

Legal Aspects of Antipsychotic Drug Use

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

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California Advocates for Nursing Home Reform



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 *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 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



Despite Horribles, Awash in Drugs

LEADER (U.S.) | DECEMBER 20, 2007

ALTERNATIVE MEDICINE

Nursing Homes Struggle To Kick Drug Habit

New Therapies Sought For Dementia Sufferers; Music and Massages

HOME / NEWS / HEALTH AND FITNESS NEWS FROM THE BOSTON GLOBE

The Boston Globe

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 - ANTI-PSYCHOTICS

BRAND NAMES (GENERIC NAME)

JMPAZINE (prochlorperazine)	HALDOL (haloperidol)	INAPSINE (droperidol)
OXITANE (loxapine)	MELLARIL (thioridazine)	MOBAN (molidone)
AVANE (thiothixene)	ORAP (pimozidine)	PROLIXIN (fluphenazine)
JERENTIL (mesoridazine)	SPARINE (promazine)	STELAZINE (trifluoperazine)
TARACTAN (chlorprothixene)	THORAZINE (chlorpromazine)	TRILAFON (perphenazine)
TINDAL (acetyphenazine)	VESPRIN (trifluorpromazine)	RISPERDAL (risperidone)

It is recommended that you take the medication named Zyprexa
For the treatment of aggressive verbal behavior

ADVANTAGES: The medication is designed to relieve you of your symptoms. Research & clinical experiences have shown that it is safe & effective. The benefits from taking the medications usually outweigh the risks. Resident &/or responsible party always retain the right to revoke this decision.

SIDE EFFECTS: Any medication may produce unwanted side effects along with the desired results. Some effects may appear even before benefit from the medicine is experienced. If side effects do appear, consult your physician. Side effects usually disappear with continued treatment, although some side effects will persist, even after stopping the medication.

COMMON SIDE EFFECTS: Sedation, drowsiness, dry mouth, constipation, blurred vision, extrapyramidal reaction, weight gain, edema, postural hypotension, sweating, loss of appetite, urinary retention.

SPECIAL ATTENTION FOR: Tardive dyskinesia, seizure disorder, chronic constipation, glaucoma, skin pigmentation.

When you consent to treatment with this medication, you will have been informed as to the amount of medication, how often it will be given to you, whether or not it is available on request (PRN), how it will be given and how long you may expect to take it. Often different medications within this group may be given, or adjustment made to dosage. You have been informed of the common side effects of all listed medications, however some side effects are more likely to occur with one or more medications than others. Also, some residents are more prone to side effects. For this reason, you should notify your doctor if you think you are having side effects.

I hereby give consent to start treatment with Zyprexa, because I believe my emotional problem represents a greater danger to my health & wellbeing than do possible side effects.

Signature: [Redacted] Date: 1/4/10 Relationship: Self

The information above has been discussed with the resident or responsible party who reports having read & understood it except for comments listed:

Physician Signature: [Signature]

Addressograph: [Redacted]

WEE MEMORIAL HOSPITAL
Illod Nursing Unit

YD0002547887 - HCLN03
ADVANCE DIRECTIVE 1

Informed Consent?

No, battery.

FACILITY C.V. WEST

Family Name [REDACTED]		First Name	Attending Physician <u>SCWAL</u>	Room No.	Admission No.
Date/Term Ordered	Date Discontinued	ORDERS			Diagnosis
<u>7.8.09</u>		<u>RISPERDAL 25mg IM Q 2 weeks</u> <u>(↑ RISK OF SLOPEMENT)</u>			
		<u>1/2 HALOPERIDOL 1mg IM Q 4 HRS PRN.</u>			
		<u>1/2 RISPERDAL 0.5mg PO BID</u>			
Signature of Nurse Responsible for Order <u>[Signature]</u>			Signature of Physician		Date
<input checked="" type="checkbox"/> On Medication Sheet	<input checked="" type="checkbox"/> Medication Sheet		<input type="checkbox"/> Resident Informed drug effects / side effects		<input type="checkbox"/> Res. Care Plan
<input checked="" type="checkbox"/> Pharmacy	<input checked="" type="checkbox"/> Nurses Notes		<input type="checkbox"/> And Documented in Nap Notes / Med Sheet		<input checked="" type="checkbox"/> Communicated

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

http://www.cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf (F-Tag 329, 42 CFR 483.25(l))

No Unnecessary Drugs

Inadequate Indications for Use:

http://www.cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf (F-Tag 329, 42 CFR 483.25(l))

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)

Gradual Dose Reduction



Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated. (42 CFR 483.25(I))

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)

BPSD

- 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

TOXIC MEDICINE



WHAT YOU **SHOULD KNOW** TO
FIGHT THE MISUSE OF PSYCHOACTIVE DRUGS
IN CALIFORNIA NURSING HOMES

CANHR
Long Term Care Justice and Advocacy
650 HARRISON STREET, 2ND FLOOR
SAN FRANCISCO, CA 94107

CANHR
CALIFORNIA ADVOCATES FOR NURSING HOME RESIDENTS

The Campaign to
STOP Chemical Restraints
in Nursing Homes.

[HOME](#) [ABOUT DRUGGING](#) [DOWNLOAD GUIDE](#) [BLOG](#) [JOIN THE CAMPAIGN](#) [LEGISLATION](#) [NEWS & RESOURCES](#)



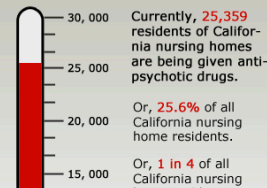
The Problem

About 25,000 California nursing home residents are currently given antipsychotic drugs that greatly increase their risk of death.

[Learn More](#) ▶

Our Mission

Help end the drugging of California nursing home residents. The goal of the campaign is to stop nursing homes and doctors from misusing dangerous antipsychotic drugs and other types of psychoactive drugs to chemically restrain residents and to replace drugging with individualized care. Through education, advocacy and political action, we seek to bring Californians together to end this harmful practice.



Get Involved

Drugging of California's Nursing Home residents is at an all-time high. Join our Campaign Against Drugging and sign our petition to the Governor urging him to crack down on misuse of psychoactive drugs in nursing homes. Together we can turn the tide of



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["Outing" Nursing Home Drug Offenders](#)

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stopdrugging@canhr.org

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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

