



Friday, March 05, 2010

Meyer bill requires written consent for 'black-boxed' drugs

Risperdal death sparked legislative effort

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A bill by state Rep. Dan Meyer (R-Eagle River) would require nursing homes to obtain written informed consent when an antipsychotic drug that has received a federal Food and Drug Administration black box warning is prescribed for a patient with a degenerative brain disorder.

The bill received a public hearing in late January. State Sen. Jim Holperin (D-Conover) is a cosponsor of the measure.

Meyer has pushed the legislation at the behest of Rhinelander resident Lisa MaKarrall, whose father died in 2008 after receiving the antipsychotic drug Risperdal. The FDA had issued a federal black box warning in 2005 that the drug placed elderly patients with dementia-related psychosis at an increased risk of death.

However, MaKarrall and her family never received the warning when Taylor Park Nursing Home in Rhinelander put him on the medication. Neither did they receive a 2003 FDA warning that Risperdal could increase risks for diabetes and stroke, nor, for that matter, she says, did they receive any other warning of Risperdal's potentially fatal risks when the facility asked the family for permission to use the drug to treat aggression.

In fact, the Informed Consent for Medication form the family signed was out of date, having been fashioned by the state Department of Health and Family Services in May 2003, almost two years before the FDA issued its black-box warning.

At the public hearing, Meyer said nursing homes are already required by law to use informed consent for medication forms if the resident is being treated for a mental illness or developmental disability, though Alzheimer's and dementia-related psychosis are not included.

"What that means is that residents of a nursing home who have these conditions are not entitled to receive the written informed consent form that explains potential benefits and risks," Meyer testified. "Current law does require these factors to be discussed orally with the patient or their guardian."

No-brainer

Meyer said requiring such consent only makes sense.

"If there is higher risk of death to these patients, shouldn't they, or their guardians whom they have entrusted with their care, have the opportunity to verifiably consent to the administration of these drugs?" he asked.

Meyer said he was aware of extensive patient rights existing in state and federal law, but he said he had found no state or federal regulation that would provide the same information his bill would provide.

"It is my understanding that many nursing homes already voluntarily present informed consent for medication forms to patients or their legal guardians," he said. "This proposal aims to solidify this practice, ensuring the patient or their legal guardian is presented with up-to-date information about benefits and risks."

Meyer said his bill would also help ensure that out-of-date forms would not be used, as they were in MaKarrall's father's case, and provide accountability.

"A second, vital component to the bill specifies that informed consent forms include a description, using the most recently issued information from the FDA, of the side effects or risks of side effects of the medication and any warnings about the medication," he said. "The bill would require the Department of Health Services to keep abreast of new risk information that is issued from the FDA."

Meyer dismissed those who have downplayed the issue of out-of-date forms.

"While I am aware of contentions that this is not a widespread problem, that can only be true if an institution did not download an informed consent form from the Department of Health Services website between the dates 2005, when the FDA issued this warning, to 2008, when DHS updated their forms," he said. "In some cases, the forms being downloaded are still outdated today."

Meyer said recent studies have estimated that the number of seniors receiving antipsychotic medication has doubled between 1996-2006, making written informed consent necessary.

"While the use of medication is a decision to be made between the patient and health care providers, it is imperative the patient or their legal guardians have accurate and up-to-date information to make an informed decision," he said.

First line of treatment

At the hearing, Rob Gundermann, the public policy director of the Alzheimer's and Dementia Alliance of Wisconsin, testified in support of the measure.

"If I get Alzheimer's disease and someone wants to give me a drug that has a specific black box warning stating that I am 'at an increased risk of death' and 'is not approved for the treatment of patients with dementia-related psychosis,' I want someone to tell my family and get permission to use that drug before someone who might not care about me as much as my family starts giving it to me," Gundermann said. "I think we would all want that for ourselves."

The first line of treatment for people with dementia should be dementia-specific interactions and environments, he said.

"With the support of this kind of best practice, most behaviors can be prevented or moderated without psychotropic drugs," Gundermann said.

Dr. Kim Peterson, a geriatrician and dementia specialist with 35 years of experience in long-term care, also supported the bill.

Peterson said it was important to know that numerous clinical studies of effectiveness show "at best" the antipsychotics are no more than 30 percent effective in reducing behavioral problems, while most studies show no benefit.

"Side effects of these drugs are significant and occasionally result in permanent neurological disabilities, such as Parkinson's symptoms or EPS," Peterson testified. "A number of studies of use of these drugs with dementia patients show an increase in dementia symptoms, such as confusion and increased memory loss. Therefore, physicians who prescribe these drugs for dementia patients are using them 'off label.'"

As such, families and decision makers need to know that the drugs are not FDA approved, and they need to be aware of the identified risks as defined by the black box warning, he said.

"In weighing the risks of antipsychotic drugs, deciders need to know what other alternative treatments are an option, and what the risks/consequences are of not treating with antipsychotics," Peterson testified. "There also needs to be an emergency process if the protocol cannot be followed. This bill addresses these concerns."

While facility staff, families and physicians want a quick fix for behavioral problems, Peterson said, in his 35 years of experience with dementia patients there is no quick fix for behavior issues.

"Drugs, especially antipsychotics, are usually not effective, make the patient worse or decrease (quality of life)," he said.

Meyer's bill, he said, would bring "daylight" to the issue of treating behavioral problems with antipsychotics and make the process of obtaining informed consent consistent with what is in place for the mental health population who also receive those drugs.

"It is my hope that by improving the process of informed consent for the use of antipsychotic medications for dementia patients, we will start turning the management of behavior away from drug management to person-centered care for persons with dementia," Peterson said.

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