

March 17, 2009

Senator Elaine Alquist, Chair
Senate Committee on Health
State Capitol, Room 2191
Sacramento, CA 95814

RE: SB 303 (Alquist) – Support

Dear Senator Alquist:

Thank you for introducing SB 303, the Nursing Facility Resident Informed Consent Protection Act of 2009. As the sponsor of SB 303, CANHR is writing in strong support of this vital bill. SB 303 will help prevent the excessive use of psychoactive drugs, one of the most serious problems facing nursing home residents today.

In recent years, nursing homes have increasingly turned to psychoactive drugs to sedate and control residents, especially those who display confused or agitated behaviors caused by dementia. Nearly 60 percent of California nursing home residents are given psychoactive drugs, a 30 percent increase since 2000. Although these drugs are sometimes appropriately prescribed to treat mental health conditions (such as antidepressant medications used to treat dementia), many of the psychoactive drugs being used in nursing homes are dangerous and used without medical justification.

We are particularly concerned about abuse of powerful antipsychotic drugs, such as Zyprexa, Seroquel, Risperdal, and Haldol. These drugs were designed to treat serious psychiatric disorders, such as schizophrenia and psychosis, but drug manufacturers have aggressively marketed them to nursing home doctors as a treatment for dementia. According to nursing home reported data, almost 20 percent of California nursing residents are given antipsychotic drugs despite the absence of psychotic or related conditions.

In recent years, the U.S. Food & Drug Administration (FDA) issued its most dire warning – known as a black box warning – that many antipsychotic drugs cause elders with dementia to die.

The FDA has never approved use of antipsychotic drugs to treat dementia, yet this type of drug misuse is rampant in nursing homes. These drugs are not only dangerous, they sometimes worsen the agitation and other behaviors they are prescribed to treat.

SB 303 will address these concerns by: (1) Codifying existing regulations that establish a nursing home resident's right to informed consent concerning the use of psychoactive drugs; (2) Specifying the type of information about psychoactive drugs nursing home residents shall receive; (3) Requiring nursing home staff to verify a resident has given informed consent prior to the administration of a psychoactive drug; (4) Clarifying that the Department of Public Health shall inspect nursing homes for compliance with resident informed consent requirements during periodic inspections currently required by law; and (5) Clarifying existing law pertaining to representatives of nursing home residents to exercise the rights of residents who lack capacity.

The need for each of the proposed requirements is discussed below.

1. Codify Informed Consent Regulations

Section 4 of SB 303 would amend Health and Safety Code §1599.1 by adding the general right of nursing home residents to informed consent established by regulation at 22 CCR §72527(a)(5). Section 5 of the bill would add section 1599.15 to the Health and Safety Code to codify the more specific informed consent requirements, established at 22 CCR 72528, that describe the information an attending physician must disclose concerning the proposed use of psychotherapeutic drugs or physical restraints.

By codifying these requirements, the Legislature will draw long overdue attention to a fundamental right that is poorly understood by physicians, nursing home staff, regulators, residents and their representatives.

Although never well-enforced, the right to informed consent disappeared from regulator and provider attention earlier this decade when the Department of Public Health suspended licensing inspections of nursing homes. For at least several years, DPH did not inspect nursing homes to determine compliance with California requirements, including the right to informed consent. Effective July 1, 2007, SB 1312 (Alquist, Statutes of 2006) mandated DPH to restore the licensing inspections; however, DPH has been slow to establish an inspection process and carry out the licensing inspections.

Drug manufacturers have taken full advantage of the lax oversight to market antipsychotic drugs to nursing homes and physicians as the method of choice to sedate and control residents with dementia. The extreme nature of these abuses is documented in charges filed by the U.S. Department of Justice (DOJ) against Eli Lilly for illegally marketing Zyprexa, an antipsychotic drug, for unapproved use by elders and children. On January 15, 2009, Eli Lilly agreed to a landmark settlement of the criminal and civil charges against it by agreeing to pay a record \$1.415 billion in criminal and civil penalties.

The U.S. DOJ accused Eli Lilly of targeting its illegal marketing of Zyprexa to doctors who treat the elderly in nursing homes and assisted living facilities. According to DOJ, Eli Lilly did so despite lack of FDA approval for this purpose and known severe side effects for this population. Reportedly, Eli Lilly promoted the use of Zyprexa by claiming it would help long term care facilities sedate residents who would otherwise require more care.

On January 15, California Attorney General Jerry Brown issued a press release on the Eli Lilly prosecution that reports California will receive almost \$112 million from the settlement. Eli Lilly's agreement to pay that amount for aggressively marketing Zyprexa for unapproved uses helps demonstrate the magnitude of the drug abuse in California, especially considering that Zyprexa is just one of several antipsychotic and antianxiety drugs commonly used to sedate nursing home residents,

The U.S. DOJ's and Attorney General Brown's press releases and related documents are available at: <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf> and <http://ag.ca.gov/newsalerts/release.php?id=1651>

The illegal drug marketing campaigns are just one part of the problem. Many nursing homes and doctors who treat residents have a profound misunderstanding of the informed consent requirements. This fact is most recently demonstrated by criminal elder abuse charges Attorney General Brown filed on February 18, 2009 against a nurse, physician and pharmacist for forcibly administering psychoactive drugs and directly causing the deaths of three residents of a skilled nursing facility operated by the Kern Valley Healthcare District.

The Attorney General's charges and an investigation report by the Department of Public Health describe widespread drugging of residents and nursing staff forcibly injecting residents with dangerous psychoactive drugs if they dared to question their care. In addition to the three deaths, other residents suffered severe medical and psychological trauma. When the drugging triggered behavioral problems, residents were given even stronger drugs. Once they were sedated to a "zombie" status, residents were confined in gerichairs and lined up in hallways.

According to the AG's charges, the physician and pharmacist routinely rubber-stamped drug orders from the facility's nursing director, and the nursing staff carried out the orders despite knowing that they were acting without the consent of the residents or their representatives. Many residents and family members were not informed that psychoactive drugs were being used. The AG's press release and related documents are posted at: <http://ag.ca.gov/newsalerts/release.php?id=1682>

Although extreme, the deplorable conditions at the Kern Valley Healthcare District facility reveal the perilous risk nursing home residents throughout California face of being chemically restrained by psychoactive drugs. "Doctors are just giving it (antipsychotic drugs) out like candy and nurses are administering it without any knowledge of what to look out for," reports Dr. Kathryn Locatell in a February 20, 2009 article in the Bakersfield Californian. Dr. Locatell is a geriatric physician who specializes in forensic investigation of elder abuse and served as the Attorney General's medical expert in the Kern Valley Healthcare District case.

In many nursing homes, drugs are used as substitute for care and supervision needed by residents with dementia, saving operators staffing costs. Residents with dementia are usually helpless to resist since they are often unable to question medical decisions. Their family members and representatives are often not informed about decisions to drug them or

told about drug risks. Those who are told about plans to use psychoactive drugs are often pressured to agree to them under threat that residents will be transferred, discharged or hospitalized if they don't go along.

In this environment, legislative action is urgently needed to make the informed consent requirements relevant again. Codifying them will immediately strengthen awareness by nursing home operators, their staffs, physicians, regulators and the public.

2. Specify Information on Drug Risks that Must be Disclosed

Section 5 of SB 303 would codify regulatory language on the information that physicians must convey, and would add the following language at new Health & Safety Code §1599.15(c)(4) to ensure that pertinent information on side effects and significant risks is communicated:

Information on risks associated with psychotherapeutic drugs shall include, but not be limited to, whether a proposed medication is being prescribed for a purpose or medical condition other than the purpose or medical condition for which the United States Food and Drug Administration (FDA) has specifically approved that medication. Information on risks of a proposed medication shall also include, in writing, any current boxed warning labels and accompanying detailed information regarding contraindications, warnings, and precautions required by the FDA.

Thus, SB 303 will explicitly require physicians to inform residents and their representatives about pertinent FDA warnings and advise them if proposed psychoactive drugs would be used for off-label purposes. Although physicians are already required to inform residents about side effects and significant risks, the bill spells out these elements of notification because many residents and their representatives are not being told about essential FDA warnings.

As noted earlier, the FDA has issued black box warnings concerning the use of antipsychotic drugs for treatment of elders with dementia. On June 16, 2008, the FDA issued its most recent alert stating that it has not approved antipsychotic drugs for treatment of dementia, that these drugs cause an increased risk of death for persons with dementia, and physicians who prescribe these drugs to this population should discuss the increased risk of death with patients and their families. It advises healthcare professionals to consider other treatment options. The alert is available at: http://www.fda.gov/CDER/drug/InfoSheets/HCP/antipsychotics_conventional.htm

SB 303 would require that residents and their representatives be given timely information about findings of this nature.

The bill's disclosure requirement is urgently needed because few residents or their representatives are aware of the dire FDA warnings about antipsychotic drugs. It is very unlikely that the tens of thousands of California nursing home residents who are currently being given antipsychotic drugs would consent to their use if they were told that these drugs are likely to cause or speed their death.

3. Require Skilled Nursing Facilities to Verify Informed Consent

Section 5 of SB 303 codifies and clarifies an important regulatory requirement at 22 CCR 72528 (c) that requires nursing homes to verify a resident has given informed consent before administering psychotherapeutic drugs or physical restraints. It requires facility staff to verify the consent with the resident or resident's representative and specifically document the consent in the resident's health record.

4. Require DPH to Inspect for Compliance with Informed Consent Requirements

As noted earlier, SB 1312 (Alquist, Statutes of 2006) requires the Department of Public Health to conduct licensing inspections of nursing homes to determine compliance with California standards, including the informed consent requirements. Section 5 of SB 303 adds Health and Safety Code §1599.15(g) to reinforce this requirement. Strong enforcement by DPH is necessary to ensure that all nursing homes respect the right to informed consent and stop using psychoactive drugs to chemically restrain residents.

DPH is already funded to carry out the licensing inspections through approved budget allocations in FY 07-08 and 08-09 that added funding for a large number of inspectors (evaluators) for this purpose.

5. Clarify Status of Residents' Representatives in Exercising Rights

Section 6 of the bill repeals Health and Safety Code §1599.3, which describes who can exercise the rights of an incapacitated resident. Section 7 replaces the repealed section with regulatory language on this subject at 22 CCR §72527(d).

The regulatory language is being codified because it contains a more complete and accurate list of the persons who can exercise a resident's rights. For example, the regulation appropriately recognizes that a resident's attorney-in-fact designated through a valid durable power of attorney for healthcare can exercise his or her rights. The existing statutory language does not.

By so doing, SB 303 removes a problematic conflict between the statute and the regulation.

In summary, SB 303 is a carefully crafted measure to help fight the rampant misuse of psychoactive drugs in nursing homes. The bill will give nursing home residents and their representatives a fighting chance to prevent or stop inappropriate use of psychoactive drugs by giving them the information they need to make informed decisions before drugs are used. Additionally, the law will draw much needed attention to a severe threat to residents' health and well-being. By taking this action, the Legislature will put nursing homes and physicians on notice that California will not tolerate the unnecessary use of psychoactive drugs.

Importantly, SB 303 will not create any new costs. Doctors are already required to obtain informed consent, nursing homes are already required to verify consent and the Department of Public Health is already required and funded to inspect for compliance with these requirements. SB 303 will help ensure that these existing duties are carried out in an appropriate manner.

We are attaching a listing of recent articles that help illustrate our concerns.

Please help us fight against excessive drugging of California nursing home residents by voting "yes" on SB 303.

Sincerely,



Patricia L. McGinnis
Executive Director



Michael Connors
Advocate

cc: Members, Senate Health Committee