Estate of Baker v. University of Vermont, No. 233-10-03 Oscv (Morris, Jr., J., May 5, 2005)

STATE OF VERMONT
ORLEANS COUNTY, SS.

ESTATE of KEVIN BAKER.
Ann Baker, Administrator,
Plaintiff

V. Docket No. 233-10-03 Oscv

UNIVERSITY of VERMONT,
FLETCHER ALLEN HEALTH CARE,
WARREN BICKEL, JOHN BROOKLYN,
LISA MARSH, LOUIS GIORDIANO, and
JOHN or JANE DOE aka "staff member,"
Defendants.

Orleans Superior Court
Docket No. 233-10-03 Oscv

DECISION AND ORDER-MOTION FOR SUMMARY JUDGMENT

The case is before the Court on Defendant Fletcher Allen Health Care's ("FAHC") Motion for Summary Judgment, pursuant to V.R.C.P. 56. FAHC seeks judgment in its favor on all of Plaintiff's claims against it. Summary judgment is "appropriate only when there are no genuine issues of material fact and a party is entitled to judgment as a matter of law." LoPresti v. Rutland Regional Health Services, Inc., 2004 VT 105, ¶ 14. Summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits ... show that there is no genuine issue as to any material fact and that any party is entitled to a judgment as a matter of law." V.R.C.P. 56 (c)(3). In making such a determination, the Court "will take as true the facts alleged by the nonmoving party, and give the nonmoving party the benefit of all reasonable doubts and inferences." Fireman's Fund Ins. Co. V. CNA Ins. Co., 2004 VT 93, ¶ 8 (citation omitted). Further, "[i]t is not the function of the trial court to resolve disputed facts when ruling on a motion for summary judgment." Quinn v. Grimes, 2004 VT 89, ¶ 7.

Undisputed Facts

1. Warren K. Bickel, Ph.D., a professor of psychiatry at the University of Vermont ("UVM") and the "principal investigator," and Lisa Marsch, M.A. submitted a grant application to the United States Department of Health and Human Services ("DHHS") National Institute on Drug Abuse ("NIDA") for a research project entitled "Improving Combined Buprenorphine-Behavioral Treatment" ("research project"), naming Regina H. White, Director of UVM's Office of Sponsored Programs, as the "official" for the "applicant organization" and UVM's Office of Sponsored Programs as the "applicant organization."

2. The other key personnel noted on the grant application were Stephen T. Higgins, Ph.D., co-investigator, Alan Budney, Ph.D, co-investigator, a TBD Resident Assistant Professor, co-investigator, Gary J. Badger, M.S., biostatistician, and John R. Brooklyn, M.D. All these individuals work for UVM, with the exception of Dr. Brooklyn who works for the Community Health Center. None of these individuals are employed by Fletcher Allen Health Care.

3. The "performance sites" designated on the grant application are the Human Behavioral Pharmacology Lab at UVM and UVM's Substance Abuse Treatment Center ("SATC").

4. Project personnel's salaries followed UVM policy, with UVM covering the difference in salary coverage for Drs. Bickel and Higgins, as necessitated by the National Institute of Health's salary cap.

5. UVM operates the SATC in Burlington, Vermont, on the FAHC campus under the terms of a lease agreement for use of the designated space.

6. Buprenorphine is a narcotic analgesic and also an opioid antagonist, displacing heroin opioids from the mu-opioid receptors when administered to persons using heroin. Buprenorphine is commonly dispensed under the trade names, "Subutex" and "Suboxone".

7. Buprenorphine also acts as a partial agonist, easing withdrawal symptoms experienced by heroin addicts.

8. Federal law requires that an Institutional Review Board ("IRB") review, approve, and supervise research projects involving human subjects.

9. Federal law requires that all IRBs "include at least one member who is not otherwise affiliated with the institution...." 45 C.F.R. § 46.107(d).[1]

10. The University of Vermont's IRB is referred to as the "Committees on Human Research". These are the "Committee on Human Research in the Medical Sciences" ("CHRMS"), and the "Committee on Human Research in the Behavioral Sciences" ("CHRBS"). The work of the latter committee is not in issue in this case. FAHC maintains its own IRB, designated the "Fletcher Allen Health Care Committee on Human Studies". From time to time, FAHC has used UVM's CHRMS as its own IRB, consistent with the by laws of the Committees on Human Research and CHRMS, which authorize such. The by-laws of the UVM CHRMS provide that FAHC's Committee on Human Studies meets "jointly" with the CHRMS only to consider human research protocols that will be carried out in FAHC facilities. The said by-laws also reference the FAHC Committee on Human Studies as "functioning under the by-laws of the Fletcher Allen Health Care Medical Staff". The said by-laws also provide in pertinent part that "To the extent that it is feasible, members of the Fletcher Allen Health Care Committee on Human Studies will also be members of CHRMS…..".

11. The IRB seeks to ensure compliance with DHHS regulations for research projects "that are sponsored by the University of Vermont (UVM) *or* Fletcher Allen health Care (FAHC)." IRB Policy and Procedure Handbook at 2 (emphasis added). Further, all research projects involving human subjects "conducted by University [of Vermont] *and/or* Fletcher Allen Health Care personnel, including students, or done under the auspices or sponsorship of *either* institution must be reviewed by" the appropriate IRB or review committee. Investigator Guidelines for Human Subjects Research, Committees on Human Research, September 27, 2001, at 3 (emphasis added).

12. Members of the CHRMS receive no compensation for their service on the

[1] The referenced regulation clearly mandates a diversity of membership reflecting a variety of interests, and expertise as relates to the work of IRBs. In pertinent part, the regulation provides that: "Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas." "No IRB may consist entirely of members of one profession." "Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas." "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." 45 CFR Part 46, § 46.107 (a)—(e).

Committee. Actions by members of the CHRMS carried out as a function of Committee appointments are as provided in the by-laws to be included under the University's general liability insurance coverage. Members of the CHRMS are appointed by the Vice Provost of UVM. Members of UVM's CHRMS are not appointed by FAHC. Meetings of the CHRMS are held on UVM premises. All meetings of the CHRMS pertinent to review of the research project in issue in this case were convened at 5:00 PM.

13. Both FAHC and UVM personnel serve on the twenty-two member CHRMS. At the time of initial approval of the buprenorphine study in issue in this case, the CHRMS included nine physicians who were employed both as professors at UVM and as physicians at FAHC. In addition, two members--Marcia Dunham, a research pharmacist and Michealanne Rowen, cardiology research nurse, both solely employees of FAHC served on the Committee. Nine additional members of the CHRMS were employed solely by UVM. The twenty-first member of the CHRMS was an attorney in private practice, and the twenty-second member a priest employed by St. Michael's College. Excepting the nine physicians who were employed both by UVM and FAHC, only two other members of the CHRMS are employees of FAHC. The by laws applicable to CHRMS provide that the chair of the CHRMS must be a UVM faculty member.

14. The project in issue in this case was assigned number "99-207" for reference by the CHRMS. The CHRMS reviewed, approved, and supervised the research project, including its protocol and informed consent form. From May 19, 1999 through October 17, 2001, the CHRMS met a total of seven times to consider and take action with respect to the research project protocols in issue in this case. The CHRMS engaged in active and objective review of the project and its protocols, including the informed consent, as reflected in the minutes of CHRMS meetings and suggestions made from time to time as to content of protocols and informed consent. The chair of the CHRMS at each of these meetings was a physician, employed both as a professor at UVM and a physician at FAHC (Dr. Bernstein, 3/19/99-6/20/01; Dr. Homans thereafter).

15. Under the terms of the project design, UVM/SATC contracted with FAHC to provide pharmacy-related services required for the research project. Specifically, the contract provided for the services of a "full time pharmacy technician". This individual was to "prepare all medications, monitor the inventory and paper trail of all medications. S/he will insure compliance with FDA regulations and assist in the preparation of INDs". The sum payable to FAHC under the contract was to be $23,000.00. See grant proposal, Defendant FAHC's Exhibit A, p. 10.

16. FAHC pharmacy technicians and pharmacists prepared doses of buprenorphine

for individuals enrolled in the research project. These FAHC employees acted under the direction of UVM employees and pursuant to the referenced contract with UVM.

17. All buprenorphine required for the research project was ordered by and shipped to Dr. Bickel, a UVM employee. A member of Dr. Bickel's staff delivered the buprenorphine to the Investigational Drug Services Division of FAHC's Pharmacy Services. Required individual doses were then prepared and packaged by FAHC-IDS at the direction of Dr. Brooklyn of the SATC, delivered to the SATC and stored in a safe within the SATC to be later dispensed to individual patients by SATC staff, per Dr. Brooklyn's instructions, in accordance with the research project's protocol.

18. FAHC personnel were not involved with and did not engage in determining eligibility of individuals for the research project, determining when to administer buprenorphine, the size or frequency of any administered dose, actually administering a dose to an individual enrolled in the research project, monitoring an individual before or after getting a buprenorphine dose, or evaluating whether any individual participating in the project should be released and permitted to drive home after having received a dose of buprenorphine.

19. On November 29, 2001, Theodore Pecor enrolled in the UVM study and received doses of Buprenorphine—three 2 milligram-dose Subutex tablets, as prescribed for the so-called "induction phase" of Buprenorphine treatment. This medication was provided to Mr. Pecor by SATC staff, from a stock of induction doses maintained in a safe at the SATC. Mr. Pecor had previously been in treatment as a patient at the SATC, for a period of approximately ten months beginning in April, 1999. During that period of time, Mr. Pecor drove himself to the SATC three days per week to receive doses of buprenorphine, driving home afterward without any apparent adverse incident.

20. At time of his enrollment in the study, Mr. Pecor reviewed and signed an Informed Consent form stating "you must agree to limit your activities, especially driving and operation of machinery, according to the advice of the investigators while participating in this study.... Please understand that you are free not to participate in this study or to withdraw from it at any time." The Informed Consent form also provided Mr. Pecor with warning of potential adverse side effects of administration of buprenorphine, and indicated that buprenorphine may produce temporary sedation and coordination difficulties which could increase the risk of accident. Informed Consent, signed by Mr. Pecor on November 29, 2001, at 7.

21. Pursuant to the research project's protocol, certain sobriety tests were administered by SATC personnel prior to allowing an enrolled individual to leave the SATC.

22. No FAHC personnel were involved in administering the buprenorphine or monitoring and releasing Mr. Pecor from the SATC on November 29, 2001. There is no evidentiary showing that any FAHC personnel or employees were aware of Mr. Pecor's treatment, personal status, or circumstances of his departure from the SATC on November 29, 2001.

23. The Project's protocol and underlying agreements did not assign to FAHC personnel any functional responsibilities for actual administration of the buprenorphine or the monitoring of and the circumstances of release of patients from the program.

24. On November 19, 2001, buprenorphine, in its forms of Suboxone or Subutex, were "investigational drugs". They were not approved by the Food and Drug Administration ("FDA") until October, 2002. As such, the FDA had not generated any patient information literature, or counseling materials/guidelines or "warnings" recommended for use in conjunction with the dispensing or administration of these drugs. No such literature or documents accompanied the drugs provided to the FAHC pharmacy in conjunction with its preparation and provision of buprenorphine doses to the SATC.

25. As a research pharmacist employed in the Investigational Drug Service Division of FAHC's Department of Pharmacy Services, Marcia Dunham, is, and was on November 29, 2001, familiar with the properties of buprenorphine, and its effects upon patients following administration of the drug. Ms. Dunham had worked with Dr. Bickel on buprenorphine studies for a number of years preceding the events in issue in this case. As noted, Ms. Dunham also served as a member of the CHRMS during the period in issue, and participated in Committee review and approval of the Project #99-207 and its protocols.

26. Participation in the SATC research project was a voluntary undertaking on the patient's part. If an individual enrolled in the SATC research project chose to disregard or otherwise not follow either the terms of informed consent related to treatment, or a research project investigator's recommendation not to leave the SATC or operate a motor vehicle, research project personnel did not have the

authority to prevent an enrolled individual from doing so.[2]

27. On November 29, 2001, Mr. Pecor "passed" the protocol's sobriety tests in the assessment of the SATC screener, and SATC staff permitted him to leave SATC. Mr. Pecor left and began driving towards his home in Johnson. The state of Mr. Pecor's sobriety upon departure from the SATC is a matter of factual dispute among the parties.[3]

28. While Mr. Pecor was driving home, the vehicle that he was operating crossed the center line and struck Mr. Baker's car. The collision resulted in the deaths of Mr. Baker and his two passengers.[4]

Discussion

The parties have provided the Court with a compelling view into the world of issues associated with the state of federally-supported therapeutic medical studies involving human subjects. Along the way, the Court is well reminded of the historic evils that have been recognized in the annals of human medical experimentation, as well as the virtually miraculous discoveries that have inured to the benefit of all in consequence of scientific studies involving human subjects. With respect and care owing to such profound concerns and interests, we venture to determine the present Motion.[5]

The key to Plaintiff's claims against FAHC is the well-recognized doctrine of *respondeat superior,* under the terms of which an employer is vicariously liable for the actions of employees committed "within the scope of their employment". Poplaski v. Lamphere, 152 Vt. 251, 257 (1989). Thus, it is critical to the maintenance of Plaintiff's claims against FAHC that it be shown that FAHC employees, acting within the scope of their employment, breached specific cognizable duties resulting in harm to Plaintiff's deceased, and thus Plaintiff.[6] Plaintiff has stated its claims as to FAHC essentially as consisting of four components: (1) *respondeat superior/vicarious* liability; (2) negligent review/approval/supervision of SATC activities by FAHC employees as members of the CHRMS; (3) breach of duty by FAHC employees serving

[2] "Authority" being of course distinct from the issue of any duty or responsibility flowing from patient declination of SATC recommendation.
[3] Resolution of this dispute is not essential to disposition of the present Motion.
[4] Two other cases related to this incident are pending before the Court: *Fountain v. University of Vermont,* Docket No. 256-10-03 Oscv, and *Dezotelle v. University of Vermont, et. al.*, Docket No. 275-11-03 Oscv.
[5] As noted in Grimes v. Kennedy Krieger Institute, Inc., 366 Md. 29, 782 A.2d 807, 835 (2001), cited by Plaintiff, "There have been very few court decisions involving human experimentation. It is therefore very difficult for a "common law" of human experimentation to develop." Federal statutes and regulations of pertinence do of course apply broadly to the conduct of medical research involving human subjects.
[6] This formulation of the "test" on the Court's part of course omits certain other elements of the negligence calculus; the issue presented for determination is institutional culpability under the theory of *respondeat superior.*

on the CHRMS to control the conduct of patient Pecor; and (4) actual control of patient Pecor's operation of a motor vehicle by FAHC employees serving on the CHRMS. A related claim is discerned from the pleadings that sounds in pharmaceutical malpractice, addressed to the conduct of FAHC pharmacy staff in dispensing buprenorphine to the SATC. This claim is addressed separately herein.

The determinative criterion as to the primary claims clearly lies in the *respondeat superior* claim and the sufficiency of evidence related thereto. In the Court's assessment, Plaintiff's claims against FAHC fail because FAHC owed no actionable duty to Mr. Pecor or Mr. Baker, and FAHC connections to the UVM study are, in the Court's assessment, otherwise too tenuous to attach institutional liability.

Were FAHC Employees Serving on the CHRMS Acting "Within the Scope of Their Employment"?

It is necessary to review FAHC's connections to the research project and the November 19, 2001 accident. It is undisputed that FAHC employees were members of the CHRMS that reviewed and approved the research project, including the informed consent form. Further, under contract, FAHC pharmacy technicians and pharmacists stored and provided the doses of buprenorphine to UVM-SATC employees and research project investigators, who in turn administered the dose to Mr. Pecor. The SATC, while located on the FAHC campus, is, in all respects, operated by UVM.

Plaintiff maintains that FAHC employees serving on the CHRMS acted within their scope of employment when the CHRMS reviewed, approved, and supervised the research project. Further, Plaintiff points out that one FAHC employee serving on the CHRMS, Marcia Dunham, may have provided some contracted pharmaceutical services to UVM. Indeed, the credible record establishes that Ms. Dunham possessed considerable expertise as to buprenorphine and its trade versions, and impacts of the drug upon administration to patients. Ms. Dunham had participated in work and studies related to buprenorphine for a period of years preceding approval and conduct of the project in issue. Plaintiff contends that FAHC is vicariously liable for the actions of its employees who serve on the CHRMS. Notwithstanding these contentions, in the Court's assessment it is clear on the state of the record that FAHC personnel were not acting within the scope of their employment while serving on the CHRMS.

The test to determine whether certain conduct falls within the scope of employment is set forth in Doe v. Forrest, 2004 VT 37, ¶ 15. While a determination of the scope of employment is often a question of fact, it may be decided as a matter of law where "facts and the inferences to be drawn there from are not in dispute," as is the case here. Sweet v. Roy, 173 Vt. 418, 433 (2002)(internal marks omitted), *quoting* Ploof v. Putnam, 83 Vt. 252, 259 (1910).

> To establish that a servant's conduct falls within the scope of his or her employment, a plaintiff must demonstrate that the conduct: (a) is the kind the servant is employed to perform; (b) occurs substantially within the authorized time and space limits; [and] (c) is actuated, at least in part, by a purpose to serve the master.

Doe, 2004 VT 37, ¶ 15 (internal marks omitted); *see also* Brueckner v. Norwich Univ., 169 Vt. 118, 123 (1999); Restatement (second) of Agency § 228(2). Even assigning a broad interpretation to these criteria, the nature and extent of the activities of FAHC personnel serving on the CHRMS in reviewing the UVM-SATC project and protocols in this case plainly fall short of conduct "within the scope of employment" at FAHC.

FAHC employees serving on the CHRMS were not providing the services for which FAHC had employed them, thus failing the first prong of the test. The primary functions of FAHC personnel as FAHC employees were to serve FAHC's needs in providing health care and services to FAHC clients, medical professionals, and patients. Service on the CHRMS was an entirely voluntary undertaking; on this record, there was neither an expectation of service on the CHRMS as a condition of FAHC employment, nor any apparent consequence of an individual's election not to serve. FAHC employees serving on the CHRMS may have been asked to serve on the CHRMS based upon the same expertise and credentials that led to FAHC employment; however, this does not equate to a conclusion that their service on the CHRMS was the kind of service FAHC employed them to do. Indeed, CHRMS members were asked to serve by and worked at the discretion of UVM's Vice Provost for Research and acted under the direction and control of the Chair of the Committee, a physician employed by both UVM and FAHC. The by laws provide that the Chair of the Committee must be a UVM faculty member. As to the nine physician members of the CHRMS who were employed both by UVM as medical faculty and FAHC as staff physicians, a stronger case might be made as to "scope of employment" of the physicians, as UVM faculty employees. That is, as medical faculty members rather than staff physicians, medical research and related activities might be considered to be not an unexpected consequence of employment as a medical faculty member. However, as relates to FAHC employment, it is clear on this record that the staff physician's responsibility with regard to FAHC is to provide patient care and directly related treatment services.

FAHC from time to time presented its own research projects to the CHRMS for review, utilizing the CHRMS as its IRB. However, it was not required to do so, and apparently FAHC maintained its own IRB, the FAHC Committee on Human Studies, which could be utilized. The project in issue in this case was generated and implemented entirely by UVM through its SATC. The sole exception being the contract with FAHC for pharmacy services, a relatively insignificant component monetarily of the project and the grant providing the financing. There is no genuine issue that as related to CHRMS review of Project/Protocols # 99-207, the CHRMS was functioning as UVM's IRB, and not FAHC's IRB.

UVM in its by laws for the CHRMS provided that actions of the members of the CHRMS

were to be included in the University's general liability insurance coverage. Certainly, this latter action on the part of UVM does not equate to a legal conclusion; however, it serves as a declaration on the part of UVM that the institution considers the work of the members of the CHRMS to be University work for which the institution may be liable.

CHRMS members were not paid for their service on the board, which met at UVM. The meetings at which the project and protocols in issue in this case were the subject of CHRMS review and action all were convened at or shortly after 5:00 PM. On this record, and giving due consideration to the fact that the employees here were in professional service, there is no evidence fairly and reasonably tending to establish that FAHC employee service on the CHRMS occurred "substantially within the authorized time and space limits" customarily expected in performance of job functions at FAHC.

Was CHRMS service by FAHC employees "actuated, at least in part, by a purpose to serve the interests" of FAHC? Probably, at least from the perspective of the employee. It would be quite ingenuous to ignore the motivations and professional interests of the individuals involved, as concerns the decision to engage in volunteer service on the CHRMS. As health care professionals, the individuals would no doubt have professional interest in remaining abreast of developments in medical research, being exposed to the various research proposals presented to the CHRMS for review. Information gained in course of service on the CHRMS certainly might enable the individual to perform his/her assigned duties more effectively. Service on the CHRMS might be perceived as helpful in provision of knowledge as to CHRMS procedures, as relates to preparation of FAHC research projects that might go before the CHRMS for review, even if the particular member/employee might be obliged to recuse from the review. Of more immediate impact, an individual volunteering to serve on the CHRMS might view such service as an important asset in career progression or employment competition. For bad or good, such motivations and purposes cannot be ignored. They would certainly extend as well to a wide variety of activities engaged in as a volunteer and related to profession, such as participation in professional societies or community service efforts related directly or indirectly to professional role. Standing alone though, they do not serve to establish that CHRMS service was within the "scope of employment" at FAHC.

The conclusion urged by Plaintiff—that FAHC employees serving as volunteers on the CHRMS were acting within the scope of their employment at FAHC—is just not sustainable on the record presented. The "threads" are just too tenuous. While it is tempting to engage in speculation as to institutional interests that might play out, or be invoked in consequence of the decisions of any institution's IRB, we must be governed by the competent record in our determinations, and not speculation. There is in our assessment no genuine issue of fact presented as to scope of employment.

Since FAHC employees serving on the CHRMS were not acting within the scope of their employment, Plaintiff's claims asserting institutional culpability on the part of FAHC for

CHRMS' actions are unsustainable.[7]

FAHC Pharmacy Negligence

Plaintiff's other claims involve alleged negligence in the pharmaceutical services provided to the research project by FAHC. As the undisputed facts demonstrate, FAHC pharmacists and pharmacy technicians acted pursuant to the requests of research project investigators and the research project's protocol. There is no claim here to the effect that FAHC provided medications other than as specified; that is, that there was negligence associated with erroneous dosage or quantity or quality of the medication prescribed. There is no claim of pharmaceutical malpractice premised upon erroneous "filling" of a prescription. FAHC pharmaceutical services prepared the dose of buprenorphine and gave it to a research project investigator to administer, and never interacted in any way with Mr. Pecor or others enrolled in the research project. The actions of those pharmaceutical employees cannot, as a matter of law, be viewed as negligent.

Plaintiff's negligence claim rests on the theory that FAHC pharmacy employees made no effort to ensure that proper release procedures were being used by SATC, or that they otherwise failed to provide proper warnings related to the consequences of administration of buprenorphine during the so-called "induction" phase. In the present case, FAHC pharmacy employees were acting within their scope of employment with FAHC in dispensing the buprenorphine to research project investigators; however, their actions, as a matter of law, were not negligent.

It is well established that liability for negligence must be predicated upon a duty of care, the existence of which is primarily a question of law to be determined by the Court. Duty may be viewed as an expression of the sum total of those considerations of policy which lead the law to say that the plaintiff is entitled to protection. Denis Bail Bonds Inc. v. State of Vermont, 159 Vt. 481, 487 (1993) (internal marks and citations omitted); Sorge v. State, 171 Vt. 171, 174 (2000); W. Prosser & W. Keeton, The Law of Torts § 53, at 538 (5th ed. 1984). Plaintiff in this case asks the Court to extend a duty of care from a pharmacist or pharmacy to a patient and a third person for what amounts to the lawful filling of a prescription given directly to the prescribing doctor. We decline, as a matter of law in this case, to recognize such a duty on the

[7] Is an IRB ever to be considered an entity separate from its parent institution for purposes of claims arising in the conduct of research projects that have been reviewed and approved by the IRB? Are individual IRB members liable in their individual capacities for actions undertaken as IRB members in reviewing and approving research projects? Plaintiff has provided some authority which suggests that liability might attach to IRBs under certain circumstances, noting one Oklahoma case in which IRB members were sued in their individual capacities. See, Anderlik and Elster, *Lawsuits Against IRBs: Accountability or Incongruity?,* 29 Journal of Law, Medicine and Ethics 220 (2001). As the authors note, there is very little authority on the questions, and distinct and persuasive contentions both favoring and opposing extension of liability to IRBs and members. Neither of the referenced scenarios is in issue as relates to the parties and their capacities presented in this case.

part of the FAHC pharmacy as relates to the interests of Mr. Pecor, Mr. Baker, or to SATC research project personnel.

While apparently never explicitly treated by our Supreme Court, we consider the so-called "learned intermediary doctrine" adopted in a majority of jurisdictions to be of significant dispositive effect in determining the present claims. The learned intermediary doctrine, first recognized in 1966, initially stood for the proposition that a prescription drug manufacturer had a duty to warn of possible side effects in some patients only to a purchasing doctor, the learned intermediary between the manufacturer and patient, and not directly to the patient. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). The majority of jurisdictions have expanded this approach to cover pharmacists as well. Cottam v. CVS Pharmacy, 764 N.E.2d 814, 819 (Mass. 2002) ("[T]he overwhelming majority [of jurisdictions addressing this issue] hold that, in general, a pharmacy has no duty to warn its customers of side effects."); McKee v. American Home Products, Corp., 782 P.2d 1045, 1048-49 (Wash. 1989)(joining the majority of states that hold a pharmacist has no duty to warn). Some jurisdictions have reached this conclusion through expanding the learned intermediary doctrine, while others have used an independent analysis. *See, e.g.,* Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 395 (Ill. 1987), *cert. denied*, 485 U.S. 905 (1988)(expanding the scope of the learned intermediary doctrine to pharmacists), *compare with* McKee, 782 P.2d at 1048-49(finding no duty to warn on the part of pharmacists, independent of the learned intermediary doctrine). In either case, the majority of jurisdictions have apparently concluded that pharmacists have no duty to warn patients of the dangers of a drug provided pursuant to a physician's lawful prescription. *See e.g.,* Tardy v. Eli Lilly & Co., 2004 WL 1925536 (Me.Super. 2004); Walls v. Alpharma USPD, Inc., 887 So.2d 881, *4 (Ala. 2004); Cottam, 764 N.E.2d at 819; Brooks v. Walmart Stores, Inc., 535 S.E.2d 55 (N.C. App. 2000), *review denied*, 547 S.E.2d 2 (N.C. 2001); Walker v. Jack Eckerd Corp., 434 S.E.2d 63, 67-68 (Ga. 1993); McKee, 782 P.2d at 1048-49; Adkins v. Mong, 425 N.W.2d 151, 152 (Mich.App. 1988); Eldridge v. Eli Lilly & Co., 485 N.E.551, 552-53 (Ill.App. 1985); Pysz v. Henry's Drug Store, 457 So.2d 561, 562 (Fla. Dist.Ct.App. 1984).

A number of policy considerations underpin the rationale of these cases. "[R]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment.... [T]he physician is in the best position to determine the proper drug therapy and to decide how and when to inform a patient of its risks and benefits." Silves v. King, 970 P.2d 790, 794 (Wash.App. 1999). Further, the "pharmacist owes his customers a duty to properly fill lawful prescriptions," and not to second guess or otherwise investigate a prescription that a physician has already determined is proper for his or her patient. Adkins, 425 N.W.2d at 152. Finally, a "pharmacist presented with a prescription ordered by a duly licensed physician is not at liberty to substitute his judgment of the product's safety for the patient for that of the physician." Coyle v. Richardson-Merrel, Inc., 584 A.2d 1383, 1387 (Pa. 1991).

We note that in construing whether a duty owes under the particular circumstances presented here, the existence of "warnings" or patient counseling and advisory literature

prescribed by the Food and Drug Administration and accompanying medication packaging would bear relevance. Here, the undisputed evidence is that at time of administration of the dosage of buprenorphine to Mr. Pecor, the drug was still in "investigational" status, and had not been approved by the FDA. Thus, there was no warning or patient advisory literature that had been mandated or even recommended by the FDA. No such FDA mandated or recommended literature existed, and certainly had not been provided with the drugs provided by Dr. Bickel's office to the FAHC pharmacy.

The instant case presents facts that differ from those of the majority of cases addressing the issue. This case does not involve the more typical scenario in which a physician prescribes a medication to a patient, who in turn takes it to be filled by a pharmacist. Rather, in this case, FAHC pharmacy services acted pursuant to the research project investigators' directions, who received the buprenorphine dose themselves, and in turn administered the dose to the enrolled individual. These factual differences serve in the Court's assessment to reinforce the logic and rationale underlying a conclusion that a pharmacist has no duty to warn patients or doctors under the circumstances presented here.

Accordingly, the actions of the FAHC pharmacists and pharmacy technicians cannot lead to FAHC liability under the facts of this case. FAHC pharmacy services provided the buprenorphine dose that eventually was administered to Mr. Pecor under the orders and supervision of Dr. Brooklyn and SATC professional staff. The pharmacists and pharmacy technicians provided only intermediary pharmaceutical services, and at no time played a role in carrying out or otherwise participating in the research project beyond providing contracted pharmaceutical services. They owed no duty to warn, monitor or control Mr. Pecor or to provide warning to any investigator in the research project, and indeed never even came into contact with Mr. Pecor. There is no suggestion, and certainly no evidentiary showing, that the FAHC pharmacy personnel provided anything other than medication that was precisely as indicated in the orders for its dispensation. Nor do the pleadings, much less competent evidence, serve to identify any specific employee of FAHC pharmacy who engaged in conduct that would serve as basis for assigning culpability to FAHC as alleged. No breach of applicable standard of care; no breach of obligation of cognizable informed consent obligation. Therefore, no culpability as a matter of law, entitling FAHC to summary judgment herein.[8]

[8] Plaintiff maintains that, consistent with Peck v. The Counseling Service of Addison County, Inc., 146 Vt. 61 (1985), FAHC was entrusted with a duty of care, to monitor and control the activities of Mr. Pecor, owing to a "special relationship" which existed under the terms of the project design and protocols approved by the CHRMS, and the participation of FAHC employees in both the CHRMS review and the dispensing of buprenorphine by the FAHC pharmacy. Peck is in our assessment inapposite. There, reviewing the provisions of the Restatement of Torts (2d) § 315, the Court held that notwithstanding patient privilege, a clinical therapist who knows, or should know consistent with professional standards, that the patient poses a serious risk of danger to an identifiable victim has a duty to exercise reasonable care to protect him or her from that danger. In Peck, a long standing therapeutic relationship existed between patient and therapist. Patient had revealed to therapist that he intended to burn down his parents' barn, and then did so. Under the circumstances, the therapist was privy to very specific information as to an intended harm that patient had declared that he would commit to specific victims. Quite logically, the holding imposes a duty to exercise reasonable care to avert the harm. In Peck, the Court also notes the general rule that

Conclusion

Plaintiff asserts that FAHC owed Mr. Baker a duty. Absent a duty of care owed to a plaintiff by a defendant, an action for negligence fails. Farnham v. Inland Sea Resort Properties, Inc., 175 Vt. 500, 501 (2003). Based on the analysis above, and viewing the facts in the light most favorable to Plaintiff, neither FAHC employees nor FAHC as an entity owed a duty to Mr. Baker as related to the specific claims raised in this case.

Plaintiff claims that the CHRMS-approved informed consent form created a special relationship between CHRMS and Mr. Pecor, leading to a duty on the part of CHRMS to control Mr. Pecor. Plaintiff extends this contention to a claim that CHRMS had actual control over Mr. Pecor on November 29, 2001. As we conclude above, FAHC employees were not acting within their scope of employment in their service on the CHRMS. The entity responsible for the conduct of the research study in issue in this case was, and remains, the University of Vermont acting through its SATC. The Institutional Review Board's exercise of oversight with respect to the project and its protocols does not, on this record, serve to draw FAHC into the circle of liability even though certain individuals, who happened to be employed by FAHC, also happened to serve on the IRB. It is clear, and not in the Court's assessment subject to genuine factual dispute, that in all instances of CHRMS review of Project/Protocol # 99-207, the

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ordinarily, there is no duty to control the conduct of another to protect third persons from harm. The key thread associated with attachment of duty is one's ability, consistent with the nature of the special relationship, to exercise control over the conduct of the actor. The principles detailed in Peck are certainly of application in our assessment here. However, here, it was UVM-SATC that developed and designed the project, maintained a specific treatment relationship with Mr. Pecor, and administered day to day details of Mr. Pecor's treatment, extending to administration of buprenorphine and assessment of its effects upon him. FAHC, either institutionally or through the incidental service of certain of its employees on the CHRMS, had no direct involvement in Mr. Pecor's treatment. No patient relationship existed. In the Court's assessment, review and approval of the protocols generally applicable to the conduct of the UVM-SATC buprenorphine project does not fairly and reasonably serve to establish the "special relationship" contemplated by Peck and the Restatement between Mr. Pecor, and FAHC and its employees serving as volunteers on the CHRMS, from which specific duty to control and warn might otherwise be derived. It is logical and reasonable to extend a duty to control and/or warn in a therapeutic relationship where there is a specific, current knowledge base as to a patient's status and specifically identifiable risks; no duty would otherwise extend though, consistent with Peck and related authority cited by the parties. Grimes v. Kennedy Krieger Institute, Inc., 366 Md. 29, 782 A.2d 807 (2001), referenced by Plaintiff in its contention that duty, and liability on the part of FAHC derive from a "special relationship" created by approval of the project protocols and Informed Consent, is not to the contrary. In the Grimes case, which involved a non-therapeutic research program studying effects of exposure to lead paint by children, the issue was the sponsoring institution's liability for injuries sustained in the program after the IRB's approval of an informed consent which failed to disclose known risks to the otherwise healthy children involved, whose "consent" to participation in the project was given by their parents, accompanied with certain financial and other economic benefits. In the Court's assessment, the Grimes decision, not surprisingly, holds essentially that a "special relationship" commonly exists between medical researchers and their subjects from which duties derive the breach of which may result in civil liability. The circumstances of the Grimes case would appear to have been particularly egregious: non-therapeutic study of exposure of otherwise healthy children to lead paint, without full and reasonable disclosure of known risks, with consent being given by parents under circumstances found by the Court not to have been in the children's best interests. We have determined under the circumstance presented here that no duty attaches to FAHC as an institution; that there is no genuine issue of fact pertinent to the same. While the principles of Grimes and other authority cited by Plaintiff may feature in the resolution of other claims presented in the case, they do not dictate the extension of liability as a matter of law to FAHC as an institution.

CHRMS was serving as the IRB for UVM, and not FAHC. FAHC as an institution did not participate in any significant manner in the design, monitoring, or implementation of UVM-SATC's research study. The particular circumstance of service of FAHC employees on the IRB reviewing the project here and its protocols is not reasonably shown to be within the scope of these individuals' employment by FAHC. There is in the Court's assessment no genuine issue of fact as to this point. Further, FAHC pharmacists and pharmacy technicians, while certainly bearing distinct professional responsibilities generally speaking, owed no duty to either Mr. Pecor or Mr. Baker as related to the specific claims presented here.

We grant that certain aspects of the CHRMS, its organization, procedures, lines of authority and thus accountability, may appear to some to be as in the ironic phrase not uncommonly used by Vermonters—"Plain as Mud!". However, our sworn obligation is to assess the merit of the Plaintiff's claims against FAHC upon the evidentiary showing presently made and the arguments advanced on this record. We have previously granted Plaintiff's request for extension of time to engage in further discovery and preparation to respond to the present Motion for Summary Judgment, so that Plaintiff would not be required to prematurely respond, given the complex issues in the case. In our assessment, Plaintiff has failed to present sufficient evidence to establish genuine issue on any of the theories advanced as relates to the Defendant FAHC's Motion.[9]

Construing the facts in a light most favorable to Plaintiff we conclude that there is no genuine issue as to material fact and that Defendant is entitled to summary judgment as a matter of law. Defendant FAHC's Motion for Summary Judgment is **GRANTED**.[10]

So Ordered at Newport, Vermont, this ____th day of May, 2005.

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Walter M. Morris, Jr.

Presiding Judge

[9] We have not expressly discussed an alternative theory discerned from the pleadings of the Plaintiff, that FAHC is accountable here in that the research study was in effect a joint venture of the two institutions. There is no genuine issue on this record that UVM-SATC was the sole entity directing, and in control of the conduct of the project. FAHC did not possess or exercise co-equal authority to direct and control. As noted, FAHC exercised a relatively minor role here, dispensing the required drug as directed, and in manner directed by, SATC. Participation of certain employees of FAHC as members of the IRB does not serve to convert UVM-SATC's project into a joint venture.

[10] In consequence of the Court's determination of the Motion for Summary Judgment, FAHC's Motion to Dismiss, filed on or about September 7, 2004, and the pending Motion to Compel Discovery, filed on or about September 27, 2004, are considered moot.