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On March 26, 2015, the Superior Court of Pennsylvania issued its opinion in *Beverly H. Scheer, as Administrator and Personal Representative of R. Scott Scheer v. James F. Burke, M.D., et al*. The case centers around the tragic death of R. Scott Scheer, who allegedly died as a direct result of his participation in a clinical trial at Lankenau Hospital involving the extended use of the cholesterol medication hydralazine, which was alleged to be "an out-of-favor medication that causes lupus and injures cardiac, kidney, and lung tissues," especially when used for an extended time.

The trial court had excluded the proposed testimony of Vernette Molloy, a senior good clinical practices auditor who conducts and manages national and international audits of clinical trials. Ms. Molloy had planned to testify, among other things, that the principal investigator of the clinical trial breached federal requirements regarding the conduct of clinical trials, and violated good clinical practices. The trial court excluded Ms. Molloy's proposed testimony on the ground that Ms. Molloy was not a physician and therefore not qualified to testify on a "medical matter." The Pennsylvania Superior Court reversed, holding that Ms. Molloy's proposed testimony did not constitute testimony on a "medical matter." This ruling is highly important in the world of clinical trials litigation because it recognizes that Pennsylvania trial courts must allow experts on clinical trials, such as Ms. Molloy, to testify against physicians who are running those trials. Indeed, those physicians often have *less* expertise than someone such as Ms. Molloy on how to conduct a clinical trial in accordance with the governing federal regulations.

The Pennsylvania Superior Court also held that Pennsylvania's Peer Review Protection Act provided no basis for excluding communications between the decedent's daughter, the Office for Human Research Protections, and an entity that the defense claimed was a peer-review board. This ruling is equally important in that it recognizes that participants in the research enterprise cannot hide behind the peer-review privilege in communicating with the OHRP, the government agency responsible for protecting human subjects in research.

The Plaintiff was represented on appeal by Alan C. Milstein and Michael Dube of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A. Mr. Milstein is a nationally recognized litigator in the area of human subjects research. Press inquiries should be directed to Mr. Milstein, 856-661-2078, amilstein@shermansilverstein.com.