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INTRODUCTION

In the last few years, there have been important developments that bear on the law governing clinical trials and attendant liability, insurance, regulatory, and policy issues. The developments include the globalization of pharmaceutical research, increased news coverage, the emergence of various public policy questions, and a reported increase in litigation of clinical trial issues, see, e.g., Nora Lockwood Tooher, Clinical Trials Lawsuits on the Rise Across the Country, St. Louis Daily Record & St. Louis Countian, Aug. 31, 2005, available at http://findarticles.com/p/articles/mi_qn4185/is_20050831/ai_n14913350/print. Key developments discussed in this article include:\(^1\):

I. The Globalization of Pharmaceutical Research
A. Informed consent issues
B. Insurance coverage issues, including the question of "admitted" insurers
C. The EU Clinical Trial Directive
D. Good Clinical Practice
E. The French Law on Protection of Persons Undergoing Biomedical Research
F. The Issue of Extraterritorial Application of U.S. Laws and Regulations

G. Alien Torts Claims Act Issues, Including the Pfizer case and its Nigerian Clinical Trial

II. Tort Liability Issues
   A. Products Liability, including Failure to Warn
   B. Informed Consent, and Related Medical Malpractice Issues
   C. Negligence Per Se
   D. Fraud
   E. Other Tort Theories: Trespass, Battery, Invasion of Privacy; Breach of Confidentiality

III. Possible Emerging Contract Third Party Beneficiary Theory

IV. Possible Methods of Avoiding or Mitigating Exposure to Liability
   A. Quality Control, including Monitoring During the Clinical Trial
   B. Increased Monitoring by IRBs
   C. Compensation for Research-Related Injuries
   D. The Possible Issue of a Physician Acting in the Dual Role of Treating Physician and Principal Investigator

V. Insurance Issues
   A. Nondisclosure as a Ground for Rescission
   B. Disclosure to Carrier in Connection with Reporting of Significant Adverse Events to the FDA
   C. "Notice of Circumstances" under Certain Claims-Made Policies
   D. Policy Condition of Compliance with FDA Protocol

VI. Securities Litigation and Class Action Issues: Recent Cases
   A. In re Vaxgen
   B. In re Entropin
   C. In re IntraBiotics Pharmaceuticals
   D. In re Regeneron

VII. Public Policy Issues
   A. Abigail Alliance and the Claimed Constitutional Right to Take Unproven Experimental Drug
   B. Underrepresentation of Women in Clinical Trials
   C. Underrepresentation of Minorities in Clinical Trials
   D. Reduced Protection of Persons in Military Service
   E. Liability Shields Regarding Bioterrorism Countermeasures and Vaccines
   F. Freedom of Information and Confidentiality of Clinical Trial Data
I. The Globalization of Pharmaceutical Research

Conducting clinical trials abroad is a recent phenomenon that has rapidly gained momentum. William DuBois, New Drug Research, the Extraterritorial Application of FDA Regulations, and the Need for International Cooperation, 36 Vand. J. Transnat'l L. 161, 167 (2003). The number of clinical trials conducted outside the United States increased exponentially in the 1990s, from 271 in 1990 to over 4,400 in 1999. Id. This increase is partly due to relaxed U.S. rules governing drug research, which now allows foreign data to be used. Id. See also Kupchyk & Torrente, supra, at 23. The proliferation of U.S. biotechnology companies conducting international clinical trials has created a unique set of liability, insurance, and ethical issues, which are outlined below. See, e.g., Samantha Evans, The Globalization of Drug Testing: Enforcing Informed Consent Through the Alien Tort Claims Act, 19 Temp. Int'l & Comp. L.J. 477 (2005); Frank F. Goudsmit, Navigating the International Insurance Market, J. Biolaw & Bus., Vol. 6, No. 3, 2003.

A. Informed consent issues

Given the increasing number of clinical drug trials conducted in developing countries, Evans, supra, at 477, obtaining informed consent in these nations has become increasingly challenging as well as problematic, especially, as is often the case, when research subjects are uneducated, extremely poor, do not speak English, and have very different cultures. See, e.g., Jonathan Todres, Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations? 16 N.Y.L. Sch. J. Hum. Rts. 737, 757 (2000). To further complicate matters, researchers often treat clinical subjects as patients, so the subject volunteers may assume that the researcher will decide what is in their best interest. See Benjamin Mason Meier, International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent, 20 Berkeley J. Int’l L. 513, 518-19 (2002). Women and children are especially vulnerable to coercion because of their comparative status and societal powerlessness. Id. at 540.

Critical components of informed consent may be lost easily in translation between languages. In one instance, consent forms used in AZT clinical trials in Thai and English differed greatly in the descriptions of study design. Todres, supra, at 761. The English version explained that one-half of the study group would receive a placebo, while the Thai version stated that one-half of the study group would receive a “comparison drug.” Id. Because clinical trials may be the only vehicle for receiving treatment for life-threatening diseases such as AIDS in