Concluding communique on the "Ethics of biomedical research. For a Christian vision"

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CONCLUDING COMMUNIQUÉ ON THE "ETHICS OF BIOMEDICAL RESEARCH. FOR A CHRISTIAN VISION"

24-26 February 2003

1. The Ninth General Assemby of the Pontifical Academy for Life took place at the Vatican from 24-26 February. This year it was dedicated to a crucial theme that has a strong social impact, *"Ethics of Biomedical Research. For a Christian Vision*".

It is evident that, especially in the recent decades, biomedicine has developed in an extraordinary way, helped by the enormous progress in technology and computer science that have vastly extended the possibilities for experimentation on living beings and, especially on the human being. There have been tremendous breakthroughs, for example, in the fields of genetics, molecular biology, as well as in transplants and the neurological sciences.

Today more than ever, among the factors that contributed to this development, certainly biomedical research has been instrumental in the progress of knowledge in this sector of medicine, as the Holy Father himself recently pointed out: "*It is a recognized fact that improvements in the medical treatment of disease primarily depend on progress in research*" (John Paul II, *Address to participants in the Ninth General Assembly of the Pontifical Academy for Life,* 24 February 2003, n. 2; *ORE,* 5 March 2003, p. 4).

2. In the present setting, every new discovery in biomedicine seems destined to produce a "cascade" effect, opening up many new prospects and possibilities for the diagnosis and treatment of numerous pathologies that are still incurable.

Obviously, the acquisition of a growing technical possibility of intervention on human beings, on other living beings and on the environment, and the attainment of ever more decisive and permanent effects, obviously demands that scientists and society as a whole assume an ever greater responsibility in proportion to the power of intervention. It follows that the experimental sciences, and biomedicine itself, as "instruments" in human hands, are not complete in themselves, but must be directed to defined ends and put in dialogue with the world of values.

3. The primary agent of this continuous process of "ethical orientation" is, unmistakeably, the human person. Indivisible unity of body and soul, the human being is characterized by his capacity to choose in freedom and responsibility the goal of his own actions and the means to achieve it. His burning desire to seek the truth, that belongs to his nature and his specific vocation, finds an indispensible help in the Truth itself, God, who comes to

meet the needs of the human being and reveals to him his Face through creation, and more directly, through Revelation. Thus God favours and supports the efforts of human reason, and enables the human being to recognize so many "seeds of truth" present in reality, and finally, to enter into communion with the Truth itself which He is.

In principle, therefore, there are no ethical limits to the knowledge of the truth, that is, there are no "barriers" beyond which the human person is forbidden to apply his cognitive energy: the Holy Father has wisely defined the human being as "*the one who seeks the truth"* (*Fides et ratio,* n. 28); but, on the other hand, precise ethical limits are set out for the manner the human being in search of the truth should act, since "*what is technically possible is not for that very reason morally admissible*" (Congregation for the Doctrine of the Faith, *Donum Vitae,* n. 4). It is therefore the ethical dimension of the human person, which he applies concretely though the judgements of his moral conscience, that connotes the existential goodness of his life.

4. In the commitment to research and to recognize the objective truth in every creature, a particularly important role falls to scientists in the area of biomedicine, who are called to work for the well-being and health of human beings, the ultimate aim of every research activity in this field must be the integral good of man. The means it uses, must fully respect every person's inalienable dignity as a person, his right to life and and his substantial physical integrity.

Against any false accusation or misunderstanding, let us repeat in communion with the Pope, John Paul II, that: "*The Church respects and supports scientific research when it has a genuinely human orientation, avoiding any form of instrumentalization or destruction of the human being and keeping itself free from the slavery of political and economic interests*" (*Address to participants in the Ninth General Assembly of the Pontifical Academy for Life,* 24 February 2003, n. 4; *ORE,* 5 March 2003, p. 4).

In this perspective, one must express the greatest possible gratitude to the thousands of doctors and researchers of the whole world who, generously and with great professionality, dedicate their energies every day to the service of the suffering and the treatment of pathologies. Further, the Pope recalled that: "*all, believers and non-believers, acknowledge and express sincere support for these efforts in biomedical science that are not only designed to familiarize us with the marvels of the human body, but also to encourage worthy standards of health and life for the peoples of our planet*" (*ibid.,* n. 2).

5. For the reasons already mentioned, one can and must speak of an "ethic of biomedical research" that, in fact, has been increasingly developed and expressed in the last 30 years. Christian thought too has been able to make its important contribution to this development, bringing to the fore certain new problems in the light of its original anthropological vision. Historically, at least two themes can be cited as an example of the ethical attention the Christian community pays to the world of biomedical research: the call for respect for the person when he/she is the subject of research, especially in the case of experimentation that is not directly therapeutic; the emphasis on the close bond

between science, society and the individual, which is at stake in the entire process of research.

6. Thus, in elaborating an itinerary for biomedical research that will respect the true good of the human person, it is necessary for the synergy of the different disciplines concerned to converge through an integrative methodology, that will take into account the complex constitutive unity of the human being. To this end, the proposal of the so-called "triangular method" seems to be appropriate. It is divided into three stages: the exposition of the biomedical data; the examination of the consequences for the human person and the discernment of the values this factor brings to the fore; the elaboration of the ethical norms that can guide the work of those who are involved in a given situation, in accord with the meanings and values that were previously identified.

7. Another theme of great importance in the context of biomedical research is certainly that of therapeutic and non-therapeutic experimentation, considered from the perspective of its application to the human being. It involves many problematic aspects, both of a scientific and ethical nature. It is indispensable, for example, to demand a high professional standard from the researchers involved in the experimental project, and to adopt a methodology that is rigorous in determining and applying procedural criteria. Moreover, It is also ethically necessary that the person conducting the experiment, with his collaborators, maintain total personal and professional independence with regard to possible interests (financial, ideological, political, etc.) unrelated to the goal of the research, for the good of the subjects involved and the genuine progress of humanity.

8. Besides, we want to reaffirm the need to do sufficient experimentation on animals prior to the clinical experimental phase (the application on human beings) that will enable researchers to acquire advance knowledge of the possible harm and risks that this experimentation could have in order to guarantee the safety of the human subjects involved. Naturally, experimentation on animals also has to be carried out with the observance of precise ethical norms to safeguard, as far as possible, the well-being of the specimens used.

9. Special attention must also be paid to the treatment of human subjects who undergo research who are especially "vulnerable" because of their state of life, as the example of human embryos clearly illustrates. Because of the delicate stage of their development, possible experimentation on them in the light of current technological advances would involve a very high - and therefore ethically unacceptable - risk of causing them irreversible damage and even death.

The attitude some adopt concerning the legitimacy of sacrificing the (physical and genetic) integrity of human beings at the embryonic stage in order to destroy them, if necessary, in order to benefit other human individuals is likewise totally unacceptable. It is never morally licit to do evil intentionally in order to achieve ends that are good in themselves.

Moreover, it should be borne in mind that, although the human individual at the embryonic stage deserves the full respect that is due to every human person, human embryos are certainly not subjects who can give their personal consent to experimentation that exposes them to grave risks without the benefit of any directly therapeutic effect for themselves. Therefore, any experimentation on the human embryo that does not have the goal of obtaining direct benefits for his/her own health, cannot be considered morally licit.

10. The current process of progressive globalization that involves the whole planet and whose consequences do not always seem to be positive, impels us to reflect on biomedical research under the heading of its social, political and economic implications.

Given the growing limitation of the resources that are available for the development of biomedical research, it is in fact necessary to pay great attention to achieving a just distribution between the different countries, taking into account the living conditions in the various parts of the world and the emergence of the primary needs of the poorest and most harshly tried peoples. That means that all should be guaranteed the conditions and minimal means so that they can enjoy the benefits deriving from research, and develop and support an endogenous capacity for research.

11. At the legislative level, once again, we express the hope and the recommendation that an international legislation with a unified content can be arrived at, based on the values inscribed in the nature of the human person. In this way, one could overcome the actual disparities which frequently make possible the abuse and exploitation of the individual as well as of entire peoples.

12. Finally, recognizing the enormous influence of the mass media in the formation of public opinon and the important role they play in inspiring in the broader public, expectations and desires that are more or less well-founded, it appears ever more necessary that those engaged in the sector, who choose to be concerned with the biomedical sector and with bioethics, should be properly trained, both in the scientific and the ethical fields, to be able to communicate the facts in simple, and concise language without confusion or misrepresentation.

13. To conclude, the Pontifical Academy for Life, with great enthusiasm and a deep sense of responsibility, desires to renew its commitment and dedication to the cause of life, in sincere and respectful collaboration with all who are involved in the field of biomedical research, as the Pope himself said in his recent address to the Pontifical Academy for Life: "*In the area of biomedical research, the Academy for Life can therefore be a point of reference and enlightenment, not only for Catholic researchers, but also for all who desire to work in this sector of biomedicine for the true good of every human being*" (*ibid.,* n. 3). The Academy's principal task continues to be to make available to the Church, to society at every level, and, especially, to the scientific community, its own "statutory" service of *study, formation and information,* in the attempt to identify and to point out to the whole of society the values rooted in the dignity of the human person that are indispensable if we aspire to the true good of *every* person and of the *whole person,*

with the goal of deducing from them the ethical directives that can guide those involved in this field in their daily endeavour.

Proposal of an Ethical Commitment for Researchers in the Biomedical Field

Introductory note

The following "manifesto" is published as an appendix to the Final Communiqué of the Ninth General Assembly of the Pontifical Academy for Life. It is a concrete result of the assembly's deliberations, whose theme this year was: "Ethics of Biomedical Research: For a Christian Vision", *offerred as an open proposal to be freely supported*.

The invitation for a personal adherence is addressed to all researchers and those involved in research in the biomedical field and also to researchers in bioethics.

Those who wish to adhere to this "manifesto", which means that they embrace the principles it contains, to should communicate to the Academy by one of the following ways:

- *by e-mail to: pav@acdlife.va*
- *by fax to: +39 06 69882014*
- *by post to: Pontificia Accademia per la Vita, Via della Conciliazione, 3, 00193 Rome, Italy*.

Whatever the chosen modality, it is obligatory to include one's personal details (name, surname, address, telephone, fax, email), profession and place of employment, academic degrees and other qualifications.

Premise

The scientific developments of recent decades have brought about important cultural and social transformations, modifying in a qualitative way many aspects of human life. Indeed, the advance of scientific progress in many sectors has given rise to great hopes of concrete improvements for the life and future of the human person. However, in certain sectors of scientific research problems and/or doubts of an ethical and religious nature have arisen; they have demonstrated unequivocally the real need for constant dialogue/integration between the experimental sciences and the broader human sciences and philosophy in terms of operating in a more ample perspective so that the acquisition of greater knowledge may effectively serve the true good of the human person.

Human life and human nature appear to be realities too complex to be exhaustively evaluated from a single perspective; a multidisciplinary approach therefore appears

indispensable for a better understanding of the human being in his integrity and contribute to a meaningful growth of a science that would truly be *for* the human being.

Moreover, such an interdisciplinary dialogue, by re-focusing attention on the centrality of the human person, would make the scientists more aware of the ethical implications of their work, and, conversely, would incite those involved in philosophical and theological anthropology to assume toward the scientists a mission of dialogue, collaboration and practical support, with the mutual intention of developing cognitive and applied tools for the service of the human community.

In this perspective, the reference to human values, and finally, to an anthropological and ethical vision, is an indispensable premise for a correct scientific research, that recognises the person's responsibility to himself and to others.

In fact, without reference to ethics, science and technology can be used either to kill or to save human lives, to manipulate or to promote, to destroy or to build. It is therefore necessary that, through responsible management, research be addressed toward the true common good, a good that transcends any merely private interest, going beyond the geographical and cultural boundaries of nations and keeping one's vision directed toward the good of future generations.

For science to be really placed at the service of the human being, it is necessary that it goes "beyond matter", intuiting in the corporeal dimension of the individual the expression of a greater spiritual good. Scientists should understand the human body as the tangible dimension of a unitary personal reality, which is at the same time corporeal and spiritual. The spiritual soul of the human being, although not in itself tangible, it is always the root of his existential and tangible reality, of his relationship with the rest of the world, and consequently, of his specific and inalienable value.

Only such a vision can make scientific research effectively respectful of the human person, considered in his complex corporeal-spiritual unity, every time he/she becomes the object of investigation, with particular reference to those events that constitute the beginning and the end of the individual human life.

For this reason, emerges a strong need to offer to young researchers formative programmes that put the accent not only on the scientific preparation, but also on the acquisition of the fundamental notions of anthropology and ethics. The expression of such programmes could, then, crystallize in the elaboration of a true and proper *Deontological Code* for researchers, to which each researcher could safely refer in his work, and which, at the same time, would represent a sign of hope and commitment for a truly "humanized" medicine in the new millennium.

A first indication of the way to take, might concern the manner in which the researchers should behave and the norms they should observe in order to direct their research towards the objective just recalled above. It is our desire to propose such ethical indications, to which we firmly adhere, to all others who are involved in the world of biomedical

research; somehow, they delineate the principal features of the researcher's "moral personality".

Commitment

- I commit myself to adhere to a methodology of research characterized by scientific rigour and a high quality of the information that is furnished.

- I will not take part in research projects in which I could be subject of a conflict of interests, from the personal, professional or economic point of view.

- I recognise that science and technology must be at the service of the human person, fully respecting his dignity and rights.

- I recognise and respect all researches and their applications which are based on the principle of "moral goodness" and referring to the correct vision of the corporeal and spiritual dimensions of the human being.

- I recognise that every human being, from the first moment of his existence (process of fertilization) up to the moment of his natural death, is to be guaranteed the full and unconditional respect due to every human person by virtue of his peculiar dignity.

- I recognise, because of my duty to safeguard human life and health, the usefulness and the obligation of a serious and responsible experimentation on animals, carried out according to determined ethical guidelines, before applying new diagnostic and therapeutic methodologies to human beings. I also recognise that the passage from the experiments with animals to the clinical experimental stage (on man) should take place only when the evidences resulting from the experiments with animals sufficiently demonstrate the harmlessness or the acceptability of the possible harms and risks that such experiments might involve.

- I recognise the legitimacy of clinical experiments on the human being, but only under precise conditions, including, in the first place, the safeguarding of the life and physical integrity of human beings who are involved. Then, there is the need that the experiments be always preceded by proper, correct and complete information regarding the significance and developments of the same experiments. I will treat each person who submits to an experiment as a free and responsible subject and never as a mere means to achieve other ends. I will never let a person be involved in an experiment unless he/she has given his/her free and informed consent.