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Globalization of Clinical Research during Acute Epidemics: Lessons from the Pfizer Meningitis Study

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Abstract

Pharmaceutical research and development is crucial in medicine, but the history of medical science is fraught with examples of unethical research performed on vulnerable human subjects. Increasingly, multinational pharmaceutical companies have been performing clinical drug trials in developing countries where regulatory mechanisms are lax often to curb costs. In the developing world, a lack of access to healthcare produces a sense of urgency for medical treatment, which often compels the sick and impoverished to participate in experimental research. Respect for persons as an ethical concept is operationalized in medical research through the informed consent procedure. However, the consent mechanisms should be contextualized and modified to serve the various cultural environments, particularly when research crosses borders and reaches impoverished areas. The Pfizer meningitis study performed in 1996 in Nigeria provides an example of how regulatory mechanisms failed in protecting a subject population during an acute epidemic. Details of this drug trial trickled gradually, and subjects sought redress across decades, all of which revolved around conceptualizations of informed consent. This paper examines the contemporary impact of the regulatory and legal fallout, both civil and criminal, of this unprecedented ethics failure. Ultimately, the author concludes that, no matter how distinct the ethical duties and guidelines appear to be, sound enforcement mechanisms rather than clarity of clinical trial procedure provide the most effective human subjects protections.

Keywords: sub-Saharan Africa, clinical trials, informed consent, research ethics, drug trials