**EXPERT REPORT OF**

**RICHARD A. PARENT, PHD, DABT, FATS, RAC, ERT**

**IN THE MATTER OF**

[redacted], **AS SISTER, NEXT FRIEND AND SURVIVOR OF**

[redacted], **DECEASED**

**VS.**

[redacted] **INC., d/b/a** [redacted]

**IN THE**

**DISTRICT COURT OF OKLAHOMA COUNTY**

**STATE OF OKLAHOMA**

**CASE NO.** [redacted]

**CONSULTOX, LIMITED**

**DAMARISCOTTA, MAINE**

**July 6, 2005**

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## QUALIFICATIONS

I, Richard A. Parent, PhD, DABT, FATS, RAC, ERT, am a board certified toxicologist with over 12 years' experience in the field of industrial toxicology and an additional 20 years' experience in litigation support for both the plaintiff and defense. I have testified in local and federal courts as an expert in toxicology and have given expert testimony in the disciplines of toxicology and chemistry. During my career, I have spent 10 years in research on organic chemicals at American Cyanamid Company. In the field of toxicology, I have initiated and carried out an active program in product safety relating to toxicology for the Xerox Corporation. I have directed two contract toxicology laboratories: Food and Drug Research Laboratories, Inc. and Gulf South Research Institute, Life Sciences Division. In 1984, I established Consultox, Limited, a toxicology consulting firm, and have since consulted in product safety for various industries and have designed toxicology studies to assess the safety of materials being considered for use in various products. For litigants, I have provided toxicological support and have addressed causation issues for the plaintiff as well as the defense. I am board certified by the American Board of Toxicology, the Academy of Toxicological Sciences, and the Regulatory Affairs Professional Society. I am a recognized expert in toxicology in France and the European community. I present myself to the Court as an expert in the fields of toxicology and chemistry. For the Court's information, I offer my curriculum vitae in Appendix A.

## MATERIALS REVIEWED

- Letter of retention from [redacted] dated 06/20/05
- Certificate of Death, [redacted] dated 09/18/02
- Report of Investigation by Medical Examiner dated 9/13/02
- Autopsy No. ML [redacted] Case No. [redacted] signed by [redacted] MD on 08/21/02
- Report of Laboratory Analysis by the Office of Chief Medical Examiner dated 9/9/02 and signed by [redacted] PhD, DABFT, Chief Forensic Toxicologist
- Morgue Register and Release of Body Form dated 8/3/02
- Supplemental Report by [redacted] FAC describing meeting with decedent's stepfather and subsequent Drug Information Form dated 8/14/02
- Plaintiff's Responses to Defendants First Set of Requests for Production by [redacted] with attached medical expenses
- Plaintiff's Answer to Defendant's First Set of Interrogatories by [redacted]
- Answers of Defendant [redacted] Inc., d/b/a [redacted] to Plaintiff's First Set of Interrogatories by [redacted] Executive Director, [redacted] Inc., and [redacted] attny
- Responses of Defendant [redacted] Inc., d/b/a/ [redacted] to Plaintiff's First Request for Production of Documents by [redacted]
- Responses to Request for Production No. 1
  - Consent to Treatment with an Approved Narcotic Drug by Dr. [redacted], DO but not signed by [redacted]

- Patient Certification of Household Gross Annual Income - signed
- Release Form for Methadone Patients only - signed
- [redacted] Statement Corroborating Drug Addiction - signed by [redacted] (7/23/02), another signed by [redacted] (7/26/02)
- [redacted] Certification of Sole Methadone Treatment, signed by [redacted] dated 07/30/02
- Agreement to Pay, Li[redacted] signed by [redacted] dated 07/27/02
- Rules for Patients, [redacted] signed by [redacted] dated 07/27/02
- Policy on Terminating Patients, signed by [redacted] but undated
- Grounds for Termination of Privileges, [redacted] signed by [redacted] 07/27/02
- Patient Acknowledgment of Receipt of Forms, signed and dated 07/27/02
- Medication Profile, [redacted] 07/29/02
- Evaluation and Assessment of Patient for Treatment with Methadone Maintenance signed by admitting nurse, physicians assistant and Medical Director, [redacted] DO and dated 07/30/02
- Patient History from Eckerd Drugs from 10/31/99 to 3/30/01 and dated 07/29/02
- Consent to Disclosure of Information to Case Review Team, [redacted] signed and dated July 27, 2002
- Patient History from Eckerd Drugs from 1/9/00 to 7/24/02; dated July 29, 2002
- Patient Profile, Wallgreens Pharmacy from 12/25/01 to 6/2/02
- [redacted] Examination form for [redacted] dated 7/30/04; a two page check list signed by Deborah Doray, PA
- Confidential Personal Questionnaire reviewed by [redacted] LPN
- Recordation of Observations Upon Intake of New or Readmitted Patient, signed by [redacted] LPN dated 7/30/02
- Adult Discharge Criteria
- [redacted] Patient Medication from 7/1/02 to 7/31/02
- [redacted] Patient Medication from 8/1/02 to 8/31/02; note: actually only goes to 8/2/02 because Mr. [redacted] died
- [redacted] Patient Master Problems Index - blank
- [redacted] ASAM Assessment Profile - blank
- [redacted] Initial Intensive Interview Form - blank
- [redacted] Global Assessment of Functioning (GAF Scale) - blank
- [redacted] Medical Progress Notes describing dosing from 7/30/02 to 8/2/02
- [redacted] questionnaire filled out by [redacted], PA and contains nurses orders to start MMTP at 30 tomorrow and increase by 10 mgs each day; Cosigned by [redacted] DO
- Patient Report Upon Discharge - alleges that patient obtained illicit opiates and did not present for interview; last dose of 60 mg methadone on 8/2/02

  - Ammon Analytical Laboratory report for [redacted] sample collected 7/30/02
  - [redacted] Blood Test Status Report, dated 7/30/02
  - San Diego Reference Lab; Rapid Plasma Reagin Test (RPR) not reactive; 8/1/02
  - [redacted] Record of Mantoux Tuberculin Skin Test 7/30/02
  - [redacted] Record of Patient Non-Methadone Prescriptions
  - [redacted] New Patient 14-Day Review Form dated 7/30/02
  - [redacted] Computer Information Datasheet
- Response to Request for Production No. 3
  - Policies and Procedures Manual 2004; [redacted] - Admissions, Retentions and Discharges; 16 pages - missing pages
  - Policies and Procedures Manual 2004; [redacted] - Counseling - pages missing
  - Policies and Procedures Manual 2004; [redacted]- Medical Testing - pages missing
  - Policies and Procedures Manual 2004; [redacted]- Medication Management - pages missing
  - [redacted] Standing Medical Orders - five pages signed by Bob Weeks, DO, Medical Director
- Photographs of decedent as found after death

**FINDINGS AND CONCLUSIONS**

I understand that [redacted], a 44-year-old white male, passed away on August 3, 2002, at his home in Edmond, Oklahoma and that the body was found on August 3, 2002, at 0900 hours by his parents. Previously, on August 2, he had visited the Veterans Hospital for an IVP, but those results have not been made available to me. I understand further that Mr. [redacted] had a long history of right flank pain, kidney stones and hypertension and was being treated for Lortab abuse. His father reportedly checked on him the evening prior to his death at around 2200 hours, and he was fine.

Upon post-mortem examination, Mr. [redacted] was found to have severe coronary artery disease, pulmonary edema and congestion, and acute urinary retention. External examination showed no signs of trauma. Based on a finding of 0.63 ug/ml [0.63 mg/L] in a blood sample taken from the femoral artery and a concentration of 5.1 ug/g [5.1 mg/kg] in liver tissue, the medical examiner concluded that Mr. [redacted] had expired from a methadone overdose.

On July 30, 2002, the week prior to his death, Mr. [redacted] was subjected to a drug screen, and only benzodiazepines at >200 ng/ml was found in his urine. Negative findings were noted for methadone, opiates, cocaine, barbiturates, amphetamines, alcohol, propoxyphene, phencyclidine, and marijuana. On August 14, 2002, however, the decedent's stepfather, [redacted] presented a number of prescription bottles that

were found in Mr. [redacted] s room including Prinivil (lisinopril), Plendil (felodipine), Adalat (nifedipine), Zoloft (sertraline), and some unidentified pink tablets. In addition, various prescription records list the following drugs that were prescribed for Mr. [redacted]: Ranitidine Hcl, Sertraline Hcl, sodium bicarbonate, Sulindac, Citalopram, Lisinopril, Trazodone, butalbital, Norco, Hydrocodone, Ultram, lortab (hydrocodone/acetominophen), diazepam, Xanax, Alpraxolam, Ciprofloxin, Felodipine, hydrochlorothiazide, methocarbamol, and percocet (ocycodone/acetominophen). In the post-mortem toxicology report, there was no indication that any of these drugs were present or that any analysis had been performed for them.

It is my further understanding that on or about July 30, 2002, Mr. [redacted] began a detoxification program at the [redacted] which involved methadone treatments and that according to their own protocol, the Center orally dosed Mr. [redacted] with methadone in a liquid formulation supplied by Mallinckrodt Chemical beginning with 30 mg on Day 1, 40 on Day 2, 50 on Day 3. On August 2, Day 4, the day prior to his death, he was dosed with 60 mg methadone.

Methadone is a synthetic opioid which peaks in the blood about four hours after oral administration.[1] When orally dosed chronically, at 100-200 mg per day, a peak plasma mean concentration of 830 ng/ml[830 ug/L; 0.830ug/ml] had been measured four hours after dosing.[1] The drug has a half life of elimination from 15-55 hours[2] but is generally thought to be around 26.8 hours for addicts.[3]

Fatal cases of methadone poisoning have shown average blood concentrations of 1 mg/L [1 μg/ml] with a range from 0.4 to 1.8 mg/L. Concentrations of methadone found in post-mortem liver, the primary site for methadone metabolism, have been reported as a mean of 3.8 mg/kg [μg/g] with a range of 1.8 to 7.5 mg/kg.[4] An English study analyzed findings from 55 cases where methadone poisoning was the sole cause of death and reported a mean blood methadone concentration in adult decedents of 584 ng/ml [0.584 μg/ml], where the median was 435 and the values ranged from 84-2700 ng/ml.[5] In another study of 38 decedents where methadone was detected, the mean blood methadone concentration was 975± 681 ng/ml.[6] Thus, it would appear that the methadone level found in the decedent's [redacted] s, femoral blood are well within the range of concentrations deemed fatal elsewhere. Of particular interest is the decedent's liver concentration of methadone which is well above the norm found in fatal cases. This finding may reflect a competition for the cytochrome P450 3A4 receptor which is known to be the active hepatic site for methadone metabolism[7] or it could be a result of the fact that naive users take much longer to clear methadone from their circulation; consequently, they are at greater risk of overdose than chronic users.[8]

Regarding the situation involving those being treated by methadone for addiction, addicts naive to methadone have been reported to succumb at doses as low as 57 mg per day.[9] Elsewhere, it has been reported that most methadone deaths occur in the first weeks of maintenance therapy as a result of rapid daily increase in dose levels; fatal respiratory depression is the result.[10,11] The relative risk for fatal respiratory depression during naive methadone therapy is about seven times higher than in untreated heroin

addicts and 97.8 times higher than for methadone maintenance patients who have been in maintenance for more than two weeks.[11,12]

In conclusion, I opine that Mr. [redacted] expired as a result of methadone intoxication resulting from a detoxification program carried out by the [redacted] Mr. [redacted]'s body was naive to methadone prior to initiation of this treatment program and, therefore, was very sensitive to the destructive action of this drug.

Richard A. Parent, PhD, DABT, FATS, RAC, ERT
CONSULTOX, LIMITED

Date