



UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
OVERPRESCRIBED: THE HUMAN AND TAXPAYERS' COSTS OF
ANTIPSYCHOTICS IN NURSING HOMES

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The misuse of antipsychotic drugs as chemical restraints is one of the most common and longstanding, but preventable, practices causing serious harm to nursing home residents today. We thank the Senate Special Committee on Aging for holding today's hearing.

In May 2011, the Inspector General of the Department of Health and Human Services issued a report indicating that

- 304,983 elderly nursing home residents (14%) received atypical antipsychotic drugs between January 1 and June 30, 2007, at a cost of hundreds of millions of dollars for the six-month period;
- 83% of the claims were for off-label conditions, including 88% for conditions specified in the black-box warning given to antipsychotic drugs by the Food and Drug Administration (FDA).¹

¹ Office of Inspector General, Department of Health and Human Services, *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>. In April 2005, the FDA issued "black box" warnings against prescribing atypical antipsychotic drugs for patients with dementia, cautioning that the drugs increased dementia patients' mortality. FDA, "Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances" (April 5, 2005), <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm>. In June 2008, the FDA extended its warning to all categories of antipsychotic drugs, conventional as well as atypical, and directly and unequivocally advised health care professionals, "Antipsychotics are not indicated for the treatment of dementia-related psychosis." FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm>.

The Inspector General's report actually understates the inappropriate use of antipsychotic drugs with nursing home residents because it does not evaluate the inappropriate use of conventional antipsychotics drugs, which are still used in nursing facilities. Nursing facilities' self-reported data, publicly reported by the Centers for Medicare & Medicaid Services (CMS), indicate that in the third quarter of 2010, 26.2% of residents received an antipsychotic drug in the previous seven days.² Facilities reported to CMS that they gave antipsychotic drugs to many residents who did not have a psychosis or related condition, including 39.4% of residents at "high risk" of receiving antipsychotic drugs because of "behavior problems."³

As Inspector General Daniel Levinson wrote in a May 9, 2011 statement, "Too many [nursing homes] fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use."⁴ He concluded, "Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions."⁵

We agree with General Levinson that the misuse of antipsychotic drugs with nursing home residents who suffer from dementia is outrageous. But what is even more shocking is that this problem is not new. More than twenty years ago, this Committee held a Workshop on "Reducing the Use of Chemical Restraints in Nursing Homes" that identified the same issues we are discussing today.⁶ Several months later, in February 1992, in the preamble to proposed regulations that would have given residents new protections from chemical restraints, the Health Care Financing Administration (HCFA) (predecessor agency to CMS) described the long-standing and "significant public health problem in many, but not all of this nation's long-term care facilities."⁷ The problem described by HCFA was, even then, more than 15 years old:

For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with the subject have appeared in a number of medical journals. These papers generally question the extent of the use

² CMS, "MDS Active Resident Information Report: Third Quarter 2010,"

http://www.cms.gov/MDSPubQandResRep/04_activeresreport.asp?isSubmitted=res3&var=O4a&date=32.

³ CMS, "Psychotropic Drug Use – July/September 2010,"

http://www.cms.gov/MDSPubQandResRep/02_qmreport.asp?isSubmitted=qm3&group=10&qtr=23.

⁴ Daniel R. Levinson, "Overmedication of Nursing Home Patients Troubling" (Statement, May 9, 2011), http://www.oig.hhs.gov/testimony/levinson_051011.asp.

⁵ *Id.*

⁶ Senate Special Committee on Aging, *Reducing the Use of Chemical Restraints in Nursing Homes*, (Workshop, July 22, 1991), <http://aging.senate.gov/publications/7221991.pdf>.

⁷ 57 Federal Register 4516, 4519 (Feb. 5, 1992), 1992 West Law 17302 (F.R.).

of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.⁸

Since at least 1975, we have been on notice as a country that nursing home residents have been overmedicated with antipsychotic drugs. Yet the problem persists. It is long past time to change this shameful record.

The Nursing Home Reform Law prohibits the antipsychotic drug practices that we see in too many nursing homes

The federal Nursing Home Reform Law, enacted in 1987, limits the use of psychopharmacologic drugs. The law expressly provides:

Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.⁹

Implementing regulations explicitly limit the use of antipsychotic drugs (under a subsection of the regulations entitled Unnecessary Drugs):

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.¹⁰

The federal regulations also require monthly review of each resident's entire drug regimen by a pharmacist, who must report "irregularities":

(c) *Drug regimen review.* (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.¹¹

⁸ *Id.*

⁹ 42 U.S.C. §§1395i-3(c)(1)(D), 1396r(c)(1)(D), Medicare and Medicaid, respectively.

¹⁰ 42 C.F.R. §483.25(1)(1).

CMS guidance to surveyors in the State Operations Manual¹² encourages facilities to use non-pharmacological alternatives, identifies situations where antipsychotic medications are not indicated,¹³ and provides an investigative protocol for unnecessary drugs, including antipsychotic drugs.

Despite these strong provisions, antipsychotic drug use remains a serious concern, in part because the law, regulations, and surveyor guidance are inadequately and ineffectively enforced. Stronger enforcement of these standards would make an enormous difference.

Changing current practice is an important goal of residents' advocates, as demonstrated by the Resolution passed this month by members of the National Consumer Voice for Quality Long-Term Care (Consumer Voice). (The resolution is attached to my testimony.)

Why antipsychotic drugs are inappropriately prescribed for nursing home residents

There are many reasons why antipsychotic drugs are inappropriately prescribed for nursing home residents who have dementia, despite the strong statutory and regulatory protections against such use.¹⁴ I offer several additional reasons here.

Nursing facilities have insufficient numbers of appropriately trained staff

The most significant cause of the inappropriate use of antipsychotic drugs is the serious understaffing in nursing facilities.¹⁵ Most facilities do not have enough staff and enough staff with specialized and professional training to meet the needs of their residents who have dementia.

This point was bluntly made by the American Society of Consultant Pharmacists (ASCP). In a Policy Statement about "Use of Antipsychotic Medications in Nursing Facility Residents," issued in response to the Inspector General's May 2011 report, ASCP

¹¹ 42 C.F.R. §483.60(c).

¹² State Operations Manual, Appendix PP,

https://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf (scroll down to page 344 for the beginning of guidance for §483.25(l)).

¹³ *Id.* 386 ("1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under 'indications' and do not represent a danger to the resident or others").

¹⁴ See David S. Sherman, "Psychoactive Drug Misuse in Long-Term Care: Some Contributing Factors," *Journal of Pharmacy Practice*, Vol. 1, No. 3 (Dec.), 1988: 198-194. Mr. Sherman identifies, among other reasons, "the desire to help residents," "belief in psychoactive drug efficacy," "underestimation of drug toxicity," "family concerns," "nursing staff stress," "inadequate training," and "influence of drug manufacturers." Many of these reasons remain valid today.

¹⁵ Lucette Lagnado, "Prescription Abuse Seen In U.S. Nursing Homes; Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense," *Wall Street Journal* (Dec. 4, 2007). This article, which led to Senator Charles Grassley's requesting review by the Office of Inspector General, cited a statement by Bruce Pollock, president-elect of the American Association of Geriatric Psychiatry, that high use of antipsychotic drugs in a nursing facility can reflect inadequate staffing.

acknowledges that “non-pharmacological approaches are generally preferred as initial therapy when possible,” but then states:

Nursing homes have evolved to the point where the vast majority of residents have one or more mental health problems, yet few nursing homes have staff with specialized training in psychology or behavior management. The result is that medications have become the dominant approach to management of BPSD [Behavioral and Psychological Symptoms of Dementia].¹⁶

Jonathan Evans, M.D., incoming president of the American Medical Directors Association, has called for “a different paradigm” – a recognition that “behavior is communication, . . . not a disease.”¹⁷ He urges that caregiving staff learn new methods to figure out the meaning of residents’ behaviors and to address the behaviors creatively, without drugs.

Two additional staffing issues – the enormous turnover in staff and lack of consistent assignment of staff to residents – both contribute to the inappropriate medication of residents with antipsychotic drugs in order to address behavior issues. When staff do not know the residents they are caring for, they are less able to recognize and understand residents’ non-verbal communications or changes in condition that could warrant a care intervention.

Physical restraints are used less often

General recognition that physical restraints are not appropriate has led nursing facilities to use drugs as an alternative way to deal with residents with behavior issues. When the 1987 Nursing Home Reform Law was implemented in 1990, the federal government made a strong effort through the survey and certification system to reduce the use of physical restraints. Strong federal regulations and guidance were supported by residents’ advocates’ and nursing facilities’ recognizing the dangers of physical restraints and promoting alternative methods of care. While physical restraints are still used far more widely than they should be, they are less common than they were 20 years ago. But physical restraints have been replaced by less visible chemical restraints.

Some drug companies have engaged in illegal off-label marketing of antipsychotic drugs for nursing home residents

The aggressive off-label marketing of antipsychotic drugs, especially the atypical antipsychotic drugs that were promoted as having fewer side effects than conventional

¹⁶ American Society of Consultant Pharmacists, “Use of Antipsychotic Medications in Nursing Facility Residents” (Policy Statement), <https://www.ascp.com/sites/default/files/ASCP-antipsychotics-statement.pdf>.

¹⁷ Jonathan Evans, MD, MPH, CMD, “The Ethics of Antipsychotics in Alzheimer’s,” *Caring for the Ages* (May 1, 2011), <http://www.caringfortheages.com/issues/may-2011/single-view/the-ethics-of-antipsychotics-in-alzheimers/ba6ff721b07f61a5d15888345dd9e1bc.html/>.

antipsychotic drugs, led to their expanded use after a brief period of declining use.¹⁸ To cite one example: In January 2009, the Eli Lilly Company settled civil and criminal charges under the federal False Claims Act, paying \$1.45 billion in civil and criminal fines.¹⁹ The United States alleged that between September 1999 and March 31, 2001, the company engaged in off-label promotion of Zyprexa “as treatment for dementia, including Alzheimer’s dementia.”²⁰ Eli Lilly had trained its long-term care sales force to promote Zyprexa for the treatment of dementia, depression, anxiety and sleep problems in nursing home and assisted living residents.

Consultant pharmacists often work for long-term care pharmacies

Consultant pharmacists, who are critical to implementing the federal provisions governing drug regimen review, have not been independent.

One example: In January 2010, the United States sued drug manufacturer Johnson & Johnson for paying kickbacks to Omnicare, the nation’s largest nursing home pharmacy, so that Omnicare’s pharmacists would recommend Johnson & Johnson’s drugs, including Risperdal, for use by nursing home residents. The Justice Department’s January 2010 press release described the government’s allegations:

In its complaint against J&J, the United States alleges that the company paid kickbacks to Omnicare to induce the nursing home pharmacy company to purchase and recommend J&J drugs, including the anti-psychotic drug Risperdal, for use in nursing homes. According to the complaint, J&J understood that Omnicare’s pharmacists reviewed nursing home patients’ charts at least monthly and made recommendations to physicians on what drugs should be prescribed for those patients. The government further alleges that J&J knew that physicians accepted the Omnicare pharmacists’ recommendations more than 80 percent of

¹⁸ G.C. Alexander, S.A. Gallaher, A. Mascola, R.M. Moloney, R.S. Stafford, “Increasing off-label use of antipsychotic medications in the United States, 1995-2008,” *Pharmacoepidemiology and Drug Safety* (2011); Brenda Goodman, “Study: Newer Antipsychotic Drugs Are Overused,” *WebMD Health News* (Jan. 7, 2011).

¹⁹ 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” (News Release, Jan. 15, 2009), <http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf>. See also the Criminal Information at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyinfo.pdf>; the guilty plea agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyguiltypleaagreement.pdf>; the 65-page government memorandum for entry of plea and sentencing, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillygovtmententrypleasent.pdf>; the 67-page Corporate Integrity Agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillycorpintegreement.pdf>; and the 35-page settlement agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillysignedsettlementagreement.pdf>.

²⁰ *United States of America v. Eli Lilly and Company* (E.D. Pa., Jan. 15, 2009) Guilty Plea Agreement ¶6.A.(4).

the time, and that J&J viewed such pharmacists as an "extension of [J&J's] sales force."²¹

Two months earlier, in November 2009, the government had settled a False Claims Act case with Omnicare. Under the settlement, Omnicare paid \$98 million and the drug manufacturer IVAX Pharmaceuticals agreed to pay \$14 million to the United States to resolve allegations involving kickbacks paid to Omnicare by Johnson & Johnson in exchange for Omnicare's consultant pharmacists' recommending the antipsychotic drug Risperdal for nursing home residents.²²

Although these False Claims Act cases arose prior to implementation of Medicare Part D, problems with drug regimen reviews continue under Part D. Long-term care pharmacies often provide consultant pharmacist services to nursing facilities, at low or no cost. Long-term care pharmacies receive rebates from drug manufacturers, leading to "a very strong incentive to promote utilization of drugs for which they receive rebates."²³ In a study of antipsychotic drug use in nursing facilities between May 2010 and June 2011, the California Department of Public Health found that consultant pharmacists failed to identify inappropriate antipsychotic use in 18 of 20 facilities (90%).²⁴

Antipsychotic drugs are a protected class under Medicare Part D

The Inspector General recently reported that the utilization control mechanism of prior authorization is prohibited "in most instances" for drugs that are protected classes under Part D, including antipsychotic drugs.²⁵ Post-payment strategies for utilization control "do not focus on medically accepted indications" for drug use. Psychoactive drugs, once prescribed, face little scrutiny from Part D prescription drug plans.

²¹ U.S. Department of Justice, "United States Files Suit against Drug Manufacturer Johnson & Johnson for Paying Kickbacks to Nation's Largest Nursing Home Pharmacy," (News Release, Jan. 15, 2010), <http://www.justice.gov/opa/pr/2010/January/10-civ-042.html>.

²² U.S. Department of Justice, "Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay \$112 Million to Settle False Claims Act Cases; U.S. Also Files Complaint Against Two Atlanta-Based Nursing Home Chains and Their Principals" (News Release, Nov. 3, 2009). Complaint of the United States, <http://www.phillipsandcohen.com/News-Reports-of-P-C-Cases/Omnicare-Mariner-complaint.pdf>; Department of Justice News Release, <http://www.justice.gov/opa/pr/2009/November/09-civ-1186.html>.

²³ Michael McCaughan, "Are Long Term Care Rebates Dangerous? One CMS Official thinks it is time for big changes in the long term care pharmacy model – to protect patients, manufacturers and Part D plans," *The RPM Report* (Jan. 2007).

²⁴ "CDPH/DHCS Antipsychotic Collaborative" (powerpoint), slide 9.

²⁵ OIG, "Memorandum Report: *Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications*," OEI-07-08-00152 (Nov. 14, 2011) (Memorandum from Stuart Wright, Deputy Inspector General for Evaluation and Inspections, to Donald M. Berwick, M.D., Administrator, CMS), <http://oig.hhs.gov/oei/reports/oei-07-08-00152.pdf>.

The high costs of using antipsychotic drugs

Antipsychotic drugs are expensive. They are the top-selling class of drugs in the United States, generating annual revenues of \$14.6 billion.²⁶ While all of these drugs are not used with nursing home residents,²⁷ a significant portion is. Drastically reducing the use of these drugs with residents for whom they are not appropriate would not only result in better care for the residents; it would also save the health care system billions of dollars.

But the costs of inappropriately using antipsychotic drugs extend far beyond the costs of the drugs themselves. Residents who are inappropriately given antipsychotic drugs experience a number of bad health outcomes that are expensive to try to correct. There is a high financial cost to the inappropriate use of antipsychotic drugs with nursing home residents.

Twenty years ago, efforts were made to quantify the “hidden costs” of antipsychotic drug use. David Sherman described research documenting that “elderly long-term care residents receiving antipsychotic drug therapy are two to three times more likely to experience a fractured hip than residents not receiving these medications.”²⁸ He identified increased urinary incontinence resulting from use of antipsychotic drugs²⁹ as well as an increase in falls and hip fractures.³⁰

More than 20 years ago, the Senate Labor and Human Resources' Subcommittee on Aging issued a staff report that identified the high cost of poor care and quantified the costs, citing research literature. The report quantified \$3.26 billion to pay for incontinence care; \$746.5 million for hip fractures for 18,500 residents (\$40,000 per person); and nearly \$1 billion for hospitalizations – all poor outcomes of care caused, in part, by antipsychotic drugs.³¹

A new report issued in April 2011 by Consumer Voice provides additional research-based data on the high costs of poor care.³² Consumer Voice cites reports by the Centers for Disease Control and Prevention (CDC) that falls and fractures in older people account

²⁶ Duff Wilson, “Side Effects May Include Lawsuits,” *The New York Times* (Oct. 3, 2010), <http://www.nytimes.com/2010/10/03/business/03psych.html?scp=1&sq=%22Side%20Effects%20May%20Include%20Lawsuits%22&st=cse>.

²⁷ Benedict Carey, “Drugs Used for Psychotics Go to Youths in Foster Care,” *The New York Times* (Nov. 20, 2011), http://www.nytimes.com/2011/11/21/health/research/study-finds-foster-children-often-given-antipsychosis-drugs.html?_r=1&ref=benedictcarey.

²⁸ David Sherman, “Using Common Sense to Reduce Antipsychotic Drug Use,” *Contemporary Long Term Care* (Oct. 1991).

²⁹ *Id.*

³⁰ David Sherman, “Medication Use and Falls,” *Contemporary Long Term Care* (Nov. 1991).

³¹ Subcommittee on Aging, Senate Committee on Labor and Human Resources, “Nursing Home Residents Rights: Has the Administration Set a Land Mine for the Landmark OBRA 1987 Nursing Home Reform Law?” pages 175-177, 102nd Cong., First Sess. (June 13, 1991).

³² The National Consumer Voice for Quality Long-Term Care (Lani G. Gallaher), *The High Cost of Poor Care: The Financial Case for Prevention in American Nursing Homes* (April 2011), <http://www.theconsumervoices.org/sites/default/files/advocate/action-center/The-High-Cost-of-Poor-Care.pdf>.

for \$31 billion in costs to the health care system (although not all of these costs, of course, reflect nursing home residents).³³ CDC also reports that in 2004, 8% of nursing home residents nationwide – 123,600 individuals – had an emergency department (ED) visit in the prior 90 days and that 40% of the ED visits, involving 50,300 residents, were preventable.³⁴ The leading cause of residents’ potentially avoidable ED visits was injuries from falls.

Solutions

A problem as far-reaching as the chemical restraint of nursing home residents cannot be resolved by a single solution. Many solutions, simultaneously implemented, are necessary. Residents’ advocates do not recommend an absolute prohibition against prescribing antipsychotic drugs for residents who have dementia, but no diagnosis of psychosis or related conditions. However, the fact that off-label use of drugs may be appropriate under some circumstances does not provide wholesale justification for the extensive use of antipsychotic drugs with residents who have dementia. The FDA’s black box warnings on antipsychotic drugs should call into question most off-label use of antipsychotic drugs with such residents.

What we recommend is implementing what virtually all commenters on all sides of this issue agree on – that non-pharmacologic approaches should be tried first. To achieve that end, we recommend a number of approaches that would call prescribers’ attention to the issue of antipsychotic drug use, slow down the process of prescribing antipsychotic drugs, teach better non-drug alternatives, and create and impose stronger sanctions for inappropriate antipsychotic drug use.

Survey

- CMS should revise the federal survey protocol and the new Quality Indicator Survey to require surveyors to include residents using antipsychotic drugs in the resident sample in every survey.
- CMS should require its Regional Offices to focus the federal surveys they undertake as part of their oversight function on facilities with high rates of antipsychotic drug use.

Training and education

- CMS should issue a Survey & Certification Letter, outlining the importance of surveyors’ determining compliance with CMS’s regulations and guidance on the use of antipsychotic drugs. The Letter could highlight the recent decision in *Washington Christian Village v. CMS*, Docket Nos. C-10-456 and C010-602,

³³ *Id.* 2.

³⁴ Christine Caffrey (CDC), “Potentially Preventable Emergency Department Visits by Nursing Home Residents: United States, 2004,” NCHS Data Brief, No. 33 (April 2010), <http://www.cdc.gov/nchs/data/databriefs/db33.pdf>.

Decision No. CR2403 (July 27, 2011), which sustained an unnecessary drug deficiency for antipsychotic drugs.

- CMS should conduct a Satellite broadcast and in-person trainings on CMS's existing (and new) regulations on antipsychotic drugs. More than twenty years ago, surveyor training on physical restraints presented the importance of the issue and information on how to provide care without physical restraints. Similar training should be provided on chemical restraints.

New legislation and regulations

- The Prescription Drug Cost Reduction Act, S. 1699, §7, introduced by Senator Kohl on October 12, 2011, requires physician certification that off-label prescription of an antipsychotic drug with a nursing home resident "is for a medically accepted indication."³⁵ This is an excellent legislative proposal that we strongly encourage Congress to enact.
- CMS recently proposed amending the consultant pharmacist regulations, 42 C.F.R. §483.60(b) to require that consultant pharmacists be independent and have no conflict of interest; prohibit rebates, kickbacks, bonuses, fee arrangements, and gain-sharing. 76 Federal Register 63018, 63038-63041 (Oct. 11, 2011). This is an excellent proposal that we strongly encourage CMS to adopt.
- CMS should adopt the 1992 proposed rules on chemical restraints. These regulations require that residents or their legal representatives give specific written informed consent for antipsychotic drug use. They also require that physician orders specify "the dose, duration and reason for the use of the drug;" that a psychopharmacologic drug "not be used unless it can be justified in the clinical record that the potential beneficial effects of the drug clearly outweigh its potential harmful effect;" that residents taking psychopharmacologic drugs "be monitored closely;" that drugs "be gradually withdrawn at least semi-annually in a carefully monitored program conducted in conjunction with the interdisciplinary team;" and that residents' drugs "be reviewed at least annually by a physician who has training or experience in geriatrics and psychopharmacology." Proposed 42 C.F.R. §483.13(a)(2).
- CMS should amend the Requirements of Participation for nursing facilities to require Medical Directors, Quality Assurance Committees, Administrators, and Pharmacists to certify that they have reviewed the facility's use of antipsychotic drugs and that the use is in compliance with 42 C.F.R. §483.25(l) (unnecessary drugs) and §483.60 (pharmacy services and drug regimen review).

³⁵ <http://thomas.loc.gov/cgi-bin/query/z?c112:S.1699>.

Transparency

- CMS should post facility rates of antipsychotic drug use on *Nursing Home Compare*.
- CMS should develop a quality measure on antipsychotic drug use in nursing facilities.

Medicare Part A

- CMS needs to explore ways to prevent the prescribing of antipsychotic drugs during nursing home residents' Medicare Part A stays. Depending on how prescriptions are physically transmitted to pharmacists, a program in a Boston hospital establishing a computerized warning system might provide a useful model.³⁶ Under the authority of section 6114 of the Affordable Care Act, a demonstration could test a computerized order entry warning system for antipsychotic drugs in nursing facilities.

Medicare Part D

- CMS needs to consider utilization control mechanisms that would establish greater oversight of the use of antipsychotic drugs *before* they are prescribed and given to residents.

Stronger enforcement of federal law, regulations, and guidance

- Stronger enforcement of limitations on antipsychotic drug use can be effective in ensuring compliance with the requirements of law and regulations. Following both the federal FDA's 2005 warning about the death risks resulting from antipsychotic prescriptions in nursing homes and CMS's 2007 revised surveyor guidance on drug use, the state of Minnesota "responded with training for inspectors on how to spot cases of unnecessary medication and for nursing home administrators on how to prevent them."³⁷ In 2007, Minnesota cited 53% of

³⁶ Melissa L.P. Mattison, Kevin A. Afonso, Long N. Ngo, Kenneth J. Mukamal, "Preventing Potentially Inappropriate Medication Use in Hospitalized Older Patients With a Computerized Provider Order Entry Warning System," *Arch Intern Med*, Vol. 170 (No. 15), Aug. 2/23, 2010. In the Boston hospital, the computerized warning system flagged medications in three primary classes of medications (not-recommended medications, dose-reduction medications, and unflagged medications) identified by the Beers criteria as inappropriate for older people. In the study, the prescribing physician could bypass the warning and order the medication, but was required to choose a reason. Three choices were offered: (1) "Patient stabilized on regimen; will monitor appropriate drug levels or laboratory values, (2) "Interaction noted, regimen clinically indicated, will closely monitor," or (3) "Other: A fourth choice was added during the study, "Warning noted, will use smaller doses and monitor for side effects." The result of the study was a reduction in the prescribing of potentially inappropriate medications to patients over age 65.

³⁷ Jeremy Olson, "Drugs often a shortcut for care; Antipsychotics can calm nursing home patients, but also can be misused," *Pioneer Press* (Nov. 29, 2008).

nursing homes in the state for unnecessary medications. As a result of the deficiencies and enforcement, Minnesota nursing facilities' use of antipsychotic drugs with nursing home residents who do not have a diagnosis of psychosis declined between 2005 and 2008.

What can eliminating antipsychotic drugs mean for residents?

A researcher working in New York State to translate the research literature about the dangers of antipsychotic drugs into practice at nursing facilities wrote me about a small facility whose Director of Nursing had heard her speak about how to provide care to residents without using antipsychotic drugs.

This young DON heard me speak and said that will never be possible, but decided to give it a go, and got her medical director involved and consultant pharmacist on board, and they now have 2 residents only on antipsychotics and they have schizophrenia diagnosis. . . . one man they found had severe back pain from a spinal injury from a car accident years ago that was never addressed, but his dementia prevented his communicating the pain and they had him in a deep seated Geri chair which only exacerbated the pain, poor man, so he had behavior issues and was on antipsychotic meds, couldn't communicate or feed himself. He now eats lunch in the dining room and converses with his wife, participates in activities, etc. They have taken away the antipsychotic and replaced with pain medication. . . . one story makes it all worth it.

But the story this researcher told could be replicated hundreds of thousands of times in nursing homes across the country. Drastically reducing the use of antipsychotic drugs with nursing home residents would vastly improve the lives of hundreds of thousands of residents and would save hundreds of millions, if not billions, of dollars. After 35 years of studies, reports, and hearings, it is time to eliminate the epidemic use of antipsychotic drugs in nursing homes.

The Center for Medicare Advocacy is a private, non-profit organization, founded in 1986, that provides education, analytical research, advocacy, and legal assistance to help older people and people with disabilities obtain necessary health care. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. The Center provides training regarding Medicare and healthcare rights throughout the country and serves as legal counsel in litigation of importance to Medicare beneficiaries nationwide. Toby S. Edelman is a Senior Policy Attorney with the Washington, D.C. office of the Center. She has advocated on behalf of nursing home residents at the national level since 1977.



National Consumer Voice for Quality Long-Term Care

Resolution To Request the Department of Health and Human Services to Address the Misuse of Antipsychotic Drugs in Nursing Homes

WHEREAS the chemical restraint of nursing home residents is a leading form of elder abuse that causes misery, loss of independence, over-sedation, confusion, falls, severe medical side effects and death;

WHEREAS many nursing homes commonly use antipsychotic drugs to chemically restrain elderly residents with dementia and as a substitute for needed care;

WHEREAS 26% of U.S. nursing home residents – more than 350,000 residents – are given antipsychotic drugs;

WHEREAS nearly 40% of U.S. nursing home residents who have cognitive impairments and behavioral symptoms are given antipsychotic drugs despite the absence of psychotic or related conditions;

WHEREAS the Centers for Medicare & Medicaid Services guidelines on unnecessary drugs state that analysis of antipsychotic drug use by 693,000 Medicare nursing home residents found that 28.5% of the doses received were excessive and 32.2% lacked appropriate indications for use;

WHEREAS the United States Food and Drug Administration (FDA) has not approved antipsychotic drugs for the treatment of dementia and has issued advisories and “black box” warnings that antipsychotic drugs greatly increase the risk of death for persons with dementia;

WHEREAS nursing home residents who receive antipsychotic drugs and their representatives are often not properly informed about the dangers of these drugs or of alternative forms of care and treatment;

WHEREAS the HHS Office of Inspector General issued a prominent report in May 2011 revealing that – despite FDA warnings on the greatly increased risk of death – 88 percent of the nursing home residents who are subjected to powerful antipsychotic drugs are elderly persons with dementia; and that Medicare overpaid \$116 million for erroneous nursing home claims for atypical antipsychotic drugs in a six-month period of 2007;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions” concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents.

The National Consumer Voice for Quality Long-Term Care (formerly NCCNHR) is a 501(c)(3) nonprofit membership organization founded in 1975 by Elma L. Holder that advocates for quality care and quality of life for consumers in all long-term-care settings.

WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors as a treatment for dementia; and whereas one large national long-term care pharmacy has entered into agreements with the Department of Justice and several state governments to settle charges that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug it manufactures;

WHEREAS a large national long-term care pharmacy continues to provide drugs to residents of hundreds of long-term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS the Nursing Home Reform Law of 1987 and implementing regulations prohibit the unnecessary use of antipsychotic drugs and chemical restraints;

WHEREAS the Department of Health and Human Services (HHS) published proposed regulations on February 5, 1992 that would significantly strengthen the protections for nursing home residents against chemical restraint and prohibit the use of psychoactive drugs without written informed consent; and whereas, however, the proposed regulations have not been finalized.

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform a monthly drug regimen review for each resident and provide consultation on all aspects of pharmacy services within the facility; however, this requirement is not serving its purpose of independent analysis of nursing home drug use because most consultant pharmacists work for large long term care pharmacies that are the exclusive provider of drugs to the nursing homes, and the long term care pharmacies often subsidize the cost of consultant pharmacist services;

WHEREAS the Affordable Care Act of 2010 requires the Centers for Medicare & Medicaid Services to review and modify the Nursing Home Compare website to provide clear, timely and comprehensive information of value to consumers;

WHEREAS numerous studies have found that antipsychotic drugs are generally ineffective in treating behavioral symptoms of dementia, and that they are sometimes outperformed by placebos; studies also show that it is often a nursing home's drug use rate, not a resident's medical condition, which determines the likelihood of whether a resident will be given antipsychotic drugs and put at risk of serious harm and premature death;

WHEREAS, a growing number of nursing homes are proving there is a better way of caring for residents with dementia that focuses on ensuring their comfort and on timely assessment and response to the underlying causes of any behavioral symptoms;

THEREFORE BE IT RESOLVED that Congress hold hearings to address the rampant misuse of antipsychotic drugs to sedate and chemically restrain nursing home residents and that Congress enact legislation to ensure that antipsychotic drugs are not given to nursing home

residents without medical justification and without the specific informed consent of residents and their representatives.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services publish up-to-date information on each nursing home's use of antipsychotic drugs on Nursing Home Compare and that it factor antipsychotic drug use into its Five-Star Rating System for nursing homes.

BE IT FURTHER RESOLVED that HHS adopt the 1992 proposed regulations on chemical restraint, subject to modifications that nursing homes be required to inform residents and their representatives in writing of the known risks of psychoactive drugs, including any black box warnings, and to advise them if the drugs are being prescribed for off-label purposes.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies strengthen enforcement of existing chemical restraint and unnecessary drug requirements by carefully examining antipsychotic drug use during surveys and complaint investigations, by consulting with consumer stakeholders on needed modifications to survey and enforcement procedures for this purpose, and by promulgating new regulatory methods to prevent or discourage the prescribing of antipsychotic drugs for residents in the absence of psychotic or related conditions (such as implementing computerized warning systems particularly related to the use of antipsychotic drugs).

BE IT FURTHER RESOLVED that HHS establish and implement effective procedures to prevent Medicare payment for non-therapeutic use of antipsychotic drugs and to recover erroneous payments for these drugs.

BE IT FURTHER RESOLVED that when the HHS Office of Inspector General and the Department of Justice find that a provider of pharmacy services is illegally engaged in marketing and promoting antipsychotic drugs to long-term care facilities, they exclude the long-term care pharmacy from Medicare and Medicaid.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies establish high-profile education campaigns to advise consumers, nursing home employees, and physicians about the dangers associated with the misuse of antipsychotic drugs and to inform them of alternative forms of care and treatment for symptoms of dementia.