

# Misuse of Antipsychotic Drugs in Nursing Homes: Are We Making Any Progress?

The recent settlement of criminal and civil charges against Johnson & Johnson for off-label marketing of Risperdal for nursing home residents once again brings the issue of antipsychotic drugs and nursing homes to public attention. A group of residents' advocates working to reduce the inappropriate use of antipsychotic drugs in nursing facilities recently issued a joint Statement about the settlement.[1] This Alert discusses the Johnson & Johnson settlement and three additional developments that are troubling to advocates who describe the misuse of antipsychotic drugs as a form of elder abuse. These developments are:

- Recent data from the Centers for Medicare & Medicaid Services (CMS) indicating that nursing facilities have fallen far short of the goal set in July 2012 for reducing the inappropriate use of antipsychotic drugs;
- The Inspector General's cancellation (as a result of sequestration) of a study of antipsychotic drug use in nursing homes; and
- CMS' decision not to require that consultant pharmacists (required by the federal Nursing Home Reform Law) be independent of long-term care pharmacies and pharmaceutical manufacturers.

## Background

The misuse and overuse of antipsychotic drugs in nursing homes have been recognized as serious problems for many decades.[2] In December 2007, Lucette Lagnado brought attention to atypical antipsychotic drugs in her *Wall Street Journal* article "Prescription Abuse Seen In U.S. Nursing Homes; Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense." [3] Lagnado reported that the drugs, while intended for only a small portion of the population, were often used instead as a substitute for adequate nurse staffing levels. The Office of Inspector General analyzed the use of atypical antipsychotic drugs in nursing facilities and found in 2011 that more than 90% of the atypical antipsychotic drug use violated one or more federal laws (*i.e.*, is prescribed off-label or is otherwise illegal).[4]

## Johnson & Johnson Settlement

On November 4, 2013, the U.S. Department of Justice announced that Johnson & Johnson, in a global settlement, had agreed to pay more than \$2.2 billion dollars to resolve criminal and civil charges involving the misuse of antipsychotic drugs. Johnson & Johnson was alleged to have engaged in off-label marketing of the atypical antipsychotic drug Risperdal for nursing home residents who have dementia, but no diagnosis of psychosis, and to have paid kickbacks to physicians and pharmacists to prescribe Risperdal.[5]

A criminal information, to which a Johnson & Johnson wholly-owned subsidiary pleaded guilty, charged the company with directing its ElderCare sales force, from May 1, 1998 through November 2005, to market Risperdal for use with nursing home residents who had dementia.[6] Marketing materials emphasized use of the drug to treat symptoms, despite the Food and Drug Administration's (FDA) approval of Risperdal solely for patients with a diagnosis of schizophrenia and the FDA's Black Box warnings for both atypical and conventional antipsychotic drugs (warning that antipsychotic drugs may cause the death of older people with dementia).

A related civil complaint charged the company with providing false and misleading information about Risperdal and paying kickbacks to physicians to prescribe the drug. The civil settlement also resolved allegations made in a separate 2010 lawsuit that Johnson & Johnson paid kickbacks to Omnicare, the largest pharmacy company in the country serving nursing homes, "under the guise of market share rebate payments, data-purchase agreements,

'grants' and 'educational funding'" and that Omnicare treated its consultant pharmacists as part of its sales force to promote off-label use of Risperdal.

On November 4, 2013, *The New York Times* reported that Risperdal was among Johnson & Johnson's top-selling drugs, accounting for \$3.1 billion in sales (and 5% of the company's revenues) in 2004.[7] In the past five years, the *Times* reported, other drug companies have settled similar cases with the Federal Government for marketing antipsychotic drugs for nursing home residents – Eli Lilly (Zyprexa) and AstraZeneca (Seroquel).[8]

*The Wall Street Journal* reported that in 2011, Medicare Part D (Medicare's prescription drug program) spent \$7.68 billion on antipsychotic drugs (not all for nursing home residents and not including Medicare Part A spending for residents), an increase from \$4.5 billion in 2007.[9]

### **Partnership to Improve Dementia Care Goal Not Met**

In March 2012, the Centers for Medicare & Medicaid Services initiated a campaign (with nursing facilities, ombudsman programs, Quality Improvement Organizations, and others) to reduce the misuse of antipsychotic drugs in nursing homes. As part of its *Partnership to Improve Dementia Care in Nursing Homes*, CMS set a goal of reducing antipsychotic drug use for long-stay residents by 15% by the end of calendar year 2012.[10] The 15% reduction meant that the rate of antipsychotic drug use would be reduced from 23.9% in July 2012 to 20.2% by the end of 2012.[11]

When the goal was not reached in 2012, CMS continued the goal for calendar year 2013. As reported by *The Wall Street Journal*, the decline from 23.9% to 21.7% (as of March 31, 2013) represented only a 9% decrease in the use of antipsychotic drugs.[12] More recently, CMS reported in October 2013 that, as of June 30, 2013, the antipsychotic drug rate for long-stay residents was 21.14%, still far above the initial goal that CMS set for December 2012. The 21.14% rate means that more than one-in-five residents nationwide – more than 300,000 people – continue to be given antipsychotic drugs.

### **Inspector General's Cancellation of Audit**

In its Fiscal Year 2013 Work Plan, the Office of the Inspector General (OIG), Department of Health and Human Services, described a proposed study of nursing homes' use of antipsychotic drugs – specifically, "nursing homes' administration of atypical antipsychotic drugs, including the percentage of residents receiving these drugs and the types of drugs most commonly received" and a description of "the characteristics associated with nursing homes that frequently administer atypical antipsychotic drugs." [13] However, in July 2013, the Center for Public Integrity reported that, as a result of sequestration and the loss of 20% of its workforce, OIG cancelled the antipsychotic drug project, among others.[14]

### **CMS' Decision Not to Require the Independence of Consultant Pharmacists**

The federal Nursing Home Reform Law requires facilities to employ or obtain the services of a consultant pharmacist to review each resident's entire drug regimen monthly and to make recommendations to the attending physician.[15]

The Reform Law also requires the attending physician to respond to the consultant pharmacist's recommendations.[16]

Describing the role of consultant pharmacists, CMS reports that physicians adopt the recommendations of consultant pharmacists in 74% of cases, and that long-term care pharmacies often provide consultant pharmacist services as part of their contracts with facilities, often at cost and below fair market value.[17] Accordingly, CMS indicated in the Federal Register in October 2011 that it was considering requiring that consultant pharmacists be independent of long-term care pharmacies and pharmaceutical manufacturers.[18]

Although CMS reported receiving overwhelming evidence from commenters that conflict-of-interest problems are pervasive and serious, and concluded that changes were necessary to assure the independence of consultant

pharmacists, CMS did not act on its proposed recommendation.[19] Instead, it stated that requiring independent consultant pharmacists would not solve the entire problem of the misuse of antipsychotic drugs and would be "significantly disruptive for much of the LTC industry." [20] CMS declined to publish rules requiring the independence of consultant pharmacists and called on the long-term care industry, voluntarily, to adopt changes, but warned, "[s]hould marked improvement in inappropriate utilization not occur, we will use future notice and comment rulemaking to propose requirements to address these concerns." [21]

## Conclusion

Inappropriate use of antipsychotic drugs by nursing facilities remains a significant problem. While this misuse is slowly declining, CMS must do more to protect the more than 300,000 residents who are given these drugs. The failure to act more aggressively risks the life and health of nursing facility residents and adds to the spiraling cost of nursing home care.

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[1] See Statement at <http://www.medicareadvocacy.org/2-2-billion-johnson-johnson-settlement-sends-new-warning-antipsychotic-drugs-should-not-be-used-to-treat-dementia/>.

[2] See Center for Medicare Advocacy (the Center), "Antipsychotic Drugs," <http://www.medicareadvocacy.org/medicare-info/skilled-nursing-facility-snf-services/antipsychotic-drugs/>. In addition, the Center recently completed, with Dean Lerner Consulting, a study of antipsychotic drug deficiencies in seven states, finding that 95% of antipsychotic drug deficiencies are cited as causing "no harm" to residents. Additional findings of this study will be reported in a future Weekly Alert.

[3] <http://online.wsj.com/news/articles/SB119672919018312521>.

[4] OIG, *Medicare Atypical antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011), <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>.

[5] U.S. Department of Justice, "Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations," (News Release, Nov. 4, 2013), <http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html>.

[6] <http://www.justice.gov/opa/documents/jj/janssen-info.pdf>.

[7] Katie Thomas, "J.&J. to Pay \$2.2 Billion in Risperdal Settlement," *The New York 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).

[8] *Ibid.*

[9] Lucette Lagnado, "Nursing Homes' Drug Use Falls; Effort to reduce use of antipsychotic drugs falls short of goal," *The Wall Street Journal* (Aug. 27, 2013), <http://www.lucettelagnado.com/news/nursing-homes-drug-use-falls>.

[10] CMS, *Description of Antipsychotic Medication Quality Measures on Nursing Home Compare*, <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/AntipsychoticMedicationQM.pdf>.

[11] In announcing the goal, CMS stressed that the 15% reduction was just a beginning: "The initial target for the national partnership was to ensure that we made rapid progress and put systems and infrastructure in place to continue to work toward lower antipsychotic medication use. It does not mean that we believe that a rate of 20.3% is acceptable. We will set 2013 goals with our partners toward the end of 2012." *Description of Antipsychotic Medication Quality Measures on Nursing Home Compare*, <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/AntipsychoticMedicationQM.pdf>.

[12] Lucette Lagnado, "Nursing Homes' Drug Use Falls; Effort to reduce use of antipsychotic drugs falls short of goal," *The Wall Street Journal* (Aug. 27, 2013), <http://www.lucettelagnado.com/news/nursing-homes-drug-use-falls>.

[13] HHS Office of Inspector General, *HHS OIG Work Plan FY 2013*, <https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf>.

[14] The Center for Public Integrity, Fred Schulte, "ObamaCare oversight among health watchdog cuts; Budget squeeze, staff departures force HHS inspector general to trim investigative targets" (July 25, 2013), <http://www.publicintegrity.org/2013/07/25/13048/obamacare-oversight-among-health-watchdog-cuts>. See also Fred Schulte, "Advocates for nursing home reform push back against proposed health watchdog cuts; Groups alarmed by

IG's plans to scrap audit of how drugs are prescribed for patients" (Aug. 1, 2013),

<http://www.publicintegrity.org/2013/08/01/13091/advocates-nursing-home-reform-push-back-against-proposed-health-watchdog-cuts>

[15] 42 C.F.R. §483.60(c).

[16] *Ibid.*

[17] 76 Fed. Reg. 63017, 63038-63041 (Oct. 11, 2011), <http://www.gpo.gov/fdsys/pkg/FR-2011-10-11/pdf/2011-25844.pdf>.

[18] *Ibid.*

[19] 77 Fed. Reg. 22071, at 22110-22107 (Apr. 12, 2012), <http://www.gpo.gov/fdsys/pkg/FR-2012-04-12/pdf/2012-8071.pdf>.

[20] 77 Fed. Reg., 22106.

[21] 77 Fed. Reg., 22106.