KANSAS ADVOCATES for BETTER CARE
making elder care better every day

March 20, 2018

Chairwoman Davis and Members of House Children & Seniors Committee,

KABC appreciates the opportunity to testify in support of HB 2704 regarding a resident's Informed Written Consent for use of anti-psychotic drugs in nursing facilities.

I am Mitzi McFatrich, executive director of Kansas Advocates for Better Care (KABC). KABC is a non-profit organization, which advocates with and on behalf of older Kansans for better quality long-term care, at home and in facilities.

What this bill does

*This bill does not ask you to grant the right to informed consent to a resident or their representative. The resident has that right.

*This bill does not ask you to impose a different standard of practice on prescribers (includes Physicians, Physician Assistants, or Advanced Practice Nurses) with regard to their existing duty for informed consent to patients.
The physician or prescriber has that duty.

*This bill does ask that prescribers along with care facilities adhere to the current standards-of-care surrounding the use of anti-psychotic medications in the elderly in their facilities.

*The bill does ask that there be written confirmation that an adult care home resident or their representative has been fully informed with regard to anti-psychotic medications by the prescriber, and that the resident or representative has agreed or declined to use the medication after being fully informed.

*This bill does have clear provisions to allow for the prescribing and use of anti-psychotics in an emergency situation.

Why is this bill needed

Older Kansans are at significant risk of receiving anti-psychotic drugs if they have dementia, even though these drugs are not approved for the treatment of dementia, and in fact pose hazardous health risks to them.

- Sadly, this bill comes too late for thousands of older adults who have already died, been injured, and had the quality of their lives significantly reduced, due to the inappropriate use of these drugs.
- By 2030, the prevalence of dementia will triple due to aging demographics.
- 2,550 older adults in KS nursing facilities are currently inappropriately receiving anti-psychotic drugs[1], in the absence of a mental health diagnosis for which the use is approved. Dementia is not.
- Kansas is ranked 50th worst among states for making improvement to reduce the inappropriate and overuse of anti-psychotic drugs in nursing facilities[2]. KS is ranked best/1st for not using physical restraints. In 2011 KS use rate was 26.1%, Quarter 3 of 2017 it was 19.2%. So that we

[1] Appendix 2 of the HRW They Want Docile report: the data on this chart includes data on nursing facilities, residents of nursing facilities, and anti-psychotic drug use in states visited by Human Rights Watch
"The number of long-stay residents in nursing facilities with a majority population of >65 taking anti psychotic drugs without an exclusionary diagnosis in KS was 2,550."

are not confused, this testimony is in regard to the proper use and regulation of only anti-psychotic drugs. The larger world of all "psychotropic drugs" is a much broader and inclusive designation that would include not only anti-psychotic medications (that we are addressing) but a larger number of other drug categories including anti-anxiety drugs, sedatives, hypnotics, etc. Many states (such as Wisconsin, see below) already have enacted broader laws to include informed consent for all of these other categories of medication. This bill is limited to "anti-psychotic" drugs only.

- Black Box Warning: against anti-psychotic drug – the FDA's highest warning, issued specifically regarding dangers to elders with dementia[3]. A-P drugs are not an approved treatment for dementia. The full text of this Black Box Warning was issued 10 years ago in 2008, "**WARNING: Increased Mortality in Elderly Patients with Dementia—Related Psychosis.** Elderly patients with dementia-related psychosis treated with anti-psychotic 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 2.6% in the placebo group"…with additional verifying information following.

  Clearly, since 2008 the use of anti-psychotics in elderly patients with dementia has been shown not only to be in conflict with medical standards of care and practice but harmful to older adults with dementia.

  In 2005 the FDA first issued a Black Box Warning specific to atypical antipsychotic use on elders with dementia.

- Thus, anti-psychotic drugs pose significant risks to older adults including death, stroke, cardio events, pneumonia, infections. The many other drug side effects also include cognitive challenges, confusion, sedation, falls, and muscle contractures and Tardive Dyskinesia which are often irreversible. Anti-psychotic drugs also diminish the quality of life
- Benefits of antipsychotic medications prescribed routinely for the elderly are at best questionable, while there is consistent evidence that antipsychotics are associated with clinically significant adverse effects, including mortality.[4] There is next-to-no benefit for the older person.
- Abbott Labs Paid $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote - Company Maintained Specialized Sales Force to Market Drug for Off Label Purposes; Targeted Elderly Dementia Patients in Nursing Homes[5]
- Johnson & Johnson Paid More Than $2.2 Billion to Resolve Criminal and Civil Investigations Allegations Include Off-label Marketing and Kickbacks to Doctors and to the nation's largest long-term care pharmacy provider[6]

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[2] CMS published national data and by state, 12/2017.

[3] https://www.fda.gov/Drugs/DrugSafety/ucm094303.htm

[4] From They Want Docile, HRW report. American Psychiatric Association, which issued practice guidelines on the use of antipsychotic drugs in people with dementia, the "expert consensus suggests that use of an antipsychotic medication in individuals with dementia can be appropriate."[59] Yet the guidelines conclude, "in clinical trials, the benefits of antipsychotic medications are at best small."[60] Meanwhile, countering these meager potential benefits is the "consistent evidence that antipsychotics are associated with clinically significant adverse effects, including mortality."[61]

5 https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote

6 https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations

- Based on this information and guidance (now 10 years old from its time of origin in 2008) it would be our expectation that the medical and caring communities at all levels would not only be supportive of this legislation and clear directives but would provide leadership in making these legislative changes for the benefit and safety of the elderly population for which they care.
- Today you have testimony from resident representatives who have experienced or are experiencing not being informed, or who received very abbreviated information about these drugs, or who are notified only after the fact and without information which addresses the significant risks and very limited benefits of anti-psychotic drugs.
- It is not the older adult with dementia who is primarily benefitting from the use of these drugs, yet they assume all of the risk. As noted by Bethany Brown in her testimony to the Committee on 2-13-2018, the benefits are primarily to others, who are understandably distressed by expressions of need a person with dementia is communicating, but which we may not be able to understand or which cause us discomfort.

Emerging Trends and Better Practices Currently in Use

Hospitals and doctors are increasingly using written informed consent in areas like oncology which use drugs which present significant risks to patients. These written informed consents are in addition to the signed forms hospitals ask patients to sign to verify they are agreeing to treatment. Written Informed Consent is the trend. It offers clarity for the patient who often is not able to take in all the information provided during a medical visit and for providers it offers protection from liability[7]. Written informed consent for anti-psychotics is comparable to what is in place around end of life choices, or a living will and which are routinely done and requested by hospitals, doctors, and nursing facilities.

When I visit my doctor, she does explain suggested medications to me, including the common and less common side effects, and alternatives treatments. She may write me a prescription, and then I have the choice – fill it or not. If I take it to the pharmacy to have it filled, before the pharmacist will hand over the medication, she too talks to me about the medication, the dosage, potential side effects of concern, and before I pay or leave, I am asked for my signature on a form that the medication has been explained to me by the pharmacist.

Persons with dementia living in nursing facilities are at twice the risk of being given an anti-psychotic than if they live in the community. If I live in a nursing home it is very unlikely that I will see the doctor who prescribes the medicine for me, and very unlikely that the doctor will fully explain to me the medication's risks and benefits, the common side effects, the alternative treatments, and answer my many questions. I won't be able to exercise my right to choose to fill or not fill the prescription, the facility will do that. It is very unlikely the facility will ask if I want to take the medication and will label me as non-compliant if I attempt to avoid taking it. It is just as unlikely that I will see a pharmacist or that I'll have the opportunity to have the medication and its side effects and risks explained to me, or that I'll be asked to sign off that I've had this information given to me.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2708008/ Liability Associated With Prescribing Medications. Judith G. Edersheim, J.D., M.D. and Theodore A. Stern, M.D. Most physicians are aware that they must obtain the informed consent of their patients before starting a treatment or medication. Many do not know, however, that the failure to obtain and document high-quality informed consent or informed treatment refusals can give rise to a claim of professional negligence. Some risk management experts recommend asking the patient to sign the informed consent document and inserting the original form in the patient's chart.

This is what it really comes down to, "How is it that a person or group of people, simply by virtue of having a particular medical condition and of living in a facility have lost their right to be fully informed and to choose to use or refuse a health care treatment, a right that is available to everyone of us living outside a facility." In addition, it seems the intrinsic responsibility of the caregivers involved (those physicians or providers authorizing any prescription and the care facility that administers those medications) to be certain that the "standard of care" and best interests of those patients are both observed and carried out as professional standards would dictate.

Other states have passed laws requiring written informed consent, and more bills are in state legislatures this year. Wisconsin as noted above has an Informed Written Consent law. Wisconsin Stats. 50.08 is the new requirement for written informed consent for an individual with a degenerative brain disorder who receives a psychotropic medication with a black box warning. *As indicated previously HB 2704 encompasses the use of the anti-psychotic drug category only.*
https://www.dhs.wisconsin.gov/regulations/nh/infconsent-psychotropic.htm The state also provides downloadable forms for use https://www.dhs.wisconsin.gov/forms1/f2/f24277h-haldol.doc)

References to existing law and regulations which govern nursing facilities and use of medication
The 1987 Nursing Home Reform Law and Regulations: (ii) FREE FROM RESTRAINTS.--*The right to be free from* physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or *chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms*. Restraints may only be imposed (I) to ensure the physical safety of the resident or other residents. (i) FREE CHOICE.--*The right* to choose a personal attending physician, *to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident's well-being,* and (except with respect to a resident adjudged incompetent, then her/his representative) to participate in planning care and treatment or changes in care and treatment.

We ask that you act for Informed Written Consent and pass HB 2704 out of Committee.

Mitzi E. McFatrich, on behalf of volunteers, members and older Kansans
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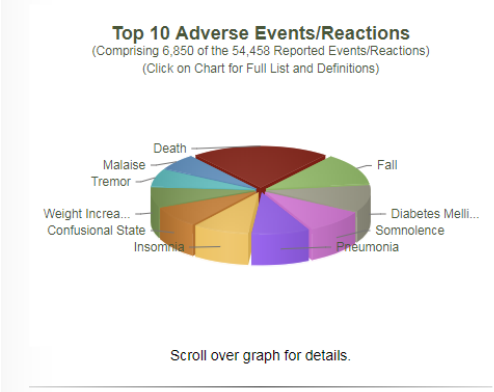

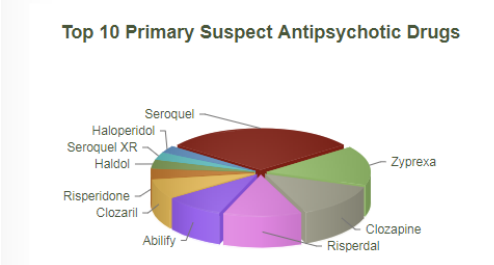

Medication induced contractures & tardive dyskinesia.