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Medical Malpractice Liability in Human Research

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INTRODUCTION

In addition to the plethora of statutes and regulations, human research in America is influenced by medical malpractice litigation. The fear of such litigation may be a larger influence than the actual litigation. Unfortunately, much of American medical practice is conducted with this fear in mind. The following discussion is intended to explain the theories and process of medical malpractice litigation when focused on human research.

THEORIES OF LAW THAT MAY ARISE IN LAWSUITS BY RESEARCH PARTICIPANTS

Theories That a Research Participant May Use to Recover Damages

The most common allegation against an investigator, an institution, or a sponsor is one of negligence. Negligence in a medical malpractice action is defined as a deviation from the standard of care for a reasonable physician in the same or similar circumstances. The law does not apply a scientific formula to this definition, and in some areas of research, the denominator of such an equation would be extremely small. However, a study participant who claims to have been injured by a study also may raise many other theories. Examples include

- **Lack of informed consent:** A participant may contend that he was not told of a risk of injury that materialized. The specifics of what constitutes informed consent in the research setting is discussed at length in Chapter Five. The burden is on the investigator to obtain informed consent. An institution may also be held liable. In contrast, one federal court of appeals has held that a sponsor cannot be held liable for failure of an investigator to obtain informed consent (Anderson v. Lanier Memorial Hospital).
- **Battery:** If a person does not consent to a touching, the defendant is liable for battery. The interesting feature of this tort is that a battery requires that the defendant act intentionally but the plaintiff does not have to prove a physical injury or offer expert testimony as to what a reasonable physician would do (Woodbury v. Courtney). Most courts disfavor this cause of action in looking at medical care because a patient usually consents to some touching and the true issue is the nature of the touching. Did the physician act negligently in performing the surgery or was he negligent in failing to disclose a risk that eventually materialized?
- **Breach of confidentiality:** A participant may seek damages for unauthorized disclosure of medical or other personal information collected during a study. The mere disclosure that a participant is in a study may be the basis for such a lawsuit.
- **Infliction of emotional distress**: A researcher may be accused of causing emotional distress to a participant, either negligently or intentionally. This claim, for example, could arise in behavioral studies where a researcher is examining the response of participants to horrific, but false, information. Participants, or

even their family members, may also seek damages for events during a biomedical study that cause emotional distress.

- **Fraud:** A disgruntled participant often alleges fraud by an investigator in that the participant contends he was not aware that he was enrolled in a study or did not know the extent of the study. This was intentionally hidden from him. The allegation of fraud extends the statute of limitations (discussed below) to some period after the true nature of the events was discovered.
- **Breach of contract:** Though usually not successful, a participant may contend that the relationship between the investigator and the participant was one of contract and the researcher failed to keep his end of the bargain. Most courts do not favor categorizing the physician-patient relationship in this manner, but the detailed documents related to informed consent for a research study may sway a court to allow a breach of contract claim to go forward.
- **Product liability:** Though a common cause of action in lawsuits stemming from the use of medications or medical devices that are being marketed, product liability is not frequently seen in lawsuits arising from research studies. However, such allegations can be alleged against the sponsor, the institution, the investigator, or all of them. The strong interest in pursuing a claim under product liability in most states is that the tort is one of strict liability. This is a higher standard of care for the defendant than just simple negligence.
- **Violations of civil rights:** Research participants have also tried to recover under theories of civil rights violations. Violations of constitutional rights by government employees may give rise to a cause of action (Bivens v. Six Unknown Fed. Narcotics). For example, plaintiffs have alleged that research sponsored by government entities violated their right to privacy and right to be free from state-sponsored invasion of a person's bodily integrity under the right to due process. The key elements of a claim under a constitutional violation are "that (1) a government actor, (2) without obtaining informed consent and utilizing false pretenses to obtain participation, (3) conducted medical experiments known to have no therapeutic value and indeed known to be possibly harmful to the participants" (Heinrich v. Sweet). Exposure to government-sponsored radiation experiments that had no therapeutic value and were not disclosed to the participants have been held to be violations of the right to bodily integrity (Bibeau v. Pacific Northwest Research Foundation); Stadt v. Univ. of Rochester, In re Cincinnati Radiation Litigation.
- **Vicarious liability:** An institution, a sponsor, or even another researcher may be held liable for the acts of another because the negligent party was the employee or agent of the defendant. Many states have also endorsed the concept of apparent agency, which means that a defendant can be held liable for the acts of another where the injured party reasonably believed that the negligent party was the employee or agent of the defendant. This allegation, for example, frequently is raised in cases arising from emergency department care in a hospital. The patient assumed that an ED physician was the employee of the hospital, and the patient contends that he came to the defendant hospital because he believed it employed good physicians. The same allegation might be raised where an independent contract research organization (CRO) operates on a medical facility's campus.

Potential Liability of IRB Members

The IRB members and vicariously the institution may be liable for negligence in performing their responsibilities in reviewing, approving, and monitoring studies. For example, the university's chief bioethicist and the members of IRB were sued in Robertson v. McGee et al.

However, to date, the authors have not been able to find a verdict against an IRB or its members. Immunity provided under state peer review statutes may provide a defense.

In one of the few judicial opinions examining the role of an IRB, the failure of a facility's review committee to consider the ramifications of the interinstitutional transfer of cryopreserved human prezygotes did not vitiate the contract between parties nor did it usurp the court's jurisdiction to settle contractual disputes between the parties (York v. Jones, interpreting former Virginia statute on human research).

The Food, Drug & Cosmetic Act as Creating a Private Cause of Action

The Food, Drug & Cosmetic Act (FDCA) does not create a private cause of action. The U.S. Court of Appeals, Sixth Circuit has held that the estate of a patient who died from a toxic reaction when he took a medication refilled without a prescription could not use the FDCA as a basis for a civil lawsuit. Only the federal government can enforce the FDCA (Bailey v. Johnson). Likewise, a violation of the FDCA during clinical trials should not give rise to a separate cause of action. However, violation of a statute or regulation may be admissible as evidence of negligence.

The Venues in Which a Research Participant May File a Lawsuit

Where a lawsuit can be filed varies from state to state. Some states have a very expansive view of who can be sued in its courts. For example, New York very liberally construes what is sufficient contact with the state to give its state court's jurisdiction over a defendant (Stadt v. Univ. of Rochester). Other states are more conservative in allowing a defendant to be sued in its courts. Most states follow a "minimum contacts" analysis looking at whether the defendant could "reasonably anticipate being hauled into court there" (Stadt citing World-Wide Volkswagen Corp. v. Woodson).

To be sued in federal district court, not more than one party can be from the state in which the district court sits. This is referred to as complete diversity. Plaintiff may also gain access to the federal district court by alleging a federal cause of action.

Defenses That an Investigator, an Institution, or a Sponsor May Raise

Depending on the facts of a case, a defendant may be able to argue that he was not negligent, the participant was not injured, and the alleged injury was not proximately caused by any action or inaction of the defendant. In addition, the defendant may be able to raise one or more affirmative defenses such as the following:

- **Statute of Limitations**: Procedural law of each state mandates the time limit in which a research participant has to file a lawsuit. This ranges from one year to many years. Further confounding the calculation of a time limit are various exceptions to the statute of limitations. For example, some jurisdictions do not start the clock until the patient discovers the injury regardless of how long ago the medical care was. Many jurisdictions toll the statute of limitations until a child reaches the age of majority or for as long as an incompetent patient remains incompetent. Some states have imposed limits on these long-tails of exposure.
- **Consent:** A researcher may raise the affirmative defense that the participant consented to the touching (the study protocol). Consent is a complete defense to an allegation of battery.
- **Assumption of the risk:** Similar to the defense of consent, a researcher may allege that the participant was aware of the risk and agreed to assume the risk. The informed consent process is very useful in this defense. The more explicit and well documented that the process was, the stronger the defense (assuming the risk that is at issue was appropriately disclosed). Assumption of the risk should not be confused with a pre-injury release. Pre-injury releases of liability

by a participant are prohibited in federally regulated research studies. Likewise most state court decisions and statutes either severely restrict or prohibit such agreements on the rationale that the injured person cannot agree to release the defendant from liability before he knows what the negligence will be or what his injury will be.

- **Contributory negligence:** A jury can consider whether a participant was also negligent. In a few states, any negligence by the plaintiff is a complete bar to recovery. In other states, negligence merely reduces the amount that the plaintiff can recover. This is often referred to as comparative negligence.
- **Learned intermediary:** Some states have adopted the defense of the learned intermediary. A product manufacturer can use this as a shield where its product must be prescribed or dispensed by a physician or other licensed professional. A physician, for example, is the one who has the superior knowledge of whether an investigational drug is appropriate for a particular patient. To illustrate the point, the Illinois Supreme Court held that a drug manufacturer could not be held liable for a patient who took a medication shortly before wrecking his car and injuring his passenger. The physician, not the manufacturer, had the responsibility to determine whether the drug was appropriate for the patient and to advise the patient of the risks (Kirk v. Michael Reese Hospital).
- **Sovereign immunity:** Governmental entities, whether federal, state, or local, enjoy immunity from civil liability. This extends to its employees when they are acting in their official capacities. By statute and court decisions, a multitude of exceptions have been created to this broad doctrine. For example, in Virginia, resident physicians but not faculty physicians are entitled to sovereign immunity (James v. Jane). The federal government permits itself to be sued under the conditions set forth in the Federal Tort Claims Act, 28 USC §2671 et seq. Employees of the federal government enjoy qualified immunity for their actions.

Government Liability for Injury to Military Personnel

The Feres doctrine holds that active duty military personnel cannot sue the government or other soldiers for alleged negligence (Feres v. United States). For example, soldiers are not allowed to sue a government hospital or physicians for negligent medical care. This doctrine extends even to situations where the soldier discovers that he was an unwitting human participant in a secret military experiment (United States v. Stanley). Some justices of the U.S. Supreme Court, in a dissenting opinion, pointed out the egregiousness of the Feres doctrine in this circumstance:

Having invoked national security to conceal its actions, the Government now argues that the preservation of military discipline requires that Government officials remain free to violate the constitutional rights of soldiers without fear of money damages. What this case and others like it demonstrate, however, is that Government officials (military or civilian) must not be left with such freedom. See, e.g., Jaffee v. United States, 663 F.2d 1226 (CA3 1981) (en banc) (exposure of soldiers to nuclear radiation during atomic weapons testing); Schnurman v. United States, 490 F. Supp. 429 (ED Va. 1980) (exposure of unknowing soldier to mustard gas); Thornwell v. United States, 471 F. Supp. 344 (D.C. 1979) (soldiers used to test the effects of LSD without their knowledge); cf. Barrett v. United States, No. 76 Civ. 381 (SDNY, May 5, 1987) (death of mental hospital patient used as the unconsenting participant of an Army experiment to test mescaline derivative). [483 U.S. 669, 690].

The Time Period in Which a Research Participant Can File a Lawsuit

The statute of limitations, as discussed above, varies from state to state. For example, Virginia has a two-year limit on filing actions alleging medical malpractice. Tennessee has a one-year limitation (Hughes v. Vanderbilt University).

Another state-dependent issue is when the statute of limitations period begins to run. Some states hold that the period begins to run from the date that the cause of action accrued. This is usually the date on which the negligence occurred. However, it may also be construed to be the date that the injury occurred (when the cancer developed) or the date that the injury was discovered (when the patient discovers that he had cancer). For example, a plaintiff was not barred from filing a lawsuit in 1995 stemming from a 1945 experiment where school children were given radioactive lemonade. The press did not cover the story until 1994. However, a suit filed in 1997 was untimely in light of the 1994 press coverage (Hughes v. Vanderbilt University). As to when a plaintiff first has or reasonably should have knowledge of the critical facts of his injury, which are that he has been hurt and who has inflicted the injury, is a question of fact generally to be decided by a jury (Bibeau v. Pacific Northwest Research Foundation). In the Bibeau case, for example, the U.S. Court of Appeals held that the key question was "whether, had Bibeau seen a doctor about his symptoms [severe testicular pain, rash, enlarged lymph nodes, etc.], the doctor would have discovered Bibeau's participation in the experiments [testicular radiation of state prison inmates] and then made a connection between the two" (Id. at 11).

The limitations period for allegations of fraudulent concealment does not usually begin to run until the fraud is discovered (Heinrich v. Sweet et al.). The date of discovery by a plaintiff is a question of fact to be determined by a jury when fraud is alleged (Anderson v. Lanier Memorial Hospital) (interpreting the tolling of Alabama's statutes of limitation). The judge should decide this issue as a matter of law only when a plaintiff actually knew of the facts that would put a reasonable person on notice of fraud (Id. quoting Green v. Wedowee Hospital).

GENERAL CONCEPTS OF PROFESSIONAL NEGLIGENCE

The Basic Elements of a Negligence Lawsuit

A plaintiff must allege and prove that the defendant was negligent, that the plaintiff was injured, and that the plaintiff's injury was proximately caused by the defendant's negligence.

In a negligence action stemming from human research, a research participant must prove the standard of care for a reasonable clinical investigator, the defendant investigator deviated from the standard of care (negligence) and the participant was injured by the deviation from the standard of care (damages and proximate cause). Other causes of action may require different elements of proof.

Negligence

Negligence when applied to a medical malpractice case is usually defined as a deviation from the standard of care. Standard of care means what a reasonable physician or clinical investigator would do in the same or similar circumstances. This is not a scientific formula and is determined by the testimony of expert witnesses.

Damages

Damages are often obvious (blindness or other physical impairment, medical bills, lost income, etc.). However, a plaintiff may also seek to recover for psychological injuries, embarrassment, loss of companionship, and other hard-to-quantify damages. The challenging task for a jury is to attach a dollar figure to any damages that the plaintiff has proved that he suffered.

Punitive Damages

Also called exemplary damages, punitive damages are intended to punish the defendant for willful or wanton misconduct. This requires more than simple negligence by a defendant. The conduct must have been egregious.

Proximate Cause

Proximate cause is the legal requirement that a defendant's negligence must have caused or contributed to the plaintiff's injuries. In other words, the plaintiff would not have suffered the alleged injury (or the extent of injury) but for the defendant's negligence. This is often a challenging task when the plaintiff's condition before the alleged negligence was likely to lead to some physical impairment. The task for the jury to determine was what amount of a plaintiff's condition was caused or contributed to by the defendant's negligence.

Expert Testimony in a Research Negligence Lawsuit

Usually the testimony of an expert witness is required on the issue of what a reasonable investigator would have done. Plaintiff, because he has the burden of proof, usually must have an expert witness who will state to a reasonable degree of certainty that the defendant deviated from the standard of care for a reasonable investigator. Plaintiff, using the same expert witness or another, is usually also required to present evidence that the plaintiff's injury was proximately caused by defendant's negligence. If the plaintiff's alleged damages are not obvious, he may also need an expert witness to describe the kind and extent of injury suffered. (For a more in-depth discussion, see Morin (1998).)

Proving the Standard of Care in a Research Protocol

In order to prove the standard of care for an investigator in a clinical trial, plaintiff will usually be required to call an expert witness. The expert witness must have expertise in the same or similar field as the defendant investigator. The expert witness must show through education, training, or experience that he knows what the standard of care for a reasonable investigator in similar circumstances is. He then must testify that the defendant deviated from the standard of care for a reasonable investigator. Obviously, the precision of matching clinical experience to that of the defendant can be difficult where the defendant is on the cutting edge of a field. The trial court may give leeway in qualifying an expert witness in this area. The decision is left to the jury as to the credibility of an expert witness.

Another means of trying to establish the standard of care is by proving that an investigator violated a federal or state regulation. State courts have interpreted the significance of violating a statute or regulation differently. Many states have held that the violation of a statute is some evidence of negligence. Others, such as Maryland, have held that violating a federal research regulation is negligence per se (Grimes v. Kennedy Krieger Institute, Inc.).

A research agreement between an investigator and a participant can, as a matter of law, create a special relationship giving rise to duties of the investigator to the participant. A breach of those duties may constitute negligence (Restatement of Torts, 2nd; Grimes v. Kennedy Krieger Institute, Inc.; Moore v. Regents of University of California).

Proving a Lack of Informed Consent

Traditionally, a plaintiff must prove what a reasonable physician would tell a patient (standard of care), a deviation from that by the defendant, plaintiff was injured, and that but for the defendant's deviation from the standard of care the plaintiff would not have been injured (proximate cause). Plaintiff usually must offer expert testimony on these elements. The state courts have split as to whether the standard for determining proximate cause is one of an objective nature or subjective nature. The objective test is whether a reasonable patient would have refused the intervention if he had been told of the risk that materialized. The plaintiff's testimony, while relevant, is not determinative (Pardy v. U.S., Dessi v. U.S.). In contrast, the subjective test is whether the plaintiff, based on whatever was important to

him, would have refused the intervention if he had been advised of the risk that materialized (Canterbury v. Spence). Although not often considered by courts in the clinical research setting, the subjective standard, which has been rejected in most jurisdictions for medical malpractice actions, may be accepted as the rule for informing patients in purely elective studies. The amount of information that must be disclosed to a patient is usually inversely related to the immediacy of needing treatment. For example, emergency repair of a ruptured aortic aneurysm does not have to be preceded by the degree of detailed discussion on risks and benefits as compared with an elective breast augmentation.

Some states require in a medical malpractice trial that an expert witness testify as to what a reasonable patient would do when a plaintiff alleges that informed consent was not obtained. That is, a plaintiff must elicit from an expert witness that a reasonable patient would not have agreed to undergo the experimental therapy. Other states do not require, and some do not permit, an expert witness to testify as to what a reasonable patient would do. This is left to the jury to determine. Due to the elective nature of participation in a research project, few states are likely to require expert testimony as to what a reasonable participant would do if he had been informed of a risk that materialized.

LIMITING LIABILITY

Use of a Waiver or Release in an Effort to Limit Liability

Federal regulations expressly prohibit a clinical investigator from attempting to limit his liability through the use of a waiver or release signed by the participant prior to enrolling in the study (21 CFR §50.20). Several states have similar statutes. The law frowns on a person being asked to waive his right to be compensated for the negligence of another before the negligence occurs and before the extent of the injury is known. This is particularly true where a study participant is at a disadvantage to the better-informed investigator about the potential risks of a study.

The Supreme Court of Washington, for example, has held that a pre-injury release of negligence by a medical investigator is void as a matter of public policy. However, it made a point of saying that a patient or research participant remains free to waive the right to recover for injury in other situations. The courts in Washington will enforce a pre-injury release of liability for recreational activities. It apparently would also recognize a patient's right to give informed consent (as distinguished from a release) in a clinical study setting: "With proper informed consent, an ill patient may wish to consent to a highly experimental treatment which might otherwise not be generally accepted" (Vodopest v. MacGregor). A well-crafted informed consent document will advise the participant of risks, benefits, and alternatives. This is important from the perspective of reducing allegations that the participant was not adequately warned of potential adverse outcomes before agreeing to enroll in the study. Though not usually well received by a jury, an investigator may raise the defense that the participant assumed the risk of injury after being fully advised.

Compensation of Participants for Injury Occurring as a Result of Participation in a Research Study

Institutional policy, not federal regulation, determines whether compensation and medical treatment(s) will be offered and the conditions that might be placed on participant eligibility for compensation or treatment(s). The FDA informed consent regulation on compensation (21 CFR §50.25(a)(6)) requires that, for research involving more than minimal risk, the participant must be told whether any compensation and any medical treatment(s) are available if injury occurs and, if so, what they are, or where further information may be obtained (FDA, Information Sheets, 1998). Many commentators contend that the sponsor of a clinical trial should be responsible for providing medical care and compensation for study-

induced illness or injury, regardless of the cost and strength of the proximate cause relationship.

Sponsor Indemnification of the Investigator and Others Involved in a Clinical Study

Federal regulations do not prohibit a sponsor from agreeing to indemnify an investigator for any expenses related to defending claims for compensation for injuries suffered in a clinical trial. The investigator would be well advised to carefully review the contract with a sponsor to ascertain the scope of such an indemnity agreement: Does it include attorney's fees and other costs related to defending a claim or lawsuit? Does it include allegations of willful misconduct by the investigator? Does the investigator have the right to determine whether or not the sponsor settles a claim? Does the investigator have the right to choose what lawyer will defend him? Likewise, an institution would be well advised to consider these issues before hosting a research study.

NIH Certificate of Confidentiality

The National Institutes of Health (NIH) has the authority under federal law to issue a Certificate of Confidentiality. The certificate protects an investigator and institution from being compelled by a subpoena or court order to divulge information that would identify research participants in civil, criminal, or administrative tribunals (42 USC §241(d)). The certificates can be granted for studies collecting information that if disclosed could have adverse consequences on the research participants or damage their financial standing, employability, insurability, or reputation. The federal government need not fund a study in order to grant a certificate. Additional information on this recent federal initiative can be found at http://grants1.nih.gov/grants/policy/coc/.

Insurance Issues for Clinical Research

Investigators and institutions need to confirm that existing insurance coverage extends to research activities. As soon as an institution, investigator, or sponsor becomes aware of potential liability claims, their insurance company needs to be notified. Failure to do so in a timely manner may be a breach of the insurance contract, resulting in the defendant having no insurance coverage (United States Fire Ins. Co. v. Vanderbilt University).

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