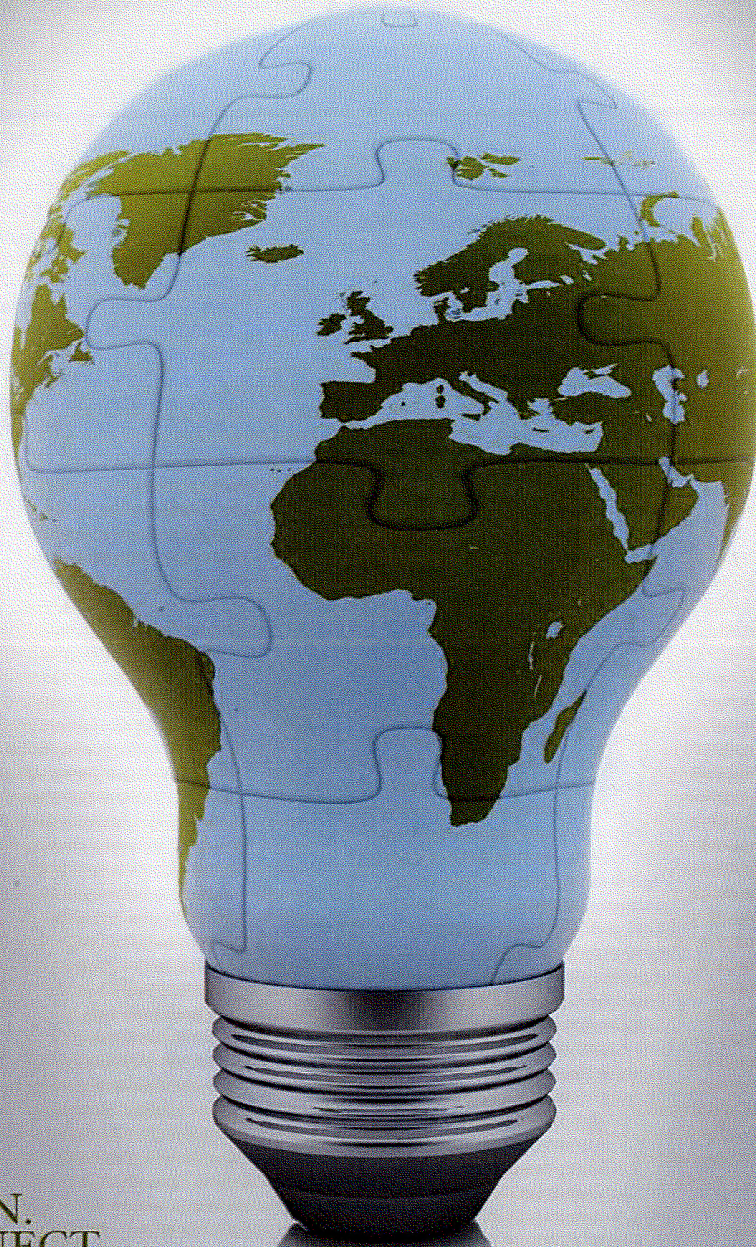


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## Spotlight on Clinical Trial Sponsorship

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**Abstract:** *What liability is associated with assuming the role of the “sponsor” in a clinical trial? This article discusses the Food and Drug Administration (FDA) regulations governing sponsorship, and how courts have interpreted those regulations in cases with a claim of injury.*

*There is a natural concern with the responsibility implied by assuming the role of “sponsor” in a clinical trial agreement. In a commercially sponsored clinical trial, for example, the site can reasonably require that a drug company assume most liability for subject injury. Pharmaceutical companies are not the sponsor; however, for Investigator Sponsored Trials (ISTs, sometimes called Investigator Initiated Trials IITs).<sup>1</sup> Between these extremes are the complex cases where a mix of delegated roles and responsibilities are assigned, and where the “duty of care” relation between a physician and their patient may take precedence in any case. This article discusses sponsorship in terms of the FDA regulations, and reviews several cases where judicial interpretation of a sponsor’s duties had an impact on liability.*

Keywords: *Sponsor, Investigator, Clinical Trial, Injury Claims*

### The Company as Sponsor

The FDA regulations define “sponsor” as

a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators. 21 CFR § 312.3(b) (2014)

As this definition makes clear, there is a difference between sponsoring a trial and conducting a trial, and this distinction can impact the sponsor’s responsibilities and liability. Further, an

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<sup>1</sup> An IST is a clinical trial where the sponsor is not a commercial entity. *What is an IST? IST JOURNAL*. Retrieved from <http://www.istjournal.eu/for-authors>



investigator can also operate as a sponsor, with all the attendant responsibilities, if they both initiate and conduct an investigation.<sup>2</sup> *Id.* Sponsors are primarily responsible for selecting investigators, providing them with the information necessary to conduct a trial, monitoring the investigation, ensuring that it is conducted in accordance with the general investigational plan and protocols contained in the [Investigational New Drug Application (“IND”)], maintaining an effective IND with respect to the investigations, and informing investigators or the FDA of any new risks or adverse effects associated with a drug. 21 CFR §312.50. Investigators are also responsible for ensuring the investigation is conducted according to the investigational plan, but are also directly responsible for protecting the trial subjects, obtaining the informed consent of human subjects, and controlling the investigational drug. 21 CFR § 312.60.

Both the sponsor and the investigator are responsible parties. The Sponsor initiates the investigation, but the investigator actually conducts the trial.

### Sponsor and Investigator Responsibilities

Subpart D of Sec. 312.50 outlines the general responsibilities of sponsors and investigators. These are shown in Table 1 below, along-with 312.20 where the responsibility for the submission of an IND to FDA is explained.

Table 1. Responsibilities of Sponsors and Investigators

Activity/ Responsibility	Sponsor – Sponsor roles and responsibilities can be delegated to a CRO unless otherwise noted	Investigator – all Sponsor responsibilities are also responsibilities for a sponsor-investigator
21 C.F.R. §§ 312.20 and Subpart D		
312.20 IND Application	<b>Responsible</b>	
312.50 General	<b>Responsible</b> for investigator selection, monitoring, study protocols, and adverse event notification	
312.52 Transfer of Obligations to a CRO	<b>CRO is Responsible</b> when assuming any obligation of a sponsor	
312.53 Selecting investigators and monitors	<b>Responsible</b> , includes verifying investigator qualifications, control of drug, and monitor selection	

<sup>2</sup> Crucially, a commercial sponsor does not operate as a sponsor-investigator merely because they initiate a trial and their employees conduct the trial; the drug company funding the trial only assumes the roles of a sponsor, while its employees conducting the trial assume the roles of an investigator. See 21 CFR § 312.3(b) and the discussion of *Darke v. Estate of Isner, infra*.



Table 1. Responsibilities of Sponsors and Investigators (continued)

312.54 Emergency research	<b>Responsible</b> for monitoring exceptions and reporting to the FDA	<b>Responsible</b> for conducting exceptions from informed consent
312.55 Informing investigators	<b>Responsible</b> for the investigator brochure, and new observations	
312.56 Review of ongoing investigations	<b>Responsible</b> for investigator compliance, evaluating investigator reports, and determining discontinuation	
312.57 Recordkeeping and retention	<b>Responsible</b> for drug shipping records, financial interest related to payments, 2-year record retention, and reserve samples for testing	
312.58 Inspection of sponsor's records and reports	<b>Responsible</b> for permitting FDA access	
312.59 Disposition of unused supply of investigational drug	<b>Responsible</b> for assuring return of unused supplies	
312.60 General responsibilities of investigators		<b>Responsible</b> for conduct according to the signed (Form 1572) investigator statement, the investigational plan, protecting the rights, safety, and welfare of subjects, control of drugs, and obtaining the informed consent
312.61 Control of the investigational drug		<b>Responsible</b> for administering the drug to subjects
312.62 Investigator recordkeeping and record retention		<b>Responsible</b> for disposition of the drug, case histories, and record retention,
312.64 Investigator reports		<b>Responsible</b> for progress reports, safety reports, final report, and financial reports,
312.66 Assurance of Institutional Review Board ("IRB") review		<b>Responsible</b> for IRB review and approval, and reporting to the IRB



312.68 Inspection of investigator's records and reports		<b>Responsible</b> for permitting FDA access
312.69 Handling of controlled substances		<b>Responsible</b> for secure storage and access
312.70 Disqualification of a clinical investigator	<b>Responsible</b> for complying with FDA determinations	<b>Responsible</b> for complying with FDA determinations
MISCELLANEOUS 312.110 Import and export requirements if a drug is subject to an IND that is in effect, then	The consignee in the United States is the sponsor of the IND, or the consignee is the domestic agent of a foreign sponsor	The consignee is a qualified investigator named in the IND
Subpart I—Expanded Access to Investigational Drugs for Treatment Use	The responsibilities of sponsors set forth in subpart D of this part are applicable to expanded access use under this subpart	The responsibilities of investigators set forth in subpart D of this part are applicable to expanded access use under this subpart
FDA 801 Requirements	<b>Responsible</b> for registering trials on <a href="http://clinicaltrials.gov">clinicaltrials.gov</a> . Can be delegated to the PI (see qualifications)	<b>The PI</b> can register the trial if the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information <sup>5</sup>

In Table 1, Section 312.52 is a unique feature because sponsors can delegate roles and responsibilities to a Contract Research Organization (“CRO”), which is able to “assume, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.”

### **The Role of a Contract Research Organization (CRO)**

A sponsor can delegate sponsor responsibilities to CROs. 21 C.F.R. § 312.52. Delegated responsibilities must be detailed by the sponsor on an attachment to the New Drug Application (“NDA”) Form 1571, 21 C.F.R. § 312.23. An investigator, by contrast, is not allowed to delegate roles and responsibilities in terms of conducting the trial. A drug manufacturer, on the other



hand, must assume responsibility for applying current good manufacturing practice (CGMP) required under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The manufacturer's responsibility is transferred if a CRO assumes the roles and responsibilities of the sponsor.<sup>3</sup> See 21 C.F.R. § 312.52 ("A sponsor may transfer responsibility for any or all of the obligations set forth in [21 C.F.R. Part 312] to a contract research organization."). A manufacturer who desires to retain commercial rights to a drug after it has been successfully tested must only show, "substantial support"—or more than 50 percent of the cost for conducting the trial. 21 C.F.R. § 314.50(j)(4)(iii). Delegation of sponsor roles and responsibilities has been an important feature in determining liability for subject injury.

### Sponsor's Responsibility for Conducting a Clinical Trial

In the case of *Kernke v. the Menninger Clinic* ("Kernke"), for example, Aventis sponsored a trial to test their neuroleptic compound M100907, with Menninger Clinic defendants identified as the investigator. 173 F.Supp.2d 1117, at 1119. A patient named Joseph Kernke participated in both Phase I and Phase II of the trial, and he received the investigational drug in both phases. *Id.* at 1120.

Mr. Kernke was an outpatient who later voluntarily became an inpatient to take part in the study, and he signed the consent form. *Id.* at 1119–20. The court noted, however, that throughout the treatment he repeatedly told his relatives and the clinical staff that he desired to return home. *Id.* at 1120. After two months, when the Dose Limiting Toxicity had been established in Phase I, he became eligible to participate in Phase II of the trial, and again signed a consent form. *Id.* Three days after beginning the Phase II treatment, he left the clinic and was later found dead of exposure. *Id.*

The plaintiffs alleged that Aventis, as sponsor, owed Mr. Kernke the following three duties: (1) determining patient eligibility in terms of benefit and risk, (2) securing informed consent, and (3) supervising patients. *Id.* at 1124.

The court disagreed, and ruled for Aventis, stating:

According to the FDA regulations, an investigator — in this case the Menninger defendants — is defined as "an individual who actually conducts a clinical investigation. . . ." On the other hand, a sponsor — in this case Aventis — "does not actually conduct the investigation unless the sponsor is a sponsor-investigator." All of the duties alleged by plaintiffs in this case fall within the purview of the Menninger defendants as the investigator conducting the M100907 study; the duties do not rest with Aventis. *Id.*

In addition:

The court notes that Aventis was not acting as a sponsor-investigator in this case. In fact, the record indicates that Aventis had delegated most of its duties as a sponsor of the drug study

<sup>3</sup> For complete statutory definitions and more information on the meaning of Responsible Party and sponsor, see Food and Drug Admin. (2009). *Elaboration of definitions of responsible party and applicable clinical trial*. Retrieved from <https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>; Food and Drug Admin. (2015). *ClinicalTrials.gov protocol data element definitions*. Retrieved July 13, 2015 from <https://prsinfo.clinicaltrials.gov/definitions.html#RespParty>



to Worldwide Clinical Trials, Inc., a nationally-known contract research organization hired by Aventis. *Id.* n. 3.

The court agreed that patient supervision was part of the conduct of the trial, and not a sponsor responsibility. *Id.* at 1123–24. Therefore, Aventis was only obligated to give adequate warning about the risks to the patient’s prescribing physician. *Id.* at 1121. The physician then assumed investigator responsibility for the conduct of the trial by virtue of administering the drug. *Id.* at 1122.

The claimants also argued that Aventis failed to warn patients about the risks associated with the experimental drug, but the court held that Aventis was shielded from liability by the “learned intermediary doctrine.” *Id.* at 1121. In *Humes v. Clinton*, cited by the *Kernke* court, the Kansas Supreme Court stated that the learned intermediary doctrine “allows a drug manufacturer to assume a patient places reliance on the physician’s judgment and relieves the manufacturer of a duty to assist the physician in communicating with patients.” 792 P.2d 1032, 1039 (1990). Thus, so long as a pharmaceutical company sponsor informs a prescribing physician of the dangers associated with a drug’s use, “the manufacturer’s duty to warn is satisfied.” *Id.* Although each state determines its own liability standards, the rule stated by the Kansas Supreme Court is currently the majority rule nationwide. See *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 977 (Wash. 1978) (“it has become a well-established rule that in such cases, the duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it”).

It is worth noting that a recent Texas decision casts doubt on whether the learned intermediary doctrine applies as a matter of law in clinical trials, automatically shielding a sponsor from liability regarding improper consent. In *Rodriguez v. Gilead Sciences, Inc.*, the court stated that the learned intermediary doctrine may not apply if a physician was “incentivized to act as a drug marketer rather than as a treating physician.” No. 2:14-CV-324, 2015 WL 236621, at \*5 (S.D. Tex. Jan. 16, 2015). As a result, the court declined to dismiss claims against the sponsor at the pleading stage, stating that whether the physician was adequately informed of the risks associated with a drug, or over-incentivized to enlist patients in a trial, was a question of fact that required further evidence before the learned intermediary doctrine could apply. *Id.*

As demonstrated by the above cases, the majority rule provides that a sponsor will typically have no duty to warn subjects of a trial’s risks so long as the sponsor provides adequate warnings to the investigator administering the trial. However, this does not mean that a sponsor is automatically shielded from all liability, as at least in Texas, over-incentivizing an investigator might negate the learned intermediary doctrine, and in all cases a sponsor is still potentially liable for subject injuries if they fail to adequately warn the prescribing physician or investigator.

### **The Sponsor’s Obligations as Employer**

A treating physician’s obligation to their patient is called a “duty of care.” This is the first element that must be established to proceed with an action in negligence.

In *Darke v. Estate of Isner* (“*Darke*”), the court also held that the sponsor is not responsible for the care of the patient because, again, the sponsor does not conduct the trial unless they are a



sponsor-investigator. No. 022194E, 2005 WL 3729113, at \*14 (Mass. Super. Nov. 22, 2005). In this case, the sponsor Vascular Genetics, Inc. (“VGI”) was named in a malpractice suit by the wife of Roger Darke, who died after receiving a gene therapy treatment—an injection of a substance called VEGF2 that promotes the formation of blood vessels—as part of his surgery to increase vascular blood flow. *Id.* at \*3.

VGI’s gene therapy had been approved by the FDA in 1999 to allow experimental treatment for patients who were not candidates for bypass surgery or other standard procedures. *Id.* at \*1. Mr. Darke had been advised by his physician not to repeat the coronary revascularization surgery he had previously received, and he was referred to the hospital’s gene therapy program. *Id.* at \*2. There he consulted with Dr. Isner, who had formed VGI to develop and commercialize the gene therapy. *Id.* Both Dr. Isner and the hospital held a twenty percent ownership interest in VGI and were represented on the Board of Directors. *Id.* at \*1.

Mr. Darke signed a consent form for the experimental procedure, but the form did not disclose Dr. Isner’s or the hospital’s financial interest in sponsor VGI. *Id.* at \*2. The court stated:

In its role as sponsor, VGI supplied VEGF-2 to the clinical investigators to administer to patients participating in the trial. Furthermore, VGI, in accordance with the relevant FDA regulations, took on the responsibility of selecting qualified investigators, ensuring the proper conduct of the trial, monitoring the progress of the study, and ensuring the safety and effectiveness of the gene therapy treatment. 21 C.F.R. § 312.50. In essence, VGI supervised the implementation of the study. *Id.* at 14.

In other words, VGI maintained all the general supervisory responsibilities of a sponsor. However, the court found that, as a general rule, VGI’s control—in its role as the sponsor—over the conduct of the clinical protocol did not demonstrate control over the conduct of the investigators and, thus, this activity of a sponsor “is not enough by itself to inspire” liability on the sponsor. *Id.*

However, the court noted that its inquiry did not stop here and, thus, the court analyzed other factors and theories of law that might impose some liability on VGI. With regard to a claim that VGI was directly negligent, the court held that VGI owed Mr. Darke no direct duty of care, and thus could not be held independently negligent. *Id.* at \*15. “Instead, such duties inhered in the responsibilities imposed upon the investigators in this case,” and the general sponsor responsibilities enumerated under 21 C.F.R. § 312.50 were not violated. *Id.* Therefore, the court found in favor of VGI regarding this claim of negligence. *Id.*

The court next evaluated VGI’s potential “vicarious liability” in its status as an “employer” for the actions of any of its “employees.”<sup>4</sup> The court declined to state, as a matter of law, that the relation between VGI and Dr. Isner was *not one* of an employer-employee because VGI was paying Dr. Isner as a Principal Investigator (PI), and because Dr. Isner “devoted a significant portion of his professional life to VGI.” *Id.* While VGI had argued that Dr. Isner was only an independent contractor and not an employee, the court said it didn’t matter what the parties called Dr. Isner,

<sup>4</sup> “Vicarious liability” of an employer is the legal doctrine by which an employer might be held liable for the actions or omissions of its employee if it can be proven that the applicable actions/omissions occurred within the scope of employment.



as the financial relationship between the two parties militated against holding that Dr. Isner was not acting in the furtherance of VGI's objectives as a matter of law. *Id.* Therefore, the court left open the critical possibility that VGI might be vicariously liable for the actions of Dr. Isner due to an employer-employee relationship—which, in turn, would impute the potentially tortious conduct of Dr. Isner (as the employee) to the trial sponsor (as the employer). *Id.*

The key takeaway from the *Darke* case is that while a sponsor's control over the conduct of the clinical protocol does not, in and of itself, demonstrate control over the conduct of the investigators, a sponsor could potentially be held liable for the tortious acts of an investigator if a court finds an "employer-employee" relationship existed between the sponsor and a particular investigator and that particular investigator committed the tortious act within the scope of that employment relationship.

### Fiduciary Duties and Other Claims

The sponsor role has also been the basis for claims that a drug company should provide free study drug after the end of a clinical trial. In the case of *Abney v. Amgen* ("Abney"), Amgen sponsored two trials to test a drug delivery method for patients suffering from Parkinson's disease, but unfortunately, both studies failed to prove that the experimental procedure was safe or effective. 443 F.3d 540 at 544 (2006).

This study was originally designed and initiated by physicians at the University of Kentucky (UK), but the court noted that "Amgen became a sponsor of the study, meaning it had funded the study and provided the study drug." *Id.* at 543 n. 1. The Amgen trial at UK also used Amgen's protocol, and UK was only one of several sites. *Id.* at 543.

The plaintiffs claimed that Amgen promised to continue providing the experimental treatment to subjects after the study ended. *Id.* at 544. However, the plaintiffs had entered into a contract with the investigators at UK, not with Amgen. *Id.* at 547. Further, because the investigators were independent contractors, not agents of Amgen, they had no authority to enter into a binding contract on Amgen's behalf. *Id.* at 548. As a result, plaintiffs could not show that Amgen had ever directly promised anything to the study participants.

The plaintiffs also claimed that Amgen, working through its principal investigators, owed them a fiduciary duty to treat their illness. *Id.* at 550. However, a fiduciary duty is only created when two parties agree that one will act in the interest of the other, and there was no evidence that Amgen had undertaken sponsorship of the study primarily for the benefit of the plaintiffs. *Id.* Amgen further asserted that its role as the sponsor of clinical trials would be undermined if it could not terminate trials that were found to present a risk to study participants. *Id.* at 552. The court echoed the lower court's sentiment that requiring pharmaceutical companies "to continue to produce and distribute a drug they believed to be dangerous" might deter those companies from sponsoring clinical trials. *Id.* at 553.

This same Amgen study was also at issue in *Suthers v. Amgen* ("Suthers"), which arose out of a controversy at another trial site, the New York University School of Medicine. 441 F.Supp.2d



478 (2006). In *Suthers*, two defendants who were part of the placebo group in Phase I were later recruited for the Phase II expansion, at which point they “experienced marked improvement” in their condition. *Id.* at 481. When Amgen received news of toxicity in a primate animal study, they terminated the human clinical trial and stopped supplying drug because they thought it was unsafe.<sup>5</sup> *Id.* The plaintiffs alleged that their condition worsened in the months following the end of the trial and reverted to their state prior to the administration of the study drug. *Id.* at 481–82.

As in *Abney*, the court sided with Amgen and concluded that “there is no basis to impose a fiduciary duty on the sponsor.” *Id.* at 488. Further, the consent form made no promise of continued drug supply, and informed subjects that the study could be terminated or cancelled by the sponsor. *Id.* at 483. The court also found that there was no evidence the investigator had made any promise of continued drug supply—as in UK study—and that any alleged promise was contradicted by the clear terms of the informed consent document. *Id.* at 484. Finally, the negligence claim was also rejected, as the plaintiffs claimed to have benefitted from administration of the drug and their condition did not worsen from the pre-treatment baseline, and thus the plaintiffs could not allege that Amgen had violated a duty of care or caused an injury by ceasing its gratuitous conduct. *Id.* at 489–90.

### The Investigator as Sponsor

“Sponsor-Investigator” means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor. 21 C.F.R. § 312.3(b).

All sponsor obligations under 21 C.F.R. Part 312 apply to an investigator who takes on the role of sponsor. *Id.* An investigator typically does this by writing a protocol for the new use of an approved drug, which it sends to the manufacturer as a proposal to support the study with drugs and sometimes money. Although the pharmaceutical company is unlikely to profit from such a clinical trial, it might be willing to provide this support because the trial could generate useful information or yield a humanitarian benefit if successful. The support is not considered sponsorship under FDA regulations because the investigator writes the protocol, typically submits the IND, oversees the sites and other investigators, and generally assumes all other sponsor responsibilities except drug manufacturing and initial shipping. An investigator-sponsor therefore takes most of the roles and responsibilities of sponsorship away from the drug company. As a result, claims of injury arising out of the above-mentioned sponsor obligations expose the investigator to liability, instead of the drug manufacturer.

<sup>5</sup> Interestingly, the investigator at NYU contended that the primate test subjects had received dosages at least ten times higher than what would have been given to a human and that the cause of the primates' cerebral toxicity was the abrupt withdrawal of the study drug. 441 F.Supp.2d at 481.



## Conclusion

Liability (and the practical aspects at play with regard to potential liability) is often addressed in contract negotiation of indemnification provisions prior to the study. The scope of this article was not intended to address indemnification provisions. In light of the court cases cited above, the effect that indemnification provisions have on the actual allocation of risk is worth further investigation.

In any case, claims of injury arising from clinical trial investigations may involve everyone from the investigator and their institution to CROs and the drug manufacturer. The identity of the sponsor, and their obligations in any trial, depends on the nature of the investigation and the division and delegation of responsibilities. Initiating an investigation is distinct from conducting a clinical trial, and this distinction has important implications for one's liability exposure. The ill-defined boundaries of responsibility and liability amongst sponsors, investigators, CROs, and research sites will continue to evolve with revisions to FDA regulations and guidelines, and judicial interpretations of those regulations and guidelines. However, hopefully this article provides some guidance as to what liability is currently associated with assuming the role of "sponsor" in a clinical trial.

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