

COMBATting THE EXCESSIVE AND ILLEGAL USE OF PSYCHOTROPIC DRUGS ON PEOPLE WITH DEMENTIA IN NURSING FACILITIES

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Objectives

- Raise awareness and understanding of the problem
- Discuss litigation 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
 - ✓ increased vulnerability to infections
 - ✓ excessive sedation, lethargy, dizziness and unsteadiness (increased falls and injuries, increased risk of bed sores)
 - ✓ parkinsonism (tremors and rigidity), body restlessness
 - ✓ reduced well-being, loss of appetite, social withdrawal
 - ✓ 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 Nov. 3, 2015, at <http://goo.gl/oy1kR>.

Antipsychotic Drugs, Risks

- Increased risk of death when used by elderly persons with dementia.
- Research has shown that there is up to a 9-fold risk of stroke in the first four weeks and that there is almost a doubling in the risk of mortality.

Source: Food and Drug Administration, 2005.

- NOT approved to treat dementia-related psychosis in the elderly
- FDA Black Box Warning

Black Box Warning

WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY is not approved for the treatment of patients with dementia-related psychosis. (5.1)
- Children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders are at increased risk of suicidal thinking and behavior. (5.2)

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)

Off-Label Uses in Nursing Facilities

- **Despite known dangers**, antipsychotic 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)
- **Off-label promotion by Pharma industry**, e.g., J&J 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>.

Antipsychotic Drugs Not Effective Treatment for Dementia

- There is no FDA-approved pharmacological 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.

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

*See materials for pre-conference intensive workshop on this issue (on NCV website).

Antipsychotics or Not, Who Decides?

Why important:

- Deadly risks for elderly people with dementia
- Off-label use and lucrative off-label promotion
- Other options available, more effective, and safer
- ❖ Residents and/or their representatives are not given this information and, thus, not given the opportunity to give or deny informed consent

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 believes 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 a court order that sets clear standards for the facility to verify that the physician has had a meaningful and complete discussion with the patient (or legal representative for incapacitated patients) about the medications prescribed, possible side effects, and alternatives, before administering a drug. The settlement also provides financial compensation to the members of the class and attorneys' fees to counsel.
- 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

Keller v. Life Care Centers of Greeneville

- Greene County Circuit Court—Greeneville, Tennessee (14-cv-500)
- Filed in December 2014 against Life Care Centers of America, Life Care Centers of Greeneville (LCG), and various employees and contractors of LCG
- Claims in negligence and medical battery
- Currently in discovery

Keller v. Life Care Centers of Greeneville

- Bobby Tweed was a 79 year old resident of Life Care Centers of Greeneville (LCG) in Greeneville, Tennessee.
- Mr. Tweed was admitted to LCG in January 2013 for management of dementia and Alzheimer's symptoms, but was never diagnosed with any other mental illness.
- Beginning in August 2013, Mr. Tweed was removed from his regimen of Aricept and Namenda and placed on psychotropic drugs—including Depakote, Geodon, and Seroquel.

Keller v. Life Care Centers of Greeneville

- Mr. Tweed's daughter and Power of Attorney, Robin Keller, was never notified of these changes to his medication.
- Since August 2013, Mr. Tweed experienced loss of appetite, dramatic weight loss, and dehydration.
- Robin Keller learned for the first time of the psychotropic drugs and asked they be gradually discontinued; LCG instead immediately withdrew the medications.
- Mr. Tweed's health continued to decline until his death in November 2013.

Keller v. Life Care Centers of Greeneville

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.”

Keller v. Life Care Centers of Greeneville

Lessons Learned

- Role of APRNs, PAs, and NPs in Resident Care
 - Scope of Practice Issues
 - Applicable Standard of Care
- Status as “Employees” v. “Independent Contractors”
- Impact of FDA Warning Label

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
- Bring suits, hold NFs accountable
- LTCO critically important in helping to effect this change!

Thank you!!

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