



Advocating Against The Illegal and Excessive Use of Psychotropic Drugs with People with Dementia

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OBJECTIVES

- Raise awareness and understanding of the problem
- Discuss advocacy strategies for accountability and deterrence
- Engage in dialogue about other strategies that advocates can use to identify and reduce the use of psychotropic drugs in nursing facilities

Impact of Psychotropic Drugs

- Psychotropic drugs affect mental activity, emotion, and behavior (e.g., antipsychotics, antidepressants, mood stabilizers)
- Includes antipsychotic drugs that favorably modify psychotic symptoms
- Side effects can be very harmful; lower quality of life
 - v/increased vulnerability to infections
 - v/excessive sedation, lethargy, dizziness and unsteadiness
(increased falls and injuries, increased risk of bed sores)
 - v/parkinsonism (tremors and rigidity), body restlessness
 - v/reduced well-being, loss of appetite, social withdrawal
 - v/accelerated cognitive decline

Antipsychotics, Approved Uses

FDA has approved the use of 10 atypical antipsychotic drugs for the treatment of schizophrenia and/or bipolar disorder.

Source: FDA Website, last accessed on April 11, 2017, at <http://goo.gl/oy1kR>.

Drugs – KNOW both Generic and Name Brand

Aripiprazole (marketed as Abilify)
Asenapine Maleate (marketed as Saphris)
Clozapine (marketed as Clozaril)
Iloperidone (marketed as Fanapt)
Lurasidone (marketed as Latuda)
Olanzapine (marketed as Zyprexa)
Olanzapine/Fluoxetine (marketed as Symbyax)
Paliperidone (marketed as Invega)
Quetiapine (marketed as Seroquel)
Risperidone (marketed as Risperdal)
Ziprasidone (marketed as Geodon)

What is a Black Box Warning Drug??

A boxed warning (sometimes "black box warning", colloquially) is a type of warning that appears on the **package insert** for certain prescription drugs, so called because the U.S. Food and Drug Administration specifies that it is formatted with a 'box' or border around the text.

Drugs With Black Box Warning

Risperdal (Risperidone)
Zyprexa (Olanzapine)
Seroquel (Quetiapine Fumarate)
Geodon (Ziprasidone Hydrochloride; Ziprasidone Mesylate)
Abilify (Aripiprazole)
Invega (Paliperidone; Paliperidone Palmitate)
Haldol (Haloperidol Decanoate; Haloperidol Lactate; Haloperidol)
Moban (Molindone Hydrochloride)
Navane (Thithixene)
Orap (Pimozide)
Symbyax (Fluoxetine Hydrochloride; Olanzapine)
Clozaril (Clozapine)
Fazaclo (Clozapine)

Content of Label

Warning Label - Geodon

“Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at **an increased risk of death.**”

“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 [and] **most of the deaths appeared to be either cardiovascular...in nature.**”

Warning Label - Seroquel

“Antipsychotic drugs are **associated with an increased risk of death...[and Seroquel]** is not approved for elderly patients with Dementia-Related Psychosis.”

Off-Label Uses in Nursing Facilities

- **Despite known dangers**, antipsychotic (sometimes called psychotropic) drugs are commonly prescribed to elderly nursing facility residents for uses not approved by the FDA
- To **control unwanted/challenging behavior** caused by dementia
- To **avoid increased staffing and training** for non-pharmacological interventions to modify these behaviors
- Doctors are allowed to prescribe Rx for off-label uses
- Serious concerns that the risks and alternative interventions are NOT given appropriate consideration and consent not obtained

Off-Label Use in Nursing Facilities

Prevalent, Costly & Suspect

- In 2012, 38% of adults in nursing facilities had dementia
- In 2012, 33% of adults with dementia who spent more than 100 days in a nursing facility were prescribed antipsychotic drugs, off-label (e.g., not for the treatment of schizophrenia or bipolar disorder)
Source: Government Accountability Office Study, January 2015.
- Medicare pays millions in Rx costs for this off-label use (OIG Report, 2011)
- Significant number Medicare claims for off-label prescriptions of antipsychotics to elderly NF residents did not comply with the requirement that they be for medically appropriate uses supported by specific medical compendia (OIG Report, 2011)

Kickbacks and Other Illegal Inducements

FOR IMMEDIATE RELEASE

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Nation's Largest Nursing Home Pharmacy to Pay Over \$28 Million to Settle Kickback Allegations

The nation's largest nursing home pharmacy, Omnicare Inc., has agreed to pay \$28.125 million to resolve allegations that it solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug, Depakote, for nursing home patients....

“Every day, elderly nursing home residents suffering from dementia rely on the independent judgment of our nation's healthcare professionals for their personal care and their medical treatment,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Department of Justice's Civil Division. “Kickbacks to entities making drug recommendations compromise their independence and undermine their role in protecting nursing home residents from the use of unnecessary drugs.”

Abbott Laboratories Paid \$1.5 Billion for Promoting Depakote Be Used on Elderly Patients With Dementia

“Abbott’s off-label promotion of Depakote was multifaceted. The company entered into contracts that provided long-term care pharmacy providers with payments of rebates based on increases in the use of Depakote in nursing homes serviced by the providers. In addition to using its sales force to promote the drug to health care providers and employees of nursing homes, Abbott created programs and materials to train the pharmacy providers’ consultant pharmacists about the off-label use of Depakote to encourage them to recommend the drug for this unapproved use. Under these contracts, Abbott paid millions of dollars in rebates to the pharmacy providers.”

--2012 Press Release from DOJ

Kickbacks and Other Illegal Inducements

- Johnson & Johnson guilty plea for promoting Risperdal to treat dementia-related behavior while downplaying deadly risks, criminal and civil fines totaling \$2.2 billion. Source: FDA Office of Criminal Investigations, <http://goo.gl/NExp55>.
- Eli Lilly took a criminal plea and paid \$1.45 billion to resolve several cases alleging off-label promotion of Zyprexa to elderly people in nursing facilities. Notwithstanding the above, Zyprexa is still commonly administered in nursing facilities to people with dementia and despite the potentially fatal consequences.

Non-Pharmacological Interventions Preferred, Safer

Clinical guidelines:

- assess the scope and severity of the behavior
- identify any environmental triggers for the behavior
- determine if behavioral symptoms are associated with another medical condition, such as under-treated arthritis pain, constipation, or dehydration
- use drugs **only** when other, non-pharmacological attempts to ameliorate the behaviors have failed; AND
- the individual poses a threat to themselves or to others

Antipsychotics or Not, Who Decides?

- There is no FDA-approved psychotropic drug treatment for dementia-related behaviors
- No evidence showing significant differences in behavior attributable to atypical antipsychotic drugs as compared to non-pharmacological interventions.

*See Clinical Guidelines, The Society for Post-Acute and Long-Term Care Medicine (AMDA), reviewing clinical studies.

Levine v. Ventura Convalescent Hospital

Levine v. Ventura Convalescent Hospital

- Kathi Levine's mother was admitted to the nursing facility after suffering a hip fracture and was prescribed a variety of unnecessary medications administered without the consent required by California law. In the class action, *Levine v. Ventura Convalescent Hospital*, Ms. Levine was the lead plaintiff as representative of her mother's estate.
- Ms. Levine was the medical power of attorney for her mother but she was never consulted about the administration of medications and her consent was never obtained.
- She did not even know about the prescription of these drugs until her mother was being discharged from the facility, at which point a nurse told her about the powerful sedatives, anxiety drugs, antidepressants, and antipsychotic drugs that were given to her mother, who suffered with dementia which was manageable when she lived in the community.

Devastation from the Drugs was Quick and Complete

Ms. Levine believed that the drugs turned her mother into a person with little cognitive function who would babble nonsense at all hours of the night, too confused and sleepy to even participate in the physical therapy that had been the purpose of her admission to the facility.

Once her mother was discharged, her doctor tried in vain to wean her off the powerful medications. Within a few weeks, her mother died.

Class Action Settlement

- Ms. Levine sued the nursing facility, and AARP Foundation Litigation attorneys joined attorneys Gregory Johnson and Jody Moore to represent her and all others similarly treated.
- The lawsuit alleged that while these drugs may make residents easier to handle, by needlessly medicating residents and by failing to obtain their consent, the nursing facility violated federal and state laws particularly designed to protect residents of nursing facilities.

Settlement Results

- Settlement of the case included injunction and \$\$ and a monitor.
- In approving the settlement, the court stated that:

“But for Class Counsel's willingness to confront the defendant it is highly likely that the hundreds of patients . . . would still be receiving psychotropic medications without informed consent.”

Legacy of Levine (in materials)

- In July 2014, the AARP Bulletin ran a Special Report entitled, “Prescription for Abuse: Antipsychotics in Nursing Homes,” in which this litigation and the issue of inappropriate medications in nursing facilities was described in detail. The response to the Bulletin article has been overwhelming from members nationwide whose families suffered similar horrible experiences.
- AARP Foundation was contacted by dozens of people who had suffered terrible losses from the exact kind of scenarios as Ms. Levine and her mom.
- AARP Letter to CMS and FDA

Tennessee and Delaware Litigation

- AARP Foundation brought individual wrongful death cases in 2015 and 2016
- Cultivating experts
- Ageism impacts access to counsel

APRN vs. Psychiatrist

- Common phenomena to have
Attending Physician or Medical Director
rubber stamping recommendations
of consulting medical professional
- Diagnosis creep to fit the medications

2017 Bulletin Article -- in materials

<http://www.aarp.org/health/drugs-supplements/info-2017/wrongful-death-lawsuit-nursing-home-fd.html>

Policies vs. Reality

- Check training;
- Policies should be appropriate but likely not followed;
- Check informed consent documents;
- Check on communication between doctor and staff;
- Check on knowledge of staff about policies;
- Check on knowledge of residents about drug regimen; and
- Interview POAs about involvement in decisions.

Negligent Monitoring after Drugs are Administered

Many facilities administer the drugs and do not monitor the consequences:

Somnolence

Confusion

Restlessness

Shuffling

Falls

Loss of appetite

Dysphasia

Parkinsonian reactions

Need Cultural Transformation

- Must change culture of conformity with drugging elderly persons with dementia
- Doctors routinely prescribe
- Standing orders, not revised, side effects not monitored
- Need training on non-pharma approaches to behavior challenges
- Behavior is communication, so figure out what resident is trying to communicate
- Raise awareness, advocate for residents
- This is an abuse and neglect issue – chemical restraint

Ombudsman Programs Are the Ambassadors for Culture Change

- LTCO is essential to help to effect this change!
- Need to build a base of attorneys to whom you can refer these cases on a systemic bases.

Thank you!!

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