

Are the Votes of Ethics Committees in Germany for the Protection of Clinical Study Trial Subjects “Sovereign Acts?”

Hans-Peter Graf

Received: 29 January 2011 / Accepted: 15 July 2011
_ Springer Science+Business Media B.V. 2011

Abstract

A sudden paradigm shift has resulted in governmental measures that greatly impact the scope in which the ethics committees in Germany can perform their task of providing expert opinions for clinical research. The so-called “revaluation”

of the Medical Device Law Deutsches Medizinproduktegesetz—MPG) is, in our opinion, not based on sound political and professional judgment. In accordance with the changed regulations, ethics committees are now seen as being sub-organs of the state medical associations or the medical faculties and are therefore official authorities. It follows that the votes of ethics committees are then “sovereign acts” or authoritative measures! However, equality and justice speak against this misleading conclusion and its resulting consequence that an ethics committee’s vote is a sovereign act. This has, in turn, resulted in the public ethics committees obtaining their long-sought goal of having a state-sanctioned monopoly. The private ethics committees are not recognized as being authoritative bodies, nor are they to be seen as such in the future (i.e. such a status has been denied the Freiburg Ethics Commission International (FEKI) in Baden-Wu`rttemberg). This political mistake must be corrected, otherwise, conducting clinical research will become increasingly difficult.

Keywords

Ethics committee _ Medical association _ German medical device regulation (Deutsches Medizinproduktegesetz—MPG) _ German drug law (Deutsches Arzneimittelgesetz—AMG) _ Sovereign act _ Monopoly _ Research subject protection

H.-P. Graf
Mozartstrasse 21, 79104 Freiburg, Germany
e-mail: hp.graf@feki.com
Sci Eng Ethics