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I am Phd candidate at the University of Warsaw, Faculty of Law and Administration. My doctoral thesis concerns informed consent (European and United States legal and bioethics regulation).

Several recent years have brought new legal regulations regarding informed consent. In 1994, WHO has introduced Declaration on the Promotion of Patients' Rights in Europe, which was to serve as guidelines that shall be applied in particular countries. The reference can be found in the Polish Charter of Patient Rights, which was presented in 1998. Another step forward in the scope of protection and executing patient's rights was creation in 2002 by virtue of the regulation of the Minister of Health of December 28, 2001, The Office of Patient Rights, as single budget entity and ombudsmen of patient rights at psychiatric hospitals. All the initiatives mentioned above had limited scope of action, which led to the need of establishing a new institution, which would operate in Poland to protect patients' rights and would be independent from the Minister of Health, governments. It was decided to call the Ombudsman of Patient Rights as the central body of governmental administration, competent in cases regarding protection of patients' rights. On November 6, 2008, Sejm of the Republic of Poland passed an act on the patient's rights and the Ombudsman of Patient Rights<sup>1</sup>.

According to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine any intervention in the health field may only be carried out after the person concerned has given free and informed consent. Patient have the right to receive understandable information on health condition, diagnosis, suggested and possible diagnostics and treatment methods, possible to foresee results of their application and omission, treatment outcomes and prognosis. In my opinion unfortunately it doesn't work properly in practice in Europe. Contrary to popular point of view, one of the main problems in providing excellence in health care in Europe is not only lack of money, but lack of information. Patients are not properly advised about risks, consequences, possible results and alternative to a proposed treatment. Therefore,

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<sup>1</sup> Act dated November 6, 2008 on the patient rights and the Ombudsman of Patient Rights (Journal of Laws, **No. 52, Item 17**).

even if they consent, they are not exercising choice. They do not share responsibility for their treatment in the way they were meant to.

Relying medical intervention possibility on receiving appropriate consent gives the guarantee of respect for the patient's autonomy, and in wider perspective - respect of human's dignity, referred to in Article 30 of Polish Constitution, European Convention on Human Rights and Biomedicine.. The consent shall be thus an act executing the protection of patient's autonomy in terms of basic personal interests. It cannot be expressed under duress, mistake or in mental condition which makes conscious decision making impossible. The content of the consent shall be explicit and must not refer to any medical procedures (*in blanco* method) - it must be clear to whom and for what action it is given.

Making a medical procedure without the patient's consent is one of the offences against freedom. For example :the Polish Penal Code of 1997 has introduced in Article 192 new type of offence, which states that any person who performs medical procedure without the patient's consent, shall be liable with fine, penalty of limitation of freedom or imprisonment up to 2 years. In Portugal is similar regulation (the Article 156 of the Portuguese Penal Code).

The law should serve to commonly recognized moral values and if the legal norms will be supported by the values, application of law will be more ascertained and will lack intuitive adjudicates - in accordance with unspecified criteria - dilemmas of an ethic nature. In my opinion in the light of contemporary medicine achievements, the tasks set to the legislator are extremely difficult to perform. Undoubtedly, the possibilities of medicine and physicians' action have been primary to the legal regulation, which aren't always compatible with the reality, thus, respecting legal norms in force is necessary, especially in the field of health and patient's rights. In addition creating health care regulation we cannot forget about European and international experiences and knowledge.