

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
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“...you have probably got 15,000 elderly people in nursing homes dying each year from the off-label use of antipsychotic medications for an indication that the FDA knows the drug doesn’t work...With every pill that gets dispensed in a nursing home, the drug company is laughing all the way to the bank... We have got so many clinical trials that show these drugs don’t work, that it is like malpractice to be using it.”

— Testimony of Dr. David Graham, a prominent FDA drug safety expert, at a February 13, 2007 hearing of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: The Adequacy of FDA Efforts to Assure the Safety of the Nation’s Drug Supply.

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Introduction

Nursing homes often conjure images of elderly people lying in bed or slumped in wheelchairs completely detached from the world around them. Many visitors and even staff members believe that unresponsive residents are the sad evidence of unavoidable mental declines brought about by dementia or simple old age. However, the poor quality of life for many nursing home residents is often caused not by the symptoms of their disease but by the side effects of their medications.

There is rampant misuse of psychoactive drugs in California nursing homes. Nearly 60% of all California nursing home residents are given psychoactive drugs, a 30% increase since 2000. Many psychoactive medications have dangerous side effects, especially antipsychotic drugs.

Tens of thousands of nursing home residents with dementia receive powerful antipsychotic drugs that are not intended or approved for their medical conditions. Rather, the drugs are often used to sedate and control them, a terrible substitute for the individualized care they need and deserve. The U.S. Food and Drug Administration (FDA) has issued its most dire warning – known as a black box warning – that antipsychotic drugs cause elders with dementia to die.

Antipsychotic drugs don't just hasten death, they often turn residents into people their own families barely recognize by dulling their memories, sapping their personalities and crushing their spirits. When families win battles to take residents off these drugs, they sometimes find that the person they've always known is still there. As one resident's daughter told us, "I got my dad back."

The increased use of psychoactive drugs in nursing homes has been accompanied by an epidemic disregard for the rights of residents to give or withhold their informed consent. Despite legal requirements, the informed consent of residents or their representatives is often ignored.

It is possible to stop a loved one from being drugged by a nursing home. This Guide gives you important facts about psychoactive drugs and advice on how to stop their inappropriate use.

What are Psychoactive Drugs?

Psychoactive drugs – sometimes called psychotropics or psychotherapeutics – contain powerful chemicals that act on the brain to change a person's mood, personality, behavior, and/or level of consciousness.

Types of Psychoactive Drugs

THERE ARE 4 MAJOR CLASSES OF PSYCHOACTIVE DRUGS:

- antipsychotics such as Zyprexa and Haldol;
- anti-anxiety drugs such as Ativan and Valium;
- anti-depressants such as Prozac and Zoloft; and
- sedative/hypnotics such as Halcion and Restoril.

Psychoactive drugs have positive uses, such as treating depression. However, many nursing homes routinely use psychoactive drugs as a substitute for needed care and as a form of chemical restraint.

Antipsychotics are the drug of choice in California nursing homes. These extraordinarily dangerous drugs are designed to treat schizophrenia and psychosis, but nursing homes often use them instead to drug residents with dementia into submission. One of every four California nursing home residents is given these drugs on a daily basis. Risperdal, Seroquel, Zyprexa, and Haldol are the most commonly used antipsychotic drugs.

Antianxiety drugs, such as Ativan and Valium, are also often used to sedate or restrain residents. Like antipsychotic drugs, they are often prescribed for unapproved uses and can cause serious side effects.

Antidepressant drugs are sometimes prescribed in nursing homes without attempting any non-drug interventions even though antidepressants have important downsides, such as increasing a resident's fall risk.

Psychoactive drugs are not the only type of drugs used to sedate or subdue residents with dementia. For example, antiseizure drugs (such as Depakote and Neurontin) are sometimes misused for this purpose.

Risks Galore, Including Death

Psychoactive drugs have numerous, potentially fatal side effects. Some of the most common include tremors, over-sedation, toxicity, anxiety, confusion, delirium and insomnia.



Perversely, psychoactive drugs often cause the agitation and anxiety they are prescribed to treat, leading to even more drugs or higher doses. Elderly nursing home residents are especially at risk of harmful drug interactions because most take many other medications and are in poor health. The use of psychoactive drugs puts them at greatly increased risk of falls and serious injuries that lead to immobility and often death.

The U.S. Food and Drug Administration (FDA) issued an advisory in June 2008 to healthcare professionals that states:

- Elderly patients with dementia-related psychosis treated with conventional or atypical antipsychotic drugs are at an increased risk of death.
- Antipsychotic drugs are not approved for the treatment of dementia-related psychosis. Furthermore, there is no approved drug for the treatment of dementia-related psychosis. Healthcare professionals should consider other management options.

The risk of death from antipsychotic drugs cannot be overstated. The California Attorney General characterized them as “deadly weapons” in

criminal charges against Kern County nursing home officials who are accused of causing the deaths of three residents through misuse of antipsychotic drugs.

The FDA has also issued its most dire warning – known as a black box warning – that antipsychotic drugs cause elders with dementia to die.

Sample FDA Black Box Warning for Risperdal. This warning applies to all antipsychotic drugs:

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 infectious (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. RISPERDAL (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

Psychoactive Drugs Cannot Be Used Without Informed Consent

Informed consent is a legal right that requires doctors to respect the decisions of their patients. As the term suggests, the concept has two components: information and consent.

The information part of informed consent requires doctors to explain any proposed treatment to their patients and, if applicable, to their patients' legal representatives.

The consent part of informed consent simply requires that patients or their representatives agree to any form of health care treatment before it is undertaken. Failure to obtain consent before administering treatment is battery against the patient.

California nursing home regulations require doctors to disclose the following information when seeking consent from residents or their representatives for the use of psychoactive drugs:

1. the reason for the particular psychoactive drug;
2. the medical condition for which the drug is needed;
3. how long and how often the drug will be used;
4. how the resident's medical condition will be affected;
5. the nature, degree, duration and probability of known side effects;
6. the reasonable alternative treatments; and
7. the resident's right to accept or refuse the psychoactive drug and, if he or she consents, the right to revoke consent for any reason at any time.

The key informed consent regulations are found at sections 72528 and 72527(a)(4) &(5) of Title 22 of the California Code of Regulations. See the Laws and Regulations section at the end of the Guide for a complete listing of pertinent laws and regulations.

Nursing homes are required to verify that consent has been given. In an emergency, psychoactive drugs can be used without consent.

Informed consent requirements are often completely or partially ignored by doctors and nursing homes. However, there are steps you can take to protect your relative from being drugged.

Questions to Ask Doctors and Nursing Homes When Psychoactive Drugs are Proposed

- What specific, documented behaviors or symptoms prompted the need for a psychoactive drug? (e.g., are there delusions or is the resident simply agitated?)
- Have all possible medical or environmental causes been ruled out? (e.g., pain, dehydration, infection, sleep disruptions)
- Has the doctor recently physically examined the resident to determine the need for the drug?
- What alternative treatments have been tried? Are other options still available?
- What are the risks and side effects of the drug?
- Has the FDA issued black box warnings for this drug?
- Has the FDA approved the use of this drug for this purpose?
- How will side effects be monitored? Who will do it?
- Will the proposed drug interact with any of the resident's other medications?
- Is the proposed drug duplicating other current medications?
- Will the resident start on the lowest possible dose of medication?
- When and how often will the need for the drug be reassessed? (the law requires a reassessment at least every three months)

Advocacy Tips When Psychoactive Drugs are Proposed

- You do not have to accept a doctor's recommendation to use psychoactive drugs.
- Do not give consent if the doctor has not directly examined the resident to determine the need for the drug.
- Antipsychotic drugs can be deadly. Don't consent to their use unless you are certain that all other care and treatment options have been exhausted.
- Insist that the doctor or nursing home provide written information on adverse consequences of the proposed drugs, including black box warnings.
- Carefully review and consider the written information before making a decision.
- Consider seeking a second opinion from a trusted physician or advocate if you have doubts about giving consent.

Periodically request a complete list of current medications from the nursing home and/or review the resident's medication administration records kept by the facility, especially if unauthorized drugging is suspected. If you discover that psychoactive drugs are being used without consent, file a formal complaint with the Department of Public Health, notify the local ombudsman program, and consult with CANHR about other actions you can take. See page 15 for more information on remedies.

Ask for a care plan meeting to discuss the need for proposed psychoactive drugs. The nursing home should hold a care plan meeting because the need for psychoactive drugs signals a significant change in the resident's condition. You have a right to attend and participate in this meeting. Use the care plan meeting to determine if the drug is really needed and whether the home has carefully considered all alternatives. Before the meeting, review CANHR's fact sheet, *Making Care Plans Work*, to learn about care plan rights and effective meeting strategies.

Your Right to Review Medical Records:

Nursing home residents and their legal representatives have the right to review their records within 24 hours of a request. Copies of records must be provided within two business days of a request. Requests for copies should be done in writing. If the nursing home refuses to honor a request to review records or for copies, see page 15 for possible remedies.

IMPORTANT NOTE: Before instructing a nursing home to stop administering an unwanted psychoactive drug, seek information on withdrawal symptoms. Sudden termination of many psychoactive drugs, especially antipsychotic drugs, can cause serious withdrawal symptoms. If such a drug is being stopped, the doctor should write an order to gradually discontinue it.

Who Can Exercise a Resident's Rights?

If the resident is capable of granting or withholding consent, only the resident may do so. If the resident lacks capacity to make a decision, then the resident's representative may grant or refuse consent. A resident and legal representative can withdraw consent to use a psychoactive drug at any time.

Under California law, persons who may act as your representative include a conservator, an agent designated under a valid advance health care directive or power of attorney for health care, your next of kin, or someone appointed by a court for this purpose.

Right to Refuse

Even if a nursing home resident has problems making health care decisions, she may refuse psychoactive drugs at any time. The right to refuse treatment is a basic constitutional right that may not be violated without a court order. A doctor's declaration that a resident does not have capacity is not enough to override the resident's right to refuse treatment. A nursing home may not retaliate or try to evict a resident who exercises her right to refuse psychoactive drugs.

Chemical Restraints and Unnecessary Drugs are Illegal

Even if a nursing home resident or representative has given informed consent to the use of a psychoactive drug, the drug's use may violate state and federal laws prohibiting chemical restraints and unnecessary drugs.

A chemical restraint is any drug imposed for purposes of discipline or convenience and not required to treat a resident's medical symptoms.

An unnecessary drug is any drug when used in excessive dose, for excessive duration, without adequate monitoring, without adequate indications for its use, or in the presence of adverse consequences that indicate the dose should be discontinued or reduced.

The federal government has even tougher standards on antipsychotic drugs. Nursing homes must not give these drugs to residents who have not used them unless they are necessary to treat a specific condition that has been diagnosed and documented in the resident's record. Federal guidelines state that antipsychotic drugs should not be used if the only symptoms are:

wandering	unsociability
poor self-care	inattention or indifference to surroundings
restlessness	fidgiting
impaired memory	nervousness
mild anxiety	uncooperativeness
insomnia	behavior that does not represent a danger to others

Measured by these standards, most antipsychotic and antianxiety drugs used by nursing homes to treat residents with dementia are both unnecessary and a form of chemical restraint.

Gradual Dose Reduction

Whenever a nursing home resident agrees to take an antipsychotic drug, the nursing home must nevertheless attempt to reduce or eliminate the drug use whenever possible. The use of antipsychotic drugs for each resident should be reviewed at least once every three months. Nursing home regulations require the drugs be reduced unless a doctor has determined that a dose reduction would be unsafe.

Nursing home residents or their representatives who have agreed to psychoactive drugs should closely monitor their administration and insist that they be discontinued whenever possible.

Alternatives to Drugs – Always the First Option

Drugs should always be the last resort for treating behavioral symptoms of dementia, not the first option.

Advocacy Tip

The best step most nursing homes can take to stop unnecessary drugging is to improve staff training on how to respond to behavioral symptoms of dementia. The quality of staff training is not necessarily outside your control. Ask the facility if it has arranged for the local Alzheimer’s Association chapter to conduct trainings for its staff. If not, urge it to do so.

Ask the doctor to assess possible medical causes of behavioral concerns. Agitation and confusion may be caused by untreated infections, dehydration, malnutrition, adverse medication reactions, pain, and other medical problems. If the doctor won’t conduct a thorough medical examination, explore options for replacing the physician or consulting with a geriatrician.

Individualized care and more attention are the best substitutes for drugs. Insist that your loved one’s care be customized by adapting personal care, sleep schedules, meals, bathing methods and other services to his or her preferences. Urge the facility to consistently assign caregivers who work well with your relative.

Adequate staffing is needed to respond quickly to physical needs such as help with toileting, getting in and out of bed, bathing, hunger and thirst. If staffing is not adequate, encourage the administrator to improve it.

Improving and simplifying the environment can relieve resident anxiety. Nursing homes must offer a homelike environment. Insist that it do so. For example, distracting noises (such as intercoms and buzzer systems) should be eliminated. Temperatures should be comfortable. So should


seating. No one wants to sit in a wheelchair all day. Hallways should be uncluttered. Lighting should be pleasant. Decorate and furnish your loved one's room to make it comfortable.

Help the facility staff plan to engage your relative in pleasurable activities throughout the day. Whatever he or she likes, such as walks, music, exercise, reading, visits from pets, group activities, and singing.

Roommate problems often trigger combative behavior. If this is a problem, ask the facility to find a compatible roommate or, if available, offer a private room.

Encourage patience and understanding. Common symptoms of dementia such as restlessness, pacing, and repeated questions should be expected and accepted.

Meet with the staff to plan care approaches at regular or specially requested care plan meetings. Learn about care plan rights and how to make care plan meetings effective in CANHR's fact sheet, *Making Care Plans Work*.



Stopping this form of elder abuse is one of CANHR's top priorities. If you would like to join CANHR's campaign to reduce the overdrugging of California's nursing home residents, please contact us at (800) 474-1116 or join the campaign at www.canhr.org.

Remedies to Illegal Drugging

If a California nursing home is using or threatening to use psychoactive drugs without consent, call CANHR at 1-800-474-1116 to discuss actions you can take to protect your rights.



There are a variety of actions you can take, including using the suggestions in this guide to seek change from the facility and the physician. Other options include:

Seeking help from local advocacy organizations: The local long term care ombudsman office (http://www.aging.ca.gov/programs/ombudsman_contacts.asp) may be helpful. The ombudsman program helps residents resolve concerns about care and rights. However, the ombudsman does not have any powers or direct authority over the nursing home. Local legal service programs may also be able to offer advocacy assistance. Contact CANHR for information.

Filing formal complaints: The California Department of Public Health (CDPH) licenses and inspects nursing homes and enforces state and federal standards. Read CANHR's fact sheet, *How to File a Nursing Home Complaint*, for instructions on how to file a complaint with CDPH. The fact sheet also explains how to file a complaint with the Bureau of Medical Fraud and Elder Abuse within the California Attorney General's Office. You can file a complaint against the doctor who prescribed the drugs through the Medical Board of California (http://www.medbd.ca.gov/consumer/complaint_info.html).

Suing the facility and doctor: Legal actions can help enforce your rights and seek damages if you or a family member has been harmed. Call CANHR to discuss referral to a qualified elder abuse attorney.



Alerting state legislators: CANHR is working to strengthen California laws against the drugging of nursing home residents. You can help by informing your assembly member and state senator about the inappropriate use of psychoactive drugs. Find your legislators at <http://www.leginfo.ca.gov/yourleg.html>.

Alerting the media: Nothing gets a nursing home's attention faster than the local media. If other options fail, consider asking the media to help expose dangerous drugging practices.

Resources

Related CANHR Fact Sheets available at www.canhr.org/factsheets:

- Making Care Plans Work
- How to File a Complaint
- Nursing Home Care Standards
- Restraint Free Care
- Outline of Nursing Home Residents' Rights

For more suggestions on caring for older adults with dementia without relying on psychoactive drugs:

- Visit www.bathingwithoutabattle.unc.edu; and
- Read the Alzheimer's Association's caregiver recommendations at www.alz.org

Laws and Regulations

LAWS ON INFORMED CONSENT:

California Code of Regulations (CCR), Title 22, §§ 72527(a)(3), (4) & (5), 72527(e) & 72528; California Health and Safety (H&S) Code §§ 1418.8 & 1418.9; United States Code (USC), Title 42, §§ 1395i-3(c)(1)(A)(i) & 1396r(c)(1)(A)(i); Code of Federal Regulations (CFR), Title 42, §§ 483.10(d)(2) & 483.10(b)(3)

LAWS ON THE RIGHT TO REFUSE CARE AND TREATMENT:

22 CCR §§72527(a)(4) & 72528(a)(6), H&S Code §1599.72; 42 CFR §483.10(b)(4)

LAWS AUTHORIZING REPRESENTATIVES TO EXERCISE RIGHTS:

22 CCR §72527(d), H&S Code §§1599.3 & 1418.8(c), 42 CFR §483.10(a)(3) & (4)

LAWS ON THE RIGHT TO REVIEW AND OBTAIN MEDICAL RECORDS:

42 USC §§1395i-3(c)(1)(A)(iv) and 1396r(c)(1)(A)(iv); 42 CFR §483.10(b)(2); H&S Code §§123100-123149.5

LAWS PROHIBITING CHEMICAL RESTRAINT:

22 CCR §72527 (a)(23) & 72319; H&S Code 1180.4(k); 42 CFR §483.13(a); 42 USC §§ 1395i-3(c)(1)(A)(ii) & 1396r(c)(1)(A)(ii)

LAWS ON UNNECESSARY DRUGS:

42 CFR §483.25(l)

LAWS REQUIRING CARE AND SERVICES FOR MENTAL OR PSYCHOSOCIAL ADJUSTMENT DIFFICULTIES:

42 CFR §483.25(f); 42 USC §§ 1395i-3(b)(2) & (4) and 1396r(b)(2) & (4) and 1396r(b)(2) & (4)

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.

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