

# Law and Ethics in Biomedical Research: Regulation, Conflict of Interest and Liability



When a young man named Jesse Gelsinger died in 1999 as a result of his participation in a gene transfer research study, regulatory agencies in the United States began to take a closer look at what was happening in medical research. The resulting temporary shutdown of some of the most prestigious academic research centres confirmed what various recent reports in the United States as well as Canada had claimed; that the current system of regulatory oversight was in need of improvement. Law and Ethics in Biomedical Research uses the Gelsinger case as a touchstone, illustrating how three major aspects of that case - the flaws in the regulatory system, conflicts of interest, and legal liability - embody the major challenges in the current medical research environment. Editors Trudo Lemmens and Duff R. Waring, along with a host of top scholars in the field, demonstrate why existing models of research review and human subject protection are in need of improvement, and how more stringent regulatory and legal means can be used to strengthen the protection of research subjects and the integrity of research. The contributors also address conflicts of interest, paying particular attention to the growing commercialization of medical research, as well as the legal liability of scientific investigators, research institutions, and governmental agencies. Legal liability is a growing concern in medical research and this fascinating study is, in the international context, one of the first to explore the liability of various parties involved in the research enterprise.

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