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I. ASSIGNMENTS OF ERROR

Western Washington Oncology P.S. (hereinafter “Employer”), respectfully asserts that the Trial Court erred in adopting Findings of Fact Nos. 3, 4, 5, 6, and 9, and Conclusions of Law Nos. 3 and 5 of the Proposed Decision and Order (PD&O) adopted by the Board of Industrial Insurance Appeals. The Employer respectfully asserts that the Trial Court erred in making any evidentiary rulings adverse to it.

II. ISSUES

- 1. Did the Trial Court err by affirming the Board’s evidentiary ruling which allowed Ms. Cunningham to give an expert opinion regarding the hazards of anti-neoplastic drugs?**
- 2. Did the Trial Court err by concluding that the Department has met its burden of proving all elements of the alleged violation of WAC 296-800-16040 when the Department failed to prove the serious exposures to a hazard by asserting that Employer violated the WAC because it did not provide impermeable gowns as recommended in the NIOSH guidelines?**
- 3. Did the Trial Court err by concluding that the Department established violations of WAC 296-800-16040 actually occurred in the citation period when it alleged that the Employer did not enforce nurse and technicians to wear the yellow gowns when they were administering chemotherapy drugs?**

III. PROCEDURAL BACKGROUND

On February 20, 2007, the Department issued Citation and Notice No. 310284104 against the Employer. A timely appeal by the Employer was made with the Department of Labor and Industries' Safety Division on March 20, 2007. On October 10, 2007, the Department filed a Motion to Amend the Citation by vacating Violation 1, Item 1-1 and Violation 1, Item 1-2. On October 23, 2007, Violation Item 1-3 was amended to allege a serious violation of WAC 296-800-16040 with an assessed penalty of \$4,500. The Citation and Notice, as amended, was affirmed and modified on March 25, 2008. The Employer's Petition for Review was filed on May 5, 2008. The Employer received the Department's response on November 17, 2008, and filed its reply on December 1, 2008. Employer's Appeal was filed timely on February 17, 2009.

IV. STATEMENT OF THE CASE

On August 24, 2006, the Department's Compliance and

Safety Health Officer Margaret Cunningham (hereinafter “Ms. Cunningham”) opened an inspection at the Employer’s Central Washington Clinic. The Employer and its predecessor companies operated oncology clinics throughout Western Washington before being bought by St. Peter’s Providence Hospital in 2007. The Employer has a staff of oncologists who treat cancer patients in Lacey, Aberdeen and Centralia. The main office is located in Lacey.

Patients receive anti-neoplastic drugs at the Employer’s clinics. Anti-neoplastic drugs are a subset of “chemotherapy” drugs used to treat patients with cancer. The goal of an anti-neoplastic drug is to target and kill cancer cells without killing other cells in the patient. There are many different kinds of anti-neoplastic drugs prescribed by the oncologists. Generally speaking, however, the Employer’s technicians or nurses administer anti-neoplastic drugs by first *diluting* the drugs in a saline solution before the drugs are intravenously delivered to the patients.

As a result of the August 24, 2006, inspection, three serious citations were recommended against the Employer, but only Violation 1, Item 1-3 as amended is before the Court:

1-3 WAC 296-800-16040 alleging that the employer did not enforce the use of necessary personal protective equipment (hereinafter "PPE"), in that the Employer did not ensure that employees mixing or working with chemotherapy complied with safety rules and WISHA regulations by wearing a gown that adequately protected them against liquid aerosols and splashes. Employees in some clinics wore Gown 241 by Graham Medical, which is inadequate protection for contact with liquid chemicals such as chemotherapy.

V. ARGUMENT

A. The Department's Compliance Safety and Health Officer, Ms. Margaret Cunningham, was not qualified to give an expert opinion that anti-neoplastic drugs were hazardous to workers.

ER 702 allows an expert witness to provide an expert opinion provided such opinion is helpful to the trier of fact and the expert is qualified to give such an opinion. This rule declares:

“If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.”

Application of this rule involves a two-step inquiry:

whether the witness qualifies as an expert and whether the expert testimony would be helpful to the trier of fact. *Reese v. Stroh*, 128 Wn.2d 300, 306, 907 P.2d 282 (1995). The allowable bases of an expert's opinion are set forth in ER 703:

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Even if a witness is allowed to testify as an expert, the expert must stay within the area of his expertise. *Queen City Farms, Inc. v. Cent. Nat'l Ins. Co. of Omaha*, 126 Wn.2d 50, 102, 882 P.2d 703, 891 P.2d 718 (1994); *see, e.g., Boeing Co. v. Sierracin Corp.*, 108 Wn.2d 38, 50-51, 738 P.2d 665 (1987).

The premise of the Department's remaining citation was that employees mixing or administering anti-neoplastic drugs that had been diluted in the mixing process needed to be protected against health hazards of the chemotherapy medication. The only testimony offered by the Department to establish such health hazards was through the Compliance Officer Margaret Cunningham. At CABR page 41, line 4, Testimony of Cunningham November 14, 2007, the Department asked the following question:

Q. Can exposure to antineoplastic drugs be toxic?

A. Yes. They—

Mr. Owada: Objection; beyond the scope of her expertise as an industrial hygienist.

However, over the Employer's objections, the Department's only testimony admitted into evidence on this point came from Compliance Officer Ms. Cunningham. See CABR page 41, line 12 through page 42, line 1, Testimony of Cunningham November 14, 2007. This testimony was adopted

by the IAJ at Finding of Fact number 3. The Employer respectfully asserts that the IAJ erred in admitting the evidence and to further conclude that the testimony of Ms. Cunningham was more persuasive than that of Dr. Gordon, a Board Certified oncologist.

On voir dire, the Employer asked Ms. Cunningham the following questions to demonstrate that she was not qualified to give a scientific opinion that exposure is toxic. (CABR Cunningham, Transcript, November 14, 2007, Pg. 42 & 43, Lines 16-26 & 1-2):

- Q. Ms. Cunningham, you're not a board certified physician, are you?
- A. No, I am not.
- Q. You've never conducted any kind of research on the effects of cytotoxic drugs, have you?
- A. No.
- Q. And in fact, you've never published any kind of articles on this?
- A. No.
- Q. And you never taught specifically the adverse health effects, if any, of cytotoxic

drugs to non patients; isn't that true?

A. That is correct.

MR. OWADA: Your honor, based on the testimony Ms. Cunningham is certainly well qualified as an industrial hygienist but certainly not as to the cause and effect relationships, if any, of cytotoxic drugs. She simply doesn't have the scientific background under the Frye analysis to give that kind of opinion.

Based on the testimony from Ms. Cunningham, the IAJ found in Finding of Fact Number 3, CABR, page 51, lines 10 – 13 that:

“Exposure to antineoplastic drugs (chemotherapy) can be toxic and terminal to healthy cells as well as cancer cells. Accordingly, exposure outside the skin can cause irritation, rash, itching, and damage to the skin. Absorption through the skin and/or inhalation can cause system effects such as leukemia, birth defects and premature miscarriage.”

For scientific testimony to be admissible, the expert (1) must qualify as an expert, (2) the expert's opinion must be based upon a theory generally accepted in the relevant scientific community, (3) the testimony must be helpful to the trier of fact, and (4) testimony must be relevant. *State v. Cheatam*, 150

Wash.2d 626 (2003), 81 P.3d 830, denial of habeas corpus affirmed 177 Fed.Appx. 716, 2006 WL 1069700.

Expert testimony concerning evidence derived from a scientific theory is admissible only if the theory has achieved general acceptance in the relevant scientific community; this rule is concerned only with whether the expert's underlying theories and methods are generally accepted. *Ruff v. Department of Labor and Industries of State of Wash.* 107 Wash.App. 289 (2001), 28 P.3d 1.

In our present case, it was clear that the Department offered no scientific theory that has achieved general acceptance in the relevant scientific community. For questions concerning the cause and effect of cancer drugs related to leukemia, birth defects and skin conditions, oncologists such as Dr. Gordon would constitute the relevant scientific community.

As held by ,

“To be admissible, expert testimony concerning novel scientific evidence must both satisfy both Frye and ER 702. FN13 Under Frye, evidence derived from a

scientific theory is admissible only if the theory has achieved general acceptance in the relevant scientific community.FN14 Washington courts have applied the Frye rule to both criminal and civil cases.FN15 The Frye rule is concerned only with whether the expert's underlying theories and methods are generally accepted. The result-the conclusion reached by the expert in the case at hand-is by definition fact-specific and need not be generally accepted in the scientific community.FN16 Thus, a **7 Frye analysis need not be undertaken with respect to evidence that does not involve new methods of proof or new scientific principles from which conclusions are drawn.FN17

As the Department did not offer any evidence that the scientific community generally accepts a cause and effect relationship between cytotoxic drugs and hazards to workers, it was necessary for the Department under the Frye test to scrutinize the theory relied on to support such opinion. As Ms. Cunningham freely admitted that she has never engaged in such research, she was not qualified to give the medical opinion she did. It was error for the Board and the Trial Court to rely on her testimony.

The Board erred in overruling the Employer's objection.

Her opinions should be stricken as a matter of law.

B. The Trial Court erred by concluding that the Department has met its burden of proving all elements of the alleged violation of WAC 296-800-16040 when the Department failed to prove the serious exposures to a hazard by asserting that Employer violated the WAC because it did not provide impermeable gowns as recommended in the NIOSH guidelines.

1. Standard of Review

The meaning of a statute is a question of law which is reviewed by the courts de novo. *Dep't of Ecology v. Campbell & Gwinn, L.L.C.*, 146 Wn.2d 1, 9, 43 P.3d 4 (2002). The Washington Industrial Safety and Health Act (hereinafter WISHA) is to be liberally construed to carry out its purpose of assuring, insofar as may reasonably be possible, safe and healthful working conditions for every man and woman working in the state. *Inland Foundry Co., Inc. v. Department of Labor and Industries*, 106 Wn. App. 333 (2001). However, the Administrative Procedure Act, Ch. 34.05 RCW requires state

agencies to comply with the administrative rule making process when it promulgates administrative requirements.

The Department has the burden of establishing such substantial evidence to prove prima facie elements of the alleged violation. Washington was granted authority by the federal government to administer the Occupational Safety and Health Act as a state plan administration. As such, the Washington State Department of Labor & Industries has statutory authority to issue a serious citation and levy a monetary penalty for serious violations of a WISHA safety or health code. However, the ability to issue a serious citation is not without limit. Not only must the Department establish that an employee was exposed to a serious hazard (one that could cause serious bodily injury or death), the Department must also establish that the cited employer either knew, or should have known of the presence of the violation. In relevant part, RCW 49.17.180(6) declares:

(6) For the purposes of this section, a serious

violation shall be deemed to exist in a work place if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use in such work place, unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation.

There is no doubt that the statute requires that there be an exposure to serious bodily injury or death that could occur by the condition alleged to be in violation. As WISHA is required to be as effective as the federal OSHA counterpart, Washington courts will consider decisions interpreting OSHA to protect the health and safety of all workers. *Adkins v. Aluminum Company*, 110 Wn.2d 128, 147 (1988). Federal case law is similar to RCW 49.17.180(6).

In a significant decision, the Board held in *Olympia Glass Company*, 95 W0455, that, the Department bears the burden of proof in WISHA cases. The Board declared:

[I]n appeals filed under the Washington Industrial Safety and Health Act (WISHA), it is the Department who has the burden of proving both the existence of a violation and the appropriateness of the resulting penalty. WAC 296-12-115(2)(b). An employer is not required to prove the Department acted arbitrarily in order to prevail in an appeal. **Our decision on appeal must**

determine whether there is sufficient evidence in the record to affirm the Department's citation and the resulting penalty.

(Emphasis added).

As set forth in WAC 263-12-115 “Procedures at hearings”, “In all appeals subject to the provisions of the Washington Industrial Safety and Health Act, the Department shall initially introduce all evidence in its case-in-chief.” *In re Savage Enterprises, Inc.*, BIIA Docket No. 86-W053 (1988) concerned a Corrective Notice of Redetermination that alleged a serious violation of WAC 296-62-07517 and declared that “[t]he Department of Labor and Industries has the burden of establishing all of the elements necessary to prove a violation of the cited standard. WAC 263-12-115(2)(b).” *In re Atkinson-Dillingham*, BIIA Docket No. 88-W091 (1990) involved alleged violations of WAC 296-155 and stated that “it was the Department’s responsibility to present evidence establishing that the alleged violations actually occurred. Because the Department has failed to meet that burden, the Corrective Notice must be vacated in its entirety.” *In re North Fork*

Timber Company, BIIA Docket No. 98-W0015 (1999) regarded an alleged violation of 296-54-557(22) and determined that “[w]e do not believe that the Department carried the burden of establishing the existence of the violation.... The Department had to show by a preponderance of the evidence that the violation occurred.”

As the Board ruled in the case of *In re Western Plant Services, Inc.*, BIIA Dkt. Nos. 95-W281 and 95-W282 (1998), at page 11:37-47:

“The elements that the Department had to establish for each violation were:

1. An applicable standard
2. Non-compliance
3. Employee exposure
4. Employer knowledge of the **cited condition**, and
5. Existence of feasible and effective counter-measures

M. Rothstein, Occupational Safety & Health Law, (3d. ed. 1990).” This was the Board’s same finding in *In re Hall-Buck Marine, Inc.*, BIIA Dkt. Nos. 95-W262 and 96-W263 (1998) at 12:3-13.

The Employer respectfully asserts there was no substantial evidence in the record.

2. **Non-Compliance With NIOSH Guidelines Should Not Be Equated With A Violation of Cited Standard.**

The Department failed to prove the serious exposures to a hazard because it erroneously asserts that not providing “impermeable gowns” to nurses and technicians handling anti-neoplastic drugs in the clinic, Respondent’s Brief, p. 18, lines 12-15, as recommended in the NIOSH guidelines a violation of cited standard under WAC 296-800-16040.

However, impervious gowns are only *recommended* by NIOSH Alert guidelines. None of these guidelines have been adopted by either the Washington legislature or the Department through the administrative rule making process set forth in Ch. 34.05 RCW. Additionally, there is no WISHA regulation that prohibits chemotherapy drugs from coming into contact with the skin. Cunningham, Tr. 11/14/07, p. 101-103, Lines 16-26, 1-26 & 1-19:

- Q. And you would also agree that there's a difference between a Washington Administrative Code and a guideline, correct?
- A. Correct.
- Q. Because a code such as the Washington Administrative Code is a standard that's mandatory and guidelines is just a recommendation, correct?
- A. That is correct.
- Q. You would agree that the WISHA code that you had cited under WAC 296-800-16050 that is did not specifically reference any kind of OSHA technical manual, correct?
- A. That's correct.
- Q. And it didn't mention anything about a NIOSH alert, does it?
- A. No, it does not.
- Q. And you know the difference between a specification standard versus a performance standard?
- A. That's correct. I do.
- Q. A specification standard is one in which the WISHA standard tells the employer specifically how they must comply, correct?
- A. Correct.
- Q. And a performance standard is one in which it tells the employer that they must comply but they can determine and devise the means and methods to provide the protection so long as it's appropriate, correct?
- A. Correct.
- Q. And when we're dealing with hazardous chemicals, you're familiar with the term PEL?
- A. Yes, I am.
- Q. That stands for permissible exposure level,

- correct?
- A. Yes.
- Q. And a permissible exposure level is the amount that an employee can be exposed up to and still be in compliance, correct?
- A. By a specific means of exposure, yes.
- Q. Okay. And so that's usually measured in micrograms per cubic meter or micrograms of milligrams per deciliter depending on the kind of measurement that it's being written down in, correct?
- A. Correct.
- Q. And there's a specific list that WISHA writes in its regulations as to those permissible exposure levels, correct?
- A. Correct.
- Q. Your training is such that an employer cannot be cited for violation a guideline; isn't that true?
- A. Solely a guidance?
- Q. Yeah.
- A. That is true.
- Q. And you would agree, then, that the OSHA technical manual is a guideline?
- A. Yes, it is.
- Q. And the NIOSH alerts are guidelines?
- A. yes, it is.

The Washington legislature passed no specific requirement for an employer to comply with the ONS publications, the OSHA Technical Manual or any NIOSH Alert. Moreover, the Department of Labor and Industries has

never promulgated any administrative rule requiring employers to adopt these recommendations under WAC 296-800-16040. As the Department has not prohibited skin contact with anti-neoplastic drugs, nor has the Department regulated the amount of permissible skin contact with anti-neoplastic drugs, the Department has no jurisdiction to impose a specific guideline on an employer.

3. Yellows Gowns Provide Adequate “Personal Protective Equipment” (PPE).

The Department alleges that the employees should have been wearing impermeable gowns both when mixing anti-neoplastic drugs in the biological safety cabinet (hereinafter “BSC”) and administering anti-neoplastic drugs.

As discussed above, the Department has no authority to specifically require impervious gowns, as none of the PPE standards promulgated in Ch. 296-800 WAC require impermeable gowns for diluted anti-neoplastic drugs. Furthermore, the cited standard, WAC 296-800-16040 on its

face does not presume the existence of a safety hazard. *See, Modern Drop Forge Co. Secretary of Labor*, 683 F.2d 1105, 1114–15 (7th Cir. 1982). Instead the standard requires an employer to use adequate personal protection.

In fact, the Employer did provide PPE (gloves, yellow gowns and lab coats) and the Department further failed to establish that the PPE provided by Employer was inadequate. As the testimony of Steven Gordon M.D. (hereinafter “Dr. Gordon”), a board certified oncologist who has engaged in research and the treatment of cancer with anti-neoplastic drugs for over 30 years, demonstrates, the PPE provided is in fact adequate under the regulations, Dr. Gordon, Tr. 10/17/07, Pg. 24, Lines 11-20:

- Q. Have you formed an opinion on whether that violation is appropriate or not?
- A. Yes.
- Q. What is your opinion?
- A. It’s not appropriate.
- Q. And could you tell me why?
- A. Because that gown 241 is an appropriate, lint-free, low permeability gown. I have tested the gown

where I have thrown water on it and it bounces off and doesn't go through.

Further, Dr. Gordon's research shows no change in the current medical standards and the yellow gowns at issue are an adequate barrier. Additionally, the following testimony of Dr. Gorton demonstrates the Employer's knowledge of regulation standards pertaining to adequate gown protection (Dr. Gorton, Tr. 10/17/07, Pg. 20, Lines 7-217):

- Q. Yes, I'll ask the question then. What would you recommend as appropriate protective apparel for nurses mixing chemotherapy infusions?
- A. The standard that we've used and the standard that I'm aware of being used in our office and in the hospital is that they are provided a hood, that they wear a gown which need to be I think it's lint-free and either impermeable or low permeable, either/or, and cuffed and that they wear gloves. That is my understanding of the standards, published standards in like the nursing journals and the oncology nursing society.

Therefore, the Department's assertion only proves that impermeable gowns are "preferable" to the yellow gowns provided by the Employer. The Department's obligation is to prove that the yellow gowns, in fact, fail to provide the

minimum level of protection required by the cited standard, not whether it is preferable to one another.

C. The Trial Court erred by concluding that the Department established violations of WAC 296-800-16040 actually occurred in the citation period when it alleged that the Employer did not enforce nurse and technicians to wear the yellow gowns when they were administering chemotherapy drugs.

1. Standard of Review

The standard for judicial review of a WISHA citation is set forth in RCW 49.17.150(1). In relevant part, this section declares:

The findings of the board or hearing examiner where the board has denied a petition or petitions for review with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive.

(Emphasis added).

The Trial Court's conclusions must be based on its findings of substantial evidence. The Department has the burden of establishing substantial evidence to prove all prima facie elements of the alleged violation. In order to cite a serious violation, the Department must establish that an employee was exposed to a serious hazard (one that could cause serious bodily injury or death) and that the cited employer either knew, or should have known of the presence of the violation. In relevant

part, RCW 49.17.180(6) declares:

(6) For the purposes of this section, a serious violation shall be deemed to exist in a work place if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use in such work place, unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation.

The Employer respectfully asserts there was no substantial evidence in the record.

2. No Employee Exposure To A Hazard Existed

The Department asserts that, even if the yellow gown provided adequate protection, the Employer failed to enforce the use of the yellow gown to nurses and technicians or to discipline the employee who wore only cotton scrubs or lab coats when misting or administering chemotherapy drugs. However, the Department failed to meet its burden of proving prima facie case by not establishing an employee exposure to a hazard.

First, the BSC protects the employees from being

exposed to the chemotherapy drugs while mixing them. Photographs provided by the Department shows that a hypodermic syringe is used inside of the BSC while the employee works behind the glass barriers. The employee's hands and half of her forearm are inside the BSC, and the hands are sufficiently protected by gloves.

In addition, the testimony of Dr. Gordon establishes that BSC protects the employees, who mix the chemotherapy drugs, from a hazard that WAC 296-800-16040 is designed to protect. Dr. Gordon testified that he was not aware of any research that indicates that skin exposure to anti-neoplastic drugs would cause skin cancer and that the yellow gowns and use of lab coats were sufficient to protect employees. In fact, these same drugs are even used to cure skin cancer and are *applied directly to the skin* of patients undergoing treatment.

Thirdly, the Department failed to meet its burden of proving that there was in fact employee exposure to a hazard that has a substantial probability of causing a severe injury or

death without knowing the amount of exposure, the absorption rate, or the type of medication. Once the concentrated medication is diluted with saline, it is then administered by registered nurses to the patients. However, the Department has failed to provide any testimony regarding the amount of the concentrated drug that is mixed with the saline solution to establish exposure. Without knowing the amount of the hazardous substance in the concentrated form and the amount mixed with the saline solution, the Department presented no evidence of the amount of exposure, if any, to nurses who might come into contact with the diluted saline solution.

Finally, the Department failed to offer specific testimony regarding whether the anecdotal instances actually caused an employee to be exposed to a serious hazard capable of causing serious bodily injury or death.

CSHO Cunningham testified that she did not observe any employees administering anti-neoplastic drugs at any of the Employer's clinics. But Ms. Cunningham took statements of

Lori Lindley, Leah Guilford-Elenes, Christine Batchelor-Hancock, and Robert Hilkemeier.

Although some of the nurses provided descriptions of situations when the diluted medical mixed with saline came into contact with them, they were isolated instances and nothing that occurred on a regular or frequent basis. The concentration of the anti-neoplastic drugs was never identified, nor did the Department provide any evidence on whether the diluted form of the drug was in fact hazardous to the employees. More importantly, these instances occurred several years ago. From the time of the opening conference in August 2006, to the closing conference in February 2007, the Department did not observe or investigate any instance involving an employee being exposed to a serious hazard for not wearing appropriate PPE.

Therefore, the Department failed to meet all of its required prima facie elements for the alleged violation by not establishing that there was an exposure of a hazard to an

employee.

VI. CONCLUSION

Based on the above, the Trial Court's Decision relating to the Department's citation should be reversed and the citation vacated in its entirety.

DATED this 19th day of April, 2009.

AMS LAW, P.S.



Aaron K. Owada, WSBA No. 13869
Attorney for Appellant

COURT OF APPEALS, DIVISION TWO
STATE OF WASHINGTON

WESTERN WASHINGTON
ONCOLOGY,

Appellant,

v.

WASHINGTON STATE
DEPARTMENT OF LABOR AND
INDUSTRIES,

Respondent.

NO. 38877-4-II

**CERTIFICATE
OF SERVICE BY
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DEPUTY

I, Lisa Ockerman of AMS LAW, P.C., hereby certify under penalty of perjury under the laws of the State of Washington that on this date I served the Original APPELLANT'S OPENING BRIEF via U.S. Mail Postage Prepaid to the Court of Appeals, Division Two; and a copy of the same to:

Bourtai Hargrove, AAG
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SIGNED in Lacey, Washington on April 20, 2009.

[Signature]

Lisa Ockerman

ORIGINAL