

WORKSHOP 1

Status of International Activities in Bioethics Bioethical Considerations in Cross-Cultural Research Francis P. Crawley European Forum for Good Clinical Practice

Current European activities in bioethics related to international biomedical research are pushed forward by a number of underlying events influencing the discussion from a variety of origins and interests. While biomedical research within Europe has nearly always been international with regard to both its practice and its breath of influences, nonetheless ethical reflection on this research has been largely modeled on national systems. The ethical review of proposed research (the institutional structure of IRBs) is - for example - in all countries different, among the 41 member states of the Council of Europe, even among the 15 member states of the European Union.

The Fall of the Berlin Wall and the process of reunifying Europe politically, economically, and socially has had an enormous effect on how Europe conceives the present international, cross-cultural framework of its activities. Even the formation and the development of the European Union since the Maastricht Treaty in 1992 has been strongly influenced by the recognition and the possibilities of a greater political unity. While much policy and decision is driven by economic and security interests, the social dimension of international activities has also been brought to the fore. Indeed, the years 2000-2010 have been designated 'The European Decade of Public Health' within the European Union.

It was with the Treaty of Maastricht that the European Union was first given a clear - though well circumscribed - mandate to act in the area of public health. This mandate was slightly expanded recently with the Treaty of Amsterdam. Yet, the domain of ethics was clearly withheld from lawmakers in the European Union, closely guarded as a matter for national interest alone. This means that while the promotion of research (and industry) falls within the mandate of the European authorities, ethics remains exclusively characterized (legally) by national regulation and institutions. This is not to say that there is no ethical reflection or research at the level of the European Union, but rather that any such activity comes about as a (necessary) annex to another interest that takes priority.

On the other hand, with Europe conceived in the broader sense, though politically and legally weaker, there is a clear mandate for action in the area of ethics, even bioethics, within the remit of the Council of Europe. Thus, the drafting and promotion of the European Convention on Human Rights and Biomedicine was carried out under a clear charge originating from a Recommendation in the Council's Parliamentary Assembly. The weakness of the Convention (also a strength) is that it only becomes legally binding when it is ratified by the individual member state governments.

The upshot of this is that within Europe there is a strong awareness of the challenges regarding international and cross-cultural research. The need to promote public health within the European Union, while harmonizing policies and regulations, has led to strong dialogue between institutions and representatives of the various member states. Meanwhile, as Western, Central, & Eastern Europe rediscover common cultural, social, and political values, an enormous dialogue has arisen on shared societal concerns. One important part of this dialogue concerns the ethics of biomedical research.

The dialogue on the ethics of biomedical research has been strongly influenced on a more global level by the International Conference on Harmonization, a process bringing together the pharmaceutical industry and government regulatory authorities in the United States, the European Union, and Japan. As the scientific and academic communities push the discussion of biomedical research in developing countries to the fore, Europe find itself in a strong position to contribute, not only to the issues of the discussion, but perhaps in the first place to models for framing the discussion.