Given the risks involved in human clinical trials, there are fewer lawsuits brought by clinical trial participants than one might expect. However, when participants do bring suit, oftentimes they will attempt to blur the lines of legal responsibility between the clinical study investigator and the manufacturer/sponsor. When faced with this scenario, it is important to clearly identify the role that the manufacturer/sponsor played in the clinical trial to determine whether they owed any legal duty to the plaintiff.

The U.S. Food and Drug Administration established guidelines to safeguard patient safety, minimize or eliminate study bias, ensure data reliability, and promote the continued development of safe and effective new drug therapies through clinical trials. These guidelines define the respective duties of the entities involved in clinical trials, which include the following:

- **Clinical Trial Sponsor**: Clinical trial sponsors initiate the clinical trial. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. 21 C.F.R. § 312.3(b). Generally speaking, the clinical trial sponsor provides funding for the trial and is responsible for selecting qualified investigators, who will actually conduct the trial. 21 C.F.R. § 312.50. Sometimes, but certainly not always, the manufacturer of the drug being tested is also the clinical trial sponsor.

- **Clinical Trial Physician Investigator**: The investigating physician is responsible for conducting the clinical trial itself. See 21 C.F.R. § 312.3(b) (investigator is the individual who actually conducts the clinical trial and under whose immediate supervision the drug is administered to the patient). These responsibilities include obtaining informed consent from the participants in the study, as well as protecting their safety and welfare. See 21 C.F.R. § 312.60.

- **Institutional Review Board (IRB)**: The IRB is the committee designated by an institution to review and approve the initiation of a clinical trial. They also conduct periodic reviews of the trial to assure the protection of the rights and welfare of the clinical trial participants. See 21 C.F.R. § 56.102(g).
Although the unique roles and responsibilities of entities involved with clinical trials are clearly defined, plaintiffs oftentimes attempt to assign legal duties to the wrong entity — sometimes suing the clinical trial sponsor as if it were directly providing medical services to the participant — or attempt to create novel legal duties. Case law that has addressed this issue has consistently held that this is not appropriate.

*Kernke v. The Menninger Clinic*, 173 F.Supp.2d 1117 (D.Kan. 2001), is the leading case on the issue. *Kernke* involved decedent Kenneth Kernke, who participated in a clinical study involving a new investigational drug for the treatment of schizophrenia. Aventis was the manufacturer of the drug and the clinical trial sponsor, and the Menninger Clinic (“Menninger”) was the clinical trial investigator. At some point during the trial, Kenneth Kernke left the facilities where the study was being performed and was later found dead in a wooded area nearby.

Plaintiffs brought a wrongful death products liability action alleging negligence and failure to warn (among other claims) against several defendants, including Aventis and Menninger. However, the court dismissed plaintiffs’ claims against Aventis, finding that as the clinical trial sponsor, Aventis did not owe plaintiff the legal duties alleged.

With respect to plaintiffs’ negligence claim against Aventis, plaintiffs alleged that Aventis failed in their duty to (1) determine whether the benefit of participating in the study outweighed the risks to decedent; (2) secure informed consent from decedent; and (3) to supervise decedent while he participated in the study. *Id.*, at 1124.

However, the court dismissed plaintiffs’ claim and held that all of these duties rest with the clinical trial investigator (Menninger), not the clinical trial sponsor or drug manufacturer (Aventis). Specifically, the court cited to FDA regulations 21 C.F.R. § 312.60 (investigators are responsible “for protecting the rights, safety, and welfare of subjects under the investigator’s care”) and 21 C.F.R. § 50.20 (responsibility for obtaining informed consent lies with the investigator). *Id.*

With respect to their failure to warn claim, plaintiffs’ argued that Aventis failed to warn Kenneth Kernke of the risks. The court noted that Kansas, like the majority of jurisdictions, follows the Learned Intermediary Doctrine. “Under the Learned Intermediary Doctrine, a drug manufacturer fulfills its legal duty to warn a patient of the risks associated with using a prescription drug if it adequately warns the patient’s prescribing physician of the risks. *Id.*, at 1121 (citing *Wright v. Abbott Labs. Inc.*, 259 F.3d 1226, 1233 (10th Cir. 2001).

The court then correctly concluded that the clinical trial sponsor (Aventis) provided adequate warnings regarding the investigational drug study to the clinical study investigator (Menninger). As a result, Aventis was entitled to rely on Menninger to properly relay the risks and warnings to the study subjects, including Kenneth Kernke, thereby relieving Aventis of any liability for failure to warn. *Kernke*, 173 F.Supp.2d at 1122.
This decision is consistent with other jurisdictions that have looked at the issue of whether or not the Learned Intermediary Doctrine applies to investigational drugs in the clinical trial setting. See, e.g., Tracy v. Merrell Dow Pharmaceuticals Inc. 58 Ohio St.3d 147 (Ohio, 1991) (“We have found no cases distinguishing between investigational drugs and FDA-approved drugs when applying the learned intermediary rule.”)

Abney v. Amgen Inc., 443 F.3d 540 (6th Cir. 2003), also clarified the separate and distinct legal duties owed by various entities involved in clinical drug studies. In Abney, the clinical study at issue was investigating a new drug and delivery system for the treatment of Parkinson’s disease. Prior to the completion of the study, the clinical study sponsor (Amgen) announced that it was terminating the study based on scientific concerns regarding the risks of the investigational treatment.

The plaintiff participants in the study believed that the treatment was helping to treat their Parkinson’s disease and brought suit seeking to compel Amgen to continue providing them with the investigational drug. In their motion for a preliminary injunction, plaintiffs asserted claims for breach of contract, promissory estoppel and breach of fiduciary duty. The district court denied plaintiffs’ motion and the Sixth Circuit affirmed.

With respect to their breach of contract claim against Amgen, plaintiffs relied on an Informed Consent Document as the basis for their claim. The physician investigators and the plaintiff participants in the study each signed the Informed Consent Document, which indicated that the study participants were informed of the risks of the study and that they could elect to continue treatment for 24 months after the end of the study. The document also informed the participants that they might be required to withdraw from the study. Id., at 544.

Rather than focus on the substance of the Informed Consent Document, the court correctly pointed out that the document did not directly bind Amgen because it did not sign the document. Further, the court concluded that the clinical trial investigators could not enter into a binding contract with the plaintiffs on behalf of the clinical sponsor (Amgen), as the investigators “were independent contractors rather than Amgen’s agents.” Id., at 548.

Plaintiffs’ promissory estoppel argument against Amgen was premised on their claim that the clinical trial investigators informed them that they would make decisions based upon the patients’ best interests and that if investigational drug proved to be safe and effective, study participants could continue to receive the medication following termination of the study. Id., at 549.

The court concluded that plaintiffs’ promissory estoppel claim failed because there was no evidence of any promise provided by Amgen directly to the study participants. Again, the court noted that clinical study investigators are not agents of clinical trial sponsors and do not have the authority to make binding promises on their behalf. Id., at 549-550.
Plaintiffs’ final claim against Amgen was that they breached their fiduciary duty to treat plaintiffs’ illness with the best medicine available. The court noted that while “[f]iduciary relationships can be informal, [ ] they must evidence circumstances showing both parties agreed that one party would be acting in the interest of the other.” Id., at 550 (citing In re Sallee, 286 F.3d 878, 892 (6th Cir.2002). Here, plaintiffs’ claim failed because there was simply no evidence that Amgen and the plaintiffs entered into any agreement that Amgen would be acting primarily for the benefit of the plaintiffs.

Consistent with the holding in Kernke, the Sixth Circuit in Abney stressed the importance of limiting the legal duties of each party to their respective roles in a clinical trial. While denying plaintiffs’ on all of their claims against the clinical trial sponsor (Amgen), the court suggested that plaintiffs could have filed their lawsuit against the other entities involved in the clinical trial, explaining that “[u]nder the FDA’s regulatory scheme it is not the pharmaceutical companies that are charged with ensuring trial participants’ well being. Rather, it is the Institutional Review Board that is meant to ‘protect the rights and welfare’ of trial participants during a clinical trial.” Abney, 443 F.3d at 551 (citing 21 C.F.R. § 56.101).

Both Kernke and Abney exemplify the importance of carefully defining the roles and responsibilities of the various entities involved in a clinical trial. Because clinical trial documents will help define these roles and dictate an entity’s legal duties (and possibly serve as a legal defense), it is imperative to focus on these documents with liability issues in mind.

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Kevin Lohman is an associate in Reed Smith’s Los Angeles office. He is a member of the firm’s Life Sciences Health Industry (LSHI) Group, practicing in the area of product liability litigation. He specializes in representing medical device and pharmaceutical companies involved in complex product liability litigation.

The opinions expressed are those of the authors and do not necessarily reflect the views of the firm, its clients, or Portfolio Media, publisher of Law360. This article is for general information purposes and is not intended to be and should not be taken as legal advice.