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No. 73538-1

COURT OF APPEALS
STATE OF WASHINGTON
DIVISION I

In re the Guardianship of:
WILLIAM SUTTON,
An Alleged Incapacitated Person.

APPELLANTS' BRIEF

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I. ASSIGNMENTS OF ERROR

1. The Trial Court erred in refusing to consider credible evidence that the medication administered to AIP Sutton was inappropriate, and posed substantial detrimental risk to his health and safety, and was against the AIP's previously stated medical preference.

2. The Trial Court erred in failing to consider Appellants' challenge to the neurophysiological evaluation of AIP based on evidence of bias, conflict of interest and incompetence of the neuropsychologist selected by the GAL.

3. The Trial Court erred in considering the scope of power of attorney (POA) rights as exceeding the rights of the vulnerable adult AIP in regards to medical preferences and decision-making.

4. The Trial Court erred by dismissing the guardianship petition and Appellants' pending *Motion For Discovery Re Accounting & Inspection Of Evidence*, without a specific hearing or consideration of outstanding discovery issues.

5. The Trial Court erred in assessing attorneys fees' and costs to co-petitioners for bringing a non-frivolous and good faith guardianship petition on behalf of their brother AIP William Sutton.

II. ISSUES PERTAINING TO ASSIGNMENT OF ERROR

(1) Did the Superior Court err in dismissing the Appellants' guardianship petition on May 18, 2015, without providing a separate hearing and/or specifically and comprehensively addressing specific and extensive material discovery issues raised in Appellants' pending motion for discovery re accounting & inspection of evidence?

(2) Did the trial court improperly disregard and/or fail to consider co-petitioners allegations of concern over bias, conflict of interest and lack of competence of the neurophysiologist selected by the GAL to conduct the neurophysiological examination of the AIP to determine if the medication of the AIP is detrimental to his health and safety, and against the AIP's previously stated medical preference?

(3) Did the trial court's failure to adequately address the conflict of interest that existed for the neuropsychologist conducting the evaluation of the AIP and the power of attorney's wife Christine Sutton constitute error?

(4) Did the trial court improperly considered the scope of power of attorney (POA) rights as exceeding the rights of the vulnerable adult AIP in regards to medical preferences and related decision-making?

(5) Did the trial court err by dismissing the petition for guardianship only two days after co-petitioners filed a motion for reconsideration re: neutral medical evaluation and accounting/financial

investigation (of the AIP) and an accounting and/or financial investigation.

(6) Did the court err in assessing attorney fees and costs against co-petitioners for bringing a non-frivolous and good faith guardianship petition on behalf of their brother AIP William Sutton to protect both his health, general welfare and financial assets from irreparable harm?

III. STATEMENT OF THE CASE

A. PROCEDURAL FACTS

On December 15, 2014, an original petition for guardianship was filed on behalf of Appellants by their attorney.

On December 15, 2014, an order was entered appointing a Guardian Ad Litem (hereinafter referred to as GAL).

On February 17, 2015 Appellants filed a guardianship petition because they were concerned about the actions of power of attorney(POA) Ben Sutton regarding his father AIP William Sutton's personal care and financial assets. Appellants' petition sought the appointment of a certified guardian, suspension and/or revocation of the current Power of Attorney to limit Benjamin Sutton and his wife Christine Sutton to only supervised visits with the AIP; full access and full disclosure of information regarding the AIP to Appellants, including, but not limited to, medical and financial records, medication treatment history, including pharmacies and all prescription files with all pharmacist notes; approval for AIP funds to be

used for all attorney fees and court costs; authorization for independent objective medical evaluations of AIP; the transfer of AIP to a neutral facility for urgent medical care; and to require an accounting and complete disclosure for all health and financial decisions by POA Benjamin Sutton, including all funds gifted and transferred from AIP accounts.

On March 23, 2015, co-petitioners/Appellants concerned about the health and safety of their brother AIP William Sutton filed a *Motion for Order to Show Cause RE Contempt* regarding the interference with their visitation rights to the AIP's residence facility in furtherance of abuse of the AIP by isolation and seclusion and denial of the AIP's rights and quality of care.

On March 30, 2015, Appellants filed their *Supplemental Filing: List of Filed Exhibits and Other Documents For Motion for Order to Show Cause RE Contempt*.

On April 30, 2015, Appellants' filed a *Motion For Discovery Re: Accounting And Inspection Of Evidence* regarding financial and medical records of the AIP, including those in possession of the power of attorney.

On May 6, 2015, Appellants' filed a motion for reconsideration regarding a neutral medical evaluation (of the AIP) and an accounting and/or financial investigation.

On May 6, 2015, Appellants' filed its *Counter to Respondent's*

Motion to Dismiss Guardianship Petition/Approve Fees and Costs and Response to Motion to Show Cause RE Contempt.

On May 8, 2015, the court entered its order granting dismissal of Appellants' petition and approving fees and costs against Appellants.

B. SUBSTANTIVE FACTS

Appellants/Co-Petitioners, Claudia Harris and Cynthia (Brown) Murders, are the sisters of William Charles Sutton, who is an alleged incapacitated person (AIP).

AIP William Sutton was taken advantage of as a disabled and vulnerable person.

AIP was forced from his home while still able and functioning independently.

Before his short-term memory loss, the AIP was adamant that he not be made to live in a Nursing home or care unit.

AIP was placed at Silverado living facility against his will.

AIP was/is forced to be institutionalized against his will while he had the means to afford assistance.

AIP's son Ben Sutton has violated his duty as power of attorney(POA)/agent for his father by neglecting to protect AIP's rights and neglecting to protect AIP from damaging use of medication.

Much of AIP's considerable estate has been transferred and is

being controlled for the primary benefit of the one entrusted as POA

AIP William Sutton is at times being restrained by the use of medication and at times possibly by physical force.

William Sutton, the alleged incapacitated person, needs specific areas of protection and assistance: The AIP is agitated, depressed and panicked by his current living situation. AIP is being forced to live at his current residence facility.

AIP Sutton is forced to take medications against his will. The FDA explicitly does not approve these medications for AIP's condition due to risk of life-threatening harm. The drugs are administered for purposes of restraint, as doctor and nurse indicated in their reports

AIP has been isolated from family, friends, phone calls and mail for fifteen (15) months of the eighteen months he has been confined against his will.

AIP's health has suffered immensely under the control of the POA and Appellants fear for his safety.

Appellants/co-petitioners want to help their brother AIP William Sutton live in his own home with professional assistance, in accordance with the AIP's previously stated medical preference(s).

IV. ARGUMENT

A. The trial court improperly refused to consider credible evidence that medication administered to the AIP was dangerous to the AIP's health and safety.

Appellants raised concerns regarding the safety and propriety of the medication of their brother AIP William Sutton. Appellants provided the court various documents from leading authorities, including the Federal Drug Administration (FDA), Mayo Clinic and PubMed, an online medical database maintained by the he United States National Library of Medicine (NLM) at the National Institutes of Health. Co-petitioners raised concerns that the medicine administered to AIP Sutton posed a dangerous risk to his health and safety and subject to black box medical warnings, was erroneously disregarded by the trial court.¹ FDA black box warnings are generally admissible as a matter of law. *See Estate of LaMontagne v. BMS*, 111 P.3d 857 (Wash. Ct. App. 2005)(Warning for a prescription drug may be adequate as a matter of law, if specific and detailed information about the risks are provided). At a hearing on February 27, 2015, the Court, orally declined to consider medical authorities and information obtained from the Internet regarding the risks of the drugs at issue. [February 27, 2015 Hearing Transcript at 26.] However, on

¹ A black box warning is the strictest warning by the Food and Drug Administration (FDA) when there is reasonable evidence of an association of a serious hazard with the drug, means that an adverse reaction to the drug may lead to death or serious injury; 21 C.F.R. § 201.57(c)(6)(i) (formerly 21 C.F.R. § 201.57(e)) [See Appendix A].

February 26th, the day before the hearing Appellants also provided written documentation stamped and certified from a local pharmacist [see Appendix B], by personally delivering it to the Judge's chambers, which the Court also failed to consider and rejected. This is reversible error.

B. The trial court failed to consider Appellants' challenge to the neurophysiological evaluation of AIP based on evidence of bias, and incompetence of the neuropsychologist selected by the GAL.

At the February 27, 2015 hearing, the Court verbally ordered a neurophysiological examination of the AIP to be conducted only by a local Whatcom County provider. [February 27, 2015 Hearing Transcript at 32-33, Appendix C] The Court ordered the POA's attorney Mr. Neubeck to draft a written order to that effect. [*Id.* at 41, Appendix C]

The court also verbally ordered that co-petitioners could raise objections to the neuropsychological evaluation --Appellants subsequently challenged the objectivity of the GAL-selected neuropsychologist, Jody Veltkamp, based on her sharing the same medical facility as the POA's wife Christine Sutton, a registered nurse, in their Motion For Reconsideration Re: Neutral Medical Evaluation And Accounting/ Financial Investigation, filed on May 6, 2015.

Co-petitioners also noted that the written order drafted by the POA's attorney ignored and circumvented the Court's instruction that the co-petitioners/Appellants had a right to participate in neuropsychologist

selection. Furthermore, Appellants submitted a letter to neuropsychologist Veltkamp prior to the evaluation informing her that the court's main interest was evaluating the effects of the medication upon the AIP William Sutton. [February 27, 2015 Hearing Transcript at 35, Appendix C] Ms. Veltkamp did not respond but later met with Appellants after ostensibly conducting her evaluation and acknowledged she had no expertise in evaluating medications of this type and that another doctor would be required for such a task.

Finally, Ms. Veltkamp's written neuropsychological evaluation, submitted to the court, recited a version of events as dictated by the POA Benjamin Sutton and his wife Christine, thus comprising the objectivity of the evaluation. Finally, despite the court's assurance that co-petitioners would have an opportunity to object to the report at a later time, stating:

"If the parties can't agree, in other words if one party believes that the report doesn't give a basis to proceed and the other party believes that it does, I'll resolve that dispute.

[*Id.*, Transcript at 38, Appendix C]

The Court did not properly address Appellants' concerns regarding this issue prior to dismissing their petition on May 8, 2015.

C. The trial court improperly considered the scope of POA rights as exceeding the rights of the vulnerable adult in regards to medical preferences and related decision-making.

The Court erred in placing the scope of the authority of the power of attorney (POA) Benjamin Sutton above those of AIP William Sutton in regards to medical care, specifically medication. In fact, Washington law does not allow a POA to authorize the administering of antipsychotic medication against the AIP's will and contrary to a stated medical preference. Here, it is documented in the GAL's field report that AIP William Sutton would prefer not to have such a high level of medical intervention, noting that AIP Sutton "has historically not sought out medical care if he could at all avoid it" and that the (disputed) diagnosis of "onset of dementia has required intervention that (AIP Sutton) would not have wanted." [Sealed Report Of Guardian Ad Litem, Dated 01-26-15 at 4.]

Pursuant to Chapter 11.94 RCW - Power Of Attorney, a POA is "is subject to the same limitations as those that apply to a guardian under RCW 11.92.043(5) (a) through (c)." RCW 11.92.043(5) - Additional duties, states as follows:

(5)... No guardian, limited guardian, or standby guardian may involuntarily commit for mental health treatment, evaluation or observation, an alleged incapacitated person who is unable or unwilling to give informed consent to such commitment unless the procedures for involuntary commitment

set forth in chapter 71.05 or 72.23 RCW are followed.

RCW 11.92.043(5)

Accordingly, the Court erred in assuming the POA's scope of authority is allowed to exceed and contradict the stated medical preference of the AIP.

Likewise, Washington law recognizes a person's right to refuse antipsychotic medicine regardless of a person's disability or perceived incapacity, as follows:

RCW 71.05.215 Right to refuse antipsychotic medicine — Rules
1) A person found to be gravely disabled or presents a likelihood of serious harm as a result of a mental disorder has a right to refuse antipsychotic medication unless it is determined that the failure to medicate may result in a likelihood of serious harm or substantial deterioration or substantially prolong the length of involuntary commitment and there is no less intrusive course of treatment than medication in the best interest of that person.

RCW 71.05.215(1); *see also Harper v. State*, 759 P.2d 358 (Wash. 1988) (recognizing a fundamental liberty interest in refusing antipsychotic drug treatment).

D. The trial court improperly denied Appellants' Motion For Discovery Re Accounting & Inspection Of Evidence, by dismissing the guardianship petition without specifically resolving material discovery issues.

The Court dismissed Appellants' guardianship petition on May 8, 2015, without a specific hearing or due consideration of outstanding discovery issues raised by Appellants' pending motion for discovery regarding accounting and inspection of evidence, filed on April 30, 2015.

Appellants' motion for discovery sought extensive medical and

financial records regarding the POA Ben Sutton and AIP William Sutton

that was materially relevant to the underlying petition, stated as follows:

1. The items requested are in the exclusive possession, custody and control of Benjamin Sutton, and Petitioners have no other means of ascertaining the disclosure requested.
2. The items requested are essential for the purpose of demonstrating to the Court the injustice to, and exploitation of the vulnerable adult, and the need for the court to restore his rights and protections under the law.
3. The items and information are material to this cause and the issues of good faith execution of William C. Sutton's financial matters and ultimately matters of his health, safety, and civil rights to be determined in this case.
4. The Petitioners cannot provide the court necessary evidence as required by the court to successfully represent this cause without such discovery and inspection, nor can Petitioners adequately prepare for the hearings in this case without full disclosure and accounting of the actions by our brother's assigned Power of Attorney, for the court to make a fully informed ruling in behalf of the AIP (principal).
5. The discovery is necessary under WA Code 11.94.110, which states: "In ruling on a petition filed under RCW 11.94.090 and ordering any relief, the court must consider the best interests of the principal and will order relief that is the least restrictive to the exercise of the power of attorney while still adequate in the court's view to serve the principal's best interests. Upon entry of an order ruling on a petition, the court's oversight of the attorney-in-fact's actions and of the operation of the power of attorney ends unless another petition is filed under this chapter or unless the order specifies further court involvement that is necessary for a resolution of the issues raised in the petition."

6. Absent such discovery the rights of the Vulnerable Adult in accordance with RCW 70.129.140 (Resident Rights), and the universal guarantee in the Fifth Amendment to the U.S. Constitution which provides "No person shall...be deprived of life, liberty, or property, without due process of law," which is applied to all states by the 14th Amendment of the United States of America will be violated, to William C. Sutton's irreparable injury and thus deprive the vulnerable adult of fair representation and protection herein.

Motion for Discovery re Accounting & Inspection of Evidence at 3-4.

The trial court failed to specifically and comprehensively address these outstanding discovery issues prior to its dismissal of Appellants' guardianship petition and ignored Appellants' continued assertion of its material relevance to the underlying petition, including AIP's medical and fiduciary concerns. [May 8, 2015 Hearing Transcript at 8, Appendix D]

Appellants' testimony regarding the POA's financial dealings with AIP's considerable assets, estimated to be approximately \$1 Million or more, remains unrebutted to date by the POA. Despite this, the court denied Appellants' motion for discovery upon its dismissal of the petition without providing a separate hearing or argument regarding discovery issues. Appellants' reasserted their concerns in their *Counter to Respondent's Motion to Dismiss Guardianship Petition/Approve Fees and Costs and Response to Motion to Show Cause RE Contempt*, which was also improperly disregarded by the trial court. Accordingly, the court's dismissal of the guardianship petition and approval of attorneys fees and

costs was not a well-considered and fully informed decision on the merits, and instead was improper error and an abuse of discretion.

V. CONCLUSION

For the foregoing reasons, Appellants ask that the Court reverse and remand the trial court's dismissal of their petition for guardianship, in its entirety, for further proceedings. The trial court's order of dismissal and for attorneys fees and costs is flawed for several reasons, both procedural and substantive. The Appellants respectfully request that the Court of Appeals rule that the court's decision to dismiss their Petition below violated fundamental principles of due process, including Washington State and U.S. constitutional and statutory laws as referenced herein. The Appellants also ask that, at a minimum, the Motion For Discovery Re: Accounting and Inspection of Evidence be reinstated for full consideration and hearing by the court below.

DATED: October 19, 2015

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CERTIFICATE OF SERVICE BY _____
DEPUTY

I hereby certify that on October 21, 2015, I caused a true and correct copy of the foregoing:

Appellants' Brief & Appendices

The undersigned caused the original document to be filed with the appellate court clerk, by mailing the same via First-Class U.S. Mail to the following:

Washington State Court of Appeals Division I
950 Broadway, Suite 300
M IS TB-06
Seattle, WA 98402-4454
Attention: Court Clerk

And to

to be served on the following counsel of record VIA US MAIL on October 21, 2015 as follows:

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Attorney for Respondent

Dated: October 21, 2015 at Seattle, Washington.

By: E. Saadiq Morris
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APPELLANT'S BRIEF
In re the Guardianship of: WILLIAM SUTTON AIP
WA Court of Appeals, Division One
Case NO73538-1

APPENDIX A

FDA
21 C.F.R. § 201.57

§ 201.57

interaction) must be assigned a decimal number that corresponds to their placement in labeling. The decimal numbers must be consistent with the standardized identifying numbers listed in paragraph (d)(1) of this section (e.g., subheadings added to the "Warnings and Precautions" section must be numbered 5.1, 5.2, and so on).

(3) Any reference in Highlights to information appearing in the full prescribing information must be accompanied by the identifying number (in parentheses) corresponding to the location of the information in the full prescribing information.

(4) Omit clearly inapplicable sections, subsections, or specific information. If sections or subsections required under paragraph (d)(1) of this section are omitted from the full prescribing information, the heading "Full Prescribing Information: Contents" must be followed by an asterisk and the following statement must appear at the end of Contents: "* Sections or subsections omitted from the full prescribing information are not listed."

(5) Any risk information that is required under § 201.57(c)(9)(iv) is considered "appropriate pediatric contraindications, warnings, or precautions" within the meaning of section 505A(1)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355A(1)(2)), whether such information appears in the "Contraindications," "Warnings and Precautions," or "Use in Specific Populations" section of labeling.

(e) *Labeling requirements for older prescription drug products.* This paragraph applies only to approved prescription drug products not described in paragraph (b)(1) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.80 under the following section headings and in the following order:

- Description
- Clinical Pharmacology
- Indications and Usage
- Contraindications
- Warnings
- Precautions
- Adverse Reactions
- Drug Abuse and Dependence
- Overdosage
- Dosage and Administration

21 CFR Ch. I (4-1-12 Edition)

How Supplied

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with § 201.80(l) and (m):

- Animal Pharmacology and/or Animal Toxicology
- Clinical Studies
- References

(3) Omit clearly inapplicable sections, subsections, or specific information.

(4) The labeling may contain a "Product Title" section preceding the "Description" section and containing only the information required by § 201.80(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(1)(iv) and § 201.100(e). The information required by § 201.80(a)(1)(i) through (a)(1)(iv) must appear in the "Description" section of the labeling, whether or not it also appears in a "Product Title."

(5) The labeling must contain the date of the most recent revision of the labeling, identified as such, placed prominently immediately after the last section of the labeling.

(6) The requirement in § 201.80(f)(2) to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling must be implemented no later than June 30, 2007.

[71 FR 3986, Jan. 24, 2006]

§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

The requirements in this section apply only to prescription drug products described in § 201.56(b)(1) and must be implemented according to the schedule specified in § 201.56(c), except for the requirement in paragraph (c)(18) of this section to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling, which must be implemented no later than June 30, 2007.

(a) *Highlights of prescribing information.* The following information must appear in all prescription drug labeling:

(1) *Highlights limitation statement.* The verbatim statement "These highlights do not include all the information needed to use (insert name of drug product) safely and effectively. See full prescribing information for (insert name of drug product)."

(2) *Drug names, dosage form, route of administration, and controlled substance symbol.* The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in §600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug's dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must be included as required by §1302.04 of this chapter.

(3) *Initial U.S. approval.* The verbatim statement "Initial U.S. Approval" followed by the four-digit year in which FDA initially approved a new molecular entity, new biological product, or new combination of active ingredients. The statement must be placed on the line immediately beneath the established name or, for biological products, proper name of the product.

(4) *Boxed warning.* A concise summary of any boxed warning required by paragraph (c)(1) of this section, not to exceed a length of 20 lines. The summary must be preceded by a heading, in upper-case letters, containing the word "WARNING" and other words that are appropriate to identify the subject of the warning. The heading and the summary must be contained within a box and bolded. The following verbatim statement must be placed immediately following the heading of the boxed warning: "See full prescribing information for complete boxed warning."

(5) *Recent major changes.* A list of the section(s) of the full prescribing information, limited to the labeling sections described in paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of this section, that contain(s) substantive labeling changes that have been approved by FDA or authorized under §314.70(c)(6) or (d)(2), or §601.12(f)(1) through (f)(3) of this chapter. The head-

ing(s) and, if appropriate, the subheading(s) of the labeling section(s) affected by the change must be listed together with each section's identifying number and the date (month/year) on which the change was incorporated in labeling. These labeling sections must be listed in the order in which they appear in the full prescribing information. A changed section must be listed under this heading in Highlights for at least 1 year after the date of the labeling change and must be removed at the first printing subsequent to the 1 year period.

(6) *Indications and usage.* A concise statement of each of the product's indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: "(Drug) is a (name of class) indicated for (indication(s))."

(7) *Dosage and administration.* A concise summary of the information required under paragraph (c)(3) of this section, with any appropriate subheadings, including the recommended dosage regimen, starting dose, dose range, critical differences among population subsets, monitoring recommendations, and other clinically significant clinical pharmacologic information.

(8) *Dosage forms and strengths.* A concise summary of the information required under paragraph (c)(4) of this section, with any appropriate subheadings (e.g., tablets, capsules, injectable, suspension), including the strength or potency of the dosage form in metric system (e.g., 10-milligram tablets) and whether the product is scored.

(9) *Contraindications.* A concise statement of each of the product's contraindications, as required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) *Warnings and precautions.* A concise summary of the most clinically significant information required under

paragraph (c)(6) of this section, with any appropriate subheadings, including information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm.

(11) *Adverse reactions.* (i) A list of the most frequently occurring adverse reactions, as described in paragraph (c)(7) of this section, along with the criteria used to determine inclusion (e.g., incidence rate). Adverse reactions important for other reasons (e.g., because they are serious or frequently lead to discontinuation or dosage adjustment) must not be repeated under this heading in Highlights if they are included elsewhere in Highlights (e.g., Warnings and Precautions, Contraindications).

(ii) For drug products other than vaccines, the verbatim statement “To report SUSPECTED ADVERSE REACTIONS, contact (*insert name of manufacturer*) at (*insert manufacturer’s phone number*) or FDA at (*insert current FDA phone number and Web address for voluntary reporting of adverse reactions*).”

(iii) For vaccines, the verbatim statement “To report SUSPECTED ADVERSE REACTIONS, contact (*insert name of manufacturer*) at (*insert manufacturer’s phone number*) or VAERS at (*insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions*).”

(iv) For manufacturers with a Web site for voluntary reporting of adverse reactions, the Web address of the direct link to the site.

(12) *Drug interactions.* A concise summary of the information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(13) *Use in specific populations.* A concise summary of the information required under paragraph (c)(9) of this section, with any appropriate subheadings.

(14) *Patient counseling information statement.* The verbatim statement “See 17 for Patient Counseling Information” or, if the product has FDA-approved patient labeling, the verbatim statement “See 17 for Patient Counseling Information and (*insert either FDA-approved patient labeling or Medication Guide*).”

(15) *Revision date.* The date of the most recent revision of the labeling, identified as such, placed at the end of Highlights.

(b) *Full prescribing information: Contents.* Contents must contain a list of each heading and subheading required in the full prescribing information under §201.56(d)(1), if not omitted under §201.56(d)(4), preceded by the identifying number required under §201.56(d)(1). Contents must also contain any additional subheading(s) included in the full prescribing information preceded by the identifying number assigned in accordance with §201.56(d)(2).

(c) *Full prescribing information.* The full prescribing information must contain the information in the order required under paragraphs (c)(1) through (c)(18) of this section, together with the headings, subheadings, and identifying numbers required under §201.56(d)(1), unless omitted under §201.56(d)(4). If additional subheadings are used within a labeling section, they must be preceded by the identifying number assigned in accordance with §201.56(d)(2).

(1) *Boxed warning.* Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The box must contain, in uppercase letters, a heading inside the box that includes the word “WARNING” and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the “Contraindications” or “Warnings and Precautions” section, accompanied by the identifying number for the section or subsection containing the detailed information.

(2) *1 Indications and usage.* This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.

(i) This section must include the following information when the conditions listed are applicable:

(A) If the drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet, surgery, behavior changes, or some other drug), a statement that the drug is indicated as an adjunct to that mode of therapy.

(B) If evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (e.g., patients with mild disease or patients in a special age group), or if the indication is approved based on a surrogate endpoint under §314.510 or §601.41 of this chapter, a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to the "Clinical Studies" section for a discussion of the available evidence.

(C) If specific tests are necessary for selection or monitoring of the patients who need the drug (e.g., microbe susceptibility tests), the identity of such tests.

(D) If information on limitations of use or uncertainty about anticipated clinical benefits is relevant to the recommended intervals between doses, to the appropriate duration of treatment when such treatment should be limited, or to any modification of dosage, a concise description of the information with reference to the more detailed information in the "Dosage and Administration" section.

(E) If safety considerations are such that the drug should be reserved for specific situations (e.g., cases refractory to other drugs), a statement of the information.

(F) If there are specific conditions that should be met before the drug is used on a long term basis (e.g., demonstration of responsiveness to the drug in a short term trial in a given patient), a statement of the conditions; or, if the indications for long term use are different from those for short term use, a statement of the specific indications for each use.

(ii) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the

drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective or that the therapeutic benefits of the product do not generally outweigh its risks, FDA may require that this section state that there is a lack of evidence that the drug is effective or safe for that use or condition.

(iii) Any statements comparing the safety or effectiveness of the drug with other agents for the same indication must, except for biological products, be supported by substantial evidence derived from adequate and well-controlled studies as defined in §314.126(b) of this chapter unless this requirement is waived under §201.58 or §314.126(c) of this chapter. For biological products, such statements must be supported by substantial evidence.

(iv) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in §314.126(b) of this chapter unless the requirement is waived under §201.58 or §314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(v) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(3) *2 Dosage and administration.* (i) This section must state the recommended dose and, as appropriate:

(A) The dosage range,

(B) An upper limit beyond which safety and effectiveness have not been established, or beyond which increasing the dose does not result in increasing effectiveness,

(C) Dosages for each indication and subpopulation,

(D) The intervals recommended between doses,

(E) The optimal method of titrating dosage,

(F) The usual duration of treatment when treatment duration should be limited,

(G) Dosing recommendations based on clinical pharmacologic data (e.g., clinically significant food effects),

(H) Modification of dosage needed because of drug interactions or in special patient populations (e.g., in children, in geriatric age groups, in groups defined by genetic characteristics, or in patients with renal or hepatic disease),

(I) Important considerations concerning compliance with the dosage regimen,

(J) Efficacious or toxic concentration ranges and therapeutic concentration windows of the drug or its metabolites, if established and clinically significant. Information on therapeutic drug concentration monitoring (TDM) must also be included in this section when TDM is necessary.

(ii) Dosing regimens must not be implied or suggested in other sections of the labeling if not included in this section.

(iii) Radiation dosimetry information must be stated for both the patient receiving a radioactive drug and the person administering it.

(iv) This section must also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams of active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed (e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs or diluents; and the following verbatim statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.")

(4) *3 Dosage forms and strengths.* This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible, including:

(i) The strength or potency of the dosage form in metric system (e.g., 10

milligram tablets), and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation; and

(ii) A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable. The National Drug Code number(s) for the drug product must not be included in this section.

(5) *4 Contraindications.* This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state "None."

(6) *5 Warnings and precautions.* (1) *General.* This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a

drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the "Indications and Usage" section may be required by FDA in accordance with sections 201(n) and 502(a) of the act if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.

(ii) *Other special care precautions.* This section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection).

(iii) *Monitoring: Laboratory tests.* This section must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) *Interference with laboratory tests.* This section must briefly note information on any known interference by the product with laboratory tests and reference the section where the detailed information is presented (e.g., "Drug Interactions" section).

(7) *Adverse reactions.* This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.

(1) *Listing of adverse reactions.* This section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if

applicable. The list or lists must be preceded by the information necessary to interpret the adverse reactions (e.g., for clinical trials, total number exposed, extent and nature of exposure).

(ii) *Categorization of adverse reactions.* Within a listing, adverse reactions must be categorized by body system, by severity of the reaction, or in order of decreasing frequency, or by a combination of these, as appropriate. Within a category, adverse reactions must be listed in decreasing order of frequency. If frequency information cannot be reliably determined, adverse reactions must be listed in decreasing order of severity.

(A) *Clinical trials experience.* This section must list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database. The rate of occurrence of an adverse reaction for the drug and comparators (e.g., placebo) must be presented, unless such data cannot be determined or presentation of comparator rates would be misleading. If adverse reactions that occurred below the specified rate are included, they must be included in a separate listing. If comparative rates of occurrence cannot be reliably determined (e.g., adverse reactions were observed only in the uncontrolled trial portion of the overall safety database), adverse reactions must be grouped within specified frequency ranges as appropriate to the safety database for the drug (e.g., adverse reactions occurring at a rate of less than 1/100, adverse reactions occurring at a rate of less than 1/500) or descriptively identified, if frequency ranges cannot be determined. For adverse reactions with significant clinical implications, the listings must be supplemented with additional detail about the nature, frequency, and severity of the adverse reaction and the relationship of the adverse reaction to drug dose and demographic characteristics, if data are available and important.

(B) *Postmarketing experience.* This section of the labeling must list the adverse reactions, as defined in paragraph (c)(7) of this section, that are identified from domestic and foreign spontaneous reports. This listing must be separate

from the listing of adverse reactions identified in clinical trials.

(iii) *Comparisons of adverse reactions between drugs.* For drug products other than biological products, any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined in §314.126(b) of this chapter unless this requirement is waived under §201.58 or §314.126(c) of this chapter. For biological products, any such claim must be based on substantial evidence.

(8) *7 Drug interactions.* (i) This section must contain a description of clinically significant interactions, either observed or predicted, with other prescription or over-the-counter drugs, classes of drugs, or foods (e.g., dietary supplements, grapefruit juice), and specific practical instructions for preventing or managing them. The mechanism(s) of the interaction, if known, must be briefly described. Interactions that are described in the "Contraindications" or "Warnings and Precautions" sections must be discussed in more detail under this section. Details of drug interaction pharmacokinetic studies that are included in the "Clinical Pharmacology" section that are pertinent to clinical use of the drug must not be repeated in this section.

(ii) This section must also contain practical guidance on known interference of the drug with laboratory tests.

(9) *8 Use in specific populations.* This section must contain the following subsections:

(i) *8.1 Pregnancy.* This subsection may be omitted only if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection must contain the following information:

(A) *Teratogenic effects.* Under this subheading, the labeling must identify one of the following categories that applies to the drug, and the labeling must bear the statement required under the category:

(1) *Pregnancy category A.* If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester

of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category A. Studies in pregnant women have not shown that (*name of drug*) increases the risk of fetal abnormalities if administered during the first (*second, third, or all*) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (*name of drug*) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies. If animal reproduction studies are also available and they fail to demonstrate a risk to the fetus, the labeling must also state: "Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (*name of drug*)."
The labeling must also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(2) *Pregnancy category B.* If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling must state: "Pregnancy Category B. Reproduction studies have been performed in (*kind(s) of animal(s)*) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (*name of drug*). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed." If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: "Pregnancy Category B. Reproduction studies in (*kind(s) of animal(s)*) have shown (*describe findings*) at (x) times the human dose. Studies in pregnant

women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (*second, third, or all*) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (*name of drug*) should be used during pregnancy only if clearly needed." The labeling must also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(3) *Pregnancy category C.* If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling must state: "Pregnancy Category C. (*Name of drug*) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (*name(s) of species*) when given in doses (*x*) times the human dose. There are no adequate and well-controlled studies in pregnant women. (*Name of drug*) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." The labeling must contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: "Pregnancy Category C. Animal reproduction studies have not been conducted with (*name of drug*). It is also not known whether (*name of drug*) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (*Name of drug*) should be given to a pregnant woman only if clearly needed." The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(4) *Pregnancy category D.* If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential

benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See 'Warnings and Precautions' section." Under the "Warnings and Precautions" section, the labeling must state: "(*Name of drug*) can cause fetal harm when administered to a pregnant woman. (*Describe the human data and any pertinent animal data.*) If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

(5) *Pregnancy category X.* If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," the labeling must state: "(*Name of drug*) may (*can*) cause fetal harm when administered to a pregnant woman. (*Describe the human data and any pertinent animal data.*) (*Name of drug*) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."

(B) *Nonteratogenic effects.* Under this subheading the labeling must contain other information on the drug's effects on reproduction and the drug's use during pregnancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading must include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman's chronic use of

the drug for a preexisting condition or disease.

(ii) *8.2 Labor and delivery.* If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the Indications and Usage section, this subsection must describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, it must state that the information is unknown.

(iii) *8.3 Nursing mothers.* (A) If a drug is absorbed systemically, this subsection must contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects observed in animal offspring must be described.

(B) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or if the drug has a known tumorigenic potential, the labeling must state: "Because of the potential for serious adverse reactions in nursing infants from (*name of drug*) (or, "Because of the potential for tumorigenicity shown for (*name of drug*) in (*animal or human*) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: "Caution should be exercised when (*name of drug*) is administered to a nursing woman."

(C) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or has a known tumorigenic potential, the labeling must state: "It is not

known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from (*name of drug*) (or, "Because of the potential for tumorigenicity shown for (*name of drug*) in (*animal or human*) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (*name of drug*) is administered to a nursing woman."

(iv) *8.4 Pediatric use.* (A) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(H) of this section, the terms *pediatric population(s)* and *pediatric patient(s)* are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(B) If there is a specific pediatric indication different from those approved for adults that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the "Indications and Usage" section, and appropriate pediatric dosage information must be given under the "Dosage and Administration" section. The "Pediatric use" subsection must cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection should be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or "Clinical Studies" section. As appropriate, this information must also be contained in the "Contraindications" and/or "Warnings and Precautions" section(s).

(C) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the "Pediatric use" subsection and discussed in more detail, if appropriate, under the "Clinical Pharmacology" and "Clinical Studies" sections. Appropriate pediatric dosage must be given under the "Dosage and Administration" section. The "Pediatric use" subsection of the labeling must also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information must also be contained in the "Contraindications" and/or "Warnings and Precautions" section(s).

(D)(1) When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the "Pediatric use" subsection of the labeling must contain either the following statement or a reasonable alternative:

The safety and effectiveness of (*drug name*) have been established in the age groups _____ to _____ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (*drug name*) in these age groups is supported by evidence from adequate and well-controlled studies of (*drug name*) in adults with additional data (*insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population*).

(2) Data summarized in the preceding prescribed statement in this subsection must be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or the "Clinical Studies" section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose response information should be described in the "Clinical Pharmacology" section. Pediatric dosing instructions must be included in the "Dosage and Administration" section. Any differences between pediatric and

adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients must be cited briefly in the "Pediatric use" subsection and, as appropriate, in the "Contraindications," "Warnings and Precautions," and "Dosage and Administration" sections.

(E) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the "Pediatric use" subsection must contain an appropriate statement such as "Safety and effectiveness in pediatric patients below the age of (____) have not been established." If use of the drug in this pediatric population is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section and this subsection must refer to it.

(F) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection must contain the following statement: "Safety and effectiveness in pediatric patients have not been established." If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section and this subsection must refer to it.

(G) If the sponsor believes that none of the statements described in paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(F) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling and that the alternative statement is accurate and appropriate.

(H) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk must be made, generally in the "Contraindications" or "Warnings and Precautions" section.

(v) *8.5 Geriatric use.* (A) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the "Indications and Usage" section, and appropriate geriatric dosage must be stated under the "Dosage and Administration" section. The "Geriatric use" subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the "Geriatric use" subsection must pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection must be discussed in more detail, if appropriate, under "Clinical Pharmacology" or the "Clinical Studies" section. As appropriate, this information must also be contained in the "Warnings and Precautions" and/or "Contraindications" section(s).

(B) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the "Geriatric use" subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biologics license application, or a supplement or amendment to one of these applica-

tions (e.g., postmarketing studies or adverse drug reaction reports). The "Geriatric use" subsection must contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(1) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection must include the following statement:

Clinical studies of (*name of drug*) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(2) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor's applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection must contain the following statement:

Of the total number of subjects in clinical studies of (*name of drug*), ___ percent were 65 and over, while ___ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(3) If evidence from clinical studies and other reported clinical experience

available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the "Geriatric use" subsection must contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, must refer to more detailed discussions in the "Contraindications," "Warnings and Precautions," "Dosage and Administration," or other sections.

(C)(1) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they must be described briefly in the "Geriatric use" subsection and in detail under the "Clinical Pharmacology" section. The "Clinical Pharmacology" and "Drug Interactions" sections ordinarily contain information on drug/disease and drug/drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to use concomitant drugs.

(2) If a drug is known to be substantially excreted by the kidney, the "Geriatric use" subsection must include the statement:

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

(D) If use of the drug in the elderly appears to cause a specific hazard, the hazard must be described in the "Geriatric use" subsection, or, if appropriate, the hazard must be stated in the "Contraindications" or "Warnings and Precautions" section, and the "Geriatric use" subsection must refer to those sections.

(E) Labeling under paragraphs (c)(9)(v)(A) through (c)(9)(v)(C) of this section may include statements, if they are necessary for safe and effective use of the drug, and reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely.

(F) If the sponsor believes that none of the requirements described in paragraphs (c)(9)(v)(A) through (c)(9)(v)(E) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(vi) *Additional subsections.* Additional subsections may be included, as appropriate, if sufficient data are available concerning the use of the drug in other specified subpopulations (e.g., renal or hepatic impairment).

(10) *9 Drug abuse and dependence.* This section must contain the following information, as appropriate:

(i) *9.1 Controlled substance.* If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) *9.2 Abuse.* This subsection must state the types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identify particularly susceptible patient populations. This subsection must be based primarily on human data and human experience, but pertinent animal data may also be used.

(iii) *9.3 Dependence.* This subsection must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state and the principles of treating the effects of abrupt withdrawal must be described.

(11) *10 Overdosage.* This section must be based on human data. If human data are unavailable, appropriate animal and in vitro data may be used. The following specific information must be provided:

(i) Signs, symptoms, and laboratory findings associated with an overdosage of the drug;

(ii) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis);

(iii) Concentrations of the drug in biologic fluids associated with toxicity or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section also may be referenced here, if applicable to overdoses;

(iv) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life threatening;

(v) Whether the drug is dialyzable; and

(vi) Recommended general treatment procedures and specific measures for support of vital functions (e.g., proven antidotes, gastric lavage, forced diuresis, or as per Poison Control Center). Such recommendations must be based on data available for the specific drug or experience with pharmacologically related drugs. Unqualified recommendations for which data are lacking for the specific drug or class of drugs must not be stated.

(12) *11 Description.* (i) This section must contain:

(A) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug or, for biological products, the proper name (as defined in § 600.3 of this chapter) and any appropriate descriptors;

(B) The type of dosage form(s) and the route(s) of administration to which the labeling applies;

(C) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for drug labels or §§ 610.60 and 610.61 of this chapter for biological product labels;

(D) If the product is sterile, a statement of that fact;

(E) The pharmacological or therapeutic class of the drug;

(F) For drug products other than biological products, the chemical name and structural formula of the drug; and

(G) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(ii) If appropriate, other important chemical or physical information, such as physical constants or pH, must be stated.

(13) *12 Clinical pharmacology.* (i) This section must contain information relating to the human clinical pharmacology and actions of the drug in humans. Pharmacologic information based on in vitro data using human biomaterials or pharmacologic animal models, or relevant details about in vivo study designs or results (e.g., drug interaction studies), may be included in this section if essential to understand dosing or drug interaction information presented in other sections of the labeling. This section must include the following subsections:

(A) *12.1 Mechanism of action.* This subsection must summarize what is known about the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this subsection must contain a statement about the lack of information.

(B) *12.2 Pharmacodynamics.* This subsection must include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity. Exposure-response relationships (e.g., concentration-response, dose-response) and time course of pharmacodynamic response (including short-term clinical response) must be included if known. If this information is unknown, this subsection must contain a statement about the lack of information. Detailed dosing or monitoring recommendations based on pharmacodynamic information that appear in other sections (e.g., "Warnings and Precautions" or "Dosage and Administration") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(C) *12.3 Pharmacokinetics.* This subsection must describe the clinically significant pharmacokinetics of a drug or active metabolites, (i.e., pertinent absorption, distribution, metabolism, and excretion parameters). Information regarding bioavailability, the effect of food, minimum concentration (C_{\min}), maximum concentration (C_{\max}), time to maximum concentration (T_{\max}), area under the curve (AUC), pertinent half-lives ($t_{1/2}$), time to reach steady state, extent of accumulation, route(s) of elimination, clearance (renal, hepatic, total), mechanisms of clearance (e.g., specific enzyme systems), drug/drug and drug/food (e.g., dietary supplements, grapefruit juice) pharmacokinetic interactions (including inhibition, induction, and genetic characteristics), and volume of distribution (V_d) must be presented if clinically significant. Information regarding nonlinearity in pharmacokinetic parameters, changes in pharmacokinetics over time, and binding (plasma protein, erythrocyte) parameters must also be presented if clinically significant. This section must also include the results of pharmacokinetic studies (e.g., of metabolism or interaction) that establish the absence of an effect, including pertinent human studies and in vitro data. Dosing recommendations based on clinically significant factors that change the product's pharmacokinetics (e.g., age, gender, race, hepatic or renal dysfunction, concomitant therapy) that appear in other sections (e.g., "Warnings and Precautions," "Dosage and Administration" or "Use in Specific Populations") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(ii) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section only under the following circumstances:

(A) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown."

(B) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled studies, as defined in §314.126(b) of this chapter, to be necessary for the safe and effective use may be included in this section only if a waiver is granted under §201.58 or §314.126(c) of this chapter.

(14) *13 Nonclinical toxicology.* This section must contain the following subsections as appropriate:

(i) *13.1 Carcinogenesis, mutagenesis, impairment of fertility.* This subsection must state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If results from reproduction studies or other data in animals raise concern about mutagenesis or impairment of fertility in either males or females, this must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. Human data suggesting that the drug may be carcinogenic or mutagenic, or suggesting that it impairs fertility, as described in the "Warnings and Precautions" section, must not be included in this subsection of the labeling.

(ii) *13.2 Animal toxicology and/or pharmacology.* Significant animal data necessary for safe and effective use of the drug in humans that is not incorporated in other sections of labeling must be included in this section (e.g., specifics about studies used to support approval under §314.600 or §601.90 of this chapter, the absence of chronic animal toxicity data for a drug that is administered over prolonged periods or is implanted in the body).

(15) *14 Clinical studies.* This section must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s), including discussion of study design, population, endpoints, and results, but must not include an encyclopedic listing of all, or even most, studies performed as part of the product's clinical development program. If a specific important clinical study is mentioned in any section of

the labeling required under §§ 201.56 and 201.57 because the study is essential to an understandable presentation of the information in that section of the labeling, any detailed discussion of the study must appear in this section.

(i) For drug products other than biological products, any clinical study that is discussed in prescription drug labeling that relates to an indication for or use of the drug must be adequate and well-controlled as described in § 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the “Indications and Usage” or “Dosage and Administration” section. For biological products, any clinical study that is discussed that relates to an indication for or use of the biological product must constitute or contribute to substantial evidence and must not imply or suggest indications or uses or dosing regimens not stated in the “Indications and Usage” or “Dosage and Administration” section.

(ii) Any discussion of a clinical study that relates to a risk from the use of the drug must also refer to the other sections of the labeling where the risk is identified or discussed.

(16) *15 References.* When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

(17) *16 How supplied/storage and handling.* This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information must include, as appropriate:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets) and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation;

(ii) The units in which the dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100);

(iii) Appropriate information to facilitate identification of the dosage

forms, such as shape, color, coating, scoring, imprinting, and National Drug Code number; and

(iv) Special handling and storage conditions.

(18) *17 Patient counseling information.* This section must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following this section or, alternatively, accompany the prescription drug labeling. Any FDA-approved patient labeling printed immediately following this section or accompanying the labeling is subject to the type size requirements in paragraph (d)(6) of this section, except for a Medication Guide to be detached and distributed to patients in compliance with § 208.24 of this chapter. Medication Guides for distribution to patients are subject to the type size requirements set forth in § 208.20 of this chapter.

(d) *Format requirements.* All labeling information required under paragraphs (a), (b), and (c) of this section must be printed in accordance with the following specifications:

(1) All headings and subheadings required by paragraphs (a) and (c) of this section must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information. Reverse type is not permitted as a form of highlighting.

(2) A horizontal line must separate the information required by paragraphs (a), (b), and (c) of this section.

(3) The headings listed in paragraphs (a)(5) through (a)(13) of this section must be presented in the center of a horizontal line.

(4) If there are multiple subheadings listed under paragraphs (a)(4) through (a)(13) of this section, each subheading must be preceded by a bullet point.

(5) The labeling information required by paragraphs (a)(1) through (a)(4), (a)(11)(ii) through (a)(11)(iv), and (a)(14) of this section must be in bold print.

(6) The letter height or type size for all labeling information, headings, and

subheadings set forth in paragraphs (a), (b), and (c) of this section must be a minimum of 8 points, except for labeling information that is on or within the package from which the drug is to be dispensed, which must be a minimum of 6 points.

(7) The identifying numbers required by §201.56(d) and paragraphs (c)(1) through (c)(18) of this section must be presented in bold print and must precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter "m" in 8 point type).

(8) The information required by paragraph (a) of this section, not including the information required under paragraph (a)(4) of this section, must be limited in length to an amount that, if printed in 2 columns on a standard sized piece of typing paper (8 1/2 by 11 inches), single spaced, in 8 point type with 1/2-inch margins on all sides and between columns, would fit on one-half of the page.

(9) Sections or subsections of labeling that are identified as containing recent major changes under paragraph (a)(5) of this section must be highlighted in the full prescribing information by the inclusion of a vertical line on the left edge of the new or modified text.

(10) For the information required by paragraph (b) of this section, each section heading must be in bold print. Each subheading within a section must be indented and not bolded.

[71 FR 3988, Jan. 24, 2006]

§ 201.58 Waiver of labeling requirements.

An applicant may ask the Food and Drug Administration to waive any requirement under §§ 201.56, 201.57, and 201.80. A waiver request must be submitted in writing to the Director (or the Director's designee), Center for Drug Evaluation and Research, Food and Drug Administration, Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266, or, if applicable, the Director (or the Director's designee), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852-1448. The waiver must be granted or denied in

writing by the Director or the Director's designee.

[71 FR 3996, Jan. 24, 2006, as amended at 74 FR 13112, Mar. 26, 2009]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term *principal display panel*, as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however*, That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

APPELLANT'S BRIEF
In re the Guardianship of: WILLIAM SUTTON AIP
WA Court of Appeals, Division One
Case NO73538F 1

APPENDIX B

Pharmacist Notes re Medicine Warnings

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Exhibit 9 (A)

Pharmacy Stamped Print-outs

Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Olanzapine Tablets

Pronunciation (oh LAN za peen)

Brand Names: U.S. Zyprexa.

Product Dispensed: zyprexa

Warning

- There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.

What is this drug used for?

- It is used to treat bipolar problems.
- It is used to treat schizophrenia.
- It is used to treat low mood (depression).
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to olanzapine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.

- High blood sugar or diabetes, high cholesterol, and weight gain have happened with drugs like this one. These changes may raise the chance of heart and brain blood vessel disease. Talk with the doctor.
- Check your blood sugar as you have been told by your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Avoid drinking alcohol.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- This drug may cause weight gain. You may need to have your weight checked often.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance of getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore throat. Talk with your doctor.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia. Talk with your doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use with care in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

Integrated Patient Education Handouts

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Shakiness, trouble moving around, or stiffness.
- Mood changes.
- If you are planning to harm yourself or the want to harm yourself gets worse.
- Change in the way you act.
- Very bad dizziness or passing out.
- Fast or slow heartbeat.
- Not sweating during activities or in warm temperatures.
- Seizures.
- Drooling.
- Change in eyesight.
- Memory problems or loss.
- Chest pain.
- More thirst.
- Swelling in the arms or legs.
- A burning, numbness, or tingling feeling that is not normal.
- Enlarged breasts.
- Nipple discharge.
- Change in sex ability.
- For women, no period.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. The risk may be greater in older adults, mainly women. The chance that this will happen or that it will never go away is greater in people who take this drug in higher doses or for a long time. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Restlessness.
- Feeling tired or weak.

- Hard stools (constipation).
- Dry mouth.
- Feeling sleepy.
- Upset stomach.
- Weight gain.
- More hungry.
- Back pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take as you have been told, even if you feel well.
- To gain the most benefit, do not miss doses.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Take with or without food. Take with food if it causes an upset stomach.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org>), or emergency room (ER) right away.

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Exhibit 9 (B)

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Quetiapine Tablets

Pronunciation (kwe TYE a peen)

Brand Names: U.S. Seroquel.

Product Dispensed: seroquel

Warning

- There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.
- Children and teens who take this drug may be at a greater risk of having thoughts or actions of suicide. Adults may also be at risk. The risk may be greater in people who have had these thoughts or actions in the past. Watch people who take this drug closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.

What is this drug used for?

- It is used to treat bipolar problems.
- It is used to treat schizophrenia.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to quetiapine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Long QT on ECG, low magnesium levels, or low potassium levels.
- If you have had in the past a heartbeat that does not feel normal.
- If you are taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Have an eye exam every 6 months.
- This drug may affect certain lab tests. Be sure your doctor and lab workers know you take this drug.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- Avoid drinking alcohol.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Cataracts may rarely happen.
- If you have high blood sugar (diabetes), this drug may sometimes raise blood sugar. Talk with your doctor about how to fine tune this.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance of getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore throat. Talk with your doctor.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia. Talk with your doctor.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.

Integrated Patient Education Handouts

- If you are 65 or older, use this drug with care. You could have more side effects.
- Use with care in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- If you are planning to harm yourself or the want to harm yourself gets worse.
- Very bad dizziness or passing out.
- Very bad headache.
- A fast heartbeat.
- A heartbeat that does not feel normal.
- Chest pain or pressure.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Shakiness, trouble moving around, or stiffness.
- Feeling very tired or weak.
- Drooling.
- Seizures.
- Any bruising or bleeding.
- Change in eyesight.
- A burning, numbness, or tingling feeling that is not normal.
- Enlarged breasts.
- Nipple discharge.
- Change in sex ability.
- For women, no period.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. The risk

may be greater in older adults, mainly women. The chance that this will happen or that it will never go away is greater in people who take this drug in higher doses or for a long time. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.

- Call your doctor right away if you have a painful erection (hard penis) or an erection that lasts for longer than 4 hours. This may happen even when you are not having sex. If this is not treated right away, it may lead to lasting sex problems and you may not be able to have sex.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Headache.
- Feeling nervous and excitable.
- Hard stools (constipation).
- Dry mouth.
- Feeling sleepy.
- Weight gain.
- Upset stomach or throwing up.
- Feeling tired or weak.
- Belly pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take as you have been told, even if you feel well.
- To gain the most benefit, do not miss doses.
- Take with or without food.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

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Exhibit 9(c)

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Divalproex Long-Acting Tablets

Pronunciation (dye VAL proe ex)

Brand Names: U.S. Depakote.

Product Dispensed: depakote

Warning

- This drug may cause very bad and sometimes deadly liver problems. This most often happens within the first 6 months of using this drug. Call your doctor if you see dark urine, are feeling tired, are not hungry, have an upset stomach, are throwing up, or have yellowing of the skin or eyes. In patients who have seizures, loss of seizure control may happen. Have your blood work checked. Talk with your doctor.
- Children under 2 years old may be at greater risk of liver problems. Those who take more than 1 seizure drug, have a metabolic disorder, have a very bad seizure disorder along with mental retardation, or have organic brain disease are at the highest risk. Talk with the doctor.
- There is a greater risk of liver failure and death in patients who have a genetic liver problem caused by a mitochondrial disorder like Alpers-Huttenlocher syndrome. You may need to have a genetic test to check for this health problem. If you have or may have mitochondrial disorders do not take this drug before talking with your doctor.
- This drug may cause very bad birth defects if you take it while you are pregnant. It can also cause the child to have a lower IQ. Do not take this drug to prevent migraine headaches if you are pregnant. If you are pregnant and take this drug for seizures or bipolar disorder, talk to your doctor to see if you need to keep taking this drug.
- If you are able to get pregnant, you must use birth control that you can trust while you take this drug. If you get pregnant while taking this drug, call your doctor right away.
- This drug may cause very bad and sometimes deadly pancreas problems (pancreatitis). This may happen soon after use as well as many years after use. Signs of pancreatitis include belly pain, upset stomach, throwing up, or not feeling hungry. Call your doctor right away if you have any of these signs.

- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to valproic acid or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Liver disease or a urea cycle disorder.
- If you are using this drug to prevent migraines and are pregnant or may be pregnant.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert or have clear eyesight until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.
- Talk with your doctor before you drink alcohol or use other drugs and natural products that slow your actions.
- Have your blood work checked. Talk with your doctor.
- This drug may affect certain lab tests. Be sure your doctor and lab workers know you take this drug.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Some brain problems have happened with the use of valproic acid products. Sometimes, these problems

What is this drug used for?

- It is used to treat seizures.
- It is used to prevent migraine headaches.
- It is used to treat bipolar problems.

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have led to health problems that may not go away. Talk with the doctor.

- A very bad and sometimes deadly reaction has happened with this drug. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. Talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use birth control that you can trust to prevent pregnancy while taking this drug.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection. These include a fever of 100.4°F (38°C) or higher, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, wound that will not heal, or anal itching or pain.
- Chest pain.
- A heartbeat that does not feel normal.
- Very bad swelling or pain of hands or feet.
- Change in eyesight.
- Hearing loss.
- Change in thinking clearly and with logic.
- Memory problems or loss.
- Feeling very tired or weak.
- Change in balance.
- Any bruising or bleeding.
- Not able to pass urine or change in how much urine is passed.
- Swollen gland.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Muscle pain or weakness.
- Joint pain or swelling.
- Shakiness.
- If seizures are worse or not the same after starting this drug.
- Patients who take this drug may be at a greater risk of having thoughts or actions of suicide. The risk may be greater in people who have had these thoughts or actions in the past. Watch people who take this drug

closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.

- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Upset stomach or throwing up.
- Dizziness.
- Feeling sleepy.
- Hard stools (constipation).
- Loose stools (diarrhea).
- Belly pain.
- Not able to sleep.
- Feeling more or less hungry.
- Weight gain or loss.
- Hair loss.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Do not change the dose or stop this drug. This could cause seizures. Talk with your doctor.
- Take as you have been told, even if you feel well.
- Take this drug at the same time of day.
- Take with or without food. Take with food if it causes an upset stomach.
- Swallow whole. Do not chew, break, or crush.
- Take with a full glass of water.
- If you see parts of this drug in your stool, call your doctor.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Lorazepam Tablets

Pronunciation (lor AZ e pam)

Brand Names: U.S. Ativan.

Product Dispensed: ativan

What is this drug used for?

- It is used to treat anxiety.
- It is used to treat seizures.
- It is used to ease anxiety before surgery.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to lorazepam or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Glaucoma, low mood (depression), or certain mental problems.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you. Avoid drinking alcohol. You may need to do this for at least 24 hours after using this drug. Talk with your doctor.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Have your blood work checked if you are on this drug for a long time. Talk with your doctor.
- This drug may be habit-forming with long-term use.
- Do not take this drug for longer than you were told by your doctor.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you

will want to slowly stop it as ordered by your doctor.

- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low mood (depression), thoughts of killing yourself, nervousness, emotional ups and downs, thinking that is not normal, anxiety, or lack of interest in life.
- Hallucinations.
- Change in how you act.
- Change in balance.
- Change in thinking clearly and with logic.
- Memory problems or loss.
- Feeling very tired or weak.
- Very bad dizziness or passing out.
- Change in eyesight.
- Muscle weakness.
- Dark urine or yellow skin or eyes.
- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

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- Feeling sleepy.
- Dizziness.
- Headache.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take with or without food. Take with food if it causes an upset stomach.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

How do I store and/or throw out this drug?

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Protect from light.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org>), or emergency room (ER) right away.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the

healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Olanzapine Tablets

Pronunciation (oh LAN za peen)

Brand Names: U.S. Zyprexa.

Product Dispensed: zyprexa

Warning

There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.

What is this drug used for?

- It is used to treat bipolar problems.
- It is used to treat schizophrenia.
- It is used to treat low mood (depression).
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to olanzapine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.

- High blood sugar or diabetes, high cholesterol, and weight gain have happened with drugs like this one. These changes may raise the chance of heart and brain blood vessel disease. Talk with the doctor.
- Check your blood sugar as you have been told by your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Avoid drinking alcohol.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- This drug may cause weight gain. You may need to have your weight checked often.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance of getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore throat. Talk with your doctor.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia. Talk with your doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use with care in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

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- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.

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- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Shakiness, trouble moving around, or stiffness.
- Mood changes.
- If you are planning to harm yourself or the want to harm yourself gets worse.
- Change in the way you act.
- Very bad dizziness or passing out.
- Fast or slow heartbeat.
- Not sweating during activities or in warm temperatures.
- Seizures.
- Drooling.
- Change in eyesight.
- Memory problems or loss. ←
- Chest pain.
- More thirst.
- Swelling in the arms or legs.
- A burning, numbness, or tingling feeling that is not normal.
- Enlarged breasts.
- Nipple discharge.
- Change in sex ability.
- For women, no period.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. The risk may be greater in older adults, mainly women. The chance that this will happen or that it will never go away is greater in people who take this drug in higher doses or for a long time. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Restlessness.
- Feeling tired or weak.

- Hard stools (constipation).
- Dry mouth.
- Feeling sleepy.
- Upset stomach.
- Weight gain.
- More hungry.
- Back pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take as you have been told, even if you feel well.
- To gain the most benefit, do not miss doses.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Take with or without food. Take with food if it causes an upset stomach.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org>), or emergency room (ER) right away.

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Quetiapine Tablets

Pronunciation (kwe TYE a peen)

Brand Names: U.S. Seroquel. ←

Product Dispensed: seroquel

Warning

- There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.
- Children and teens who take this drug may be at a greater risk of having thoughts or actions of suicide. Adults may also be at risk. The risk may be greater in people who have had these thoughts or actions in the past. Watch people who take this drug closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouching, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.

What is this drug used for?

- It is used to treat bipolar problems.
- It is used to treat schizophrenia.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to quetiapine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Long QT on ECG, low magnesium levels, or low potassium levels.
- If you have had in the past a heartbeat that does not feel normal.
- If you are taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Have an eye exam every 6 months.
- This drug may affect certain lab tests. Be sure your doctor and lab workers know you take this drug.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- Avoid drinking alcohol.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Cataracts may rarely happen.
- If you have high blood sugar (diabetes), this drug may sometimes raise blood sugar. Talk with your doctor about how to fine tune this.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance of getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore throat. Talk with your doctor.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia. Talk with your doctor.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.

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- If you are 65 or older, use this drug with care. You could have more side effects.
- Use with care in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- If you are planning to harm yourself or the want to harm yourself gets worse.
- Very bad dizziness or passing out.
- Very bad headache.
- A fast heartbeat.
- A heartbeat that does not feel normal.
- Chest pain or pressure.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Shakiness, trouble moving around, or stiffness.
- Feeling very tired or weak.
- Drooling.
- Seizures.
- Any bruising or bleeding.
- Change in eyesight.
- A burning, numbness, or tingling feeling that is not normal.
- Enlarged breasts.
- Nipple discharge.
- Change in sex ability.
- For women, no period.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. The risk

may be greater in older adults, mainly women. The chance that this will happen or that it will never go away is greater in people who take this drug in higher doses or for a long time. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.

- Call your doctor right away if you have a painful erection (hard penis) or an erection that lasts for longer than 4 hours. This may happen even when you are not having sex. If this is not treated right away, it may lead to lasting sex problems and you may not be able to have sex.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Headache.
- Feeling nervous and excitable.
- Hard stools (constipation).
- Dry mouth.
- Feeling sleepy.
- Weight gain.
- Upset stomach or throwing up.
- Feeling tired or weak.
- Belly pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take as you have been told, even if you feel well.
- To gain the most benefit, do not miss doses.
- Take with or without food.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

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98226

Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Divalproex Long-Acting Tablets

Pronunciation (dye VAL proe ex)

Brand Names: U.S. Depakote.

Product Dispensed: depakote

Warning

- This drug may cause very bad and sometimes deadly liver problems. This most often happens within the first 6 months of using this drug. Call your doctor if you see dark urine, are feeling tired, are not hungry, have an upset stomach, are throwing up, or have yellowing of the skin or eyes. In patients who have seizures, loss of seizure control may happen. Have your blood work checked. Talk with your doctor.
- Children under 2 years old may be at greater risk of liver problems. Those who take more than 1 seizure drug, have a metabolic disorder, have a very bad seizure disorder along with mental retardation, or have organic brain disease are at the highest risk. Talk with the doctor.
- There is a greater risk of liver failure and death in patients who have a genetic liver problem caused by a mitochondrial disorder like Alpers-Huttenlocher syndrome. You may need to have a genetic test to check for this health problem. If you have or may have mitochondrial disorders do not take this drug before talking with your doctor.
- This drug may cause very bad birth defects if you take it while you are pregnant. It can also cause the child to have a lower IQ. Do not take this drug to prevent migraine headaches if you are pregnant. If you are pregnant and take this drug for seizures or bipolar disorder, talk to your doctor to see if you need to keep taking this drug.
- If you are able to get pregnant, you must use birth control that you can trust while you take this drug. If you get pregnant while taking this drug, call your doctor right away.
- This drug may cause very bad and sometimes deadly pancreas problems (pancreatitis). This may happen soon after use as well as many years after use. Signs of pancreatitis include belly pain, upset stomach, throwing up, or not feeling hungry. Call your doctor right away if you have any of these signs.

- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to valproic acid or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Liver disease or a urea cycle disorder.
- If you are using this drug to prevent migraines and are pregnant or may be pregnant.

This is not a list of all drugs or health problems that interact with this drug. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert or have clear eyesight until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly over a few minutes when sitting or lying down. Be careful climbing stairs.
- Talk with your doctor before you drink alcohol or use other drugs and natural products that slow your actions.
- Have your blood work checked. Talk with your doctor.
- This drug may affect certain lab tests. Be sure your doctor and lab workers know you take this drug.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Some brain problems have happened with the use of valproic acid products. Sometimes, these problems

What is this drug used for?

- It is used to treat seizures.
- It is used to prevent migraine headaches.
- It is used to treat bipolar problems.

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have led to health problems that may not go away.
Talk with the doctor.

- A very bad and sometimes deadly reaction has happened with this drug. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. Talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use birth control that you can trust to prevent pregnancy while taking this drug.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection. These include a fever of 100.4°F (38°C) or higher, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, wound that will not heal, or anal itching or pain.
- Chest pain.
- A heartbeat that does not feel normal.
- Very bad swelling or pain of hands or feet.
- Change in eyesight.
- Hearing loss.
- Change in thinking clearly and with logic.
- Memory problems or loss.
- Feeling very tired or weak.
- Change in balance.
- Any bruising or bleeding.
- Not able to pass urine or change in how much urine is passed.
- Swollen gland.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Muscle pain or weakness.
- Joint pain or swelling.
- Shakiness.
- If seizures are worse or not the same after starting this drug. ?
- Patients who take this drug may be at a greater risk of having thoughts or actions of suicide. The risk may be greater in people who have had these thoughts or actions in the past. Watch people who take this drug

closely. Call the doctor right away if signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.

- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Upset stomach or throwing up.
- Dizziness.
- Feeling sleepy.
- Hard stools (constipation).
- Loose stools (diarrhea).
- Belly pain.
- Not able to sleep.
- Feeling more or less hungry.
- Weight gain or loss.
- Hair loss.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Do not change the dose or stop this drug. This could cause seizures. Talk with your doctor.
- Take as you have been told, even if you feel well.
- Take this drug at the same time of day.
- Take with or without food. Take with food if it causes an upset stomach.
- Swallow whole. Do not chew, break, or crush.
- Take with a full glass of water.
- If you see parts of this drug in your stool, call your doctor.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

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Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Lorazepam Tablets

Pronunciation (lor AZ e pam)

Brand Names: U.S. Ativan. ←

Product Dispensed: ativan

What is this drug used for?

- It is used to treat anxiety.
- It is used to treat seizures. ?
- It is used to ease anxiety before surgery.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to lorazepam or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Glaucoma, low mood (depression), or certain mental problems.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell dentists, surgeons, and other doctors that you use this drug.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you. Avoid drinking alcohol. You may need to do this for at least 24 hours after using this drug. Talk with your doctor
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Have your blood work checked if you are on this drug for a long time. Talk with your doctor.
- This drug may be habit-forming with long-term use.
- Do not take this drug for longer than you were told by your doctor.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you

- will want to slowly stop it as ordered by your doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low mood (depression), thoughts of killing yourself, nervousness, emotional ups and downs, thinking that is not normal, anxiety, or lack of interest in life.
- Hallucinations.
- Change in how you act.
- Change in balance.
- Change in thinking clearly and with logic.
- Memory problems or loss.
- Feeling very tired or weak.
- Very bad dizziness or passing out.
- Change in eyesight.
- Muscle weakness.
- Dark urine or yellow skin or eyes.
- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

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- Feeling sleepy.
- Dizziness.
- Headache.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects at <http://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read and follow the dosing on the label closely.

- Take with or without food. Take with food if it causes an upset stomach.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

How do I store and/or throw out this drug?

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Protect from light.
- Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org>), or emergency room (ER) right away.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the

healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

Issue Date: February 18, 2015

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APPELLANT'S BRIEF
In re the Guardianship of: WILLIAM SUTTON AIP
WA Court of Appeals, Division One
Case NO73538F 1

APPENDIX C

February 27, 2015 Hearing Transcript

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF WHATCOM

GUARDIANSHIP OF:

WILLIAM CHARLES SUTTON

No. 14-4-00523-1

COA No. 73538-1-I

VERBATIM REPORT OF PROCEEDINGS
FEBRUARY 27, 2015
THE HONORABLE DEBORRA GARRETT, JUDGE

PAGES 1-48

WENDY S. RAYMOND, CSR 2285
OFFICIAL COURT REPORTER
WHATCOM COUNTY SUPERIOR COURT
BELLINGHAM, WASHINGTON

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF WHATCOM

GUARDIANSHIP OF:

WILLIAM CHARLES SUTTON

No. 14-4-00523-1

COA No. 73538-1-I

REPORTER'S TRANSCRIPT

BE IT REMEMBERED THAT on FEBRUARY 27,
2015, the above-entitled and numbered cause came
regularly on for hearing before the Honorable DEBORRA
GARRETT, Judge of the above-entitled court, sitting in
Department 2 thereof, of the Whatcom County Superior
Court, in the City of Bellingham, County of Whatcom,
State of Washington;

The Petitioner appeared through pro se
CLAUDIA HARRIS & CYNTHIA MURDERS, Bellingham,
Washington;

The Respondent appeared through DAVID
NEUBECK, Attorney at Law, Bellingham, Washington;

BOTH sides having announced they were
ready for hearing, the following proceedings occurred,
to wit:

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2 FEBRUARY 27, 2015

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4 (Beginning of requested proceedings.)

5 THE COURT: Guardianship of William
6 Sutton. Good afternoon. And let's see, we have
7 Ms. Harris and Ms. Murders?

8 MS. HARRIS: Yes.

9 THE COURT: All right. Please, be seated
10 and welcome to the court. And hello,
11 Mr. Bergsbaken and of course Mr. Neubeck. Which
12 of you is Ms. Harris?

13 MS. HARRIS: I am.

14 THE COURT: And you're Ms. Murders?

15 MS. MURDERS: Yes.

16 THE COURT: Hello. Okay, I've reviewed
17 the submissions of both parties, including the
18 more recently filed package of information that
19 I received this morning actually from
20 Ms. Murders and Ms. Harris. And have you been
21 given a copy of that Mr. Neubeck and
22 Mr. Bergsbaken?

23 MR. NEUBECK: I'm not sure what they
24 submitted this morning so I don't know if we
25 have received a copy of it.

1 MS. HARRIS: It is what I took to his
2 office a couple days before.

3 THE COURT: It's a number of photographs.

4 MS. HARRIS: Oh, the photographs he
5 didn't receive because he got the video and the
6 video wasn't allowed in the court so those are
7 stills from that video.

8 THE COURT: Okay. We have a pending
9 guardianship matter in this case and then we
10 have a motion to dismiss the guardianship
11 petition. We have a pending petition and a
12 motion to dismiss the petition. And then we
13 also have a motion to have the Court grant
14 various forms of relief, including appointing a
15 certified professional guardian and suspending
16 the power of attorney that's currently in
17 existence.

18 And I think I'm going to ask the
19 Petitioners to go, to tell me their argument
20 first because it sounds like some of the issues
21 that will be raised on the petition to appoint
22 certified professional guardian, et cetera, may
23 impact the motion to dismiss the guardianship.

24 So I'm going to ask the Petitioners to go
25 first and explain to me what the basis is for

1 your petition and that will probably get you
2 into what the basis is for the guardianship that
3 you filed and that's fine.

4 So as I say, I've read all of the
5 materials you've submitted so it's not necessary
6 to recap them, but you have up to ten minutes
7 for argument and I'd ask that you take about
8 five minutes for argument so that after you've
9 heard from the other parties you reserve a
10 little time for rebuttal.

11 MS. HARRIS: Okay. Well, according to
12 the power of attorney documents our brother
13 would have had to be completely incapacitated
14 before Ben would take such drastic actions to
15 control every aspect of his life as he has. And
16 our brother was functioning at a high level, in
17 fact, able to make phone calls, dial the numbers
18 out, have conversations. He called Ben as Ben
19 said a couple of times during the two days prior
20 to him being removed from his house.

21 Ben didn't tell anybody he was going to
22 do that, including his girlfriend who was living
23 in the house. She had been there for eight
24 months, they had known each other for three
25 years. And after the fact he told everyone and

1 had her move her belongings and herself out of
2 the house. She had left for two days and during
3 that, I mean she had left for longer but she was
4 gone for two days after which he took our
5 brother.

6 THE COURT: I guess what, I'm going to
7 interrupt you and the Court's, the Court's
8 concern here is not so much the validity of the
9 power of attorney as to whether or not the legal
10 standards for ordering a guardianship have been
11 met.

12 MS. HARRIS: Okay.

13 THE COURT: And as I read the responses
14 to your petitions here the counsel for the
15 holder of the power of attorney, Mr. Sutton's
16 son, are saying that appropriate measures have
17 been taken to assure Mr. Sutton's welfare and a
18 guardianship is not needed. So I'd appreciate
19 your addressing that as well.

20 MS. HARRIS: Okay. We're very fearful
21 for our brother's life. As you could see in the
22 first picture that I submitted he looks very
23 healthy. In the video stills you can see how
24 skinny he is and this is eight months after he
25 was supposed to be incapacitated. You can see

1 that he's interacting for a fairly long period
2 of time with the realtor in a very positive way
3 and he's happy through the whole thing.

4 He has been upset in the facility the
5 entire time up until they slammed him very hard
6 with drugs in the last two or three months since
7 they stopped visitation altogether. The last
8 time I saw my brother he was in a comatose
9 state. They have criticized me for calling 911
10 that day, but I went to see him and he was being
11 restrained in a wheelchair because they had him
12 in a drug induced stupor. He had been very
13 active up until then. He was drugged to the
14 point of incapacity, they put him in a bed in
15 the daytime and when they got him into the bed
16 he looked like comatose. And I asked --

17 THE COURT: So your concern is that your
18 brother is not receiving the appropriate medical
19 care --

20 MS. HARRIS: My concern --

21 THE COURT: -- at that facility where he
22 is?

23 MS. HARRIS: My concern is they are
24 harming him to the point of death with these
25 drugs. The information that I gave you shows

1 that these drugs are harmful. They state that
2 they are not proved to use for seniors with
3 dementia, in fact, they cause death, can cause
4 death. And among many other --

5 THE COURT: I understand your concerns
6 about the drugs. And so it sounds like your
7 concern is about the facility where your brother
8 is residing; am I right?

9 MS. HARRIS: It is both the POA as well
10 because they are the ones that initiated this,
11 this is the ones that approved this.

12 THE COURT: So what you're wanting to do
13 is have your, you're asking the Court to permit
14 the guardianship matter to continue and then are
15 you also asking the Court to revoke the power of
16 attorney?

17 MS. HARRIS: To revoke or suspend the
18 guardianship, could be a temporary guardianship
19 until we can sort through all of this stuff. We
20 feel it is necessary for his protection that
21 someone else be in charge because his current
22 care management is frightening. They, the
23 doctor has been instructed to not even, by the
24 POA and his wife the RN, to not even do normal
25 screenings that they would normally do because

1 they are stating that he's in advanced
2 Alzheimer's, which he was not when he was taken.
3 He was high functioning when he was taken. He
4 could do his own hygiene, he fixed his own food,
5 he had a little extra weight on him, he was very
6 active walking about two miles a day, he had a
7 companion, he had a life, he had a social life,
8 and he was able to make notes for himself.

9 MS. MURDERS: He was aware of his memory
10 problems but he compensated by keeping careful
11 track on calendars.

12 THE COURT: So your concern is that your
13 brother's not receiving appropriate medical
14 care, right?

15 MS. HARRIS: That he's receiving harmful
16 medical care.

17 THE COURT: Okay.

18 MS. HARRIS: And he has dropped in weight
19 and his blood pressure was so low, he's going to
20 die under this care management policy. He's
21 just going to die and they are just going to let
22 him because, as they stated, given his
23 circumstances the doctor feels it's a fine
24 recommendation to not monitor him.

25 We would like him to have the chance to

1 have a neutral doctor who specialized in brain
2 conditions. As far as I know he doesn't have a
3 doctor who specializes in brain conditions. We
4 asked the guardian ad litem for an independent
5 medical evaluation and he indicated to us that
6 he was going to do that and then he accepted the
7 report of the same doctor that had been drugging
8 him.

9 But we've been complaining for, since
10 September or so about the drugging concerns
11 because our brother's choice would be to not be
12 medicated. In fact, the letter from the POA to
13 my sister, which we submitted, actually states
14 that "dad doesn't like doctors and doesn't like
15 medication", so under his RN wife's care he
16 actually went off everything altogether and was
17 off everything for many months until entering
18 the facility until they started slamming him
19 with these drugs that he didn't want. They are
20 basically keeping him incapacitated with these
21 drugs, which is the only way they would have the
22 right to intervene as they have in his entire
23 life.

24 THE COURT: I understand. I'm going to
25 ask the, I'm going to ask you first,

1 Mr. Neubeck, to respond and to tell the Court
2 why, in your view, a guardianship is not
3 necessary?

4 MR. NEUBECK: Thank you, Your Honor.
5 David Neubeck appearing on behalf Mr. Sutton's
6 son Ben Sutton. I think the Court has probably
7 had a chance to review our written materials,
8 but to sort of emphasize the main points
9 guardianships are, as the Court knows, a very
10 serious business and quite restrictive. The law
11 is very clear if there are less restrictive
12 alternatives available, including things like
13 functioning powers of attorney, that those be
14 deferred to as ways to manage, help manage
15 people's lives rather than having Court
16 oversight.

17 Mr. Sutton unfortunately, Charley Sutton,
18 is suffering from very serious dementia. I
19 think that is reflected in the medical reports
20 and report of the GAL. He has been very lucky to
21 have his son managing his care through his POA
22 and Charley is the person who executed those
23 POA's knowing full well that his son would have
24 authority to manage his life as he thought
25 Charley would best be cared for.

1 As to the medical care, I think it is,
2 Mr. Sutton has consulted and employed all the
3 best medical advisors that he can, including
4 very competent staff at Bellingham Orchard who
5 specializes in dementia. These are people, it's
6 an unfortunate disease dementia, it's very
7 difficult to deal with and we do not have the
8 best methods, well, we have the best methods
9 available to deal with it, but they are often
10 not sufficient to really deal well with the
11 medical situation.

12 So we believe that the powers of attorney
13 and Mr. Sutton have been acting appropriately,
14 that he has secured all best medical care he
15 can, and has the best living situation for his
16 father.

17 The Adult Protective Services was called
18 and investigated the matter, did not find that
19 Charley Sutton was being abused in any way or
20 was being unnecessarily restrained by
21 medication, and I believe the guardian ad litem
22 report reflects all of this, that the power of
23 attorney is working as it should and that the
24 Court's intervention here is not necessary.

25 I'll also note for the Court, I guess I

1 attorney at that point had relayed to me that
2 they had some conditions if he was to go to a
3 neuropsychological evaluation that his son not
4 transport him nor anyone from the facility and
5 otherwise they would be, they would feel that
6 the report would be suspect or be influenced by
7 the people who brought him to that report, or to
8 that doctor. And so at that point seeing no
9 conflict I didn't feel that I should attempt to
10 put him through a test that they might not even
11 see as valid, that's why I didn't pursue that.

12 I felt that the APS investigation was
13 thorough and I had a long time to talk with them
14 and they felt, like I put in my report, that not
15 only was the POA functioning as it was intended,
16 but it was actually visionary in terms of how it
17 dealt with his upcoming needs. So they saw no
18 concerns so I gave that a lot of weight.

19 I also gave a lot of weight to mister,
20 the father Charley's opinions about his son. I
21 explained to him the son's the one who is having
22 you stay in this facility. He said "well, I
23 trust my son". Even though he was unhappy there
24 and would rather be on his own where he had less
25 activity around him, a little more peaceful. I

1 had brought the idea up that the Petitioners had
2 a house that they would like to move him too, he
3 like that idea but with almost within the same
4 breath he said he trusts his son. I give that a
5 lot of weight, yeah. That's all I guess I have
6 to say at this point.

7 THE COURT: Could you address in a little
8 more detail why you, why a neuropsychological
9 evaluation didn't happen? Was it simply that
10 the conditions were untenable or was there a
11 medical decision made beyond that?

12 MR. BERGSBAKEN: Well, I felt that the
13 report from the, his current physician, because
14 they have a team, Dr. Webb the geriatric mental
15 health consultant that is used at the facility,
16 who is not affiliated, but they consult with as
17 well as the consulting psychiatric,
18 psychiatrist, I felt that that team was
19 providing enough of a report that I felt another
20 one wasn't necessary, even though the
21 information would be beneficial to me for future
22 care. I didn't see, yeah, a need to counteract
23 what the physicians are asking.

24 THE COURT: Are you aware of adverse
25 reactions to medication on Mr. Sutton's part?

1 MR. BERGSBAKEN: Well, I mean from what
2 I've witnessed in my meetings with him I just
3 did not see the type of detrimental effect.

4 THE COURT: I realize that many of the
5 concerns about medications that are raised here
6 are about of chronic problems as opposed to
7 acute problems that a visitor would notice when
8 visiting. I just wondered.

9 MR. BERGSBAKEN: Yep.

10 THE COURT: All right. Thank you,
11 Mr. Bergsbaken.

12 Ms. Harrison, Ms. Murders, would you like
13 to respond to anything that Mr. Neubeck or
14 Mr. Bergsbaken has said?

15 MS. HARRIS: Yes. As far as striking the
16 video and the stills the e-mails --

17 THE COURT: Excuse me for interrupting,
18 I'm not going to strike the video and stills so
19 you don't need to address that. I'm going to
20 deny that objection. Go ahead.

21 MS. HARRIS: Okay. I would like to point
22 out that those were taken in the house that is
23 next door to me. We do have a six-foot fence
24 around the two properties. Our plan was that he
25 would be able to come over to my house and go

1 back and forth. We would have a code gate
2 system like the facility has.

3 I was a registered nurse's assistant in
4 the past, I'm not looking for a job, I refuse to
5 be paid for my brother's, to be my brother's
6 sister and assist him. We have all along said
7 that we would have a caregiver and I would be
8 present most of the time as well. In the
9 beginning when we proposed this he would have
10 only needed part-time help but, you know, now I
11 realize in his current state he would need
12 full-time.

13 THE COURT: Let me ask you this; normally
14 the law gives the person the right to decide
15 what their care should be or who should be
16 responsible for their care if they are not able
17 to take care of themselves and that's why people
18 are permitted to sign powers of attorney that
19 give that authority to someone else. And the
20 law and courts are very reluctant to interfere
21 with a person's selection of someone to be their
22 power of attorney and so normally the Court
23 would not intervene and the law would not
24 authorize the Court to intervene in the absence
25 of some pretty clear evidence that the person

1 us. She is the alternate POA.

2 MS. MURDERS: Actually he knew he had
3 Alzheimer's, he knew it progresses, he wanted to
4 cover all aspects, you know, in the future. He
5 wanted to stay in his home just as long as
6 possible. That was his plan. That's why he
7 sold the house in Sultan and moved to Ferndale
8 to a nice little home that would be safe, it
9 was, he was familiar with his surroundings, he
10 was happy there.

11 The worst thing in the world to do to a
12 person with Alzheimer's is jerk them out of
13 their familiar surroundings and put them into
14 someplace new.

15 THE COURT: But that is what would happen
16 if your petition is granted, he would be taken
17 from the place where he lives now into another
18 form of housing.

19 MS. MURDERS: It would be. But you see
20 he asked me five years ago, don't ever let them
21 lock me up, promise me you won't and I said I
22 won't Charley. Well, my life has changed since
23 then, I would have come to help him, now my life
24 has changed, I'm remarried. And the fact of the
25 matter is that he was content there. He had a

1 women that he cared about that was living with
2 him, they were happy. And there is no reason
3 for him to get jerked out. Yes, he had
4 short-term memory loss, but that's just part of
5 Alzheimer's. He was nowhere near advanced,
6 nowhere near.

7 Yes, he was having problems, he needed
8 help. The first thing they did when they put
9 him in the nursing home, one of the first things
10 was hire around the clock care. They knew that
11 they could have gotten the same care at home,
12 but no, they put him in the nursing home then
13 they hired around the clock care to help him
14 adjust there.

15 Well, he was adjusting. I've been, when
16 Ben first talked to me about it he said dad is
17 walking all over town, he's having a gay 'ole,
18 not a gay 'ole time, but he said he's just, he's
19 walking around, he's going back, it's going to
20 work out. He's got three square meals a day,
21 got a comfortable room, you know, it sounded
22 pretty good.

23 But they didn't like Charley coming and
24 going and it was a burden on the nursing home
25 because they thought, you know, this is not

1 normal, people come here, they are old, they
2 sit, they die.

3 THE COURT: I know from my work in cases
4 that involve elderly people that it's, a nursing
5 home can't permit people to simply leave the
6 grounds and walk around --

7 MS. MURDERS: That's true.

8 THE COURT: -- if those people suffer
9 from dementia because the people will get hurt
10 or they will get lost. I don't see that keeping
11 Mr. Sutton from wandering is inappropriate.

12 MS. MURDERS: Well, I have to agree with
13 you, but this was not a nursing home, this was
14 an assisted living home and he was free to come
15 and go.

16 THE COURT: Eventually he exceeded, my
17 understanding is the assisted living facility
18 asked that Mr. Sutton be moved to another
19 facility that could take better care of his
20 needs; is that right?

21 MS. MURDERS: Yes, ma'am.

22 THE COURT: Okay.

23 MS. MURDERS: Something I don't
24 understand if he was walking all over town and
25 enjoying it, why all of a sudden, what drugs did

1 they have him on that there were problems? Did
2 they have him on drugs then? I haven't had any
3 answers to any questions.

4 But, and especially he should never have
5 been taken out of his own home in the first
6 place, he never got lost in Ferndale, never.

7 MS. HARRIS: He never had a single 911
8 incident until two days after he was removed
9 from his home, and there have been several since
10 then. We believe his situation is what caused
11 the problems for him and he's just been very
12 unhappy. And it wasn't just when he first went
13 in, he was not adjusting.

14 So that video that I have the
15 transcription for the video is very powerful, I
16 was really disappointed that I couldn't submit
17 that, but that is what he was doing the whole
18 time he was there. He was so upset he was
19 begging us to talk to Ben, please, have Ben take
20 me home. He was just very unhappy every day and
21 if you see him in the house, that's the house,
22 he was happy in there just walking through it
23 was a happy experience for him. And it was a
24 fairly lengthy, you know, experience, it wasn't
25 just like he was having moment of lucidity, you

1 can see his interacting like a normal person.
2 He looks wracked from his care, he's dropped so
3 much in weight, you know, it's just horrible to
4 see what seems to be intentionally being done to
5 him with these drugs.

6 I didn't actually submit these, I'm not
7 going to have them read or anything. I just
8 brought these just as a display because this is
9 from the website of Social & Health Services
10 Financial Exploitation of Vulnerable Adults.
11 You can see how thick that is, if you go to
12 their site you can find it.

13 This is from the Office of Inspector
14 General and it's antipsychotic drugs claims for
15 elderly in nursing home residents. This is just
16 like the tip of the iceberg. I mean there is so
17 much information now about the harmful effects
18 of these drugs and financial exploitation and we
19 don't know exactly how much money was moved from
20 our brother's account by his POA, if it was a
21 half million or three-quarters of a million or
22 what, you know, what he actually moved into his
23 own account through gifting or whatever. But
24 from that point it goes into just actually, just
25 taking him from his house while he's still

1 functioning well and he has a life.

2 THE COURT: Let me ask you this; there
3 was an Adult Protective Service investigation.
4 Did that investigation address the financial
5 aspects of your brother?

6 MS. HARRIS: That was really interesting.

7 THE COURT: I really, it's a yes or no
8 question. Did it address the financial issues
9 do you know?

10 MS. HARRIS: I would say that he touched
11 on it.

12 THE COURT: If you don't know that's
13 fine.

14 MS. HARRIS: I would say we touched on
15 it, we discussed it.

16 THE COURT: Who discussed it? You
17 discussed it with the Adult Protective Services?

18 MS. HARRIS: Can I tell you what he said
19 to me? Yes --

20 THE COURT: No, it's hearsay. I just
21 want to know whether the Adult Protective
22 Services' investigation addressed the financial
23 concerns that you're raising here?

24 MS. HARRIS: Not adequately.

25 THE COURT: Okay.

1 MS. HARRIS: He didn't discuss anything
2 that he shouldn't, I'll put it that way, he
3 didn't discuss any personal.

4 THE COURT: When you say "he" you mean
5 the Adult Protective Services --

6 MS. HARRIS: The investigator.

7 THE COURT: All right. Mr. Bergsbaken,
8 did your investigation of the situation include
9 addressing any financial issues or investigating
10 the financial concerns?

11 MR. BERGSBAKEN: No, because Adult
12 Protective Services had already done that, they
13 were investigating both financial exploitation
14 and mental exploitation. So I took their word
15 for it because that's their expertise.

16 THE COURT: All right. From the Court's
17 perspective it's true that the law provides for
18 a lesser restrictive situation and doesn't
19 require that a guardianship be ordered unless
20 there is no alternative to that. It may be that
21 there is no alternative to that that functions
22 in Mr. Sutton's best interest, but I haven't
23 seen evidence that would be admissible in Court
24 to that effect.

25 Ms. Murders and Ms. Harris raise some

1 compelling medical arguments, but I'm not a
2 doctor. And the Court and non-doctors are not
3 in a position to make a decision as to medical
4 issues like what medications are appropriate or
5 are not appropriate. That information can be
6 given to the Court if the, if there is evidence
7 from a competent medical professional that the
8 medication regimen is wrong and is harmful to
9 Mr. Sutton, that's evidence that the Court would
10 consider, but that's not evidence that
11 non-doctors are competent to give.

12 And so the fact that you have these
13 concerns about the medication and the articles
14 that you've read that give you those concerns
15 are of concern to the Court, but they are not
16 evidence that the Court can consider because
17 medical evidence can only be given to a Court by
18 a medical professional who knows the facts and
19 the medical situation.

20 I've not seen evidence of financial
21 exploitation. There is an assertion that there
22 has been financial exploitation, but I don't,
23 I've not been given evidence of financial
24 exploitation and simply the concerns that the
25 Petitioners have. And while those are valid

1 concerns, the Court is not permitted to act on
2 concerns, there has to be evidence. And I think
3 the fact that Adult Protective Services
4 investigated this situation and did not find
5 grounds to proceed is the overpowering evidence
6 for the Court here.

7 I don't, in short I don't see evidence
8 that the current situation is harmful to
9 Mr. Sutton. As I say, as a medical matter that
10 may be true, but I don't have medical
11 information to that effect in front of me. What
12 I do have is a report from a treating physician
13 who indicates that the medication regimen is
14 appropriate. I know that Alzheimer's patients
15 generally do better in facilities that are
16 equipped and certified to care for Alzheimer's
17 patients and I know that the facility where
18 Mr. Sutton is living is such a facility.

19 So I have no basis to find that what has
20 occurred so far is harmful to Mr. Sutton or is
21 contrary to the wishes he expressed in his power
22 of attorney so I don't have a basis to --

23 MS. HARRIS: Your Honor, could I make one
24 more statement?

25 THE COURT: -- bring up your petition

1 here.

2 Yes, you may make one more comment.

3 MS. HARRIS: Okay. The Adult Protective
4 Services investigator was, he actually said, I
5 asked him specifically "so are you saying that
6 there has been, that he hasn't been using the
7 money in ways that were not" --

8 THE COURT: I'm going to stop you there
9 because what you're about to tell me is hearsay.

10 MS. HARRIS: Okay.

11 THE COURT: And that's, you know, if the
12 Adult Protective Services investigator came to
13 the Court and gave me his view it would not be
14 hearsay because the other parties can
15 cross-examine him, but the reason that we don't
16 allow hearsay is just that reason.

17 MS. MURDERS: May I say one word?

18 THE COURT: Yes.

19 MS. MURDERS: Charley all his life has
20 not liked heavy medication. He vocally
21 expressed that.

22 THE COURT: I understand and you've
23 expressed that previously. What I'm saying is
24 that the law gives the person with the power of
25 attorney the right to make these decisions. And

1 in order to overcome that and have that person
2 removed you have to show not that the person
3 doesn't like the care that they are getting, but
4 that the care is, as a medical matter, harmful
5 to them, and evidence of that is simply not
6 before the Court.

7 To the contrary, the medical evidence and
8 reports that I have are from the treating
9 doctors and they indicate that the care is
10 appropriate and your brother is doing well.
11 That's why I say I simply don't have evidence
12 that there is medical negligence or medical
13 malfeasance going on. There may be, but I can
14 only make decisions based on the evidence that's
15 before me and I don't have evidence of that
16 before me.

17 MS. MURDERS: We couldn't get it for you,
18 Your Honor, the 911 calls it's protected, it's
19 private. We can't get, we don't know what
20 his --

21 MS. HARRIS: We can't intervene for him
22 because we have no access to the information.
23 Look at all the information we were able to get
24 without access, I mean if we had access to it we
25 could help him. We're afraid he's going to die.

1 How much weight can a person lose? How low can
2 their blood pressure go before they just die?

3 THE COURT: What is the situation now
4 with visitation, is there any restriction?

5 MS. HARRIS: He has no visitors, no phone
6 calls, no mail.

7 MS. MURDERS: Even my mail doesn't get
8 through.

9 THE COURT: Do you know anything about
10 this?

11 MR. NEUBECK: I do not know whether there
12 are restrictions on visitation right now. I
13 think that Mr. Sutton has been trying to
14 determine what is appropriate and what's best
15 for Charley in terms of minimizing agitation for
16 him. I don't know if, I can't speak to what
17 restrictions he has in place currently.

18 THE COURT: All right.

19 MS. HARRIS: Please protect him, he's
20 going to die under this care management and we
21 can't even get him a doctor.

22 THE COURT: Are you permitted to visit
23 him at the facility?

24 MS. HARRIS: No, nobody.

25 THE COURT: Why not? Well, is it the

1 facility that's telling you you can't visit?

2 MS. HARRIS: It's both, POA instructs the
3 facility, the facility says they are instructed
4 so they can't. They are all violating his civil
5 rights by doing this.

6 THE COURT: So you're indicating that
7 when you go to the facility, have you gone to
8 the facility and been told that you're not
9 permitted to come and visit your brother?

10 MS. HARRIS: Yes.

11 MS. MURDERS: I've called him, I was told
12 you're not allowed to speak to him.

13 MR. NEUBECK: And I think actually, Your
14 Honor, now that you say that that I believe that
15 that may have been the instructions from my
16 client after this was, this matter was initiated
17 and Mr. Sutton, Charley Sutton was being sort of
18 agitated I will say by their acting as
19 provocateurs in getting Mr. Sutton, Charley
20 Sutton riled up about his situation here and
21 that was determined not to be very healthy for
22 him.

23 If the Court is considering making an
24 order regarding Ms. Murders, Brown Murders,
25 excuse me, and Ms. Harris, it's clear that they

1 care deeply for their brother, but I would ask
2 that if the Court is thinking about ordering
3 something in regards to visitation that
4 visitation be allowed but perhaps in common
5 areas of the facility so that there could be
6 some supervision, maybe not direct, but so that
7 they're not being able to act as, like I said,
8 provocateurs for Mr. Sutton.

9 MS. HARRIS: See, that's another thing,
10 if we could have --

11 THE COURT: Hold on just a second. Can
12 you tell me the approximate size of the estate,
13 the financial estate? You may not know.

14 MR. NEUBECK: I do not know. My client
15 is in the room but I could ask him, but I'm not
16 sure of that.

17 THE COURT: What I'd like to know is
18 whether the estate is financially solvent to the
19 extent that it could pay for the uninsured
20 portion of a neuropsychological evaluation?

21 MR. NEUBECK: I think that it is
22 sufficiently solvent, yes, to pay for that.

23 THE COURT: All right.

24 MR. NEUBECK: But I'm, yes, it's solvent.

25 THE COURT: All right. As I say, I've

1 not seen evidence that permits me to establish a
2 guardianship here, but I am concerned that there
3 be a neuropsychological evaluation of the kind
4 that Mr. Bergsbaken indicated would be helpful.
5 And I would like to see Mr. Sutton's sisters be
6 able to visit him, I think the restriction that
7 the visitation occur in a public area of the
8 facility is appropriate. Do you have a
9 recommendation on that, Mr. Bergsbaken?

10 MR. BERGSBAKEN: No, I don't, Your Honor.
11 I talked to both parties about some sort of a
12 common ground that we could figure out for
13 visitation and access to like minimum medical
14 information, I know there is HIPAA laws that
15 prevent the facility from providing information
16 to the sisters, and at this point there is a lot
17 of contention between the parties and no one
18 seems to be willing to kind of go there.

19 THE COURT: What I'm inclined to do, and
20 I'll ask both parties their reaction to this,
21 what I am inclined to do is this; based on the
22 information I've seen thus far I don't find
23 sufficient basis to establish a guardianship,
24 but rather than dismissing the petition for
25 guardianship I'm inclined to defer ruling on the

1 motion to dismiss for a period of about 60 days
2 and during that 60 days a neuropsychological
3 examination should be conducted and Mr. Sutton's
4 sisters should be able to visit him in public
5 areas of the facility on a weekly or twice a
6 week basis. And then assuming that the
7 neuropsychological evaluation indicates that Mr.
8 Sutton's care is appropriate and his medical
9 regimen is appropriate to his condition the
10 Court would not see major medical issues there.

11 If that's not the result of the
12 neuropsychological evaluation the Court would be
13 willing to address those concerns, or at least
14 consider those concerns and reassess whether or
15 not the guardianship should be dismissed.

16 MR. NEUBECK: Your Honor, if I may, I'm
17 not sure that a neuropsychological exam is going
18 to be able to opine on whether or not his
19 current living situation is correct. A
20 neuropsychological evaluation would seek to
21 quantify what his illnesses are.

22 THE COURT: And assess his treatment for
23 those illnesses. It's not so much a question
24 about the facility. Unless somebody shows me
25 that the medication regimen that the facility is

1 implementing is really wrong, my questions
2 aren't so much about the facility but the
3 concerns that Mr. Sutton's sisters raise about
4 the medication and effects the medication may be
5 having on him require some exploration in my
6 view. If the result of an evaluation of his
7 abilities and his medication regimen reveals
8 concerns, it's my hope that the parties CAN work
9 together to address those concerns.

10 If the evaluation does not find concerns
11 and essentially it says that the medication
12 regimen that he's currently on is an appropriate
13 one, there would not be a basis for the Court to
14 proceed further.

15 MR. NEUBECK: Okay.

16 MR. BERGSBAKEN: Your Honor, would it be
17 all right if Mr. Sutton's son took him to that
18 neuropsychological evaluation? They have
19 concerns about him fleeing and so they want to
20 make sure the facility does --

21 THE COURT: About him leaving the
22 facility you mean?

23 MR. BERGSBAKEN: Yeah, to go the
24 neuropsychological evaluation, he needs to be
25 accompanied by someone, and his son Mr. Ben

1 Sutton at this point has the power of attorney.

2 THE COURT: That could be done. I think
3 the first choice that I'd have is have the
4 evaluator come to the facility, I think that
5 would be less disruptive to Mr. Sutton.

6 MR. BERGSBAKEN: Yeah, if --

7 THE COURT: If that's not possible, then
8 alternative arrangements could be made and
9 Mr. Ben Sutton remains the power of attorney
10 person and has the right and authority and now
11 responsibility to transport his father to that.
12 I'm hoping, Mr. Bergsbaken, that you'll remain
13 in your position as guardian ad litem and will
14 help to facilitate this.

15 MR. BERGSBAKEN: I think I've reached the
16 cap in my fees so would there be something
17 granting me more time?

18 THE COURT: Yeah, I would order that the
19 estate pay additional fees in an amount up to,
20 what's your hourly rate?

21 MR. BERGSBAKEN: One hundred dollars an
22 hour.

23 THE COURT: I would think that, well, on
24 an hourly basis I'll authorize up to \$1,500 for
25 your involvement in this and your preparation of

1 a supplement to your guardian ad litem report
2 based on the results.

3 MR. BERGSBAKEN: So an additional \$500?

4 THE COURT: No, an additional \$1,500.

5 MR. BERGSBAKEN: I don't foresee it being
6 that difficult to arrange.

7 THE COURT: All right, yes.

8 MS. MURDERS: Your Honor, I would request
9 that Mr. Bergstien --

10 MR. BERGSBAKEN: Bergsbaken.

11 MS. MURDERS: Would reimburse the \$250 I
12 paid for him to check on my brother initially
13 and since that was included in the fee that he
14 submitted for the estate I would like to be
15 reimbursed my \$250.

16 MR. BERGSBAKEN: I've only received
17 \$1,000 retainer from the petitioner or from the
18 POA, that's all I've received.

19 THE COURT: Okay. I'll have you work
20 that out and if you can't reach an agreement on
21 who has paid what I'll hear back from you.

22 MR. NEUBECK: And so is Your Honor, just
23 to be clear, requesting there be a supplemental
24 hearing after, scheduled after the
25 neuropsychological examination is completed and

1 filed with the court?

2 THE COURT: I think that's probably the
3 case. I will tell the parties in advance that
4 if the neuropsychological evaluation does not
5 identify any significant problems, any
6 significant medical problems with Mr. Sutton's
7 current care, I'm not going to reassess my view
8 that a guardianship is not appropriate in this
9 case. So it may be that, depending on the
10 results of the report, the parties may agree as
11 to whether or not a hearing is necessary or not.

12 If the parties can't agree, in other
13 words if one party believes that the report
14 doesn't give a basis to proceed and the other
15 party believes that it does, I'll resolve that
16 dispute. If both parties are agreed that the
17 report identifies a significant concern, then
18 you should simply go ahead and note the matter
19 for hearing because I'll want to hear that and
20 address it. If both parties agree that the
21 report does not identify significant concerns,
22 then the parties may stipulate to a dismissal of
23 this case and if you don't do that or if you
24 can't do that then a supplemental hearing will
25 be required.

1 MR. NEUBECK: Would it be an alternative
2 arrangement, Your Honor, if we believe that the
3 report does not indicate any further evidence
4 that drugs are being mis-administered, that the
5 drug regime is inappropriate, that we submit an
6 ex parte order to Your Honor rather than at the
7 ex parte calendar but directly to you, and if
8 you don't feel it appropriate to sign that,
9 obviously you will be provided a report, you can
10 direct us to note a hearing at that time?

11 THE COURT: That would be appropriate.
12 And of course in any order that's submitted
13 should not be submitted on the ex parte
14 calendar, it should be submitted to me rather
15 than the commissioner or ex parte calendar, and
16 of course, notice should be given to all
17 parties, including his sisters.

18 MR. NEUBECK: Notice the ex parte order
19 is going to be submitted?

20 THE COURT: Yes.

21 MR. NEUBECK: Okay.

22 MS. HARRIS: So, Your Honor, you said we
23 could respond to your recommendation?

24 THE COURT: Yes.

25 MS. HARRIS: We wonder if we could choose

1 the physician because both the geriatric nurse
2 and the doctor that they have support the use of
3 the drugs and changing the drugs and
4 administering more and changing them again and
5 both have stated the reasons for doing that, it
6 really sounds like the classic description of
7 chemical restraint. The doctor says to keep --

8 THE COURT: I'm going to interrupt you,
9 I'm ready to rule on that question.

10 MS. HARRIS: It's in that report that you
11 got the doctor said to keep him more sedate and
12 the nurse to keep him from getting out.

13 THE COURT: I understand. These are
14 medical issues that, again, the Court can't
15 determine, that's why I'm asking for a medical
16 report from an expert. I will permit, it would
17 be better for the progress of this case that the
18 parties can agree on a physician to do that
19 report. If that's not possible I will accept a
20 report from a local, and by that I mean Whatcom
21 County, medical practitioner who has expertise
22 in neuropsychological and cognitive issues. If
23 that person has a particular focus on dementia
24 that would be very good from the Court's
25 perspective, but I'm not going to require that.

1 After that person has done a report the Court
2 will rely on that report. If Ms. Murders and
3 Ms. Harris wish to have an evaluation by a
4 different practitioner, that's something that
5 they would have to persuade the Court is
6 necessary and not too disruptive to Mr. Sutton,
7 that's an issue for another day.

8 So I'm not going to permit the
9 petitioners to dictate the identity of the
10 practitioner who does that evaluation, but I am
11 going to require that the practitioner does have
12 the medical expertise that I just described and
13 we'll review the report and go from there.

14 So that's the Court's ruling today. I'm
15 going to reserve ruling on the request for
16 attorneys' fees pending the outcome. Thank you
17 to all parties.

18 MR. NEUBECK: Your Honor, would you like
19 me to prepare an order reflecting your ruling
20 today?

21 THE COURT: Yes. Yes, I think so.

22 MR. NEUBECK: Okay. Can I repeat back to
23 the Court to make sure I've got correct
24 information? So you're directing that
25 Mr. Bergsbaken, he's not going to be discharged,

1 that he shall obtain an independent local
2 neuropsychological evaluator, one with expertise
3 in dementia, that that be submitted to the Court
4 and I also have noted that visitation shall be
5 allowed in the common spaces of the Bellingham
6 at Orchard for the petitioners at times that I
7 would also add, and the Court can opine, at
8 times that are appropriate for visitation. And
9 that if the neuropsychological evaluation shows
10 that the medication regime is appropriate and
11 medical treatment of Mr. Sutton is appropriate
12 the, an order for dismissal can be submitted ex
13 parte to Your Honor, not on the ex parte
14 calendar, and if there, if you wish at that time
15 for us to note hearings it will be so directed?

16 THE COURT: Yes, that's the essence of
17 it. I would say though that the issue is if the
18 neuropsychological report does not identify
19 significant problems or issues in Mr. Sutton's
20 current medical regimen so that if the report
21 identifies something that are other than the
22 medication issue the Court would want to know
23 that as well.

24 MR. NEUBECK: Okay. So not just
25 medication regimen, but also medical treatment

1 in general?

2 THE COURT: Yes, yes. All right,
3 continue this matter for a week to next Friday's
4 calendar for entry of the order that you're
5 drafting now or that entry of order that
6 incorporates the findings that I'm making today.
7 If you draft the order and you and Ms. Murders
8 and Ms. Harris agree, what you're being asked to
9 agree to is not that you agree to what the Court
10 is ordering, but you agree that this is what the
11 Court ordered, the written order can be simply
12 submitted.

13 If you don't agree as to what I ruled
14 today, and that's the only issue about this
15 order is whether it accurately says what I just
16 told you, then I'd recommend any way that you
17 put this on the calendar for next Friday.

18 MR. NEUBECK: Your Honor, I know that
19 neither I nor Mr. Myers are available next
20 Friday. I'm actually gone all week and I know
21 that Mr. Myers has another hearing I believe on
22 Friday in a different county. So I'm wondering
23 if submission of the order can take place the
24 following Monday and perhaps note it on the
25 following Friday's calendar. Is that too late?

1 THE COURT: It's just that next Friday's
2 calendar is the last Friday calendar that I'll
3 be here for for several weeks because I'll be
4 going out of town.

5 MR. NEUBECK: Okay. I will attempt to
6 craft this order still before, I'm leaving town
7 very early tomorrow morning, I will try to craft
8 it this evening, circulate it to Ms. Murders, I
9 believe I do have Ms. Murders' e-mail and ask to
10 be able to circulate it that way. And if no
11 objections are received -- well, what I'm trying
12 to figure out if objections are received how we
13 are to address those if Your Honor's calendar
14 next Friday is the only time that she is
15 available, that you are available?

16 THE COURT: I think that we should do
17 this by e-mail. I think that you should draft
18 the order and share it with Ms. Murders and
19 Ms. Harris and if you can do that later today
20 then they should be able to get a response to
21 you. Are you going to be able to respond to the
22 response though?

23 MR. NEUBECK: I'm not going to be able to
24 respond to the response. I can give direction
25 to Mr. Myers, so I'm actually out of both e-mail

1 and phone communication.

2 THE COURT: Here's what I think you
3 should do; you should draft the order and send
4 it to me and to Ms. Murders and Ms. Harris. I
5 will not seriously review the order until I've
6 heard from Ms. Murders and Ms. Harris and I'll
7 want to hear from you by next Wednesday. If I
8 have not heard from you by next Wednesday I'll
9 simply read the order and adopt it as long as I
10 feel that it accurately states what I've ruled
11 today. If I don't feel that it accurately
12 states what I ruled today, I'll change it so I
13 think it does and I'll enter it.

14 MR. NEUBECK: That seems appropriate.
15 Would you like me to send the order to your
16 judicial assistant or to you directly?

17 THE COURT: Either is workable.

18 MR. NEUBECK: Okay. I ask to Ms. Brown,
19 Ms. Murders that any communication with the
20 judge be also, that I be c.c.'d on that
21 communication.

22 THE COURT: Absolutely.

23 MR. NEUBECK: And likewise I will c.c.
24 you on all my communication.

25 THE COURT: I'll tell you that e-mailing

1 a judge in a case is not something that a person
2 can do unless and until the judge has authorized
3 it. I'm authorizing this e-mail communication
4 for purposes of circulating this order but
5 that's the only communication that should happen
6 by e-mail, everything else has to be submitted
7 in open court so that both parties have a chance
8 to review it and know about it.

9 But I would like to get this order
10 entered and entered quickly and it doesn't seem
11 possible without e-mail communication so that's
12 why we'll do it here in this case.

13 MR. NEUBECK: I appreciate your
14 flexibility, Your Honor.

15 THE COURT: All right. That finishes our
16 proceedings in this matter today. Thank you to
17 all parties and we look forward to reaching a
18 resolution here soon.

19 (End of requested proceedings.)

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF WHATCOM

GUARDIANSHIP OF:

WILLIAM CHARES SUTTON

NO. 14-4-00523-1
COA No. 73538-1-I

NOTICE OF FILING

DAVID NEUBECK
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Division I
One Union Square
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Seattle, WA 98104-4170

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Please take notice that on the 1st day of
July, 2015, the original of the above numbered
and named Verbatim Report of Proceedings, dated
FEBRUARY 27, 2015 was filed with the Whatcom
County Clerk's office.

DATED this 1st day of July, 2015.

WENDY S. RAYMOND
OFFICIAL COURT REPORTER
WHATCOM COUNTY SUPERIOR COURT
311 Grand Avenue
Bellingham, WA 98225
(360) 676-6748
July 1st, 2015

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CERTIFICATE OF OFFICIAL COURT REPORTER

STATE OF WASHINGTON)
) SS.
COUNTY OF WHATCOM)

I, Wendy S. Raymond, Official Court Reporter,
County of Whatcom, State of Washington, do hereby
certify that the foregoing pages comprise a true and
correct transcript of the proceedings had in the
within-entitled matter, recorded by me by stenotype on
the days herein written and thereafter transcribed into
being by computer-aided transcription, and constitute my
record on this matter.

DATED THIS 1st day of July, 2015.

Wendy S. Raymond, CCR
Official Court Reporter

APPELLANT'S BRIEF
In re the Guardianship of: WILLIAM SUTTON AIP
WA Court of Appeals, Division One
Case NO73538F 1

APPENDIX D

May 8, 2015 Hearing Transcript

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF WHATCOM

GUARDIANSHIP OF:

WILLIAM CHARLES SUTTON

No. 14-4-00523-1

COA No. 73538-1-I

VERBATIM REPORT OF PROCEEDINGS
MAY 8 2015
THE HONORABLE DEBORRA GARRETT, JUDGE

PAGES 1-21

WENDY S. RAYMOND, CSR 2285
OFFICIAL COURT REPORTER
WHATCOM COUNTY SUPERIOR COURT
BELLINGHAM, WASHINGTON

1 - o 0 o -

2 MAY 8, 2015

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4 (Beginning of requested proceedings.)

5 THE COURT: Guardianship of William
6 Sutton. Good afternoon Mr. Neubeck, good
7 afternoon Ms. Harris and Ms. Murders and
8 Mr. Bergsbaken. Hello to you all.

9 I've reviewed the submissions of all of
10 the parties and I've reviewed the report of the
11 neuropsychologist and I find that there is not a
12 basis for the Court to order a guardianship.
13 This is a medical dispute and the law does not
14 authorize or permit courts to be involved in
15 medical disputes.

16 The reason that I asked for, or the
17 reason I required the parties to have a
18 neuropsychological evaluation done was my
19 concern that perhaps there was some element or
20 some reality of mistreatment or that the
21 medication regimen Mr. Sutton is on is
22 inappropriate and not right for him, but that's
23 not the conclusion of the neuropsychologist.
24 What we have is a difference of medical opinion,
25 that's not a matter that the Court will insert

1 itself into unless there is some other basis for
2 the Court to do that.

3 Part of the system of rights that we have
4 in this country is that the Court will not
5 intervene simply because the Court thinks that
6 the conditions aren't optimum. In this case
7 Mr. Sutton executed a power of attorney that
8 gave his son certain rights, I've not seen the
9 power of attorney, but there is no question that
10 it exists, and there is no question in my mind
11 that Mr. Sutton Junior's decisions for the care
12 of his father are appropriate decisions and
13 authorized by the power of attorney. So --

14 MS. HARRIS: Your Honor?

15 THE COURT: You shouldn't interrupt the
16 Court, I'll give you an opportunity to talk but
17 it's not yet.

18 MS. HARRIS: All right.

19 THE COURT: Having reviewed all of the
20 materials in the case I find myself in some
21 sympathy with the notion that medication should
22 be minimized, Mr. Sutton didn't use a lot of
23 medication during his life and I too have tried
24 to minimize medication in my life because I
25 think that's a healthier way to live. But,

1 again, the Court's personal feelings about what
2 is a better way to live and the place that
3 medication should have in people's lives, those
4 are simply personal decisions, those aren't
5 decisions about the law. And the law says that
6 a Court will not intervene unless it's clear
7 that Court intervention is absolutely necessary
8 because no lesser restrictive alternative is
9 appropriate. And in my view I've simply not
10 been given evidence that the lesser alternative
11 of the power of attorney that Mr. Sutton gave
12 his son is not, not functional. So I'm going to
13 dismiss the petition for guardianship and that's
14 why.

15 I do believe that the parties have
16 incurred a great deal of expense in the course
17 of these, of running down these issues and I'm
18 reluctant to award onerous awards of attorneys'
19 fees or sanctions against a party that uses the
20 Court to resolve a dispute. I think people
21 should have access to the Court to do that. But
22 in this case I'm concerned about the estate of
23 Mr. Sutton and its ability to bear all of the
24 costs of this litigation. I'm told by one party
25 that the estate assets are quite limited, I'm

1 told by the other party that the estate assets
2 are really quite extensive.

3 What's, so I want to know more about the
4 estate assets and I guess I'd like to hear from
5 the Petitioners first on that issue. You
6 indicated in your, in one of your declarations
7 that there is extensive investment assets in
8 savings and intangible assets, but in the
9 petition that was filed at the inception of this
10 those assets were not reflected in the petition,
11 which reflected pretty modest assets. So what
12 is the situation as you understand it to be?

13 MS. MURDERS: Well, I know that our
14 brother had invested approximately \$250,000 into
15 stocks and bonds.

16 THE COURT: Why wasn't that listed in the
17 petition?

18 MS. MURDERS: I told our attorney but he
19 failed to list it and I didn't watch that when
20 the petition went through, but he failed to
21 catch that. Over the years I'm sure that it
22 grew, but he also owned his home, which he paid
23 his --

24 THE COURT: Yes, that's listed in the
25 petition as is the collections. Let me ask you,

1 Mr. Neubeck, what is the size of the estate to
2 your knowledge?

3 MR. NEUBECK: Your Honor, I do not have
4 any, I cannot make any attestations as to the
5 exact size of the estate, but I do know the
6 facility where Mr. Sutton is residing is very
7 expensive, we're talking in excess of I believe
8 \$8,000 a month. His assets are going to be
9 depleted in relatively short order I mean on the
10 grander scale of things.

11 And honestly, Your Honor, although we may
12 not be at that point to address this yet, I
13 don't know that the extent of Mr. Sutton's
14 assets are the deciding factor on whether
15 attorney fees are appropriate in this matter.

16 THE COURT: Probably not the deciding
17 factor, but certainly a factor that the Court
18 considers.

19 MR. NEUBECK: Understood.

20 MS. MURDERS: We have no idea of what his
21 savings were and he had, he has a good income
22 monthly, which I don't really know for sure what
23 that is, but I know it's sizable.

24 THE COURT: Yes, I know he has retirement
25 benefits from several sources but I also know

1 that medical facilities are very expensive and I
2 don't doubt that the costs exceeds his monthly
3 income by quite a bit.

4 MS. HARRIS: Your Honor, may I speak now?

5 THE COURT: I'm sorry?

6 MS. HARRIS: Can I speak now?

7 THE COURT: You may speak briefly.

8 MS. HARRIS: The POA's intention is to,
9 was to leave just enough in there for Charley to
10 be put in this place and when that money runs
11 out to petition of VA to kick in the balance
12 between what Charley gets monthly.

13 THE COURT: How do you know this?

14 MS. HARRIS: Because he told us.

15 THE COURT: Okay.

16 MS. HARRIS: And he was having our
17 brother give him large chunks of money through
18 the three-and-a-half years from the time that
19 the POA documents were filed. So we don't know
20 how much money was transferred into Ben's name
21 but that's why we filed a motion for disclosure
22 because without that information we don't have
23 the information we need for this case.

24 THE COURT: Well, in my view here's what
25 happened, the estate is asking that the Court

1 award or require Petitioner to pay the guardian
2 ad litem's fees and for the guardian ad litem's
3 service in this case, the attorneys fees for the
4 attorneys legal work in this case, and basically
5 that's what the Respondent is asking.

6 Mr. Bergsbaken, your fees, the most
7 recent statement I have puts your fees at \$1,795
8 I think and 94 cents?

9 MR. BERGSBAKEN: Well, since then there
10 has been a number of motions filed and as of
11 today it's, there was a motion as of yesterday
12 so I had to update it.

13 THE COURT: Would you bring that forward,
14 please?

15 MR. NEUBECK: Your Honor, just for
16 clarity I think our proposed order also
17 requested payment for Dr. Veltkamp's services,
18 she was the neuropsychologist in this matter.

19 THE COURT: Yes. If it did I missed
20 that, but I'm going to deny that motion because
21 when I originally ordered that a
22 neuropsychological evaluation be done I ordered
23 that it be done at the expense of the estate.
24 I'm going to allocate that expense to the
25 estate.

1 MR. NEUBECK: Could I ask one question on
2 that, Your Honor?

3 THE COURT: Yes.

4 MR. NEUBECK: At the last hearing Your
5 Honor deferred a decision so the Petitioners
6 would have a chance to be heard by Ms. Veltkamp.

7 THE COURT: To talk with Dr. Veltkamp,
8 yes.

9 MR. NEUBECK: They never went to that
10 appointment and Dr. Veltkamp's time was still
11 incurred and charges incurred as part of that,
12 they never attended that appointment. And we
13 would be, we believe it is not appropriate to
14 charge the, Mr. Sutton for an appointment that
15 they did not go to and they requested.

16 MS. HARRIS: We rescheduled that
17 appointment, Your Honor, we did attend.

18 THE COURT: You did meet with
19 Dr. Veltkamp?

20 MS. HARRIS: We rescheduled the
21 appointment.

22 THE COURT: Okay. I'm going to order
23 that Dr. Veltkamp's cost remain with the estate
24 and I'm going to order that Petitioners
25 participate in the legal costs in approximately

1 the amount that in my view is appropriate for
2 the work that has been done on the Petitioners'
3 motion to reconsider and Petitioners' motion for
4 contempt, which in my view were not well-founded
5 because in my view the Court ordered, pretty
6 clearly ordered a neuropsychological evaluation,
7 but did not order the other relief that the
8 Petitioners were seeking.

9 So I'm going require the Petitioners to
10 pay \$2,000 of the costs that have been incurred
11 in this matter. That leaves Dr. Veltkamp's
12 bill, which is probably about \$1,500 to \$2,000,
13 payable by the estate. The estate will also be
14 responsible for payment of the legal fees and
15 Mr. Bergsbaken's fees, which I do find to be
16 appropriate at \$1,907.40. That's unusually high
17 for guardian ad litem services, but it is
18 certainly merited in this case where
19 Mr. Bergsbaken was called on for unusually
20 expensive guardian ad litem services. So --

21 MR. NEUBECK: Your Honor?

22 THE COURT: Yes.

23 MR. NEUBECK: May I be heard for a
24 moment?

25 THE COURT: You may.

1 MR. NEUBECK: I would ask if the estate
2 is going to bear the costs for Mr. Bergsbaken's
3 fees, at least the amount of fees he has spent
4 over the same matters that the attorneys fees
5 are being covered for the contempt and discovery
6 and reconsideration motions, which I believe
7 were not warranted, those amounts be broken out
8 and they also be apportioned to the Petitioners.

9 THE COURT: Well, that's what I had in
10 mind when I estimated the cost of \$2,000, that
11 that be the cost.

12 MR. NEUBECK: Inclusive?

13 THE COURT: Inclusive of the guardian ad
14 litem and the lawyers.

15 MR. NEUBECK: Okay.

16 THE COURT: And I don't know, I'll leave
17 it to the parties as to how you want to arrange
18 for payment of those amounts. Those amounts
19 should be paid to the estate, which in
20 reimbursement for the costs that I'm assuming
21 the estate is paying directly to the guardian ad
22 litem and to the law firm that represents the
23 estate.

24 So I'm ready to enter an order dismissing
25 the guardianship and awarding judgment for

1 \$2,000 to Mr. Sutton.

2 MS. MURDERS: Are you denying our motion
3 for disclosure?

4 THE COURT: Yes. Yes, the order
5 dismissing the guardianship will end the
6 guardianship proceeding, so further procedures
7 including discovery aren't appropriate because
8 the matter's dismissed. Yes, Ms. Harris?

9 MS. HARRIS: You said, you told us that
10 we did not have proof for you and we, we have
11 not we have not been able to have any discovery,
12 it's been very hard. But Dr. Veltkamp did at
13 least, she did at least tell us how much
14 quantities they are administering the
15 medications. Dr. Webb never did tell that. She
16 has told us 500 milligrams of --

17 THE COURT: I understand, but
18 Dr. Veltkamp's conclusion is that Mr. Sutton's
19 care is appropriate. If you want to argue with
20 the doctor you need another doctor to do that.

21 MS. HARRIS: We need another doctor.
22 Because you see she told us she knows nothing
23 about the medication. And we said, well, was he
24 medicated, was he medicated when you did your
25 examination? She didn't know. She didn't know.

1 THE COURT: I understand.

2 MS. HARRIS: She said she was not the
3 correct kind of doctor to actually make
4 decisions about medications because she knew
5 nothing about it, she said it would take a
6 different type of doctor.

7 MS. MURDERS: The manufacturer of that
8 particular drug states that 60 milligrams per
9 day is the maximum. He's prescribed 500 per
10 day.

11 THE COURT: Well, if you want to take
12 this new information back to Adult Protective
13 Services you can do that. If you want to appeal
14 this Court's dismissal of the guardianship
15 matter, you can do that. There are notices of
16 appeal available at the clerk's office. But in
17 my view the law just does not give this Court
18 the basis for jurisdiction, that's the reason
19 that I'm dismissing the case. All right. Do
20 you have an order?

21 MR. NEUBECK: I do, Your Honor, I don't
22 believe the Petitioners have had a chance to
23 review it. It's less than a page in substance
24 so I would propose to hand it to them, there's a
25 spot for their signatures and they can have a

1 chance to review it and we can hand it forward.

2 THE COURT: That's fine as long as it's
3 short and the Petitioners can simply review it
4 here, that's fine.

5 MR. NEUBECK: I think they should be able
6 to, it's less than a page.

7 THE COURT: Okay. In signing an order
8 like this one you're simply saying you were
9 present in court and you received a copy of the
10 order. You're not saying that you agree with
11 the order, which clearly you don't.

12 MS. HARRIS: When you say that we are to
13 pay \$2,000, is that in addition to what we've
14 already paid our attorneys or does that --

15 THE COURT: Yes, it's what you owe
16 Mr. Sutton, yes.

17 MS. HARRIS: And so we do intend to
18 appeal.

19 THE COURT: Okay. That part is out of
20 this Court's hands.

21 MS. HARRIS: What about the 30 days that
22 you intend to appeal?

23 THE COURT: You have 30 days in which to
24 appeal.

25 MR. NEUBECK: Your Honor, I think she is

1 referring to the order that does say that the
2 amounts ordered by the Court due from the
3 Petitioners are due within 30 days, if they are
4 not submitted we reserve the right to take an
5 order to the ex parte calendar to seek judgment
6 on those orders.

7 THE COURT: Okay. Normally a judgment
8 isn't suspended simply because an appeal has
9 been filed. It is possible to file an appeal
10 bond and you could talk with the clerk or with
11 the lawyer about how to do that. The notice of
12 appeal has to be filed within 30 days also. So
13 that gives you time to consult with a lawyer on
14 an appeal also if you want to do that.

15 MS. HARRIS: Okay, thank you.

16 THE COURT: So if you can simply sign
17 that order to indicate that -- have you given a
18 copy to the Petitioners?

19 MR. NEUBECK: I didn't, Your Honor,
20 because I have now interlineated a significant
21 amount.

22 THE COURT: Okay.

23 MR. NEUBECK: I can arrange for them to
24 have a copy or we can take it down to the
25 clerk's office and I can make them a copy.

1 THE COURT: Why don't we do that. We'll
2 make sure that a copy is available for you at
3 the clerk's office, but that will be when this
4 calendar ends. Our clerk will take the order to
5 the clerk's office and make sure that you get a
6 copy, our clerk is Ms. Riddick.

7 Unless, Mr. Neubeck, you'd like to take
8 the order up and see to that directly, that's
9 your choice.

10 MR. NEUBECK: I think that the Court, I'd
11 like to get, Your Honor, you have a chance to
12 read the order before she signs it and I don't
13 want to delay the Court any further so at the
14 end of the calendar it will be available.

15 MS. HARRIS: So I just want to clarify
16 that by signing this we're signing that we
17 received it, we're not signing that we agree?

18 THE COURT: That's correct.

19 MS. HARRIS: Okay. Can I note that
20 "received not agreed"?

21 THE COURT: If you'd like to note that
22 you may.

23 Mr. Neubeck, I find that the other fees
24 that the attorney, the other attorneys fees in
25 addition to the \$2,000 that I've assigned to the

1 Petitioners are reasonable fees and should be
2 collected. In other words I'm not saying that
3 your fees should be reduced to \$2,000.

4 MR. NEUBECK: No, I understand. Does the
5 order read oddly then, Your Honor, the way I've
6 amended it? I mean the fees between Benjamin
7 Sutton and our offices are not really subject to
8 the Court's overview at this --

9 THE COURT: I agree, but I think that
10 order could be ambiguous. I'm writing a line in
11 there.

12 MR. NEUBECK: That's perfectly
13 acceptable, Your Honor, I appreciate the
14 clarity.

15 THE COURT: Okay. I've signed the order.
16 I'm going to detach the last two pages though
17 because I don't think you intended to pass them
18 up. They look like part of a brief.

19 MR. NEUBECK: I'm sorry, that was my
20 notes, Your Honor.

21 THE COURT: That's what I thought. What
22 I've signed is a two-page order and it was a
23 three-page order with the signature page, so
24 that's been signed, it will be entered today.

25 MR. NEUBECK: Does the Court wish to have

1 Mr. Bergsbaken's fees, is that attached to
2 the --

3 THE COURT: The order finds those fees to
4 be reasonable and, yeah, I think the invoice
5 should be attached.

6 MR. NEUBECK: Okay. All right, thank
7 you, Your Honor.

8 THE COURT: All right. Thank you to all
9 parties.

10 (End of requested proceedings.)

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IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF WHATCOM

GUARDIANSHIP OF:

WILLIAM CHARLES SUTTON,

NO. 14-4-00523-1

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NOTICE OF FILING

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Please take notice that on the 1st day of
July, 2015, the original of the above numbered
and named Verbatim Report of Proceedings, dated
MAY 8 2015 was filed with the Whatcom
County Clerk's office.

DATED this 1st day of July, 2015.

WENDY S. RAYMOND
OFFICIAL COURT REPORTER
WHATCOM COUNTY SUPERIOR COURT
311 Grand Avenue
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(360) 676-6748
July 1st, 2015

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CERTIFICATE OF OFFICIAL COURT REPORTER

STATE OF WASHINGTON)
) SS.
COUNTY OF WHATCOM)

I, Wendy S. Raymond, Official Court Reporter,
County of Whatcom, State of Washington, do hereby
certify that the foregoing pages comprise a true and
correct transcript of the proceedings had in the
within-entitled matter, recorded by me by stenotype on
the days herein written and thereafter transcribed into
being by computer-aided transcription, and constitute my
record on this matter.

DATED THIS 1st day of July, 2015.

Wendy S. Raymond, CCR
Official Court Reporter

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DIVISION II

2015 OCT 23 PM 1:16

STATE OF WASHINGTON

CERTIFICATE OF SERVICE

BY _____
DEPUTY

I hereby certify that on October 21, 2015, I caused a true and correct copy of the foregoing:

Appellants' Brief & Appendices

The undersigned caused the original document to be filed with the appellate court clerk, by mailing the same via First-Class U.S. Mail to the following:

Washington State Court of Appeals Division I
950 Broadway, Suite 300
M IS TB-06
Seattle, WA 98402-4454
Attention: Court Clerk

And to

to be served on the following counsel of record VIA US MAIL on October 21, 2015 as follows:

Phillip Buri
Buri Funston Mumford, PLLC
1601 F Street
Bellingham, WA 98225

Attorney for Respondent

Dated: October 21, 2015 at Seattle, Washington.

By: E. SAADIQ MORRIS
Ernest Saadiq Morris
WSBA No. 32201

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STATE OF WASHINGTON
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