Federal Court Holds Manufacturer of Investigational Drug and Medical Device Responsible for Clinical Trial Investigator's Allegedly Inadequate Informed Consent Form

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In a recent decision subject to multiple flaws, the United States District Court for the District of Massachusetts refused to dismiss a suit against the manufacturer of an investigational drug and medical device used in a clinical trial based on the allegedly inadequate warnings the clinical trial investigator provided to patients in obtaining their informed consent to the trial. If left unchanged, the decision could be applicable even outside the clinical trial context if it is alleged that a pharmaceutical or device manufacturer had knowledge of a physician's warnings to his or her patients.

Plaintiff in *Zeman v. Williams*, 2014 U.S. Dist. LEXIS 91501 (D. Mass. July 7, 2014), participated in a clinical trial designed to investigate the treatment of Young-Onset Parkinson's Disease by delivering an investigational gene therapy agent through an investigational brain infusion delivery system. Although the study protocol required the gene therapy to be delivered to both sides of plaintiff's brain, the clinical trial investigator allegedly erroneously delivered it only to one side, thereby causing serious harm. Plaintiff filed suit against multiple defendants, including the investigator for medical malpractice and failure to obtain an adequate informed consent to the clinical trial, asserting that the consent form he gave plaintiff failed to warn, among other things, of the possibility and risks of improper placement of the therapeutic agent and that the therapy was experimental. Plaintiff also sued the alleged manufacturer of both the gene therapy agent and brain delivery system, alleging it participated in drafting and approving the consent form.

The manufacturer moved to dismiss, arguing it owed no duty to plaintiff regarding the consent form, but the court denied the motion. The court acknowledged that under federal regulations it was the clinical trial investigator's duty actually to obtain the patient's informed consent, but the defendant manufacturer, as the clinical trial sponsor, was responsible both for selecting qualified investigators and "providing them with the information they need to conduct the investigation properly." Moreover, under the "learned intermediary" doctrine normally applicable to pharmaceutical product liability claims, a pharmaceutical manufacturer has a duty to give an adequate warning to the prescribing physician. Accordingly, the court held, notwithstanding the lack of any Massachusetts appellate authority imposing liability on a clinical trial sponsor for warnings given to trial subjects, the sponsor may be liable in tort "[i]f the investigator fails to inform a subject about some substantial risk because the sponsor has failed adequately to inform the investigator about the risk." The court concluded plaintiff's complaint specified the information lacking from the consent form sufficiently to state a claim.

Unfortunately, the court's decision appears flawed in several respects. For one thing, the United States Court of Appeals for the First Circuit has repeatedly made clear that district courts within the circuit are not to "blaze new trails" in state law by recognizing liability theories that the state appellate courts have not. While the Massachusetts courts have recognized a physician's duty to obtain an informed consent to treatment from the patient as an essential precondition to touching or otherwise invading the patient's body, they have never recognized such a duty in third parties, such as manufacturers of prescription drugs or medical devices, who do not treat the patient. Moreover, the duties that are imposed on such manufacturers under product liability law normally arise because the manufacturer is a seller or lessor of its product, while the clinical trial sponsor here provided its products without charge in order to investigate their safety and efficacy, and under the learned intermediary rule any informational duty is normally limited to warning the treating physician, not to supervising her warnings to the patient.

Most centrally, however, while the court purported to recognize a possible claim based on the sponsor's warnings to the investigator, it actually *permitted the claim to proceed based solely on the contents of the consent form provided by the investigator to the patient*, as the complaint contained no allegations whatsoever regarding what the sponsor allegedly failed to tell the investigator, much less that he did

not otherwise know that information. Indeed, the information plaintiff complained was omitted from the consent form either would have been obvious to any reasonable investigator (that he could perform the procedure erroneously, with harmful consequences), or was in fact given (the consent form, attached to the complaint, described both "human gene transfer" generally, and "[t]he study agent" specifically, as "experimental").

Finally, the decision's rationale could be expanded to contexts involving already marketed, as opposed to purely investigational, drugs and medical devices. For example, if a plaintiff were to allege that her prescribing physician gave her written information about a drug or device, and that the manufacturer had a role in authoring the information, or even was aware of its content, the court's rationale could hold the manufacturer liable for any failings in the information that the physician determined to provide.

Because the *Zeman* opinion is subject to the flaws noted above, we hope it will be corrected later in the litigation. In the meantime, however, pharmaceutical and device manufacturers should continue to exercise care when they are asked to review physicians' patient consent forms or other informational literature, and to make clear that they are relying on the clinician to secure an adequate informed consent from the patient. In addition, manufacturers who confront claims in litigation similar to those advanced by the plaintiff in *Zeman* should be sure that their counsel vigorously resist any further propagation of that court's errors.

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