Legal Aspects of Antipsychotic Drug Use

How the Law Requires Good Dementia Care Using a Least Medicating Approach

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This is Reggie and Cal
Agenda

- 15 minutes on psychotropic drugs
- 30 minutes on the law
- 5 minutes on Least Medicating Movement
- 10 minutes to party!
Psych Drugs – 5 Classes

- Anti-Depressants (Zoloft, Celexa, Lexapro)
- Hypnotics (Restoril, Ambien)
- Anti-Anxieties (Ativan, Valium)
- Antipsychotics (Risperdal, Seroquel, Zyprexa, Abilify, Geodon, Haldol)
- Anti-Convulsants (Depakote)
Numeros

1. Over 56% of California nursing home residents receive a psychotropic drug;
2. 83% of antipsychotic use in nursing homes is off-label (not approved by the FDA to treat the condition at issue);
3. Nearly all psych drug use is to control behavior.
Antipsychotics - Risks Galore, Including \textit{DEATH}

- Side Effects: strokes, falls, dizziness, weakness, headache, tardive dyskinesia, etc., etc.
- Anticholinergic - some side effects are same as symptoms! - agitation, restlessness, confusion, cognitive decline, seizures.
- Double risk of death for elderly with dementia (FDA \textbf{Black Box} warning)
More Harm than Good?

- Outperformed by placebos
- Growing belief that psych drugs are not “treatment” (disrupt normal brain functioning, long-time users experience worse outcomes, number of “mentally ill” is growing)

### WARNING

Antipsychotic drugs nearly double the risk of death for older persons with dementia. These drugs are not approved for the treatment of dementia. In addition to death, antipsychotic drug side effects may include stroke, heart attack, increased risk of pneumonia, excessive sedation, lethargy, dizziness, falls, agitation, confusion, restlessness, delirium, hallucinations, tremors, involuntary body movements, muscle weakness, seizures, parkinsonism, cognitive decline, neuroleptic malignant syndrome, headache, dry mouth, constipation, weight gain, weight loss, urinary retention, and blurred vision.
Why Deadly?

Promotes inactivity: skin breakdowns, atrophy, falls, toileting/infection, weakened immunity, eroding the will to live

![Image of a hospital room]
Nursing Homes Struggle To Kick Drug Habit

New Therapies Sought For Dementia Sufferers; Music and Massages

Nursing home drug use puts many at risk
Antipsychotics given to some with dementia
By Kay Lazar
Globe Staff / March 8, 2010

Chemical restraints killing dementia patients
Nearly 2,000 elderly patients are killed each year by unnecessary anti-psychotic medication, report finds
Why?

- Lack of physician presence (payment structure favors prescribing over observing)
- Autonomic drug requests for “behaviors”
- Overworked caregivers w/o known alternatives
- No law enforcement
- Vulnerable consumers and families

Anatomy of a Drug Problem
Posted on July 15, 2010 by admin
by Tony Chicotel, CANHR Staff Attorney
Did Somebody Say Money?

“Despite [lethality], there’s ample evidence that some drug companies aggressively marketed their products towards such populations [elderly with dementia], putting profits before safety.”

HHS Inspector General Daniel Levinson

To the tune of **$11.9 Billion** in penalties since 2007 (Abilify, Zyprexa, Geodon, Seroquel, Risperdal, Paxil, Wellbutrin, Depakote)
Why Drug?

We don’t know what else to do.
The Law is Protective

- Informed Consent
- No Unnecessary Drugs
- Chemical Restraints Prohibited
- Gradual Dose Reduction
Informed Consent

- Informed: risks, benefits, and alternatives (failure is negligence)
- Consent: all treatment requires agreement from the patient or surrogate (failure is battery)
- Regardless of “capacity,” all people have right to refuse.
A Note on Surogacy

- Surrogates include conservators, power of attorney agents, or family members.
- Surrogates can consent but only a conservator with special powers can override a person’s right to refuse.
Informed Consent (cont’d)

- **Obtaining** informed consent is a doctor’s duty.
- Nursing homes have a separate duty of ensuring that informed consent has been obtained.
- RCFE duty?
Informed Consent?

No, neglect.
Informed Consent?

No, battery.
No Unnecessary Drugs

Unnecessary if:

1) In excessive dose (including duplicate therapy);
2) For excessive duration;
3) Without adequate monitoring;
4) Without adequate indications for its use;
5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued

No Unnecessary Drugs

Inadequate Indications for Use:

wandering; poor self-care; restlessness; impaired memory; mild anxiety; insomnia; unsociability; inattention; fidgeting; uncooperativeness; behavior that is not dangerous to others

Non-Nursing Home Setting

- Malpractice
- Elder Abuse: 15610.07. "Abuse of an elder or a dependent adult" means . . . :
  
  (a) Physical abuse, neglect, financial abuse, abandonment, isolation, abduction, or other treatment with resulting physical harm or pain or mental suffering.
No Chemical Restraints

- **Federal:** any drug imposed for purposes of discipline or convenience, and *not required* to treat the resident's medical symptoms (42 C.F.R. Sec. 483.13(a))

- **State:** a drug used to control behavior and used in a manner *not required* to treat the patient's medical symptoms (22 Cal. Code Regs 72018)
Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated. (42 CFR 483.25(l))
Alternatives - Drugging Must Be Last Resort

- Diagnosis: rule out dehydration, infection, pain, sleep deprivation, etc.
- Care, attention, and observation
  - consistent assignment
  - Experiential Audit
  - change your perspective, not the patient
- Patience
- Non-drug therapy (e.g. psychologist, exercise)
Considering the memory, sensory, and communication deficits, “behavioral and psychological symptoms of dementia” are really more like “behavioral and psychological symptoms of being human.”

How do we approach a baby in distress?
The Core Dementia Care Principle

People who are comfortable do not hit.
The Core Least Medicating Principle

The use of the drugs represents a failure.
Déjà Vu All Over Again

- “Excessive use of tranquilizers can quickly reduce an ambulatory patient to a zombie, confining the patient to a chair or bed, causing the patient’s muscles to atrophy from inaction and causing general health to deteriorate quickly . . . it appears many doctors give blanket instructions to nursing home staffs for the use of tranquilizer drugs on patients who do not need them.”
The CANHR Campaign

www.canhr.org/stop-drugging
Summary Points

- Anti-psychotic risks often exceed benefits
- The law requires a least medicating approach
- Least medicating is a well-proven better way
- I will back you up 100%
Connected?
Connected!

I feel band of love of dreams.