CASE NO. A147987

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT
DIVISION FOUR

CALIFORNIA ADVOCATES FOR NURSING HOME REFORM (CANHR), GLORIA A., and ANTHONY CHICOTEL,

Plaintiffs and Appellants,

v.

KAREN SMITH, MD., MPH, as Director of the California Department of Public Health,

Defendant and Appellant.

BRIEF OF AMICI CURIAE AARP, AARP FOUNDATION, THE NATIONAL CONSUMER VOICE FOR QUALITY LONG-TERM CARE AND JUSTICE IN AGING IN SUPPORTOF PLAINTIFFS AND APPELLANTS

On Appeal From the Superior Court for the State of California, County of Alameda, Case No. RG13700100, Hon. Evelio Martin Grillo

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Pursuant to California Rules of the Court, rule 8.208, undersigned counsel for Amici Curiae AARP, AARP Foundation, National Consumer Voice for Quality Long-Term Care and Justice in Aging certifies that there are no interested entities or persons that must be listed in this certificate under rule 8.208.

Dated: September 29, 2017

Respectfully Submitted,

/s/William Alvarado Rivera

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes, Rules and Regulations

Legislative History

Other Authorities

INTRODUCTION AND SUMMARY OF ARGUMENT

Nursing facilities' overuse of psychotropic drugs is a recognized danger to nursing facility residents and highlights the danger posed by Health and Safety Code section 1418.8. Administration of psychotropic drugs is by no means a "nonintrusive and routine, ongoing medical intervention" contemplated by section 1418.8. *CANHR v. Chapman*, No. RG13700100 32 (Cal. Super. Ct. June 24, 2015) (order granting petition for writ of mandate in part and denying in part) (hereinafter "Opinion") (quoting *Rains v. Belshe*, 32 Cal. App. 4th 157, 186 (1995)). Far from an ordinary medical intervention, the administration of psychotropic drugs to older adults instead often leads to a devastatingly negative impact on their physical and mental health. Moreover, these drugs are commonly administered to nursing facility residents not to treat any specific physical or mental illness, but rather to "manage" behavior. A decision to administer these drugs to nursing facility residents without a clear expression of informed consent, either from the resident himself or from a duly-appointed surrogate decision-maker, deprives the resident of basic human rights.

The Legislature has explained that section 1418.8 is designed to address the unavailability of surrogate decision-makers to make "day-to-day medical treatment decisions." 1992 Cal. Adv. Legis. Serv. 1303 (Lexis Nexis). Now, Defendant wrongly suggests that administration of psychotropic drugs is among the range of "nonemergency but necessary and appropriate" decisions that nursing facilities are to make. Brief for Defendant at 14, *CANHR v. Smith*, No. A147987 (Cal. App. 1st Nov. 17, 2016) (hereinafter "Defendant's Br."). This claim is belied by both clinical research and amicus

AARP Foundation's own experience litigating cases. Under no circumstances should a nursing facility's decision to administer psychotropic drugs ever be considered a routine, mundane, or "day-to-day" decision.

Appellant alleges that several measures, including existing federal and state oversight mechanisms and interdisciplinary teams, serve as adequate protections against the unwarranted exercise of Section 1418.8. *Id*. at 39. However, as discussed *infra*, none of these measures adequately prevent nursing facilities' rampant overuse of psychotropic drugs.

ARGUMENT

I. THE TRIAL COURT CORRECTLY FOUND THAT THE USE OF SECTION 1418.8 TO AUTHORIZE PSYCHOTROPIC DRUGS IN NURSING FACILITIES CAN HARM RESIDENTS.

A. Psychotropic drugs are a high-risk intervention that can quickly deprive nursing facility residents of many functions of daily living.

The Superior Court recognized that psychotropic drugs can have "many serious side effects, which include…potentially permanent side effects, and on rare occasions, sudden death." Op. at 32 (citing *Keyhea v. Rushen*, 178 Cal. App. 3d 526, 531 (1986)). These side effects are especially prevalent in older adults, who tend to experience them at a faster pace and with greater severity. "Psychotropic drugs" is a "broad term referring to medications that affect mental function, behavior, and experience." Pamela L. Lindsey, *Psychotropic Medication Use among Older Adults: What All Nurses Need to Know*, 35 J. Gerontological Nursing 28, 30 (Sept. 2009). Antipsychotic drugs are a subclass of psychotropic drugs that are administered for the treatment of psychotic symptoms, such

as delusions and hallucinations. *Id.* at 33. While the administration of antipsychotic medications is potentially hazardous to patients of all ages, it is especially hazardous to older adults. *Id.* at 35. In fact, the labels for many antipsychotic drugs explicitly caution against the use of these drugs for elderly patients with dementia-related symptoms, citing an "increased risk of death." *See, e.g.*, *U.S. Food & Drug Admin, GEODON Capsules,* 1 (2008), goo.gl/JEEUQB (describing the risks of an atypical antipsychotic drug known as Geodon approved to treat schizophrenia and bipolar mania). Even among elderly individuals with actual diagnoses of psychosis, the risks of these drugs tend to far outweigh any anticipated benefits, as "[e]lderly schizophrenic patients are especially prone to the side effects of antipsychotic medications." Prakash S. Masand, *Side Effects of Antipsychotics in the Elderly*, 61 J. Clinical Psychiatry 43, 48 (2000).

Drugs such as Haldol that belong to an older class of antipsychotic drugs, called "typical" antipsychotic drugs, are known to have serious side effects in older adults that can affect their overall quality of life. Lindsey, *supra*, at 33. The side effects often include Parkinson's-like movement and other involuntary bodily movements; even when administered in low doses for short periods of time, these side effects can develop in up to half of patients. *Id.* Most critically, these symptoms "can last for several years and, in some cases, [are] irreversible even after the medication has been discontinued." *Id.*

A newer class of antipsychotic drugs, commonly called "atypical" antipsychotic drugs, likewise poses heightened risks to older adults. Drugs in this class include Geodon, Seroquel, and Zyprexa. *U.S. Food & Drug Admin., Atypical Antipsychotic Drugs Information* (2016), goo.gl/Q69Qp5. In 2005, the FDA analyzed clinical studies

concerning the use of atypical antipsychotic medications in elderly patients with dementia. The FDA concluded that patients who were given these antipsychotic drugs suffered an unusually high death rate when compared to patients who had received a placebo. Lindsey, *supra*, at 34. The results of this study prompted the FDA to require the manufacturers of many of these drugs to add "black box" warnings to their labels that would provide a clear warning of these risks and a specific advisory that these drugs are not approved for use in patients with dementia. *Id.*

These drugs have devastating effects on older adults, and those effects can begin almost immediately. AARP Foundation attorneys brought three cases challenging the use of these drugs in nursing facilities without informed consent. In each case, the resident's overall well-being and cognitive functioning declined swiftly. In one such case, a woman entered a nursing facility in Ventura, California, to recover from a broken pelvis. At her admission to the facility, she was only on prescription drugs to manage her blood pressure, cholesterol, and pulmonary disease. Jan Goodwin, *Antipsychotics Overprescribed in Nursing Homes*, AARP BULLETIN (July/Aug. 2014), https://goo.gl/OJwrIw. A mere 18 days later, the same woman was discharged from the facility "withdrawn, slumped in a wheelchair with her head down, chewing on her hand, her speech garbled," due to the side effects of the antipsychotic drugs administered to her by the nursing facility staff. *Id.*; *see also Pierce v. Genesis Healthcare*, S16C-09-002-THG (Del. Super. Ct. Sept. 2, 2016) (alleging that a resident died from the administration of the drug Zyprexa approximately two months after it was first administered to her).

Given these drugs' obvious and well-documented risks to older adults, an observer may wonder why these drugs are being prescribed and administered in nursing facilities. A recent study of the motivations behind these drugs' administration reveals a wide variety of vague, and often poorly documented, justifications. Ultimately, the study concluded that "[t]he wide variety of rationales found in this study for prescribing antipsychotic medications suggests that [nursing facility] teams articulate and understand the rationales for their use poorly." Alice F. Bonner, *Rationales That Providers and Family Members Cited for the Use of Antipsychotic Medications in Nursing Home Residents with Dementia*, 63 J. Am. Geriatrics Soc'y. 302, 308 (2015). The lack of clear justifications for the drugs was of particular concern to the study's authors "because, in many cases, safer alternatives exist for managing these problems." *Id.*

The prominence of these drugs in nursing facilities today is owed not to their success in treating actual psychiatric conditions, but rather to drug companies' promotion of them for unapproved, or "off-label," uses. In 2012, Abbott Laboratories, manufacturer of the drug Depakote, pled guilty and paid $1.5 billion in fines to resolve charges of off-label promotion of Depakote for use in nursing facilities. Press Release, U.S. Dep't of Justice, *Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote* (May 7, 2012) (https://goo.gl/QQ7uKw). In 2009, the manufacturers of the antipsychotic drugs Risperdal and Zyprexa paid $112 million and $1.4 billion in fines, respectively, to resolve similar claims. *See* Press Release, U.S. Dep't of Justice, *Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa* (Jan. 15, 2009) (https://goo.gl/8N6okA);

Press Release, U.S. Dep't of Justice, *Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay $112 Million to Settle False Claims Act Cases* (Nov. 3, 2009) (https://goo.gl/PgAX42).

As a result of the successful promotion of these drugs for unapproved uses, antipsychotic drugs administered in nursing facilities are, in real-world practice, frequently prescribed and administered for uses not approved by the FDA. A study reveals that very few nursing facility residents are actually diagnosed with the mental illnesses that these drugs are approved to treat. Dallas Seitz et al., *Prevalence of Psychiatric Disorders Among Older Adults in Long-Term Care Homes: A Systematic Review*, 22 Int'l Psychogeriatrics 1025, 1033 (2010).

B. All Californians have the basic human right to make personal health care decisions.

The dangers posed by widespread administration of antipsychotic drugs for unsafe and unapproved uses are underscored by the need to protect nursing facility residents from unconsented-to medical treatments. Californians of all ages have a fundamental right to decide whether or not to consent to a proposed medical or psychiatric treatment. They do not lose that right simply by entering a nursing facility.

On three separate occasions, the United States Supreme Court has recognized the important liberty interest that persons have in protecting their bodily integrity — including, specifically, the rights of prisoners and pre-trial detainees to be free from forced medication with psychotropic drugs. *Sell v. United States*, 539 U.S. 166 (2003); *Riggins v. Nevada*, 504 U.S. 127 (1992); *Washington v. Harper*, 494 U.S. 210 (1990). In

Harper, the Court unequivocally stated that "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." 494 U.S. at 229. Likewise, the Court recognized the fundamental purpose of antipsychotic drugs to "alter the chemical balance in a patient's brain, leading to changes, intended to be beneficial, in his or her cognitive processes… [that] can have serious, even fatal, side effects." *Id.* In his partial concurrence, Justice Stevens characterized this as "particularly intrusive" when it "creates a substantial risk of permanent injury and premature death" and "degrading" when it "overrides a competent person's choice to reject a specific form of medical treatment." *Id.* at 237 (Stevens, J., concurring in part).

In its examination of the degree to which these drugs intrude into one's body, the Court in *Riggins* again recognized that "the drugs can have serious, even fatal, side effects." 504 U.S. at 134 (quoting *Harper*, 494 U.S. at 229). Justice Kennedy's concurrence goes farther in describing the specific harms of these drugs that "would be disturbing for any patient" and how they can hinder a defendant's ability to present an adequate defense:

> The defendant may be restless and unable to sit still…The drugs can induce…a condition called parkinsonism, which, like Parkinson's disease, is characterized by tremor of the limbs, diminished range of facial expression, or slowed functions, such as speech. *Ibid.* Some of the side effects are more subtle. Antipsychotic drugs…can have a 'sedation-like effect' that in severe cases may affect thought processes.

Riggins, 504 U.S. at 142-43 (Kennedy, J., concurring).

Recognizing the clear interest of inmates and criminal defendants to be free from unwanted and dangerous medical treatment, the Court's decision in *Sell* established a

heavy burden for the government to overcome before it can involuntarily medicate a defendant with a mental illness for the purpose of rendering him competent to stand trial. The government must prove *all* of the following: (1) that important governmental interests are at stake; (2) that involuntary medication will significantly further those state interests; (3) that involuntary medication is *necessary* to further those interests; and (4) that administration of the drugs is medically appropriate. 539 U.S. at 180-181.

Likewise, the Ninth Circuit has noted that antipsychotic medications can cause a personality change that interferes with a person's autonomy and can impair his or her ability to function in particular contexts, with serious and potentially fatal side effects. *U.S. v. Ruiz-Gaxiola*, 623 F.3d 684, 691 (9th Cir. 2010). Accordingly, the Ninth Circuit also recognized an individual's constitutional right to be free from antipsychotic drugs. In *Ruiz-Gaxiola*, the court vacated a lower court's order authorizing the government to forcibly medicate a man charged with illegally entering the country. The court specifically found that the defendant possessed "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment." *Id*. (quoting *Harper*, 494 U.S. at 221-22). The court explained that "[t]ogether, *Harper*, *Riggins*, and *Sell* demonstrate the Supreme Court's reluctance to permit involuntary medication except in rare circumstances." *Id*.

California law is in accord. In *Cobbs v. Grant*, the California Supreme Court held that a patient has the right to make the ultimate informed decision regarding his treatment, and must knowledgeably consent to any treatment. *Cobbs v. Grant*, 8 Cal. 3d 229, 242-43 (1972) (en banc) (stating that "a person of adult years and in sound mind has

the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment"). Under this doctrine, physicians have the duty of "reasonable disclosure," which includes all information that is material to the patient's decision. *Id.* at 243.

Finally, California regulations also reflect the role of the nursing facility resident as health care decision-maker. Under those regulations, residents "shall have the right… [t]o consent to or to refuse any treatment or procedure…" CAL. CODE REGS. tit. 22 § 72527(a)(4).

II. THE MEASURES IDENTIFIED BY DEFENDANT DO NOT PROVIDE ADEQUATE SAFEGUARDS AGAINST UNWARRANTED USE OF PSYCHOTROPIC DRUGS.

A. Abuse and neglect in nursing facilities continue to be widespread despite the oversight of federal and state authorities.

Defendant argues that section 1418.8 satisfies due process because a "comprehensive and rigorous oversight scheme" allegedly governs the use of antipsychotic drugs in nursing facilities. Defendant's Br. at 39. The facts do not support this claim.

While it is true that that nursing facilities are subject to state and federal laws and regulations, the government has determined that the majority of facilities do not comply with those regulations. Nursing facilities that receive Medicare and/or Medicaid funding must comply with the 1987 Omnibus Budget Reconciliation Act (OBRA) and its implementing regulations, which set forth minimum standards of care for nursing facilities. *See* 42 U.S.C. §§ 1395i-3, 1396r (2012); 42 C.F.R. § 483.1-.95 (2016). In

2014, CMS cited more than 92% of nursing facilities in the country for violations of federal health and safety standards. *See* Charlene Harrington et al., *Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2014: Supplemental Tables*, Kaiser Fam. Found., Aug. 4, 2015, at 24, https://goo.gl/z8PYe8. CMS cited an average of 20.53% of all facilities surveyed in 2014 for one or more deficiencies that caused harm or immediate jeopardy to residents. *Id.* at 25. The federal government recently conceded that problems remain as to "the large number of drugs that many residents are being prescribed," including multiple psychotropic drugs. *Medicare and Medicaid: Reform Requirements for Long-Term Care Facilities*, 81 Fed. Reg. 68,688, 68767 (Oct. 4, 2016).

In California, the problem of overmedicating nursing facility residents with psychotropic drugs persists. According to the most recent data from CMS, nearly 70 nursing facilities in California place more than half of their residents on daily antipsychotic drugs. Ctrs. For Medicare & Medicaid Servs., Minimum Data Set: 4th Quarter 2016. Clearly, federal and state regulatory enforcement efforts are falling short. Nursing facilities place residents on these drugs without adequately training staff in psychiatric symptoms and without adequate oversight from a psychiatrist. Lindsey, *supra*, at 29.

Even where authorities detect abuse or neglect, many nursing facilities nonetheless continue harmful practices. U.S. Gov't Accountability Off., *GAO-07-241, Nursing Homes: Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents* (2007) [hereinafter *GAO Nursing Facility Federal Enforcement Report*], https://goo.gl/yW5dZC. The Director of Health Care for the GAO

testified before Congress that "[a] small but significant proportion of nursing homes nationwide continue to experience quality-of-care problems – as evidenced by the almost 1 in 5 nursing homes nationwide that were cited for serious deficiencies in 2006." U.S. Gov't Accountability Off., GAO-07-794T, *Nursing Home Reform: Continued Attention Is Needed to Improve Quality of Care in Small but Significant Share of Homes*, 9 (2007), https://goo.gl/9mWQ8o.

CMS's recent efforts have not deterred some facilities from repeatedly harming residents, as "sanctions may have induced only temporary compliance in these homes because surveyors found that many of the homes with implemented sanctions were again out of compliance on subsequent surveys." *Id.* at 15-16. The 2007 GAO report on federal enforcement efforts states, "almost half of the homes we reviewed – homes with prior serious quality problems – continued to cycle in and out of compliance, continuing to harm residents." *GAO Nursing Facility Federal Enforcement Report*, at 26. The types of deficiencies found in the facilities that cycled in and out of compliance included inadequate treatment or prevention of pressure sores, resident abuse, medication errors, and employing convicted abusers. *See id.* at 68. Furthermore, the scope of the problem is greater than these federal reports show, as inspections repeatedly understate serious care problems. U.S. Gov't Accountability Off., GAO-08-517, *Nursing Homes: Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses*, 11 (2008), https://goo.gl/ZzLv3a (noting that "[f]rom fiscal year 2002 through 2007, about 15 percent of federal comparative surveys

nationwide identified state surveys that failed to cite at least one deficiency at the most serious levels of noncompliance – the actual harm and immediate jeopardy levels").

B. Interdisciplinary Teams Are No Substitute for Due Process Rights.

Defendant relies heavily on the statute's authorization of interdisciplinary teams ("IDTs") to make critical decisions for nursing facility residents, including the administration of psychotropic drugs. *See* Defendant's Br. at 39 (stating that "section 1418.8 provides authority for IDTs to give substituted consent on behalf of residents for administration of antipsychotic medications in accordance with applicable regulations and standards of practice"). However, a review of these IDTs shows that these teams can be susceptible to the same biases that encourage, and not screen out, the unnecessary use of antipsychotic drugs. In no event are they an adequate substitute for informed consent and due process.

In his partial dissent in *Harper*, Justice Stevens captured the essence of the critical flaw in the use of IDTs to make medical decisions: the "failure to have the treatment decision made or reviewed by an *impartial* person or tribunal." 494 U.S. at 250 (Stevens, J., dissenting in part) (emphasis added). In *Harper*, the policy authorizing involuntary medication of inmates provided that a "nonemergency decision to medicate for up to seven consecutive days must be approved by a special committee after a hearing… [consisting of] the Associate Superintendent…, a psychologist, and a psychiatrist." *Id.* at 250-51. A similarly composed committee was required to authorize "long-term" involuntary medication over a period of seven days or more, but, unlike the "short-term" committee, current treating professionals or previous committee members were not

barred from serving on the long-term committee. *Id.* at 251. Moreover, the long-term committee "merely review[ed] the inmate's file and minutes of the 7-day hearing," rather than conducting a new hearing. *Id.* With this procedure in place, psychotropic medication could "continue indefinitely" with only a "review and report by the treating psychiatrist every 14 days." *Id.*

In Justice Stevens's view, the decision-makers in the long-term committee had two inherent conflicts of interest:

> *First*, the panel members must review the work of treating physicians who are their colleagues and who, in turn, regularly review their decisions. Such an in-house system *pits the interests of an inmate who objects to forced medication against the judgment not only of his doctor, but often his doctor's colleagues… Second*, the panel members, as regular staff of the Center, must be concerned not only with the inmate's best medical interests, but *also with the most convenient means of controlling the mentally disturbed inmate*.

Id. at 251-53 (emphasis added).

Section 1418.8 raises similar concerns. As reflected in amici's experience, the use of IDTs is no substitute for a neutral third party to make decisions as to incapacity. In fact, IDTs often reflect many of the same biases noted by Justice Stevens in *Harper*. Members of the IDT are often colleagues, not adversaries, who work for the same nursing facility and are driven to meet two potentially conflicting goals: to both ensure the health and well-being of residents and to ensure that resident behavior is under control in a manner that is convenient to the facility. The decisions made by an IDT may not be the culmination of a thoughtful and independent discussion, but rather the product of an

"echo chamber" that has the overall goal of meeting the interests of the nursing facility, and not necessarily the interests of the resident. Under section 1418.8, the only member of the IDT responsible for solely representing the patient's interests—the "patient representative"—is only required to be part of the IDT where it is "practicable" for the nursing facility. Cal. Health & Safety Code § 1418.8(e).

Empirical studies of decision-making in IDTs show that these same biases exist beyond the context of prisons as considered in *Harper*. Researchers conducted a qualitative analysis of the decision-making process in IDTs assigned to nursing facility units specific to the treatment of residents with Alzheimer's disease. Barbara G. Bokhour, *Communication in Interdisciplinary Team Meetings: What Are We Talking About?*, 20 J. of Interprofessional Care 349 (2006). Although members of the IDT expressed a belief that their team meetings were "important to providing good coordinated care of patients," the study concluded that the "actual processes and outcomes of these meetings did not always meet this goal." *Id.* at 360.

According to the study, some IDTs did not function together as a unit, but rather as "fragmented groups of individuals who assess and treat patients independently;" professionals in these IDTs tended to merely "share their information while maintaining division of professional knowledge." *Id.* The conduct during these team meetings emphasized the ritualized processes of "giving report" and "writing report," which "resulted in a narrowly focused way of talking about" symptoms experienced by the residents. *Id.* at 361. As a result, the treatment plans generated from these discussions "fail[ed] to incorporate understandings of patients as individuals with unique

characteristics and needs… [and placed] little emphasis on issues pertaining to patients' quality of life." *Id.* Instead, these treatment plans focused solely on "issues of medical and behavioral management," not on a person-centered approach to the resident's care. *Id.*

CONCLUSION

For the foregoing reasons, the judgment of the Superior Court should be affirmed with respect to (1) its requirement that the nursing facility must provide notice of its exercise of Health & Safety Code section 1418.8; (2) the procedures for the administration of antipsychotic drugs to skilled nursing and intermediate care facility residents; and (3) its prohibitions on the exercise of section 1418.8 with respect to end-of-life decisions and the administration of psychotropic drugs. The court should reverse all other aspects of the Superior Court's judgment.

Dated: September 29, 2017

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