



# Inappropriate Use of Anti-Psychotics in Nursing Homes: Issues and Advocacy

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35<sup>th</sup> National Consumer Voice Annual Meeting and Conference, Orlando,  
FL

Note: The presentation is only on antipsychotic medications – there are many other issues around other medications used in the nursing home that are just as important but not part of today's conversation



## Introduction

- What are antipsychotic drugs?
  - Haldol, Risperdal, Seroquel, Zyprexa, Geodon, Abilify –FDA approved for use in people with schizophrenia and bipolar disorder to control hallucinations and delusions.
- Problems with Antipsychotic Drug Use in Nursing Homes
  - ➔ Chemical restraint
  - ➔ Medications are dangerous and life threatening
  - ➔ Non-therapeutic, off-label (not FDA approved)
  - ➔ Used mostly with residents who have dementia
  - ➔ Appropriate consent procedures are not conducted
  - ➔ Viable alternatives to antipsychotics exist but are often not tried prior to medication.

Notes: All but Haldol are Atypical Antipsychotics

Hallucinations (see/hear things that are not there, false sense perception)/delusions (a persistent false belief held in the face of strong contradictory evidence, grandiosity, etc.)

Alternatives to Antipsychotic medication:

Seek and **treat organic causes** of problem behaviors.

Use **behavioral redirection** to turn a resident's focus to alternative actions.

Use **environmental intervention** to reduce boredom and provide stimulation.

In some nursing homes, simply **giving attention to a resident** has improved challenging behaviors seen in residents with dementia.



## Uncovering the Issue

OBRA regulations have curbed, although not eliminated, the use of physical restraints, but the use of chemical restraints (Medications used to control perceived “problem behavior” such as anxiety, wandering, verbal outbursts, restlessness, confusion) have continued and increased as evidenced by:

- Department of Health inspections in several states
- Media investigative reports
- Journal Articles
- Personal stories given to citizens’ advocates

### Why use antipsychotic medications as restraints?

Rise in number of residents with **cognitive impairment**

(Alzheimer’s Disease/Dementia)

Continued **lack of sufficient staffing**

**Lack of staff training** to work with people with cognitive impairment

Medications are expensive and a **lucrative pharmacological business**



## Goals

- Identify state actions for individual Citizens' Advocacy Groups or advocates to work on the state level.
- Discuss a suggested plan of action at the national level for The National Consumer Voice.



## Scope and Severity

- Studies have shown the use of antipsychotics in the elderly to be largely ineffective and life threatening

YET

- In 2010, 39.4% of residents with cognitive impairment were given antipsychotic medications.

AS OF 2007

- 33% of residents took an antipsychotic medication at some point in their stay.
- 98% of nursing homes nationwide had at least 1 out of 5 residents on antipsychotic medication.
- Nationwide, 25% of nursing home residents were given antipsychotics while only 7% had an approved diagnosis.

41.8% of residents are being given antipsychotic medication in direct violation of nursing home prescribing guidelines.

In a 2006 study of people with Alzheimer's disease, no significant improvement was shown for behaviors of aggression and delusions in those residents receiving antipsychotics versus placebo.

Residents receiving medication within the guideline fared no better than those receiving it outside of guidelines



## Scope and Severity

### Side Effects in the Elderly with Dementia

- Triple the risk of stroke
- Increased risk of heart attack
- Diabetes
- Lethargy and tardive dyskinesia (uncontrolled tremors) which can lead to falls
- Seizures
- Resulting inability to stay at the highest level of functioning. While on antipsychotics, residents often lose the ability to bathe, dress, eat, toilet, ambulate and engage in social interaction.

A Food and Drug Administration official estimates that unnecessary anti-psychotics kill 15,000 nursing home patients each year



## Scope and Severity

### FDA 2005 Black Box Warning for the Elderly Increased Risk of Sudden Death

- WARNING:

#### **Increased Mortality in Elderly Patients With Dementia-Related Psychosis**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration\* of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infections (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. [DRUG BRAND NAME (drug generic name)] is not approved for the treatment of patients with dementia-related psychosis.

Resource Slide



## Current Advocacy: Litigation

### The False Claims Act: Big Pharma and the Illegal Marketing of Antipsychotic Medications for Off Label Use.

“The aggressive marketing of these drugs may have contributed to this enhanced perception of their effectiveness in the absence of empirical evidence.” –Dr. Jeffrey A. Lieberman, Columbia University Psychiatry Department Chair

**False Claims** – an illegal request for government reimbursement for medications that were used in violation of medically accepted indications.

Pharma Company	Antipsychotic	Actions Leading to False Claims
Pfizer	Geodon	Illegal Promotion of Geodon, Kickbacks
Bristol-Myers Squibb	Abilify	Inappropriate marketing to child psychiatrists and nursing homes
Johnson and Johnson	Risperdal	Kickbacks for marketing to Omnicare, the nation's largest nursing home pharmacy
AstraZeneca	Seroquel	Kickbacks for marketing to doctors
Eli Lilly	Zyprexa	5mg at 5 pm to calm nursing home residents (\$515 million dollar fine)





## Current Advocacy: Litigation

- Criminal Prosecutions

### Kern Valley Nursing Home, CA

- 2003: A criminal complaint is filed by the California State Attorney General contending that 20 residents of Kern Valley were given unnecessary antipsychotic medication as chemical restraints, resulting in 3 deaths.
  - Residents forcibly injected with Antipsychotic Medications
  - Residents given medications because they “annoyed” the nursing director
  - Director of Nursing was fired from previous job for overmedication/chemical restraints.
- 2009: The Administrator, Medical Director, and Nursing Director are charged with Elder Abuse. The Chief Pharmacist enters a plea bargain.
- 8/2010: Preliminary Hearings begin on the case with 8 felony counts of elder abuse against the 3 defendants.



## Current Advocacy: Litigation

- Class Action Lawsuit

### Spindler v. Johnson and Johnson, Omnicare

- Filed by Nursing Home Residents (California and National)
- Alleges that Omnicare took money from J and J in exchange for labeling Risperdal a preferred drug in nursing home markets. Subsequently residents were:
  - Inappropriately switched to J and J medications
  - Overcharged for their medications
  - Given additional unnecessary medications
- Argues that a breach of the Best Price Law occurred
  - The Best Price Law is a federal law which mandates that Medicaid can pay the lowest price possible for prescription drugs.
  - The law also limits discounts and rebates for pharmacies like Omnicare

- Tort Cases

### Civil Suits Against Nursing Homes for Overmedication

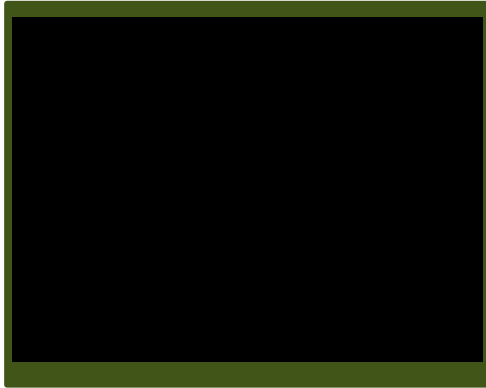


# Current Advocacy: State Citizens' Advocacy Groups

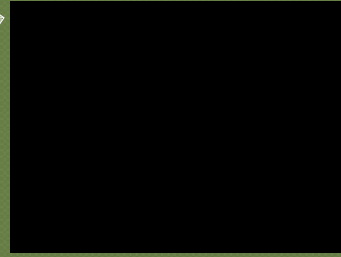
## Introduction

- Advocacy around anti-psychotic medication revolves around person centered care, individual care and informed consent.
- Advocacy is based on Federal Guidelines that:
  - Require specific protocols for the use of Antipsychotics Medication as follows
    - (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
  - Prohibit the use of chemical restraints
  - Require informed consent
  - Require the maintenance of residents at the highest level of functioning possible

## Current Advocacy: Citizen's Advocacy Groups



Stop Drugging Our Elderly: The Campaign to Stop  
Chemical Restraints in Nursing Homes  
Part 1



Part 2



California Advocates for Nursing Home Reform

Part 3

## Current Advocacy: State Citizens' Advocacy Groups

- CA – California Advocates for Nursing Home Reform
  - Passed an informed consent bill through both state legislative houses
  - Created the Toxic Medicine Guide  
[http://www.canhr.org/stop-drugging/wp-content/uploads/2010/06/Toxic\\_Medicine.pdf](http://www.canhr.org/stop-drugging/wp-content/uploads/2010/06/Toxic_Medicine.pdf)
  - Created the Stop Drugging Website-information and resources on the misuse of medications in nursing homes. Including a California petition to stop drugging.  
<http://www.canhr.org/stop-drugging/>
  - Through legislative effort and website created a statewide coalition to end overmedication in nursing homes





## Current Advocacy: State Citizens' Advocacy Groups

- Illinois-Illinois Citizens for Better Care
  - Passed Public Act 096-1372 which requires the Department of Health to create a written informed consent document for administration of Antipsychotic Medications in nursing homes.
  - Generated Press on the misuse of Antipsychotic medications  
See The Chicago Tribune  
[http://articles.chicagotribune.com/2009-12-20/news/0912190215\\_1\\_nursing-homes-psychotic-tighter](http://articles.chicagotribune.com/2009-12-20/news/0912190215_1_nursing-homes-psychotic-tighter)
  - Created a Fact Sheet on Psychotropic Drugs  
<http://illinoiscares.org/pdfs/SFSPsychotropicDrugs.pdf>
- Massachusetts
  - Senate committee referred Bill S.2509 for a vote – The bill required a nursing home *physician* to obtain informed consent and document such consent in the resident's chart.

IL requires 2 signatures for informed consent if the law is violated – bill covers all psychotropic medications



## Current Advocacy: State Citizens' Advocacy Groups

- New York-Long Term Care Community Coalition
  - FRIA: The Voice and Resource for Quality Long Term Care
    - Proposed Legislative Intent-Requires written informed consent and bans the non-therapeutic use of antipsychotic medications in nursing homes
    - LTCCC – NY Times Letter to the Editor  
<http://www.nytimes.com/2009/12/19/opinion/19drugs.html?scp=1&sq=cynthia%20rudder&st=cse>
    - LTCCC – Newsletter featuring Cobble Hill Nursing Home: Atypical Antipsychotics: Less is More
    - FRIA- Brochure on overmedication
- Wisconsin
  - AB 526 passed the Assembly and was referred to the Senate – required a written informed consent before administering antipsychotic medications to nursing home residents

WI – bill covers all psychotropic medications



## Current Advocacy: National

- Center for Medicare Advocacy
  - Off-Label drug Use Is Common and Hurts Nursing Home Residents.

[http://www.medicareadvocacy.org/InfoByTopic/SkilledNursingFacility/10\\_03.25.OffLabelDrugUse.htm](http://www.medicareadvocacy.org/InfoByTopic/SkilledNursingFacility/10_03.25.OffLabelDrugUse.htm)

- The National Consumer Voice
  - Resolution on Chemical Restraints
  - QIS indicator on antipsychotic medication
  - Letter to Senate Special Committee on Aging





## Open Discussion

Part 1: What is happening in your State?

Part 2: What is happening nationally?

Part 3: What can we do at the state level to affect change?

Fill the holes in our knowledge – what do we need to know to advocate better?

Identify barriers to advocacy approaches/Identify solutions

Dear Administrator Letters

Better surveys (QIS) and complaint substantiation

Enforcement of Person Centered Care

Media campaign

Continued work on Safe Staffing ratios

Put Pressure on pharmacists and medical directors at nursing homes

Use the financial cost issue to our advantage

Part 4: What would we like to see happen at the national level through the National Consumer Voice and other collaborative efforts?

Potential electronic medical records warning

Part 1 – Are other states observing this issue and are there other advocacy efforts we have not noted

Part 2 – Are there other efforts at the national level we have not noted.



## Presenters

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