CONGREGATION FOR THE DOCTRINE OF THE FAITH

Regarding the Instruction Dignitas Personae

Aim

In recent years, biomedical research has made great strides, opening new possibilities for the treatment of disease, but also giving rise to serious questions which had not been directly treated in the Instruction *Donum vitae* (22 February 1987). A new Instruction, which is dated 8 September 2008, the Feast of the Nativity of the Blessed Virgin Mary, seeks to provide some responses to these new bioethical questions, as these have been the focus of expectations and concerns in large sectors of society. In this way, the Congregation for the Doctrine of the Faith seeks both to contribute "to the formation of conscience" (n. 10) and to encourage biomedical research respectful of the dignity of every human being and of procreation.

Title

The <u>Instruction</u> opens with the words *Dignitas personae* – the dignity of a person, which must be recognized in every human being from conception to natural death. This fundamental principle expresses "a great 'yes' to human life and must be at the center of ethical reflection on biomedical research" (n. 1).

Value

The document is an Instruction of a doctrinal nature, published by the Congregation for the Doctrine of the Faith and expressly approved by the Holy Father, Pope Benedict XVI. The <u>Instruction</u> therefore falls within the category of documents that "participate in the ordinary Magisterium of the successor of Peter" (Instruction <u>Donum veritatis</u>, n.18), and is to be received by Catholics "with the religious assent of their spirit" (<u>Dignitas personae</u>, n. 37).

Preparation

For several years, the Congregation for the Doctrine of the Faith has been studying new biomedical questions with a view to updating the Instruction <u>Donum vitae</u>. In undertaking the examination of such new questions, the Congregation for the Doctrine of the Faith "has benefited from the analysis of the Pontifical Academy for Life and has consulted numerous experts with regard to the scientific aspects of these questions, in order to address them with the principles of Christian anthropology. The Encyclicals <u>Veritatis splendor</u> and <u>Evangelium vitae</u> of John Paul II, as well as other interventions of the Magisterium, offer clear indications with regard to both the method and the content of the examination of the problems under consideration" (n. 2).

Intended recipients of the document

The <u>Instruction</u> is meant for "all who seek the truth" (n. 3). Indeed, in presenting principles and moral evaluations regarding biomedical research on human life, the Catholic Church "draws upon the light both of reason and of faith and seeks to set forth an integral vision of man and his vocation, capable of incorporating everything that is good in human activity, as well as in various cultural and religious traditions which not infrequently demonstrate a great reverence for life" (n. 3).

Structure

The <u>Instruction</u> has three parts: "the first recalls some anthropological, theological and ethical elements of fundamental importance; the second addresses new problems regarding procreation; the third examines new procedures involving the manipulation of embryos and the human genetic patrimony" (n. 3).

First Part:

Anthropological, Theological and Ethical Aspects of Human Life and Procreation

The two fundamental principles

"The human being is to be respected and treated as a person from the moment of conception; and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life" (n. 4).

"The origin of human life has its authentic context in marriage and in the family, where it is generated through an act which expresses the reciprocal love between a man and a woman. Procreation which is truly responsible vis-à-vis the child to be born must be the fruit of marriage" (n. 6).

Faith and human dignity

"It is the Church's conviction that what is human is not only received and respected by *faith*, but is also purified, elevated and perfected" (n. 7). God has created every human being in his own image, and his Son has made it possible for us to become children of God. "By taking the interrelationship of these two dimensions, the human and the divine, as the starting point, one understands better why it is that man has unassailable value: he possesses an eternal vocation and is called to share in the trinitarian love of the living God" (n. 8.).

Faith and married life

"These two dimensions of life, the natural and the supernatural, allow us to understand better the sense in which the acts that permit a new human being to come into existence,

in which a man and a woman give themselves to each other, are a reflection of trinitarian love. God, who is love and life, has inscribed in man and woman the vocation to share in a special way in his mystery of personal communion and in his work as Creator and Father... The Holy Spirit who is poured out in the sacramental celebration offers Christian couples the gift of a new communion of love that is the living and real image of that unique unity which makes of the Church the indivisible Mystical Body of the Lord Jesus" (n. 9).

The Church's Magisterium and the legitimate autonomy of science

"The Church, by expressing an ethical judgment on some developments of recent medical research concerning man and his beginnings, does not intervene in the area proper to medical science itself, but rather calls everyone to ethical and social responsibility for their actions. She reminds them that the ethical value of biomedical science is gauged in reference to both the unconditional respect owed to every human being at every moment of his or her existence, and the defense of the specific character of the personal act which transmits life" (n. 10).

Second Part:

New Problems Concerning Procreation

Techniques for assisting fertility

Among the procedures which respond to problems of fertility are the following:

"techniques of heterologous artificial fertilization" (n. 12): that is, "techniques used to obtain a human conception artificially by the use of gametes coming from at least one donor other than the spouses who are joined in marriage" (footnote 22).

"techniques of homologous artificial fertilization" (n. 12): that is, "the technique used to obtain a human conception using the gametes of the two spouses joined in marriage" (footnote 23).

"techniques which act as an aid to the conjugal act and its fertility" (n. 12).

"techniques aimed at removing obstacles to natural fertilization" (n. 13).

"adoption" (n. 13).

Techniques are morally permissible if they respect: "the right to life and to physical integrity of every human being", "the unity of marriage, which means reciprocal respect for the right within marriage to become a father or mother only together with the other spouse" and "the specifically human values of sexuality" (n. 12), which require that the

procreation of a new human person come about as a result of the conjugal act specific to the love between a husband and wife.

Therefore, "techniques which act as an aid to the conjugal act and its fertility are permitted" (n. 12). In such procedures, the "medical intervention respects the dignity of persons when it seeks to assist the conjugal act either in order to facilitate its performance or in order to enable it to achieve its objective once it has been normally performed" (n. 12).

"Certainly, techniques aimed at removing obstacles to natural fertilization... are licit" (n. 13).

"Adoption should be encouraged, promoted and facilitated so that the many children who lack parents may receive a home... In addition, research and investment directed at the prevention of sterility deserve encouragement (n. 13).

In vitro fertilization and the deliberate destruction of embryos

The experience of recent years has shown that in all techniques of *in vitro* fertilization "the number of embryos sacrificed is extremely high" (n. 14). Even in the most technically advanced centers of artificial fertilization, the number is above 80% (cf. footnote 27). "Embryos produced *in vitro* which have defects are directly discarded"; a increasing number of couples "are using artificial means of procreation in order to engage in genetic selection of their offspring"; of the embryos which are produced *in vitro* "some are transferred into the woman's uterus, while the others are frozen"; the technique of multiple transfer in which "the number of embryos transferred is greater than the single child desired, in the expectation that some embryos will be lost... implies a purely utilitarian treatment of embryos" (n. 15).

"The blithe acceptance of the enormous number of abortions involved in the process of in vitro fertilization vividly illustrates how the replacement of the conjugal act by a technical procedure...leads to a weakening of the respect owed to every human being. Recognition of such respect is, on the other hand, promoted by the intimacy of husband and wife nourished by married love... In the face of this manipulation of the human being in his or her embryonic state, it needs to be repeated that God's love does not differentiate between the newly conceived infant still in his or her mother's womb and the child or young person, or the adult and the elderly person. God does not distinguish between them because he sees an impression of his own image and likeness.. Therefore, the Magisterium of the Church has constantly proclaimed the sacred and inviolable character of every human life from its conception until its natural end" (n. 16).

Intracytoplasmic sperm injection (ICSI)

Intracytoplasmic sperm injection is a variety of in vitro procreation in which fertilization in the test tube does not simply "take place on its own, but rather by means of the

injection into the oocyte of a single sperm, selected earlier, or by the injection of immature germ cells taken from the man" (footnote 32).

This technique, which is morally illicit, causes a complete separation between procreation and the conjugal act" (n. 17). It takes place "outside the bodies of the couple through actions of third parties whose competence and technical activity determine the success of the procedure. Such fertilization entrusts the life and identity of the embryo into the power of doctors and biologists and establishes the domination of technology over the origin and destiny of the human person" (n. 17).

Freezing embryos

"In order to avoid repeatedly taking oocytes from the woman's body, the process involves a single intervention in which multiple oocytes are taken, followed by cryopreservation of a considerable number of the embryos conceived *in vitro*. In this way, should the initial attempt at achieving pregnancy not succeed, the procedure can be repeated or additional pregnancies attempted at a later date" (n. 18). The freezing or cryopreservation of embryos "refers to freezing them at extremely low temperatures, allowing long term storage" (cf. footnote 35).

"Cryopreservation is incompatible with the respect owed to human embryos; it presupposes their production *in vitro*; it exposes them to the serious risk of death or physical harm, since a high percentage does not survive the process of freezing and thawing; it deprives them at least temporarily of maternal reception and gestation; it places them in a situation in which they are susceptible to further offense and manipulation" (n. 18).

With regard to the large number of frozen embryos already in existence the question becomes: what to do with them? All the answers that have been proposed (use the embryos for research or for the treatment of disease; thaw them without reactivating them and use them for research, as if they were normal cadavers; put them at the disposal of infertile couples as a "treatment for infertility"; allow a form of "prenatal adoption") present real problems of various kinds. It needs to be recognized "that the thousands of abandoned embryos represent a situation of injustice which in fact cannot be resolved. Therefore, John Paul II made an "appeal to the conscience of the world's scientific authorities and in particular to doctors, that the production of human embryos be halted, taking into account that there seems to be no morally licit solution regarding the human destiny of the thousands and thousands of 'frozen' embryos which are and remain the subjects of essential rights and should therefore be protected by law as human persons" (n. 19).

The freezing of oocytes

"In order avoid the serious ethical problems posed by the freezing of embryos, the freezing of oocytes has also been advanced in the area of techniques of *in vitro* fertilization" (n. 20).

In this regard it needs to be stated that while the cryopreservation of oocytes is not in itself immoral, and is employed in other medical contexts which are not the subject of this document, when it takes place "for the purpose of being used in artificial procreation" it is "to be considered morally unacceptable" (n. 20).

The reduction of embryos

"Some techniques used in artificial procreation, above all the transfer of multiple embryos into the mother's womb, have caused a significant increase in the frequency of multiple pregnancy. This situation gives rise in turn to the practice of so-called embryo reduction, a procedure in which embryos or fetuses in the womb are directly exterminated" (n. 21).

"From the ethical point of view, embryo reduction is an intentional selective abortion. It is in fact the deliberate and direct elimination of one or more innocent human beings in the initial phase of their existence and as such it always constitutes a grave moral disorder" (n. 21).

Preimplantation diagnosis

"Preimplantation diagnosis is a form of prenatal diagnosis connected with techniques of artificial fertilization in which embryos formed in vitro undergo genetic diagnosis before being transferred into a woman's womb. Such diagnosis is done in order to ensure that only embryos free from defects or having the desired sex or other particular qualities are transferred" (n. 22).

"Unlike other forms of prenatal diagnosis..., diagnosis before implantation is immediately followed by the elimination of an embryo suspected of having genetic or chromosomal defects, or not having the sex desired, or having other qualities that are not wanted. Preimplantation diagnosis...is directed toward the qualitative selection and consequent destruction of embryos, which constitutes an act of abortion... By treating the human embryo as mere 'laboratory material', the concept itself of human dignity is also subjected to alteration and discrimination... Such discrimination is immoral and must therefore be considered legally unacceptable..." (n. 22).

New forms of interception and contragestation

There are methods of preventing pregnancy which act after fertilization, when the embryo is already constituted.

"Such methods are interceptive if they interfere with the embryo before implantation" (n. 23); for example, the IUD (intrauterine device) and the so-called 'morning-after pills' (footnote 42). They are "contragestative if they cause the elimination of the embryo once implanted" (n. 23); for example, the pharmaceutical known commercially as RU-486 (footnote 43). Even if such interceptives may not cause an abortion every time they are used, also because conception does not occur after every act of sexual intercourse, it must

be noted, however, that "anyone who seeks to prevent the implantation of an embryo which may possibly have been conceived and who therefore either requests or prescribes such a pharmaceutical, generally intends abortion". In the case of contragestatives "what takes place in reality is the abortion of an embryo which has just implanted... the use of means of interception and contragestation fall within the *sin of abortion* and are gravely immoral" (n. 23).

Third Part:

New Treatments which Involve the Manipulation of the Embryo or the Human Genetic Patrimony

Gene therapy

Gene therapy commonly refers to "techniques of genetic engineering applied to human beings for therapeutic purposes, that is to say, with the aim of curing genetically based diseases" (n. 25).

Somatic cell gene therapy "seeks to eliminate or reduce genetic defects on the level of somatic cells" (n. 25).

Germ line cell therapy aims "at correcting genetic defects present in germ line cells with the purpose of transmitting the therapeutic effects to the offspring of the individual" (n. 25).

From the ethical point of view:

Procedures used on somatic cells for strictly therapeutic purposes "are in principle morally licit...Given that gene therapy can involve significant risks for the patient, the ethical principle must be observed according to which, in order to proceed to a therapeutic intervention, it is necessary to establish beforehand that the person being treated will not be exposed to risks to his health or physical integrity which are excessive or disproportionate to the gravity of the pathology for which a cure is sought. The informed consent of the patient or his legitimate representative is also required" (n. 26).

With regard to germ line cell therapy, "the risks connected to any genetic manipulation are considerable and as yet not fully controllable" and therefore "in the present state of research, it is not morally permissible to act in a way that may cause possible harm to the resulting progeny" (n. 26).

With regard to the possibility of using techniques of genetic engineering to introduce alterations with the presumed aim of improving and strengthening the gene pool, it must be observed that such interventions would promote a "eugenic mentality" and would introduce an "indirect social stigma with regard to people who lack certain qualities, while privileging qualities that happen to be

appreciated by a certain culture or society; such qualities do not constitute what is specifically human. This would be in contrast with the fundamental truth of the equality of all human beings which is expressed in the principle of justice, the violation of which, in the long run, would harm peaceful coexistence among individuals... Finally it must also be noted that in the attempt to create a new type of human being one can recognize an ideological element in which man tries to take the place of his Creator" (n. 27).

Human cloning

Human cloning refers to "the asexual or agametic reproduction of the entire human organism in order to produce one or more 'copies' which, from a genetic perspective, are substantially identical to the single original" (n. 28). The techniques which have been proposed for accomplishing human cloning are artificial embryo twinning, which "consists in the artificial separation of individual cells or groups of cells from the embryo in the earliest stage of development... which are then transferred into the uterus in order to obtain identical embryos in an artificial manner" (footnote 47) and cell nuclear transfer, which "consists in introducing a nucleus taken from an embryonic or somatic cell into an denucleated oocyte. This is followed by stimulation of the oocyte so that it begins to develop as an embryo" (footnote 47). Cloning is proposed for two basic purposes: reproduction, that is, in order to obtain the birth of a baby, and medical therapy or research.

Human cloning is "intrinsically illicit in that...it seeks to give rise to a new human being without a connection to the act of reciprocal self-giving between the spouses and, more radically, without any link to sexuality. This leads to manipulation and abuses gravely injurious to human dignity" (n. 28).

With regard to reproductive cloning, "this would impose on the resulting individual a predetermined genetic identity, subjecting him – as has been stated – to a form of biological slavery, from which it would be difficult to free himself. The fact that someone would arrogate to himself the right to determine arbitrarily the genetic characteristics of another person represents a grave offence to the dignity of that person as well as to the fundamental equality of all people... In the encounter with another person, we meet a human being who owes his existence and his proper characteristics to the love of God, and only the love of husband and wife constitutes a mediation of that love in conformity with the plan of the Creator and heavenly Father" (n. 29).

With regard to cloning for medical therapy or research, it must be said that to "create embryos with the intention of destroying them, even with the intention of helping the sick, is completely incompatible with human dignity, because it makes the existence of a human being at the embryonic stage nothing more than a means to be used and destroyed. It is gravely immoral to sacrifice a human life for therapeutic ends" (n. 30).

As an alternative to therapeutic cloning some researchers have proposed new techniques which are presented as capable of producing stem cells of an embryonic type without implying the destruction of true human embryos, for example, by altered nuclear transfer (ANT) or oocyte assisted reprogramming (OAR). Doubts still remain, however, "regarding the ontological status of the 'product' obtained in this way" (n. 30).

The therapeutic use of stem cells

"Stem cells are undifferentiated cells with two basic characteristics: a) the prolonged capability of multiplying themselves while maintaining the undifferentiated state; b) the capability of producing transitory progenitor cells from which fully differentiated cells descend, for example, nerve cells, muscle cells and blood cells. Once it was experimentally verified that when stem cells are transplanted into damaged tissue they tend to promote cell growth and the regeneration of the tissue, new prospects opened for regenerative medicine, which have been the subject of great interest among researchers throughout the world" (n. 31).

For the ethical evaluation, it is necessary above all to consider the methods of obtaining stem cells.

"Methods which do not cause serious harm to the subject from whom the stem cells are taken are to be considered licit. This is generally the case when tissues are taken from: a) an adult organism; b) the blood of the umbilical cord at the time of birth; c) fetuses who have died of natural causes" (n. 32).

"The obtaining of stem cells from a living human embryo...invariably causes the death of the embryo and is consequently gravely illicit... In this case, research...is not truly at the service of humanity. In fact, this research advances through the suppression of human lives that are equal in dignity to the lives of other human individuals and to the lives of the researchers themselves" (n. 32).

"The use of embryonic stem cells or differentiated cells derived from them – even when these are provided by other researchers through the destruction of embryos or when such cells are commercially available – presents serious problems from the standpoint of cooperation in evil and scandal" (n. 32).

Numerous studies, however, have shown that adult stem cells give more positive results than embryonic stem cells.

Attempts at hybridization

"Recently animal oocytes have been used for reprogramming the nuclei of human somatic cells... in order to extract embryonic stem cells from the resulting embryos without having to use human oocytes" (n. 33).

"From the ethical standpoint, such procedures represent an offense against the dignity of human beings on account of the admixture of human and animal genetic elements capable of disrupting the specific identity of man" (n. 33).

The use of human "biological material" of illicit origin

For scientific research and for the production of vaccines or other products, cell lines are at times used which are the result of an illicit intervention against the life or physical integrity of a human being.

Experimentation on human embryos "constitutes a crime against their dignity as human beings who have a right to the same respect owed to a child once born, just as to every person. These forms of experimentation always constitute a grave moral disorder" (n. 34).

With regard to the use of "biological material" of illicit origin by researchers, which has been produced apart from their research center or which has been obtained commercially, the moral requirement "must be safeguarded that there be no complicity in deliberate abortion and that the risk of scandal be avoided. In this regard, the criterion of independence as it has been formulated by some ethics committees is not sufficient. According to this criterion, the use of 'biological material' of illicit origin would be ethically permissible provided there is a clear separation between those who, on the one hand, produce, freeze and cause the death of embryos and, on the other, the researchers involved in scientific experimentation". It needs to be remembered that the "duty to refuse to use such 'biological material' springs from the necessity to remove oneself, within the area of one's own research, from a gravely unjust legal situation and to affirm with clarity the value of human life. Therefore, the above-mentioned criterion of independence is necessary, but may be ethically insufficient" (n. 35).

"Of course, within this general picture there exist differing degrees of responsibility. Grave reasons may be morally proportionate to justify the use of such 'biological material'. Thus, for example, danger to the health of children could permit parents to use a vaccine which was developed using cell lines of illicit origin, while keeping in mind that everyone has the duty to make known their disagreement and to ask that their healthcare system make other types of vaccines available. Moreover, in organizations where cell lines of illicit origin are being utilized, the responsibility of those who make the decision to use them is not the same as that of those who have no voice in such a decision" (n. 35).