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BIOETHICS DICUSSION GROUP

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MEDICAL EXPERIMENTS

It is a well-known fact that biomedical research that would not be accepted in the developed countries is conducted in medically less advanced countries. In general, such research is carried out in countries where legislation provides less protection for people than in the more developed countries.

This situation is causing real concern within the Secretariat of the Commission of the Bishops' Conference of the European Union (COMECE), as well as in the institutions that work for the protection and respect of persons subjected to biomedical research.

The populations of medically less advanced countries are far more vulnerable to proposals for experiments than in countries where medicine has advanced over several decades and there are numerous sources of information. The very concept of research is foreign to them. This represents a major obstacle to providing adequate information. Consent is sometimes obtained by promising material benefits (or by applying psychological pressure), or even because of the prestige of the foreign investigators that ask for their collaboration.

All too often the laws and regulations in force in the more developed countries are seen as an obstacle to advances in scientific knowledge. There is a therefore a strong temptation to conduct research in countries with lower levels of protection. We also need to be aware of the pressure generated by financial conditions and the rationale of research that is always impatient for further advances.

We welcome efforts to ensure better respect for vulnerable populations from such institutions as the World Medical Association (WMA)[1].

The COMECE fully supports the central tenet of the Helsinki Declaration, which states that "in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society" and "medical research is subject to ethical standards that promote respect for all human beings and protect

[1] See the Helsinki Declaration amended by the 32nd General Assembly in Edinburgh.

their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care."

This subject needs to be debated in depth with qualified representatives from the vulnerable populations concerned. Such consultation should largely deal with explaining the realities of the experiments conducted and obtaining genuine consent, taking into account the general level of education and cultural characteristics.

In any event, we should refuse to undertake research useful for the developed countries that is difficult to conduct in developed countries because of their rules and regulations within vulnerable populations.

The above recommendations are all the more important in cases where considerable financial and commercial interests are at stake.