The Problem

Psychotropic drugs are a tool to help improve mood and behavior. They can improve quality of life, provide relief in end-of-life care, and aid children and adolescents with detrimental impulse behaviors. But they can be used improperly to address behavioral issues caused by dementia and developmental disabilities, including aggression, agitation, hyperactivity and delirium.

This is especially true when elderly people and persons with disabilities are living in long-term care facilities. And these drugs can have serious adverse effects when used for a diagnosis for which their use is not intended. This is called "off-label" use, and the FDA has given a "black box warning" to antipsychotic drugs and antidepressants and their off-label use, calling attention to the serious or life-threatening risks associated with unapproved uses.

Evidence from clinical trials shows little benefits from using such medications for persons with dementia or disabilities. In fact, it shows that they often don't work to treat challenging behavior.

The data also shows that these drugs have significant side effects, such as excessive sedation, physical complications, cognitive decline, increased risks of falls, and even death. For every 28 elderly people treated for a year with an antidepressant, one will die who would have lived otherwise, from causes including heart attacks, strokes, and falls. That's because these medications can make people drowsy, dizzy, confused, and restless. They can also cause diabetes and heart failure.

You have in your file of testimony submitted on this bill the comments from Kevin Modeste, a surgeon practicing in general surgery and surgical critical care in Eugene. He emphasizes data reporting moderate to severe injuries in falls of older adults, and an association with the use of sedatives and hypnotics, antidepressants, and benzodiazepines. He describes the side effects of psychotropic medications. And on the $2^{\rm nd}$ page he provides a clinical scenario.

I hope that you have also read the written testimony from Bob Nikkel, mental health and addictions professional with more than 30 years' experience, who works closely with the Boston medical journalist Robert Whitaker who has specialized knowledge of unbiased research literature on the effects and side effects of psychiatric medications. Mr. Nikkel explains the national attention being given this issue and the magnitude of the problem, the risks and expense of these medications, and how this bill would benefit Oregonians.

HB 3262: Psychotropics in long term care settings

These issues and poor outcomes are caused by inappropriate use of the drug, and then exacerbated by over-prescribing, drug interactions, and a lack of proper medication management.

Data indicates that antipsychotics are often used for individuals with dementia for sustained, long-term periods, with limited monitoring of their effects. It also shows that individuals with disabilities receive excessively high dosages that exceed FDA recommendations for unnecessarily long periods of time, and sometimes with inappropriate drug combinations.

This practice robs individuals of their quality of life, and puts them at increased risk.

Oregon's rate of off-label antipsychotic drug use in nursing homes has decreased, but there is a growing fear in the medical community that the use of other psychotropic drugs, like anti-anxiety and depression medications and sedatives, have made up for the use of antipsychotics in care facilities. Those numbers, however, are only tracked in nursing homes. We do not have a system to accurately track their use in assisted living/residential care and adult foster care.

You may hear that we don't have a problem in Oregon. A statewide average for use of psychotropics shows a pretty good number, but as you know, an average can obscure a few bad situations when added in with very good results elsewhere. It's those bad situations that deserve our attention, so we can protect the well-being of the more vulnerable of our citizens.

And beyond the cost to individual's well-being, the cost of psychotropic drugs in Oregon is significant: estimated to be up to \$200 million annually for the public system alone.

A national problem, and national-level recommendations

Research shows that all psychotropic medications should be used with caution, should be prescribed at the lowest possible effective dose, and should be used in conjunction with, or as a last resort after, non-drug interventions. The use of these drugs should be reserved for severe symptoms that have failed to respond adequately to non-drug strategies and treatments.

Non-drug strategies include personal assessments to address behavioral issues and develop alternative solutions. For example, strategies might include music, art, and light therapies or psychosocial supports. Many behaviors can be attenuated by identifying the cause of the behavior and addressing an unmet physical or social need, such as hunger, thirst, pain or discomfort, tiredness, boredom, loneliness, and so on.

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Person-centered, appropriate non-drug treatments can help caregivers focus on a person's needs and abilities and can help individuals develop "helping" behaviors that promote a sense of self-control and direction. They can also help caregivers recognize signals of unmet needs and growing distress and develop new ways of responding to individuals that will reduce anxiety and improve quality of life.

The Solution for Oregon

This bill aims to reduce the known risks, and improve the safety of seniors and people with disabilities living in adult foster homes, residential care facilities, and long-term care facilities.

- 1. The bill directs DHS to collaborate with medical boards and DHS facility regulatory entities to adopt rules regulating the prescription of psychotropic medications.
- 2. If the prescription is written by a healthcare practitioner other than the primary care physician, the prescription must be reviewed by the primary care provider. This second set of eyes will help limit the risk of adverse side effects of the prescription, the dosage, or and drug combination problems. (Please note that we have submitted an amendment making it clear that instead of only a primary care physician, the second set of eyes can be the primary care provider, gerontologist, or other professional as designed by OHA rule.)
- 3. The bill requires a person-centered assessment before continued administration of a psychotropic drug. This requirement is particular to long term care settings (nursing homes, assisted living/residential care, and adult foster care) and details about what specific criteria the assessment would include could be developed in rule by DHS, OHA, and other experts.
- 4. And the bill still allows for up to two uses in case of urgent medical need, ensuring that medications are still immediately available should they be needed as part of an urgent or emergent preventive safety response.

Closing

By increasing oversight of these drugs, especially when they are prescribed for an unintended or off-label use, we reduce the risk of serious effects including the risk of serious and costly injury. We also create an opportunity for long term care providers to identify potential non-pharmaceutical alternative interventions that could be employed to address behavioral issues, alleviating the need for psychotropic medications.

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You may hear that in another bill, psychotropics or antipsychotics are included with a number of other care facility related topics, such as reporting use for data collection. That data would be provided by the facility, with no way of easily validating the accuracy of that data. But beyond that:

There's plenty of data to demonstrate that there's a problem; we need to do something more than just collect more data; we need to protect people.

We have heard from some that this bill does not go far enough and from others that this bill goes too far. This makes me think, just like goldilocks, we may have gotten it just right.