Civil Law Aspects of Medical Research

Abstract

Under Czech law, medical research on humans is divided into three branches: clinical evaluation of medicinal products, evaluation of medical devices, and evaluation of new procedures not yet introduced in clinical practice. While the first two mentioned types of research are regulated in great detail, the legal regulation of the evaluation of new procedures in the Act on Specific Health Services is significantly less extensive. In addition, new methods are still routinely introduced into clinical practice outside of the formalised evaluation regime according to the aforementioned law. As a result, both health care providers and individual physicians face legal uncertainty regarding potential liability for harm arising from the implementation of new methods. This work is focused on civil liability in the subject context.

In the first part of the thesis, as a normative basis for the evaluation of the legal regulation and its interpretation possibilities, we define the aim of law as preservation and strengthening of social cohesion. The related fundamental values this thesis is based upon consist in the limitation of judicial power in questions of a political nature, as well as the principle of trust, according to which the legal regulation of medical research and its application should take into account the importance of trust in the therapeutic doctor-patient relationship.

In its second part, the thesis analyses the traditionally treated elements of liability. In particular, we focus on breach of duty which, in the given context, can most often consist of a violation of the right to informed consent or the breach of the standard of care in implementation of new methods (while it is necessary to define what the content of the standard of care even is in relation to new methods). Nevertheless, we also discuss the issues of compensable damage, causation, and culpability.

In the third part of the thesis, the outcomes of previous chapters are applied to three typical cases of the new methods implementation, i.e., evaluation of methods in a formalised legal regime and implementation of new methods outside the formalised regime either in a situation of time constraint or without such a constraint. Each of the typical cases is discussed on the basis of a real case study (uterus transplantation, split liver transplantation for adult recipients and experimental rabies therapy, and face transplantation). In this context, we also analyse the applicability of selected circumstances excluding illegality, namely state of necessity and permissible risk. In addition to theoretical considerations, practical criteria are defined for each type of the new methods implementation, compliance with which supports legal certainty for health service providers and physicians.

Key words: new methods in medicine, civil liability in medical research, personal injury damages