STATE OF MAINE CUMBERLAND, ss.



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SUPERIOR COURT CIVIL ACTION DOCKET NO. CV-03-538

DANNY TARDY, ET AL.,

Plaintiffs

**v.** 

ELI LILLY AND COMPANY, ET AL., Defendants

ORDER ON THE DEFENDANTS' MOTIONS TO DISMISS

LANYLOL ONFERED

AUG 20 2004

Before the court is: (1) the motion of the defendant pharmacy CVS Mill Creek, LLC (hereinafter "CVS") to dismiss the plaintiffs' complaint in its entirety; and (2) the motion of the defendant manufacturer Eli Lilly and Company (hereinafter "Eli Lilly") to dismiss the plaintiffs' claims for fraud (Count VI) and fraud by concealment (Count VIII).

## BACKGROUND

The plaintiffs Danny and Diane Tardy are the personal representatives of the Estate of Michael Tardy. In January of 1999, Michael Tardy was diagnosed with Attention Deficit/Hyperactivity Disorder ("ADHD") and his physician prescribed Zyprexa (also known as olanzapine).<sup>1</sup> On June 29, 2002 Michael Tardy died. The

<sup>&</sup>lt;sup>1</sup> "ZYPREXA (olanzapine) is a psychotropic agent that belongs to the thienobenzodiazepine class." <u>Physician's Desk Reference for Prescription Drugs</u>, 30 (Micromedex, Inc. 2004). Zyprexa is currently indicated for the treatment of schizophrenia and short-term treatment of acute manic episodes associated with Bipolar I Disorder. <u>Id</u>.

plaintiffs aver that Michael Tardy's death was the result of ingestion of Zyprexa.<sup>2</sup> The plaintiffs allege that Michael Tardy's physician had been induced by defendant Eli Lilly through promotional literature downplaying known adverse and serious health effects to prescribe Zyprexa "off-label"<sup>3</sup> for treatment of ADHD. The plaintiffs also allege that the defendant CVS breached its duty under Maine law to warn its client, Michael Tardy, of the dangers of Zyprexa.

The plaintiffs' nine-count complaint alleges strict liability for failure to warn (Count I), strict liability for a defective product (Count II), negligence (Count III), breach of implied warranty (Count IV), breach of express warranty (Count V), fraud (Count VI), negligent misrepresentation (Count VII), fraud by concealment (Count VIII), and pain and suffering (Count IX). In addition, the plaintiffs demand judgment against the defendants for wrongful death, damages for pecuniary injury, funeral and last expenses, loss of the decedent's comfort, society and companionship, and for decedent's pain and suffering, loss of enjoyment of life, physical and emotional harm in

<sup>3</sup> According to a standard medical dictionary, an "off-label" use is:

The use of a drug to treat a condition for which it has not been approved by the U.S. Food and Drug Administration (FDA), esp. when such use may relieve unpleasant symptoms, or prove compassionate. During the drug approval process in the U.S., drug manufacturers present carefully accumulated data to the FDA about the safety and effectiveness of their products. Drugs are labeled for specific uses when manufacturers make an application to the FDA with data that describe their drug's performance during clinical trials. If this data withstands rigorous scrutiny the drug is labeled for a specific use. Drug effects that have been observed but not specifically proven (and for which no application has been made) may be exploited for unproven, or 'off-label' uses by licensed medical practitioners. Taber's Cyclopedic Medical Dictionary, (F.A. Davis Inc., 2002).

<sup>&</sup>lt;sup>2</sup> The report from the Office of Chief Medical Examiner for the State of Maine described Michael Tardy's death as resulting from "acute hyperglycemia due to acute olanzapine toxicity. <u>See Pls.</u>' Mot. to Remand, Briggs Dec., Ex. A.

anticipation of pending death, and for punitive damages, plus interests and costs as allowed by law.

#### DISCUSSION

## I. <u>Standard of Review</u>

When reviewing a motion to dismiss pursuant to M.R. Civ. P. 12(b)(6), the court must examine the complaint "in the light most favorable to the plaintiff to determine whether it sets forth elements of a cause of action or alleges facts that would entitle the plaintiff to relief pursuant to some legal theory." <u>Johanson v. Dunnington</u>, 2001 ME 169,  $\P$  5, 785 A.2d 1244, 1245-46 (quoting <u>In re Wage Payment Litig. v. Wal-Mart Stores</u>, Inc., 2000 ME 162,  $\P$  3, 759 A.2d 217, 220). "Dismissal is warranted when it appears beyond a doubt that the plaintiff is not entitled to relief under any set of facts that he might prove in support of his claim." <u>Id</u>.

# II. The Learned Intermediary Doctrine

The defendant CVS asserts that pursuant to the learned intermediary doctrine, it may not be held liable to the plaintiffs. The learned intermediary doctrine is "[t]he principle that a prescription-drug manufacturer fulfills its duty to warn of a drug's potentially harmful effects by informing the prescribing physician, rather than the end user, of those effects." <u>Black's Law Dictionary</u>, 898 (7th ed. 1999). The doctrine is essentially a product of the prescription drug system; under it, each time a prescription is written, physicians stand as intermediaries between their patients and drug manufacturers.

The learned intermediary doctrine was first described in a 1966 case from the Eighth Circuit concerning tort liability for an arthritis drug that damaged a patient's vision:

[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor

is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.

Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

Maine has not explicitly adopted the learned intermediary doctrine. However, the "overwhelming majority" of jurisdictions nationwide have found no general duty among pharmacists to warn patients of the dangers of drugs provided pursuant to a physician's prescription. <u>See e.g. Cottam v. CVS Pharmacy, Inc.</u>, 436 Mass. 316, 764 N.E. 2d 814, 821 (Mass. 2002) (holding that in the absence of a voluntarily assumed duty, "where the pharmacist has no specific knowledge of an increased danger to a particular customer, the pharmacist has no duty to warn that customer of potential side effects"); <u>Happel v. Wal-mart Stores, Inc</u>. 766 N.E.2d 1118, 1129 (Ill. 2002) (holding that "a narrow duty to warn exists where . . . a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient"); <u>Moore v. Memorial Hospital</u>, 825 So.2d 658, 664 (Miss. 2002) (extending the "learned intermediary" doctrine to pharmacists in Mississippi); <u>but see Dooley v.</u> <u>Everett</u>, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990) (declining to rule as a matter of law on whether the doctrine extended to pharmacists).

The rationale behind the position adopted by most courts has been summarized as follows:

The injection of a third party in the form of a pharmacist into the physician/patient relationship could undercut the effectiveness of the ongoing medical treatment by the physician; thus, a pharmacist has no duty to warn a patient of the hazards associated with a prescription drug. Consequently, a manufacturer has no duty to warn a pharmacist either. Otherwise, the patient would be receiving information about the risks of medication, information he or she would likely be unable properly to assess and weigh, from someone unfamiliar with the patient's medical

condition, after those risks had already been weighed by a physician having specific knowledge of the patient's medical needs.

Moreover, holding pharmacists liable would not serve as an incentive to safety since the pharmacist presented with a prescription ordered by a duly licensed physician is not at liberty to substitute his or her judgment of the product's safety for the patient for that of the physician.

# 63A Am. Jur. 2d Products Liability § 1206 (2003).

Based on the foregoing, the court adopts the majority view and holds that the

learned intermediary doctrine applies to the present action.

The court's position is consistent with comment k in section 402A of the

#### Restatement:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. Such product[s], properly prepared, and accompanied by proper directions and warning[s], [are] not defective, nor [are they] unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use . . .

Restatement (Second) of Torts § 402A, cmt. k (1965).4

In addition, the Maine Pharmacy Act, which holds pharmacists to a higher

standard of care, is inapplicable to the case at bar. See 32 M.R.S.A. § 13785(8). The Act

provides:

The pharmacist shall attempt to ascertain and shall record any *allergies* and *idiosyncrasies* of the patient and any *chronic conditions* which may relate to drug utilization as communicated to the pharmacy by the patient.

Upon receipt of a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the

<sup>&</sup>lt;sup>4</sup> It has been noted that the Maine Supreme Judicial Court has adopted much of the logic of the *Restatement* comments on section 402A. See Simmons, Gillman & Gregory, Maine Tort Law § 12.06, at 336 (1999).

possibility of a harmful drug interaction or reaction. Upon recognizing a potentially harmful *reaction* or *interaction*, the pharmacist shall take appropriate action to avoid or minimize the problem which may include consultation with the practitioner.

32 M.R.S.A. § 13785(8) (emphasis added). Here, the plaintiffs' complaint contains no allegations of liability for the decedent's reaction or interaction to the drug as required for liability under the statute. <u>See id.</u>

Accordingly, pursuant to the learned intermediary doctrine, the court dismisses the plaintiffs' claims for strict liability for failure to warn (Count I), strict liability for a defective product (Count II), negligence (Count III), breach of implied warranty (Count IV), and breach of express warranty (Count V), all of which are premised on a failure to warn, as to the defendant CVS. However, the court's review of the defendant's motion does not end here. The plaintiffs' claims for fraud (Count VI), negligent misrepresentation (Count VII), and fraud by concealment (Count VIII) involve a different duty and require further analysis. Similarly, the plaintiffs' damages claims warrant further attention.

# III. Fraud, Negligent Misrepresentation & Fraud By Concealment

The defendants argue that the plaintiffs' complaint fails to plead the plaintiffs' claims for fraud, negligent misrepresentation and fraud by concealment with sufficient particularity. <u>See M.R. Civ. P. 9.</u> Specifically, they assert that the plaintiffs' complaint makes general allegations against all defendants but does not apprise the defendants of the specific nature and context of the claims brought against them.

## a. Fraud (Count VI)

To sustain a fraud claim, a party must show: (1) that the other party made a false representation (2) of a material fact (3) with knowledge of its falsity or in reckless disregard of whether it is true or false (4) for the purpose of inducing him to act in

reliance upon it, and (5) he justifiably relied upon the representation as true and acted upon it to his damage. <u>Guiggey v. Bombardier</u>, 615 A.2d 1169, 1173 (Me. 1992).

Here, the plaintiffs' complaint alleges: "[t]he Defendants falsely and fraudulently represented to Plaintiffs' decedent Michael Tardy, his physicians and members of the general public, that the aforesaid product was safe for use. . ." Compl., at ¶ 56. In addition, the complaint avers that the decedent: "[was] ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiffs' decedent was induced to, and did use the aforesaid product . . ." Id., at ¶ 61. The allegations are sufficient to apprise all of the defendants of the elements of the plaintiffs' claim for fraud. See M.R. Civ. P. 9(b); Stevens v. Bouchard, 532 A.2d 1028, 1030 (Me. 1987); 1 Field, McKusick & Wroth, Maine Civil Practice, § 9.2 at 221 (2d ed. 1970). Therefore, the plaintiffs' Count VI claim for fraud withstands dismissal as to both defendants.

b. Negligent Misrepresentation (Count VII)

In <u>Chapman v. Rideout</u>, 568 A.2d 829, 830 (Me. 1990), the Law Court adopted section 552(a)(1) of the <u>Restatement (Second) of Torts</u> (1977) as the appropriate standard for negligent misrepresentation claims. <u>Rand v. Bath Iron Works Corp</u>., 2003 ME 122, ¶ 13, 832 A.2d 771, 774. Section 552(a)(1) provides:

One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others *in their business transactions*, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

<u>Restatement (Second) Torts</u>, § 552(a)(1) (emphasis added); <u>see also Rand</u>, 2003 ME 122, ¶ 13, 832 A.2d at 774.

Here, the plaintiffs' claim for negligent misrepresentation claim must be dismissed because the cause of action is limited to matters in which both parties have a pecuniary interest and here, the plaintiffs' have no such interest. <u>See Restatement</u> (Second) Torts, § 552(a)(1) (emphasis added); <u>Rand</u>, 2003 ME 122, ¶ 13, 832 A.2d at 774; <u>Maine Tort Law</u>, § 11.08, at 319. Accordingly, Count VII is dismissed against both defendants.<sup>5</sup>

c. Fraud By Concealment (Count VIII)

The cause of action "fraud by concealment" has not been recognized under Maine law;<sup>6</sup> however, it is well recognized in other jurisdictions and its elements are well established. To establish a *prima facie* case for fraud by concealment, a plaintiff must show:

(1) that the defendant had material factual information plaintiff did not have and could not have discovered through reasonable diligence; (2) that defendant had a duty to communicate that material information to plaintiff; (3) that the defendant deliberately failed to communicate the information to plaintiff; (4) that the plaintiff justifiably relied on defendant to communicate the material information; and (5) that plaintiff was injured by defendant's failure to communicate the material information.

Pulsecard, Inc. v. Discover Card Servs., No. 94-2304-EEO, 1996 U.S. Dist. LEXIS 3660, at

\*10 (D. Kan. March 22, 1996) (citations omitted).

Here, the plaintiffs have pled by inference that both defendants had material factual information that the plaintiffs' decedent did not have and could not have discovered through reasonable diligence. See Compl., at  $\P\P$  75, 78. In addition, the plaintiffs have pled that both defendants had a duty to communicate that information

<sup>&</sup>lt;sup>5</sup> Although the defendant Eli Lilly has not moved to dismiss this count, the court finds that the plaintiffs have failed to state a cause of action for negligent misrepresentation against the either of the defendants, and therefore, the court's decision applies to Eli Lilly as well.

<sup>&</sup>lt;sup>6</sup> Maine does recognize "fraudulent concealment" and has a statute addressing the concealment of a cause of action beyond the statute of limitations. See 14 M.R.S.A. § 859 (2003).

to the decedent and that they deliberately failed to do so. See id., at  $\P$  76. Further they have pled that the decedent justifiably relied on both of the defendants to communicate the material information and that he was injured by the defendants' failure to do so. See id., at  $\P\P$  78, 79, 83. Accordingly, Count VIII withstands dismissal.

# IV. Damages

### a. <u>Punitive Damages</u>

Punitive damages cannot be recovered in the absence of implied or actual malice. "Express malice exists when 'the defendant's tortious conduct is motivated by ill will toward the plaintiff.'" <u>St. Francis De Sales Fed. Credit Union v. Sun Ins. Co. of N.Y.</u>, 2002 ME 127, ¶ 16, 818 A.2d 995, 1001 (quoting <u>Tuttle v. Raymond</u>, 494 A.2d 1353, 1354 (Me. 1985)). "Implied malice arises when 'deliberate conduct by the defendant, although motivated by something other than ill will toward any particular party, is so outrageous that malice toward a person injured as a result of that conduct can be implied.'" <u>Id</u>. "Implied malice, however, is not established 'by the defendant's mere reckless disregard of the circumstances.'" <u>Id</u>.

Here, the plaintiffs' complaint alleges that the defendants acted maliciously towards the decedent. See Compl.  $\P\P$  77, 80, 81, 84. The plaintiffs' allegations of malice refer to conduct that could be so outrageous that malice towards the decedent can be implied, and hence, the plaintiffs are permitted to maintain their claim for punitive damages based on a theory of implied malice. See Tuttle, 494 A.2d at 1354.

## b. Pain & Suffering (Count IX)

Because the plaintiffs' claims for fraud and fraud by concealment withstand the defendants' motion to dismiss, the plaintiffs' request for pain and suffering damages also survives dismissal.

## **DECISION**

Based upon the foregoing, and pursuant to M.R. Civ. P. 79(a), the Clerk is

directed to enter this Decision on the Civil Docket by a notation incorporating it by

reference and the entry is

Defendant CVS's Motion to Dismiss Counts I, II, III, IV, V, & VII is GRANTED; Defendant CVS's Motion to Dismiss Counts VI, VIII, & IX is DENIED; Defendant Eli Lilly's Motion to Dismiss is DENIED; and The court Dismisses Count VII as to Defendant Eli Lilly.

Dated: August 3, 2004

Robert E. Crowley Justice, Superior Court

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VS ELI LILLY AND COMPANY - DEFENDANT

Attorney for: ELI LILLY AND COMPANY ROBERT STIER PIERCE ATWOOD ONE MONUMENT SQUARE PORTLAND ME 04101 SUPERIOR COURT CUMBERLAND, ss. Docket No PORSC-CV-2003-00538

#### DOCKET RECORD

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#### Docket Events:

10/02/2003 FILING DOCUMENT - COMPLAINT FILED ON 10/02/2003

10/07/2003 Party(s): DANNY TARDY ATTORNEY - RETAINED ENTERED ON 10/02/2003 Plaintiff's Attorney: C DONALD BRIGGS

> Party(s): ESTATE OF MICHAEL TARDY ATTORNEY - RETAINED ENTERED ON 10/02/2003 Plaintiff's Attorney: C DONALD BRIGGS

- 10/07/2003 Party(s): DIANE TARDY ATTORNEY - RETAINED ENTERED ON 10/02/2003 Plaintiff's Attorney: C DONALD BRIGGS
- 11/20/2003 Party(s): DANNY TARDY,ESTATE OF MICHAEL TARDY,DIANE TARDY DISCOVERY FILING - NOTIFICATION DISCOVERY SERVICE FILED ON 11/20/2003
- 11/20/2003 Party(s): DANNY TARDY,ESTATE OF MICHAEL TARDY,DIANE TARDY SUMMONS/SERVICE - CIVIL SUMMONS FILED ON 11/20/2003
- 11/20/2003 Party(s): DANNY TARDY,ESTATE OF MICHAEL TARDY,DIANE TARDY SUMMONS/SERVICE - CIVIL SUMMONS SERVED ON 11/14/2003 Page 2 of 7

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### STATE OF MAINE CUMBERLAND, ss.

SUPERIOR COURT CIVIL ACTION DOCKET NO. CV-03-538

DANNY TARDY and DIANE TARDY, Individually and as Personal Representatives of the ESTATE OF MICHAEL TARDY, Plaintiffs

v.

ORDER ON ALL PENDING MOTIONS

ELI LILLY AND COMPANY, Defendant

Before the Court is Defendant Eli Lilly and Company's Motion to Preclude the Expert Testimony of Dr. Michael J. Ferenc and Dr. Paul Fitzgerald and Motion for Summary Judgment.

## BACKGROUND

Defendant Eli Lilly and Company ("Eli Lilly") manufactures and distributes a drug known as Zyprexa, which is used to treat Attention Deficit/Hyperactivity Disorder ("ADHD"). Plaintiffs Danny Tardy and Diane Tardy ("Plaintiffs"), both individually and as the personal representatives of the Estate of Michael Tardy ("Michael"), sued Eli Lilly after Michael's death at the age of 27 in June 2002. The Plaintiffs' Complaint asserts counts of strict liability, negligence, breach of warranty and fraud against Eli Lilly due to Eli Lilly's alleged failure to disclose certain side effects of Zyprexa. The Plaintiffs claim that Michael's long-term use of Zyprexa caused a series of conditions that ultimately left Michael in a hyperosmotic, hyperglycemic, non-ketotic coma, which resulted in his death.

Eli Lilly now moves for summary judgment on the basis that the Plaintiffs cannot present sufficiently reliable evidence to show that Michael's injuries were caused by Zyprexa. Eli Lilly states that "the only potential sources of such evidence is [sic] Dr. Michael J. Ferenc and Dr. Paul Fitzgerald," Defendant's Motion for Summary Judgment, page 1, and their testimony is not admissible because it fails to conform to the Maine Rules of Evidence.

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Eli Lilly states that Dr. Ferenc, a forensic pathologist, bases his opinion that Michael died as a result of taking Zyprexa solely on a postmortem urine dipstick test, which Eli Lilly states "both scientific literature and various courts have deemed unreliable." Eli Lilly states that the more "generally accepted" vitreous test should have been performed immediately postmortem and used by the Doctors in rendering their opinions.<sup>1</sup> Eli Lilly objects to Dr. Fitzgerald, an endocrinologist, on the basis that his opinions are derived solely from Dr. Ferenc's conclusions, which Eli Lilly believes are unreliable.

Eli Lilly further states that the facts do not support a conclusion that Michael suffered from a hyperglycemic condition prior to his death. Eli Lilly points to the medical notes of Dr. John Bell, Michael's psychiatrist, who recorded that Michael was "fit and healthy" and "playing a lot of basketball" nine days prior to Michael's death. Eli Lilly also points to the statement of Michael's mother that Michael appeared fine at a family dinner just days prior to this death. Finally, Eli Lilly states that Dr. Ferenc failed to take into account an empty vial of 60 Zyprexa pills found in Michael's bedroom. Eli Lilly argues that these facts do not support a finding that Michael was in a hyperglycemic crisis.

<sup>&</sup>lt;sup>1</sup> A vitreous test was performed about a year after Michael's death and showed a low level of glucose. The parties disagree as to the reliability of this test as the Plaintiffs argue that the sample was not properly preserved, thus rendering the test unreliable.

In sum, Eli Lilly states that Dr. Ferenc's methodology and causation opinions are unreliable. Dr. Fitzgerald's opinions rely upon Dr. Ferenc's findings and therefore are likewise unreliable. As such, Eli Lilly argues, the Court should grant its Motion to Preclude the Expert Testimony of Drs. Ferenc and Fitzgerald. If the Court grants this Motion to Preclude, Eli Lilly argues, it must also grant the Motion for Summary Judgment because the Plaintiffs cannot prove causation, a necessary element of their claims.

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### **STANDARD OF REVIEW**

Summary judgment is proper where there exist no genuine issues of material fact such that the moving party is entitled to judgment as a matter of law. M.R. Civ. P. 56(c); Arrow Fastener Co., Inc. v. Wrabacon, Inc., 2007 ME 34, ¶ 15, 917 A.2d 123, 126. "A court may properly enter judgment in a case when the parties are not in dispute over the [material] facts, but differ only as to the legal conclusion to be drawn from these facts." Tondreau v. Sherwin-Williams Co., 638 A.2d 728, 730 (Me. 1994). A genuine issue of material fact exists "when the evidence requires a fact-finder to choose between competing versions of the truth." Farrington's Owners' Ass'n v. Conway Lake Resorts, Inc., 2005 ME 93 ¶ 9, 878 A.2d 504, 507. An issue of fact is material if it "could potentially affect the outcome of the suit." Id. An issue is genuine if "there is sufficient evidence to require a fact-finder to choose between competing versions of the truth at trial." Lever v. Acadia Hosp. Corp., 2004 ME 35, ¶ 2, 845 A.2d 1178, 1179. If ambiguities exist, they must be resolved in favor of the non-moving party. Beaulieu v. The Aube Corp., 2002 ME 79, ¶ 2, 796 A.2d 683, 685.

In response to a defendant's motion for a summary judgment, a plaintiff having the burden of proof at trial must produce evidence that, if produced at

trial, would be sufficient to resist a motion for judgment as a matter of law. *Northeast Coating Technologies, Inc. v. Vacuum Metallurgical Co., Ltd.,* 684 A.2d 1322, 1324 (Me. 1996). This requires the plaintiff to establish a prima facie case for each element of the cause of action. *Id.* 

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### DISCUSSION

In Eli Lilly's words, its Motion for Summary Judgment is "based entirely on the contention that plaintiffs are without admissible evidence that could support the conclusion that Zyprexa caused [Michael's] death" because Eli Lilly asserts that the expert testimony of Drs. Ferenc and Fitzgerald should be precluded. Maine Rule of Evidence 702 states, "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."

In a line of cases beginning with *State v. Williams*, 388 A.2d 500 (Me. 1978), the Law Court has held that in order to be admissible, expert testimony must be relevant pursuant to M.R. Evid. 401 and will assist the trier of fact in understanding the evidence or determining a fact in issue. *Searles v. Fleetwood Homes of Pennsylvania, Inc.*, 2005 ME 94,  $\P$  21, 878 A.2d 509, 515-16. In order to meet this two-part standard for admissibility, expert testimony must also "meet a threshold level of reliability." *In re Sarah C.*, 2004 ME 152,  $\P$  11, 864 A.2d 162, 165. This threshold does not require general acceptance. *Searles*, 2005 ME 94,  $\P$  22, 878 A.2d at 516 ("General acceptance is not a prerequisite for admission, however"). Rather, "requisite to the admissibility of proffered expert testimony is a showing of *sufficient reliability* to satisfy the evidentiary requirements of relevance and

helpfulness, and of avoidance of prejudice to the defendant or confusion of the fact-finder." *State v. Boutilier*, 426 A.2d 876, 879 (Me. 1981) (emphasis in original).

In upholding the admission of various expert testimony, the Law Court has considered the following factors as relating to whether the testimony was sufficiently reliable: the expert's qualifications, whether the expert based his opinion on the facts of the particular case, and whether there is support in the relevant scientific community for the expert's opinion. *Searles*, 2005 ME 94, ¶ 29, 878 A.2d at 518. The Law Court has also cited the "spirit" of the Maine Rules of Evidence as favoring admission of expert testimony. *Williams*, 388 A.2d at 503 ("We believe it would be at odds with the fundamental philosophy of our Rules of Evidence, as revealed more particularly in Rules 402 and 702, generally favoring the *admissibility* of expert testimony whenever it is relevant and can be of assistance to the trier of fact" [emphasis in original]).

When he performed his autopsy on Michael on July 1, 2002, Dr. Ferenc was a Deputy Medical Examiner for the Maine Medical Examiners Office performing the autopsy on behalf of the State of Maine. Eli Lilly argues that Dr. Ferenc's methods in conducting the autopsy and rendering his opinion on Michael's cause of death are not sufficiently reliable. First, Eli Lilly states that Dr. Ferenc performed an inadequate factual investigation, including not examining Michael's medical history and not ordering a test to see if overdose was a possible cause of Michael's death. Second, Eli Lilly argues that Dr. Ferenc's reliance on the urine dipstick test led to an unreliable conclusion, particularly because Dr. Ferenc did not save the dipsticks or take pictures of them. Eli Lilly cites various medical texts to support its argument that the urine dipstick test is not reliable. According to Eli Lilly, Dr. Ferenc should have employed the vitreous test for glucose. Finally, Eli Lilly argues that the condition that Dr. Ferenc claims caused Michael's death – hypersmolar, hyperglycemic, nonketonic coma – did not exist because Dr. Ferenc did not find dehydration, which Eli Lilly states is "an essential characteristic of this condition."

The Plaintiffs contest many of Eli Lilly's factual assertions. First, they state that Dr. Ferenc did consider (and dismiss) overdose as the cause of Michael's death. They also assert that Dr. Ferenc spoke with Michael's family and spoke with Dr. Bell, the psychiatrist treating Michael at the time of his death, before finalizing his autopsy report. The Plaintiffs also contest Eli Lilly's assertion that urine dipstick tests are unreliable and point to various comments in which Eli Lilly's experts admit to using the test to screen for hyperglycemia. The Plaintiffs refute many of the medical text passages cited by Eli Lilly by arguing that the patients offered as examples in the medical texts differ significantly from Michael (most notably, because many of the patients in the texts were known diabetics, while Michael was not). In sum, the Plaintiffs argue, Eli Lilly has raised questions about the weight of Dr. Ferenc's testimony, not its admissibility, and, thus, summary judgment is inappropriate.<sup>2</sup>

The Court agrees with the Plaintiffs. As an initial matter, the Court notes that Eli Lilly does not challenge the qualification of either Dr. Ferenc or Dr. Fitzgerald as a medical expert. Nor is there a question that the testimony of Dr. Ferenc and Dr. Fitzgerald, if admissible, is both relevant and would be helpful to the trier of fact. Thus, the sole issue before this Court is whether the testimony of the Doctors meets the threshold level of reliability. The Court finds that the

<sup>&</sup>lt;sup>2</sup> The Plaintiffs also argue that there is various evidence other than the testimony of Drs. Ferenc and Fitzgerald that they can offer to show causation, including, inter alia, laboratory test results, medical literature, testimony of Michael's doctors, and the current labeling of Zyprexa.

proffered testimony is sufficiently reliable and therefore denies Eli Lilly's Motion to Preclude the Expert Testimony and Motion for Summary Judgment.

The Court's decision is based on the facts that Dr. Ferenc is indisputably qualified to testify as an expert in forensic pathology; that Dr. Ferenc's opinion is based on the facts of this particular case and his work on Michael's autopsy; and that the parties do not disagree that urine dipstick tests are widely used by medical experts. Whether or not a urine dipstick test was proper in the particular instance of Michael's death and autopsy is a point of disagreement between the parties that goes to the weight the fact-finder should give Dr. Ferenc's testimony, but does not speak to the admissibility of that testimony in the first place. Likewise, the parties strongly disagree about the facts surrounding Dr. Ferenc's research and investigation prior and subsequent to his issuance of the autopsy report, including Dr. Ferenc's review of Michael's medical history and whether Dr. Ferenc spoke with Michael's family and doctors, which also renders summary judgment inappropriate. See, e.g., Lever, 2004 ME 35, ¶ 2, 845 A.2d at 1179 (A motion for summary judgment must be denied if there "are competing versions of the truth" that involve genuine issues of material fact"); Arrow Fastener, 2007 ME 34, ¶ 16, 917 A.2d at 126 (Though a court may believe that one party's offered proof is more persuasive, it is the responsibility of the trier of fact to weigh the evidence and render a decision).

The Court also rejects Eli Lilly's argument that Dr. Ferenc's failure to find dehydration, an "essential characteristic" of what Dr. Ferenc stated was Michael's cause of death, means his opinions are unsupported and thus should be precluded. Indeed, Dr. Ferenc did not state that Michael was not dehydrated; he stated that he did not find dehydration during the course of his testing because, as Dr. Ferenc explained, "in the postmortem state it's almost impossible for me to do much about that." Moreover, Dr. Ferenc did testify that dehydration "is slightly supported by the autopsy in the sense that [Michael's] urine was an amber color, which suggests concentration." While the Court offers no opinion about the merit of Dr. Ferenc's statements and findings, it holds that it is sufficient to defeat summary judgment.

In conclusion, the Court notes that its finding is in accord with what the Law Court has called the "spirit" of the Maine Rules of Evidence, which favors the admissibility of expert testimony when it is relevant and helpful, as it is in the instant case. As the Court declines to preclude the testimony of Dr. Ferenc, it likewise declines to preclude the testimony of Dr. Fitzgerald because the sole basis of Eli Lilly's objection to Dr. Fitzgerald's testimony is that it extrapolates from the work of Dr. Ferenc.

Therefore, the entry is:

Defendant Eli Lilly's Motion to Preclude the Expert Testimony of Dr. Michael J. Ferenc and Dr. Paul Fitzgerald is DENIED.

Defendant Eli Lilly's Motion for Summary Judgment is DENIED.

The clerk shall incorporate this Order into the docket by reference pursuant to M.R. Civ. P. 79(a).

Dated at Portland, Maine this  $2^{n}$  day of May2008.

Robert E. Crowley Justice, Superior Court

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