lilly during the course of litigation and settlement, Eli Lilly received \$36 billion in revenues for Zyprexa between 2000 and 2008, an amount more than 25 times the \$1.42 billion in total penalties paid by the company.<sup>81</sup> As large as the penalties are for drug companies found promoting an off-label use of a drug, the fines are incredibly small in proportion with the companies' annual revenue. Pharmaceutical companies spend around \$800 million to research and develop a new drug and in order to recoup the investment, the companies want doctors to prescribe their drugs as widely as possible.<sup>82</sup> In order to effectively prevent the over-prescription of antipsychotic drugs for off-label use, the

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<sup>76</sup> U.S. Department of Justice, *Pharmaceutical Company Eli Lilly to Pay Record \$1.45 Billion for Off-Label Drug Marketing; Criminal Penalty is Largest Individual Corporate Criminal Fine*, Criminal Information, available at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyinfo.pdf> (News Release Jan. 15, 2009).

<sup>77</sup> *Eli Lilly Agrees to Settle Zyprexa Marketing Cases*, WALL ST. J. ONLINE (Jan. 15, 2009) available at [http://online.wsj.com/article/SB123201838370585347.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB123201838370585347.html?mod=googlenews_wsj).

<sup>78</sup> *See In re Zyprexa Products Liability Litigation*, 671 F.Supp.2d 397, 414 (E.D.N.Y. 2009).

<sup>79</sup> *See In re Zyprexa Products Liability Litigation*, 595 F.3d 113, 119 (2<sup>nd</sup> Cir. 2010).

<sup>80</sup> *See id.*

<sup>81</sup> *See David Evans, When Profit Outweighs Penalties*, WASH. POST (Mar. 21, 2010), available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html?sub=AR>.

<sup>82</sup> *See Joseph A. DiMasi et al., The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003).

FDA must do more than simply toss speeding tickets at pharmaceutical companies. The next step should be to use FDA authority to make liable not only the pharmaceutical company marketing antipsychotics to nursing facilities for dementia patients, but also the facilities themselves for prescribing this risky treatment for resident patients. This will facilitate development of a more coherent body of patient rights in which drug companies and nursing facilities are both responsible for the informed consent and appropriate treatment of nursing home residents.

#### **IV. Informed Consent Doctrine**

Federal legislation defers to state law to determine patient competence to make treatment decisions. State law also determines the degree of process necessary to deprive a patient of these rights.<sup>83</sup> The applicability of OBRA '87 to a specific resident refusing treatment is therefore contingent on whether the individual has been deemed competent to do so as a matter of state law.<sup>84</sup> For this reason, the common law right of informed consent and the related right to refuse unwanted medical treatment are crucial to safeguarding a patient's civil rights. The interaction between a physician and a patient is grounded in the concept of informed consent, which requires competence, knowledge, and voluntariness.<sup>85</sup> Informed consent combines the physician's duty to disclose with a requirement that the consenting individual is capable of understanding the information presented.<sup>86</sup>

##### **A. Patient must be competent in order to give informed consent.**

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<sup>83</sup> 42 U.S.C. §1395i3(c)(1)(C); 42 C.F.R. §483.10(a)(3).

<sup>84</sup> See Ellen J. Scott, *Punitive Damages in Lawsuits Against Nursing Homes*, 23 J. LEGAL MED. 115, 117 (2002).

<sup>85</sup> Involuntary treatment can only be imposed when due process is afforded to the individual being treated. See *Washington v. Harper*, 494 U.S. 210, 225-26 (1990) (requiring due process for involuntary medication of individuals with mental illness).

<sup>86</sup> See Alan Meisel et. al, *Toward a Model of the Legal Doctrine of Informed Consent*, 134 AM. J. PSYCHIATRY, 285, 285 (1977).

A determination of competence must be made before the physician discloses information to the patient. The competency question must be resolved before determining whether a duty of disclosure has been met, because if incompetent, a patient by definition lacks the ability to understand and make informed decisions on the knowledge disclosed, therefore making his consent invalid. Components of competency include: (1) ability to communicate a decision, (2) ability to comprehend material information, (3) ability to understand the situation and its probable consequences, and (4) ability to use the information rationally to make an informed decision.<sup>87</sup> The competence inquiry includes a presumption of competence for patients *accepting* treatment. If a patient agrees with a physician's treatment recommendations, courts rarely if ever question the competency of that patient.<sup>88</sup> However, such inquiries should instead include a rebuttable presumption of competence for patients *refusing* treatment when treatment includes drugs carrying an FDA black box warning for the relevant use. The black box warning indicates that the particular medical intervention has questionable benefits in proportion to significant risks, and therefore the rational decision may very well be to refuse treatment. The burden should instead be shifted to the defendant nursing facility to show patient incompetence in such cases. This reframing of the competency analysis would serve to protect patients from unnecessary use of such risky treatments by easing their burden of proof as plaintiffs, thereby encouraging litigation against offending nursing facilities.

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<sup>87</sup> Paul S. Appelbaum & Thomas Grisso, *Assessing Patients' Capacity to Consent to Treatment*, 319 NEW ENG. J. MED. 1635, 1635-38 (1988).

<sup>88</sup> Erin Talati, *When a Spoonful of Sugar Doesn't Help the Medicine Go Down: Informed Consent, Mental Illness, and Moral Agency*, 6 IND. HEALTH L. REV. 171, 184-185 (2009).

## **B. Patient must be provided with adequate knowledge of the risks and benefits of treatment in order to give informed consent.**

Once the patient is determined to be competent, the next inquiry looks to the content of the information the physician gives the patient with which to make his decision. The knowledge requirement correlates with the physician duty of disclosure. Consent is invalid when given without adequate knowledge of the risks and benefits related to a particular treatment.<sup>89</sup> In many states, a customary practice standard is employed to determine whether the disclosure of information by a physician was sufficient.<sup>90</sup> Under this standard, disclosure is mandatory unless it (1) does not fall within the customary practice of physicians or (2) would violate local or national medical standards.<sup>91</sup> In other states, the focus is on the physician's perspective and judges the sufficiency of the disclosed information based on whether the physician acted as a reasonable physician would have acted under the circumstances.<sup>92</sup> The approach is problematic, however, because of the potential for abuse of discretion and threats to patient autonomy.<sup>93</sup> A majority of states now use the materiality standard, which instead considers what might be important to the decision maker, including risks that would be considered material to the patient in making treatment decisions.<sup>94</sup>

The scope of the duty to disclose becomes especially difficult to define when dealing with

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<sup>89</sup> *Id.* at 193.

<sup>90</sup> 61 AM. JUR. 2d Physicians §174 (2010).

<sup>91</sup> *See id.*

<sup>92</sup> *See id.*

<sup>93</sup> *See* Karp v. Cooley, 493 F.2d 408 (5<sup>th</sup> Cir. 1974) (recognizing that a minority of jurisdictions utilized this materiality approach but affirming the physician perspective view). The patient centered view has since become the majority view. *See* ROBERT D. MILLER, PROBLEMS IN HEALTH CARE LAW 343, 343 (9<sup>th</sup> ed. 2006) (noting that the current majority view is the reasonable patient standard).

<sup>94</sup> *See* Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cr. 1972) (“The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.”)

mental illness. The duty to disclose can be judged either from the physician's perspective or the patient's perspective.<sup>95</sup> Both formulations take into account the difficulty of disclosing every possible outcome in any given treatment and both recognize that the physician cannot be responsible for disclosing more than he knows.<sup>96</sup> The physician perspective standard provides a great deal of deference to the physician's professional judgment in disclosure to patients. One of the problems with this approach is that it allows physicians to refrain from disclosing information that might be relevant to a particular patient if it is not customary under the self-imposed standards of the medical community.<sup>97</sup> With the significant risks imposed by treatment with antipsychotic medication, obtaining consent for treatment if all potential risks were disclosed would likely be incredibly difficult; therefore, it may be customary to disclose only the most life-threatening possibilities even though other possible effects might be material to patient decision-making.<sup>98</sup>

The patient-centered materiality standard is also problematic because it inadequately accounts for variability in symptoms of mental illness. Information that may be deemed relevant by a "reasonably prudent patient" must be disclosed under this standard.<sup>99</sup> At first glance, this standard appears to require a more thorough exchange of information between physicians and patients. However, "reasonable" behavior may differ not only for different mental illnesses and different proposed treatments but also for different individuals with the same illness. Without a method by which to objectively measure disease severity for mental conditions, patients with

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<sup>95</sup> 61 AM. JUR. 2d Physicians §174 (2010).

<sup>96</sup> Erin Talati, *When a Spoonful of Sugar Doesn't Help the Medicine Go Down: Informed Consent, Mental Illness and Moral Agency*, 6 IND. HEALTH L. REV. 171, 185 (2009)

<sup>97</sup> See *Cooper v. Roberts*, 286 A. 2d 647, 650 (Pa. Super. Ct. 1971) (holding that a patient's right to know all material facts pertaining to the proposed treatment cannot be dependent upon the self-imposed standards of the medical profession).

<sup>98</sup> See Talati at 189-190.

<sup>99</sup> See, e.g., *Ball v. U.S.*, 461 F.2d 772; *Unthank v. U.S.*, 732 F.2d 1517 (10<sup>th</sup> Cir. 1984).

mental illnesses are less likely to receive the information they require relative to their level of impairment in order to make an informed decision regarding their treatment.<sup>100</sup>

### **C. Patient decision must be made voluntarily in order to be considered informed consent.**

The final requirement for judging whether a treatment decision was made with informed consent is that the decision be made voluntarily.<sup>101</sup> A decision is considered to be involuntary when “some element is involved that prevents an individual from acting freely.”<sup>102</sup> In order to establish coercion, a party must demonstrate that the patient gave consent which they would not have otherwise given had they not been under duress.<sup>103</sup>

## **V. Proposed Solutions**

In order to provide a solution to the lack of protection for a patient’s right to be free of unnecessary treatment with antipsychotics, adjustments to the existing regime are needed. The multifaceted approach to regulation of patient care in nursing facilities in turn requires a multifaceted solution to its shortcomings. First, at the federal level, Congress should follow the Third Circuit in *Grammer v. Glen Hazel* in reading a private right of action into OBRA ’87 and codify the private right of action so that patients may bring suit for violations of the Act as well under the state law duty to disclose.<sup>104</sup> Second, within the informed consent inquiry under state law, the burden of proof to show competency should be shifted to the defendant facility for instances in which the patient refuses treatment carrying a black box warning. This will give teeth to the FDA-issued warnings, as well as ease the way for plaintiff patients to present their

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<sup>100</sup> See Talati at 190.

<sup>101</sup> See Council on Ethical and Judicial Affairs, *Court-Initiated Medical Treatment in Criminal Cases*, CEJA Report 4-A-98, 3 (American Medical Association, 1998), available at [www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/2065a.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/2065a.pdf) (“informed consent is by definition voluntary.”)

<sup>102</sup> See *id.* (quoting KA Vanderzyl, *Castration As an Alternative to Incarceration: An Important Approach to the Punishment of Sex Offenders*, 15 N. ILL. L. REV. 107 (1994)).

<sup>103</sup> See *id.*

<sup>104</sup> See *Grammer v. John J. Kane Reg’l Ctrs. Glen Hazel*, 570 F.3d 520 (3<sup>rd</sup> Cir. 2009).

case. Third, once competency has been shown, the presence of a black box warning in the treatment regime should create a presumption of materiality of the risks disclosed on the label which therefore must be disclosed to the patient. Fourth, liability for federal and state law violations should be shifted from nurses and physicians to nursing facilities in order to promote adequate staffing and alternatives to antipsychotic drug treatment. Lastly, receipt of Medicare and Medicaid funding should be contingent upon the phasing in of requirements for emphasis on non-drug related behavioral treatment with increased personal care. Such requirements could include mandatory training or an employee exchange program at facilities that currently employ such techniques, government grants to fund the upfront costs of implementing additional training and alternative therapies to be off-set by the reduction in spending on unnecessary drug treatment.

#### **A. Congress should create a private right of action under OBRA '87.**

Congress should follow the Third Circuit in *Grammer v. Glen Hazel* and create a private right of action into OBRA '87 so that patients may bring suit for violations of the Act as well under the state law duty to disclose. As the Court noted in *Grammer*, the Federal Nursing Home Reform Acts (FNHRA) are “replete with rights-creating language.”<sup>105</sup> The amendments confer upon nursing home residents the right to choose their personal attending physicians, to be fully informed about and to participate in their treatment, to be free from abuse and to voice grievances and to enjoy privacy and confidentiality.<sup>106</sup> Nursing homes are required to care for residents in a manner promoting quality of life and provide services and activities to maintain the highest practicable physical and mental well-being of residents.<sup>107</sup> The statute also specifically

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<sup>105</sup> *Id.* at 529.

<sup>106</sup> 42 U.S.C. §1396(c)

<sup>107</sup> 42 U.S.C. §1396(b)



guarantees nursing home residents the right to be free from chemical restraints imposed for the purposes of discipline or convenience and not required to treat their medical symptoms.<sup>108</sup> However, only a small minority of states have created greater protection for nursing home residents through legislation that imposes liability on facilities for violation of regulations.<sup>109</sup> Attorney's fees and the cost of litigation alone can prevent residents from pursuing a claim against a nursing home. By creating a statutory cause of action for violations of regulatory standards, the need to establish the standard of care and its violation is simplified and may reduce litigation costs for potential plaintiffs. This in turn may increase nursing facility compliance with the FNHRA and ensure more effective protection for the patient rights specified in the legislation.

### **B. Burden of proof in competency inquiry should be shifted from patient to defendant facility.**

Under the state law doctrine of informed consent, the burden of proof to show patient competency should be shifted to the defendant facility for instances in which the patient refuses treatment carrying a black box warning. This will give teeth to the FDA-issued warnings, as well as ease the way for plaintiff patients to present their case. As discussed above, determination of competence should be made prior to disclosure of information.<sup>110</sup> The competency question must be resolved before determining whether a duty of disclosure has been met, because if incompetent, a patient by definition lacks the ability to logically understand and incorporate the knowledge disclosed, therefore making his consent invalid. Currently, the competency inquiry includes a presumption of competence for patients accepting treatment. However, such inquiries should instead include a rebuttable presumption of competence for

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<sup>108</sup> 42 U.S.C. §1396r(c)(1)(A)(ii)

<sup>109</sup> Ellen J. Scott, *Punitive Damages in Lawsuits Against Nursing Homes*, 23 J. LEGAL MED. 115, 128 (2002).

<sup>110</sup> See the competency requirement discussion, *supra* part III.

patients *refusing* treatment when treatment includes drugs carrying an FDA black box warning for the relevant use. Such reframing of the competency analysis would serve to protect patients from unnecessary use of such risky treatments. If OBRA '87 provided an explicit right to nursing home residents to refuse medication in all but the most extreme cases, the result would be a uniformly high standard. This might tie the hands of physicians to effectively treat patients, and possibly cause delays in treatment and lower quality of care in nursing facilities because doctors would not want to risk the increased liability of treating resident patients. However, creating a rebuttable presumption of competency for refusal of medication carrying black box warnings is a more narrowly tailored heightening of the standard and would avoid many of problems of a uniformly high standard.

### **C. Risks indicated in a black box warning should be presumed material to patient decision-making under the knowledge inquiry.**

As discussed above, under the informed consent doctrine, the physician has a duty to disclose information material to the patient's decision-making process.<sup>111</sup> Consent is only considered informed when the patient is given adequate knowledge of the material risks and benefits of the proposed treatment. The materiality standard considers what might be important to the decision-making patient, including risk that would be considered material to the patient in determining whether the proposed treatment should be undertaken.<sup>112</sup> The presence of an FDA black box warning in the treatment regimen should create a presumption that the risks disclosed on the label are material and therefore must be disclosed to the patient.

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<sup>111</sup> See the knowledge requirement discussion, *supra* part III.

<sup>112</sup> See *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cr. 1972) (“The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.”)

In promoting off-label use of drugs, pharmaceutical companies often reward physicians to incentivize prescribing their drugs.<sup>113</sup> Because the FDA has no authority to regulate physician prescription of drugs for off-label uses, patient rights are left in the hands of the informed consent doctrine under state law for protection. However, most doctors do not keep track of FDA-approved drug uses.<sup>114</sup> Therefore, in order to give teeth to FDA regulation in this area, state law informed consent doctrine should incorporate FDA regulations in order to target both drug company promotion and physician prescribing practices. If the risks disclosed in the FDA black box warning on the label are presumed material, the defendant nursing facility will not be able to show informed consent if the patient has not been informed about these risks before agreeing to treatment. Under this doctrine, even though the FDA has no authority over physicians, pharmaceutical companies will no longer be as successful in getting physicians to prescribe drugs with black box warnings for off-label uses because the physicians will be required to inform the patients of the risks listed on the warning. The physician community will have to take responsibility to perform their own due diligence about a drug beyond the information they receive from a pharmaceutical representative. However, this doctrine would still allow physicians to use their professional judgment without undue judicial interference.

**D. Liability should be shifted from nurses to the nursing facility in order to facilitate non-drug related treatment.**

Situations often occur in which a nursing home is understaffed and the nursing home is unable or unwilling to alleviate the situation for the nurses working the facility. The availability of additional care should be incentivized both positively, in the form of tax breaks and

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<sup>113</sup> For example, Pfizer's marketing program offered doctors up to \$1000 a day to allow a Pfizer salesperson to spend time with the physician and his patients in order to promote a new drug over a period of many hours. See David Evans, *When Profit Outweighs Penalties*, WASH. POST (Mar. 21, 2010), available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html?sub=AR>.

<sup>114</sup> See *id.* at 2.

reimbursement benefits, as well as negatively, by shifting liability from the nurses and treating physicians to the nursing home facility itself if the facility does not provide sufficient staffing to allow alternate treatments to be available to patients suffering from behavioral problems associated with dementia. Reducing nurse stress from understaffing will also increase focus and quality of care.<sup>115</sup> Although nursing homes are required to maintain “sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident,” no specific number of required staff members is stated.<sup>116</sup> This ambiguity allows nursing homes to continue to understaff their facilities.<sup>117</sup> Additional nursing facility liability for proximately caused injuries by an employee or the facility itself would focus on the institution and the way it operates instead of on individual nurses and physicians. This would also incentivize residents and their families to act as private attorneys general in prosecuting nursing facility violations. Such litigation would create a larger potential cost for understaffing, which would in turn incentivize nursing facilities to provide adequate staffing in order to avoid litigation costs. Nurses working in adequately staffed facilities with a reduced threat of litigation against them as individual parties may be less likely to favor antipsychotic drug therapy in response to behavioral problems, a quick-fix but problematic method of treatment, and instead begin to shift towards personal care.

**E. Receipt of Medicare and Medicaid funding should be contingent upon the phasing in of requirements for emphasis on non-drug related treatment.**

Antipsychotic drugs are still overused in long-term care, and become perpetuated to treat behaviors associated with dementia. Although powerful cocktails of antipsychotic drugs

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<sup>115</sup> Miranda Richard, *Protecting Nurses from Liability for Negligence When Their Nursing Home is Understaffed*, 3 INTERNET J. OF LAW, HEALTHCARE & ETHICS 1, 4 (2005).

<sup>116</sup> *Id.*

<sup>117</sup> 42 C.F.R. §483.30 (1992).

have become the standard of care for nursing home patients with unmanageable behavior, some nursing homes use alternative treatments that focus instead on intensive staff training to mitigate resident dementia-related behavioral problems. Ecumen's Awakenings project in Minnesota is one example of nursing homes that have embraced this approach.<sup>118</sup> The facility trains its entire staff to use tools to calm and reassure residents through exercise, music, massage, and aromatherapy without resorting to pharmacological intervention.<sup>119</sup> Despite the availability of this treatment option, nursing homes continue to rely on drug treatments because the alternative is both labor-intensive and expensive.<sup>120</sup> In spite of these drawbacks, the program enabled every resident on antipsychotics to discontinue treatment, and almost half of patients taking antidepressants were able to discontinue medication as well.<sup>121</sup>

In light of the success of the Ecumen Awakenings project, alternative treatment options should be incentivized for all federally funded nursing facilities. However, mere education about reducing antipsychotic drug prescribing for nursing home patients is not enough to reduce this practice.<sup>122</sup> Medicare and Medicaid funding should be made contingent upon the recipient facility shifting treatment emphasis to alternative, nonpharmacologic care in order to ensure action. Although the government may have to provide subsidies at the onset in order to assist nursing facilities in the transition, these costs would be offset by the resulting decrease in national spending on medication. Currently, one in four nursing home residents receives

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<sup>118</sup> See also Eva S. van der Ploeg and Daniel W. O'Connor, *Evaluation of Personalized, One-to-One Interaction Using Montessori-Type Activities as a Treatment of Challenging Behaviors in People with Dementia: the Study Protocol of a Crossover Trial*, 10 BMC GERIATRICS 1 (2010).

<sup>119</sup> Paula Span, *Clearing the Fog in Nursing Homes*, N.Y. TIMES (Feb. 15, 2011, 11:10 AM), <http://newoldage.blogs.nytimes.com/2011/02/15/clearing-the-fog-in-nursing-homes/>.

<sup>120</sup> Ecumen estimates that introducing the program to a 60-bed nursing home cost an additional \$75,000 a year for two full-time employees. See *id.*

<sup>121</sup> *Id.*

<sup>122</sup> See Wayne A. Ray et al., *Reducing Antipsychotic Drug Prescribing for Nursing Home Patients, a Controlled Trial of the Effect of an Educational Visit*, 77 AM. J. PUBLIC HEALTH 1488 (1987) (concluding that visits to frequent antipsychotic drug prescribers by a trained physician counselor who stressed known drug risks for elderly patients and suggested techniques for reducing antipsychotic drug use, although well-received, did not reduce antipsychotic drug prescribing).

antipsychotic drugs, with sales in 2007 totaling over \$13 billion.<sup>123</sup> The dramatic rise in the costs of prescription drugs over the past decade is in large part due to second generation antipsychotics, which now make up a substantial proportion of increased national spending on medication.<sup>124</sup> Because many patients treated with antipsychotics are severely disabled, Medicare and Medicaid are the largest buyers of the drugs.<sup>125</sup> If the care-centered non-pharmacologic approach can successfully reduce nursing facility dependence on antipsychotics to control resident behavioral problems, then the costs to government programs will significantly decrease.<sup>126</sup> The difference in patient quality of life under a non-drug treatment regimen is incredibly significant, and the national government should take affirmative steps to achieve these results in every nursing facility in America.

## VI. Conclusion

The current framework in place to protect nursing home patient rights is complex and yet full of gaps which have allowed nursing facilities to continue to overprescribe risky antipsychotic drugs for dementia-related behavioral problems. The tools with which to correct this problem are already provided in OBRA '87, in the FDA's regulatory authority, and in the state law doctrine of informed consent. However, under the current regime, these bodies of law fit disjointedly. The adjustments to the existing system suggested by this paper are meant to develop coherence between these bodies of law in order to strengthen them into a single unified approach to protecting patient rights. All of these steps are means to an end in which nursing facilities are

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<sup>123</sup> Kris Hundley, *Dementia Relief, with a Huge Side Effect: The Off-Label Use of Some Drugs Is Helping*, TAMPA BAY TIMES (Nov. 18, 2007).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> Stephanie Kirbach, et al., *A Markov Model of the Cost Effectiveness of Olanzapine treatment for Agitation and Psychosis in Alzheimer's Disease*, 28 CLINICAL DRUG INVESTIGATION 291, 298 (2008). Total 13-year cost for a patient with Alzheimer's disease with high levels of behavioral disturbance receiving treatment with olanzapine, a frequently prescribed atypical antipsychotic, was about \$4000 higher than treatment without olanzapine.

sufficiently staffed with trained care providers able to address resident behavioral problems with personal care to calm and reassure residents, instead of overmedicating them into a barely cognizant haze. A shift away from overmedicating with antipsychotics in nursing home patient care will both stem the dramatic rise in national spending on prescription drugs as well as increase the quality of life for the elderly.