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The law and *in-silico* health technology: Help or hindrance?

The law should aim to support new technologies with potential for benefiting mankind, but also needs to protect relevant individual interests especially where these are embodied in longstanding ethical principles. In the context of health law, the regulatory focus has been on avoiding harm to individual patients and research subjects; the paradox is that, if research and/or care is made harder or delayed by legal or professional ethical restrictions, patients also stand to be harmed, by being denied better treatments. Against this background, this paper assesses how the law is faring in regulating the field of health informatics, with particular reference to *in silico* developments in research and care, as exemplified by the EU FP7 project 'Computational Horizons in Cancer' (CHIC). Two main areas are addressed where (IT and medical) researches might complain the law is over-cautious and has failed to balance risks and benefits appropriately. The first concerns restrictions on use of patient health data to evolve and validate new clinical approaches – here data protection law, particularly the EU regime, but also the rules in North America (under HIPAA and PIPEDA) is considered. The second issue concerns the onerous validation requirements to which innovative health care products, including data-driven *in silico* solutions, are subject prior to clinical deployment. Here it is suggested there are indeed reasons to favor a lighter regulatory approach than in relation to the licensing of traditional medical products and devices.

Biography

Marc Stauch gained his legal training in the UK, qualifying as a Solicitor, before lecturing law for several years at English universities. He is co-author of a popular English law student text and materials on Medical Law and Ethics, at present in its 5th edition. After moving to Germany in 2003 he wrote his Doctoral thesis comparing medical malpractice law in England and Germany. As a Research Associate at the Institute for Legal Informatics in Hannover, a principal focus of his current work is data protection law.

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