THE 'ETHICALIZATION' OF LAW

FUNDAMENTAL QUESTIONS, DANGERS AND OPPORTUNITIES FROM AN INTERDISCIPLINARY PERSPECTIVE

Symposium, Freiburg 29./30.9.2011

UNI FREIBURG

A BIRD IN THE HAND IS WORTH TWO IN THE BUSH? BIOETHICS AND HUMAN RIGHTS IN TRANSNATIONAL DRUG TRIALS

(Abstract)

Mira Chang
Heidelberg

Prof. Dr. Silja Vöneky (editor).

Max-Planck-Forschungsgruppe
Max-Planck-Institut für ausländisches öffentliches Recht und Völkerrecht
Im Neuenheimer Feld 535
69120 Heidelberg, Germany
ethikrecht2011@mpil.de

Institut für Öffentliches Recht
Abteilung 2 (Völkerrecht und Rechtsvergleichung)
Rechtswissenschaftliche Fakultät
Universität Freiburg
Platz der Alten Synagoge 1
79098 Freiburg im Breisgau, Germany
voelkerrecht@jura.uni-freiburg.de

www.ethisierungrecht.de

A Bird in the Hand is Worth Two in the Bush?
Bioethics and Human Rights in Transnational Drug Trials

Abstract

While relying on the premise that drug research is paramount for medical progress and therefore beneficial to society, the European Union, its member states, the USA and many other countries stipulate obligatory pre-marketing approval procedures for pharmaceuticals, demanding evidence inter alia for the safety and efficacy for every new drug. This evidence has to be provided by clinical trial studies, which means that eventually every new investigational drug has to be tested on human beings. And while drug trials on human beings are ultimately indispensable in protecting the general public, the interests of those individuals who participate in these trials need to be protected. The protection of human rights and human dignity are therefore of essential importance. Mentioned legislations may meet this end, but in a globalized environment clinical trials are more and more conducted outside the main markets of the EU, USA and Japan and offshored to developing countries.

The concerns raised regarding this practice are twofold: human rights of participating persons may be violated and questions of distributive justice may prove problematic. The uncoupling of individual and public interests, which occurs when test subjects are not longer part of the society that benefits from the new drugs tested and their financial gains, aggravates the former intra-societal balancing by elevating it to a global level. A society, which benefits from new drugs but does not need to bring sacrifices from its own middle to gain these benefits, may have less of an interest in formulating high standards of protection for external research. The essential problem, therefore, lies in the conclusion that standards of protection for human research subjects are mostly lower in developing countries, while richer countries benefit from the research conducted.

As drug trials have been transnationalized, the question arises if they can be regulated on a global level. The protection of test subjects has traditionally been perceived as an ethical endeavor. In the second half of the 20th century, in the

absence of a global legislator, ethical guidelines issued by private organizations especially the *World Medical Association's* (WMA) *Declaration of Helsinki* filled the void. Now a plethora of ethical guidelines with no direct legally binding force – some being codes of professional *mores*, some qualifying as *soft law* – issued by various public or private bodies or public private partnerships govern the design and conduct of clinical drug trials on a global level. The internationally most influential guidelines may be those by the previously mentioned private WMA, specifically its *Declaration of Helsinki*, furthermore the Guidelines on *Good Clinical Practice* issued by the public private partnership *International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH), the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* drafted by the private *Council for International Organizations of Medical Sciences* (CIOMS) in collaboration with the *World Health Organization* (WHO) and the *Universal Declaration on Bioethics and Human Rights* adopted by the International Organization UNESCO.

These instruments – as distinctive they may be – all claim authority on setting norms for ethically sound research involving human beings although they are not directly legally binding. In effect, there is nowadays a reflexive reference to "these ethical guidelines" by all relevant actors: from policymakers to pharmaceutical companies. Yet this global governance of ethically sound research raises an essential question this paper wants to explore: that of legitimacy. The underlying premise is that any claim of authority needs to be legitimized. Applying a normative notion of legitimacy, that is multitaristic in encompassing various parameters such as source/authorship, procedure, effectiveness and minimal ethical acceptability, varying shortcomings regarding the before-mentioned bodies and guidelines shall be observed. Concerning aspects of material legitimacy – assigning a higher degree of legitimacy to highly effective solutions – it shall be illustrated that these guidelines, which are often concomitantly referred to, differ on concrete questions. Moreover, in their vagueness they often do not meet the complexity of clinical trials and are open for the insertion of a wide and fragmented bioethical discourse.

This paper claims that the governance of transnational drug trials by ethical guidelines may generally be useful for the protection of test subjects, but that they

may not infringe upon and undermine the human rights discourse. Research involving human beings touches upon fundamental human rights based on human dignity which claims universal validity. Addressing the impact of transnational drug trials on human research subjects as a mere "ethical issue" disregards the relevance of human *rights*. In shifting the paradigm of perception to human rights, the discourse may tie up to a development already initiated by Art. 7 of the International Covenant on Civil and Political Rights. International human rights in the aftermath of World War II was still in its infancy thus historically international ethical guidelines may have filled a vacuum in this arena. Still, the international human rights discourse has seen a significant development since. Governance by ethical guidelines may be useful and better than none, but such guidelines may not conflict with or undermine human rights.