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Details:

(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2009-10

(session year)

Senate

(Assembly, Senate or Joint)

Committee on ... Public Health, Senior Issues, Long-Term Care, and Job Creation (SC-PHSILTCJC)

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Gigi Godwin (LRB) (November/2011)

Senate

Record of Committee Proceedings

Committee on Public Health, Senior Issues, Long-Term Care, and Job Creation

Senate Bill 609

Relating to: requiring informed consent before administration of psychotropic medication to a nursing home resident who has degenerative brain disorder.

By Senator Holperin; cosponsored by Representatives Meyer, Pasch, Gunderson, A. Ott, Nerison and Wood.

March 10, 2010 Referred to Committee on Public Health, Senior Issues, Long-Term Care, and Job Creation.

March 31, 2010 **PUBLIC HEARING HELD**

Present: (5) Senators Carpenter, Coggs, Vinehout, Schultz and Kapanke.
Absent: (0) None.

Appearances For

- Jim Holperin, Conover — 12th Senate District
- Rob Gundermann, Madison — Alzheimers Alliance
- Lisa MaKarrall, Rhinelander
- Jennifer Western — On behalf of Rep. Dan Meyer & 34th Assembly District

Appearances Against

- None.

Appearances for Information Only

- None.

Registrations For

- William Donaldson, Madison — Board on Aging & Long Term Care
- Pane Rusk, Madison — Alzheimers & Dementia Alliance of Wisconsin
- Mary Pike, Madison — Alzheimers & Dementia Alliance of Wisconsin
- Judy Stevenson, Madison — Alzheimers Disease Alliance of Wisconsin
- Sandy Lonergan — Elder Law Section-State Bar of Wisconsin

Registrations Against

- None.

Registrations for Information Only

- None.

April 6, 2010 **EXECUTIVE SESSION HELD**

Present: (5) Senators Carpenter, Coggs, Vinehout, Schultz and Kapanke.
Absent: (0) None.

Moved by Senator Carpenter, seconded by Senator Vinehout that **Senate Amendment 1 to Senate Amendment 1** be recommended for adoption.

Ayes: (5) Senators Carpenter, Coggs, Vinehout, Schultz and Kapanke.
Noes: (0) None.

ADOPTION OF SENATE AMENDMENT 1 TO SENATE AMENDMENT 1 RECOMMENDED, Ayes 5, Noes 0

Moved by Senator Carpenter, seconded by Senator Vinehout that **Senate Amendment 1** be recommended for adoption.

Ayes: (5) Senators Carpenter, Coggs, Vinehout, Schultz and Kapanke.
Noes: (0) None.

ADOPTION OF SENATE AMENDMENT 1 RECOMMENDED, Ayes 5, Noes 0

Moved by Senator Vinehout, seconded by Senator Carpenter that **Senate Bill 609** be recommended for passage as amended.

Ayes: (5) Senators Carpenter, Coggs, Vinehout, Schultz and Kapanke.
Noes: (0) None.

PASSAGE AS AMENDED RECOMMENDED, Ayes 5, Noes 0

Russell DeLong
Committee Clerk

Vote Record

Committee on Public Health, Senior Issues, Long-Term Care, and Job Creation

Date: 4/6/10

Moved by: Carpenter Seconded by: Vinehout

AB _____ SB 609 Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt _____

A/S Amdt 1 to A/S Amdt 1

A/S Sub Amdt _____

A/S Amdt _____ to A/S Sub Amdt _____

A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

Be recommended for:

☐ Passage ☒ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Senator Tim Carpenter, Chair	☒	☐	☐	☐
Senator Spencer Coggs	☒	☐	☐	☐
Senator Kathleen Vinehout	☒	☐	☐	☐
Senator Dale Schultz	☒	☐	☐	☐
Senator Dan Kapanke	☐	☐	☐	☐
Totals:	5	0	____	____

☐ Motion Carried ☐ Motion Failed

Vote Record

Committee on Public Health, Senior Issues, Long-Term Care, and Job Creation

Date: 4/6/10

Moved by: Carpenter Seconded by: Vinehout

AB _____ SB 609 Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt 1

A/S Amdt _____ to A/S Amdt _____

A/S Sub Amdt _____

A/S Amdt _____ to A/S Sub Amdt _____

A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

Be recommended for:

☐ Passage ☒ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Senator Tim Carpenter, Chair	☒	☐	☐	☐
Senator Spencer Coggs	☒	☐	☐	☐
Senator Kathleen Vinehout	☒	☐	☐	☐
Senator Dale Schultz	☒	☐	☐	☐
Senator Dan Kapanke	☐	☐	☐	☐
Totals:	5	0	___	___

☐ Motion Carried ☐ Motion Failed

Vote Record

Committee on Public Health, Senior Issues, Long-Term Care, and Job Creation

Date: 4/6/10

Moved by: Vinehout Seconded by: Carpenter

AB _____ SB 609 Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt _____

A/S Amdt _____ to A/S Amdt _____

A/S Sub Amdt _____

A/S Amdt _____ to A/S Sub Amdt _____

A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

Be recommended for: As Amended

☒ Passage ☐ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Senator Tim Carpenter, Chair	☒	☐	☐	☐
Senator Spencer Coggs	☒	☐	☐	☐
Senator Kathleen Vinehout	☒	☐	☐	☐
Senator Dale Schultz	☒	☐	☐	☐
Senator Dan Kapanke	☒	☐	☐	☐
Totals:	5	0	____	____

☐ Motion Carried ☐ Motion Failed

SB 604?

DIVISION OF QUALITY ASSURANCE

Jim Doyle
Governor

Karen E. Timberlake
Secretary

State of Wisconsin
Department of Health Services

1 WEST WILSON STREET
P O BOX 2969
MADISON WI 53701-2969

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dhs.wisconsin.gov

Date: April 17, 2009

DQA Memo 09-015

To: Nursing Homes

NH 04

From: Otis Woods, Administrator
Division of Quality Assurance

Antipsychotic Medication Use for Individuals with Dementia

The purpose of this memo is to address the current federal Food and Drug Administration (FDA) Public Health Advisories on antipsychotic medication use for the treatment of behavioral disorders in elderly individuals with Alzheimer's disease, dementia or other organic brain syndrome.

Background

The FDA issued Public Health Advisories for all antipsychotic medications. The advisories can be accessed at http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm and http://www.fda.gov/bbs/topics/NEWS/2008/NEW01851.html . These advisories are a response to various studies that indicated increased mortality when antipsychotics were used for the treatment of behavioral disorders in elderly individuals with Alzheimer's disease, dementia or other organic brain syndrome. The advisories highlight FDA requirements for manufacturers to include a Boxed Warning in medication product labeling that describes the mortality risk and notes that antipsychotics (e.g., aripiprazole, olanzapine, quetiapine, risperidone, clozapine, ziprasidone, haloperidol and thioridazine) are not approved for the treatment of behavioral disorders in elderly individuals with dementia.

Discussion

Federal and State regulations establish various requirements related to medication use, some of which are very specific to antipsychotic use. **These regulations have not changed.**

The Division of Quality Assurance (DQA), as part of the nursing home survey process, investigates the use of antipsychotic medications for behaviors in residents with Alzheimer's disease, dementia or other organic brain syndrome. Through the investigation, surveyors determine compliance with the various antipsychotic medication regulations. DQA surveyors apply standards of practice for behavior treatment. In applying those standards, the following questions are considered by surveyors when antipsychotic medications are used for behaviors related to Alzheimer's disease, dementia or other organic brain syndrome:

1) Was the behavior persistent?
2) Was the behavior harmful?

3) Were other environmental, psychosocial or medical causes of the behavior ruled out?
4) If a behavior was persistent and harmful; if other environmental, psychosocial and medical causes were ruled out; and, if an antipsychotic medication is used, does the antipsychotic improve the behavior and is the antipsychotic used for the shortest time possible?
5) When antipsychotic medication is used for behaviors, can the facility show that it is monitoring for benefits and risks? This includes training staff to identify and document the effects of the medication on the resident and the practice of follow-up communication within the facility.
6) Has the facility discussed the risks and benefits of the medication with the resident and/or the resident's power of attorney or guardian?

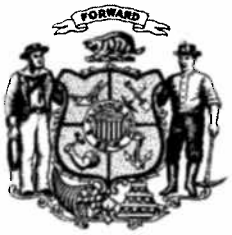
In addition to this focus area, DQA surveyors may also investigate other areas. For instance, the facility's Medical Director is responsible for care coordination and resident care policies within the nursing home. Pharmacy Consultants are responsible for assisting facilities in the identification of medication-related problems. When there are problems with the use of antipsychotic medications, DQA surveyors may look into whether facilities worked with their medical director and pharmacy consultant to develop and implement plans of care or policies related to antipsychotic medication use for behavioral disorders in residents with Alzheimer's disease, dementia or other organic brain syndrome.

It is important to remember that, for most behaviors, antipsychotic medications have, in some cases, not been shown to be any more effective than a placebo. If an antipsychotic medication is used for a single resident behavior without first conducting a complete assessment, it is likely that there was not an adequate indication for the use of the antipsychotic. When there are not adequate indications for medication use, the medication may be considered unnecessary and the nursing home is at risk of violating state or federal rules or regulations.

Existing regulations have not changed with the FDA advisories. When antipsychotic medication is used for dementia-related behaviors, facilities must discuss the use of antipsychotic medication with the residents' families, consultant pharmacists, medical directors and physicians before starting or making any changes with antipsychotic therapy. Similarly, before starting or making any changes with antipsychotic therapy, facilities should document their consideration of all the standards related to antipsychotic medication use for residents whose behaviors are the result of Alzheimer's disease, dementia or other organic brain syndrome. When antipsychotic medications are used for behavior treatment, a monitoring plan that evaluates the medication's effectiveness and side effects must be in place. Medication monitoring is essential for the determination of effectiveness and requires appropriately trained direct care staff to recognize the side effects that may result from the medication. Communication between nursing staff and the facility's medical director and pharmacy consultant is, therefore, critical to ongoing antipsychotic medication monitoring within the facility.

If you have specific information regarding the use of and the ongoing monitoring of medications that contain the FDA black box warning, please contact Douglas Englebert, RPh, Pharmacy Practice Consultant, at (608) 266-5388, or e-mail him at: douglas.englebert@dhs.wisconsin.gov


WISCONSIN STATE LEGISLATURE


FORWARD

SB 609?

DEPARTMENT OF HEALTH SERVICES
Division of Mental Health and Substance Abuse Services
F-24277 (07/2008)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
HFS 134.31(3)(o)
HFS 94.03 & 94.09
s.51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 5/12/2008

Completion of this form is voluntary. If not completed, the medication cannot be administered without a court order unless in an emergency. This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First, MI)	ID Number	Living Unit	Birthdate

Name – Individual Preparing This Form	Name – Staff Contact	Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antipsychotic Agent (Benzisoxazole)	Risperdal; Risperdal Consta (risperidone)	Adults: 2mg—16mg Older adults: 0.5—3 mg Children under the age of 18 as determined by doctor: 1—16 mg Consta: 12.5 mg—50mg IM every 2 weeks	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.
Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.
This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. **Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off Label' Use)**
   Include DSM IV diagnosis or the diagnostic "working hypothesis."

2. **Alternative mode(s) of treatment other than or in addition to medications include**
   Note: Some of these would be applicable only in an inpatient environment.

☐ -Environment and / or staff changes
☐ -Positive redirection and staff interaction
☐ -Individual and / or group therapy
☐ -Rehabilitation treatments / therapy (OT, PT, AT)
☐ -Treatment programs and approaches (habilitation)
☐ -Use of behavior intervention techniques

Other Alternatives:

3. **Probable consequences of NOT receiving the proposed medication are**

Impairment of ☐ -Work Activities ☐ -Family Relationships ☐ -Social Functioning

Possible increase in symptoms leading to potential

☐ -Use of seclusion or restraints
☐ -Limits on access to possessions
☐ -Limits on personal freedoms
☐ -Limit participation in treatment and activities
☐ -Limits on recreation and leisure activities
☐ -Intervention of law enforcement authorities
☐ -Risk of harm to self or others

Other consequences:

Note: These consequences may vary, depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

4. Possible side effects, warnings and cautions associated with this medication are listed below. This is not an all inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text such as the PDR or the United States Pharmacopoeia Dispensing Information (USPDI). As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects, in order to enhance care and treatment.

Continued -- Possible side effects, warnings and cautions associated with this medication.

Check with your doctor immediately if any of the following side effects occur: Difficulty in speaking or swallowing; inability to move eyes; muscle spasms of face, neck, and back; twisting movements of body.
Check with your doctor as soon as possible if any of the following side effects occur: Anxiety or nervousness; changes in vision, including blurred vision; decreased sexual desire or performance; loss of balance control; mask-like face; menstrual changes; mood or mental changes, including aggressive behavior, agitation, difficulty in concentration, and memory problems; problems in urination or increase in amount of urine; restlessness or need to keep moving (severe); shuffling walk; skin rash or itching; stiffness or weakness of arms or legs; tic-like or twitching movements; trembling and shaking of fingers and hands; trouble in sleeping.
Other side more common effects may include: Constipation; coughing; diarrhea; drowsiness; dryness of mouth; headache; heartburn; increased dream activity; increased length of sleep; nausea; sleepiness or unusual drowsiness; sore throat; stuffy or runny nose; unusual tiredness or weakness; weight gain.

Check with your doctor immediately if any of the following side effects occur: speech or vision problems; sudden weakness or numbness in the face, arms or legs.
Check with your doctor as soon as possible if any of the following side effects occur: Back pain; chest pain; unusual secretion of milk
Other less common side effects may include: back pain; body aches or pain; chills; dandruff; darkening of skin color; dry skin; ear congestion; fever; increase in body movements; increased sensitivity of the skin to sun; increased watering of mouth; joint pain; loss of voice; nasal congestion; oily skin; pain or tenderness around eyes and cheekbones; shortness of breath or troubled breathing; sneezing; stomach pain; toothache; tightness of chest or wheezing; vomiting; weight loss.

Although rare, stop taking risperidone and get emergency help immediately if any of the following side effects occur: convulsions (seizures); difficult or fast breathing; fast heartbeat or irregular pulse; fever (high); high or low blood pressure; increased sweating; loss of bladder control; muscle stiffness (severe); unusually pale skin; unusual tiredness or weakness (severe).
Check with your doctor immediately if any of the following side effects occur: high body temperature (dizziness; fast, shallow breathing; fast, weak heartbeat; headache; muscle cramps; pale, clammy skin; increased thirst); lip smacking or puckering; low body temperature (confusion, drowsiness, poor coordination, shivering); prolonged, painful, inappropriate erection of the penis; puffing of cheeks; rapid or worm-like movements of tongue; uncontrolled chewing movements; uncontrolled movements of arms and legs.
Check with your doctor as soon as possible if any of the following side effects occur: extreme thirst; increased blinking or spasms of eyelid; loss of appetite; talking, feeling, and acting with excitement and activity that cannot be controlled; uncontrolled twisting movements of neck, trunk, arms, or legs; unusual bleeding or bruising; unusual facial expressions or body positions.
Other rare side effects may include: back pain; body aches or pain; chills; dandruff; darkening of skin color; dry skin; ear congestion; fever; increase in body movements; increased sensitivity of the skin to sun; increased watering of mouth; joint pain; loss of voice; nasal congestion; oily skin; pain or tenderness around eyes and cheekbones; shortness of breath or troubled breathing; sneezing; stomach pain; toothache; tightness of chest or wheezing; vomiting; weight loss.

Before having any kind of surgery, dental treatment, or emergency treatment, tell the medical doctor or dentist in charge that you are using this medicine.
Risperidone may cause your skin to be more sensitive to sunlight than it is normally.

BLACK BOX WARNING: Increased mortality in elderly patients with dementia related psychosis - Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 times to 1.7 times that seen 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 about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Risperidone is not approved for the treatment of patients with dementia-related psychosis.
Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Although the causes of death in clinical trials were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Risperidone is not approved for the treatment of patients with dementia-related psychosis.

See PDR, USPDI or US Hospital Formulary Service for all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager or psychologist.

Medication : Risperdal; Risperdal Consta - (risperidone)

4. I have the right to request a review at any time of my record, pursuant to ss. 51.30(4)(d) or 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager or agency / facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the anticipated dosage range without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s) and the probable consequences, which may occur if the proposed medication is not given.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES		**DATE SIGNED**
Client – If Presumed Competent to Consent / Parent of Minor / Guardian	Relationship to Client ☐ Self ☐ Parent ☐ Guardian	
Staff Present at Oral Discussion	Title	

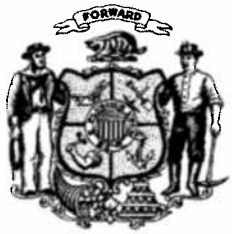
Client / Parent of Minor / Guardian Comments

As parent/guardian was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received
Obtained from – PRINT – Parent/Guardian Name	Date Expires	Date Received

WISCONSIN STATE LEGISLATURE



SB 609?

5/15/2009 11:06:00 AM *Email this article* • *Print this article*

Is Risperdal the Wisconsin way, or is it state-sanctioned murder?

Richard Moore
Investigative Reporter

Very soon, state Rep. Dan Meyer will introduce legislation requiring that a nursing home or community-based residential facility obtain written informed consent before administering a psychotropic medication with a boxed warning, including atypical antipsychotics, to any resident who has degenerative brain disorder.

It's good if narrow legislation, and long overdue, and we commend Rep. Meyer and his office for pursuing it. Of course, the real hero behind the push is Rhinelander resident Lisa MaKarrall, who was moved to action after her father died.

As those of you who have followed our recent series know, Ms. MaKarrall is convinced that **Risperdal**, an antipsychotic manufactured by Janssen Pharmaceutica, killed her father. The nursing home was administering the drug to control physical aggression in the context of dementia.

When Taylor Park Nursing Home in Rhinelander sought consent to give Bruce Bowman the medication, which is FDA-approved for schizophrenia, bi-polar disorder and certain autistic behaviors, it had given the family outdated medical consent forms that did not show a 2005 federal black-box warning associating the drug's use with an increased risk of death among the elderly.

Simply put, risperidone is not approved for the use for which it was being prescribed. So the legislation for accurate, written informed consent is important, but let us all understand that this is but a first step. As we conducted our investigation, we came to realize there's more going on in this drama - a lot more - and thousands of lives could be at stake.

Indeed, we call upon the Legislature to convene public hearings into the nature and extent of the ties between giant pharmaceutical companies such as Janssen and Wisconsin's medical community and institutions, not to mention the company's relationship with the state Department of Health Services itself.

Two broad lines of inquiry have come to light in this case.

One is the quality of care that our elderly patients receive in our state's nursing homes - whether the state is providing adequate oversight and accounting or merely serving as cover for poor care.

After her father died, Ms. MaKarrall filed a complaint against Taylor Park Nursing Home, and on two separate occasions the state found the nursing home to be in compliance with state and federal laws and regulations.

I'm not suggesting the nursing home wasn't in compliance, but I do believe the state's

investigation of Ms. MaKarrall's complaints was woefully inadequate.

At the very least, there are a trundle of questions the state never asked, and seeming inconsistencies with regulations the state never noticed in its probe or bothered to ask the facility about.

What's more, Mr. Bowman's records from the nursing home seem to flatly contradict some of the state's findings.

For instance, the state concluded that physicians are free to prescribe the drug whether it is FDA approved for that use or not (that much is true) and that when Mr. Bowman was off the medication, his physical aggression invariably increased.

The trouble with that reasoning is, nursing home staff observed aggression in Mr. Bowman even when he was on risperidone, and the facility's own investigation reveals that Mr. Bowman was placed on risperidone in the first place for behavior staff took as physical aggression - he kicked a peer in the calf- but that turned out to be a likely side effect of risperidone itself, which can cause sudden involuntary movements of the limbs.

Even when this discovery was made, the risperidone dosage was not reduced or stopped. Why? The state never asks.

The state observes that the nursing home tried several nonpharmacological interventions to control Mr. Bowman's aggression, by moving him to a private room and to a smaller dining room to avoid an annoying roommate and noisy diners.

What the investigation does not say is that such interventions must be tried and must have failed before antipsychotics are given. In fact, in Mr. Bowman's case, the records clearly indicate that nursing home staff administered **Risperdal** at the same time that they tried environmental intervention - not afterward, as they should - and, what's more, they reveal that the nonpharmacological moves worked well and his agitation subsided.

The state never mentions that the nursing home staff moved Mr. Bowman back into the room occupied by the roommate and back into the larger dining room.

Why did they do that? The state never asks.

Once he returns to those conditions, the records show, Mr. Bowman becomes agitated again. Yet, the state never probes if that was the reason for the renewed aggression. That's odd, since he was taking **Risperdal** at the time.

It simply assumes he becomes more agitated because he wasn't on risperidone, or wasn't taking a sufficient dose of it, again, despite multiple references in the records that the risperidone was not working to its intended purposes.

The bottom line is, while the state's conclusion emphasizes the facility's attempt to try

nonpharmacological intervention, it omits both that the drug was administered before the failure of such efforts and that the efforts themselves were indeed deemed successful, only to be abandoned.

Then, too, the state's investigation not only cites Bowman's physical aggression when not on risperidone but says the nursing home reduced doses appropriately when it could.

Again, the records do not indicate any such thing.

In January 2008, for example, when Mr. Bowman's agitation had subsided, his dosage should have been reduced, as the state maintains the nursing home did. In actuality, nursing home staff increased the dosage, admittedly using the drug to target restlessness, which is not allowed under the guidelines.

The state never questions this.

Finally, the state never questioned the use by the facility of the outdated consent form, and, in fact defended it, saying there was no prescriptive form the facility had to use by law. The implication is, any form or verbal information will do, even if it's inaccurate.

According to the state, conveying information about a drug's side effects that is inaccurate by omission is legal so long as the drug's name and the prescribed dosage are transmitted and the legal decision maker signs off on the prescription.

Of course, one can't be too surprised that the state wouldn't make a big deal out of the outdated form, because that would be a pot-kettle situation. As it turns out, the state's own forms were updated only in 2008, three years after the black-box warning was issued and after Ms. MaKarrall had complained about outdated forms.

The question is why? Was it incompetence? Was it something more nefarious?

That leads to the second broad line of inquiry: the power and influence of large pharmaceutical companies in Wisconsin.

I have no idea whether state officials and the medical community are too cozy with the pharmaceutical industry or not, but the answer deserves and requires a legislative probe.

There are certainly some serious red flags blowing in the wind.

We know, for instance, the state has paid Janssen and other makers of atypical antipsychotics millions of dollars in Medicaid reimbursements for the use of the drug. What we don't is how many millions and whether the state reimbursed these drugs for prescriptions for non-FDA approved uses, which could be a violation of the federal Medicaid Act.

We don't know because Jason Helgerson, the state's Medicaid director, did not return messages asking for that information. We will now issue a formal open records request for it, but the

Legislature needs to be seeking the same answers.

Here's another question the Legislature - or the attorney general - should want answered. Why are the atypical antipsychotics on the preferred Medicaid drug list with no diagnostic limitations, despite a growing number of studies indicating just how dangerous they are?

Especially in Wisconsin, doctors and nursing homes have continued to dispense the drug and other so-called atypical antipsychotics like it despite a 2003 FDA warning it could increase risks for diabetes and strokes and despite the 2005 FDA black-box warning that it could cause increased morbidity in elderly patients with dementia.

The state placed the drugs on the preferred list in 2006, after the FDA issued its black-box warning.

It remains there today, despite new studies showing these more expensive products to be no more effective or to cause no fewer side effects than older antipsychotics. Indeed, a 2009 government report linked atypical antipsychotics such as **Risperdal** to an increased risk of cardiac death.

In 2005, FDA whistleblower Dr. David Graham estimated that off-label use of atypicals could cause as many as 62,000 excess deaths a year.

Meanwhile, in other states, the light bulb has come on, and states such as South Carolina, Texas, Pennsylvania and others have sued to get their Medicaid reimbursement money returned. The drugs have disappeared from those states' preferred lists.

Yet Wisconsin continues in the opposite direction. More specifically, who appoints the advisory committees that make the recommendations to prefer these drugs? I don't know because that's another question Mr.. Helgerson didn't answer.

One thing is clear, doctors are going to use drugs that sit on preferred drugs lists. And while Medicare Part D rather than Medicaid reimburses nursing home prescriptions, the private doctors who write those prescriptions are writing them for the same medications and purposes that they do for their private patients.

And they will do so without any trepidation.

It seems pretty clear to me that **Risperdal** played a major role in the demise of Bruce Bowman. The records show a pattern. When he is taken off **Risperdal**, his physical condition improves. When he is taking **Risperdal**, it deteriorates.

The family noticed it. Nurses noticed it, and in the late stages of the game a doctor acknowledged it.

And yet, to use Ms. MaKarrall's words, Wisconsin continues to dole out risperidone as if it were candy.

The state continues to authorize its use without diagnostic limitation. It continues to encourage and prefer its use, in fact. Wisconsin is not the only state to do so. Perhaps there is a good reason.

But studies to the contrary - a sizeable and increasing compendium of work - and the negative reactions of a growing number of states give us a compelling reason to ask these questions and to get the right answers.

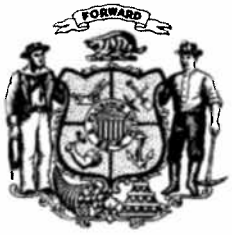
We need to know if we are sponsoring state-sanctioned murder with these drugs.

It's a pretty simple question the Legislature needs to answer, really. Is the state of South Carolina correct when it says **Risperdal** "was, and is, hazardous to human health" and is "abnormally and unreasonably dangerous as marketed" or is Wisconsin right when it prefers and encourages the drug's use?

Which way should be the Wisconsin way?

Stay tuned.

WISCONSIN STATE LEGISLATURE



SB 609?

Welcome to Risperdal.com!

If you are looking for information on schizophrenia, please read Frequently Asked Questions about Schizophrenia, or select one of the following links to other Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., Web sites.


Invega.com


RisperdalConsta.com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For information on bipolar mania, please read Frequently Asked Questions about Bipolar Mania, or select one of the following links to other Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., Web sites.


MentalWellness.com


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For information on autistic disorder, please read Frequently Asked Questions about Autistic Disorder, or select one of the following links to other Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., Web sites.


RisperdalAutism.com


Janssen.com

For other information about Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., please Contact Us.

RISPERDAL ® (risperidone) is used for the treatment of schizophrenia in adults and adolescents ages 13-17 years.

RISPERDAL ® (risperidone) is used alone or in combination with other medicines (valproate or lithium) in adults for the short-term treatment of bipolar mania; or alone in adults, children and adolescents ages 10-17 years for the short-term treatment of bipolar mania.

RISPERDAL ® (risperidone) is used for the treatment of irritability associated with autistic disorder in children and adolescents ages 5-16 years.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL ®

Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL ® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

The most common adverse reactions observed in all clinical trials with RISPERDAL ® occurring at a rate of at least 10% were somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, tremors, muscle stiffness, abdominal pain, anxiety, nausea, dizziness, dry mouth, rash, restlessness, and indigestion.

Neuroleptic Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with RISPERDAL ® and similar medicines. Call your doctor immediately if the person being treated develops symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment should be stopped if the person being treated has NMS.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with RISPERDAL ® and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is no known treatment for TD, but it may go away partially or completely if therapy is stopped.

RISPERDAL ® and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection. The connection between prolactin levels and side effects is unknown.

High blood sugar and diabetes have been reported with RISPERDAL ® and similar medications. If the person being treated has diabetes or risk factors such as being overweight or a family history of diabetes, blood sugar testing should be performed at the beginning and throughout treatment. Complications of diabetes

can be serious and even life threatening. If signs of high blood sugar or diabetes develop, such as being thirsty all the time, going to the bathroom a lot, or feeling weak or hungry, contact your doctor.

RISPERDAL ® should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

Some people taking RISPERDAL ® may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side effect may be reduced or it may go away over time.

Extrapyramidal Symptoms (EPS) are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. If you observe any of these symptoms, talk to your healthcare professional.

Some medications interact with RISPERDAL ® . Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while taking RISPERDAL ® .

Inform your healthcare professional if you are pregnant or if you are planning to get pregnant while taking RISPERDAL ® . Do not breast-feed if you are taking RISPERDAL.

RISPERDAL ® may affect your driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERDAL ® may affect alertness and motor skills; use caution until the effect of RISPERDAL is known.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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