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OBSAH / CONTENTS

■ **Citácia na úvod/Quote for Introduction** **1**
– Ethical Issues in Geriatric Medicine [Etické problémy v geriatrii.] *M. Horan* 1
■ **Pôvodné práce/Original papers** **3**
– Protokol o transplantáciách orgánov a tkanív ľudského pôvodu k Medzinárodnému dohovoru o ľudských právach a biomedicíne – Stručný komentár. [Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin - A Brief Commentary.] *J. Glasa, S. Gubová* 3
– Patent Protection for Stem Cell Procedures under the Law of the Europen Union. [Patentová ochrana postupov s kmeňovými bunkami v zákonodarstve Európskej únie.] *T. M. Spranger* 4
– Dôstojnosť starých ľudí a zdravotnícka starostlivosť. [Dignity of the Elderly and the Health Care.] *Š. Krajčík.* 8
■ **Dokumenty/Documents** **10**
– Additional Protocol to the Convention on Human Rights and Biomedicine,on Transplantation of Organs and Tissues of Human Origin. [Protokol o transplantáciách orgánov a tkanív ľudského pôvodu k Medzinárodnému dohovoru o ľudských právach a biomedicíne] (*ETS - No. 186) Council of Europe* 10
– Ethics and Biomedical Research. [Etika a biomedicínsky výskum.] *Pontifical Academy for Life.* 13
■ **O knihách/Book Reviews** **14**
– Ethics of Human Genetics. *L. Badalík* 14

Ethical Issues in Geriatric Medicine

„In both the practice of clinical medicine and the provision of health resources, Geriatric Medicine is bristling with ethical issues and this should be obvious to anyone working with the aged. The high prevalence of severely disabling and life-threatening conditions often raises questions about how aggressively or how extensively to treat. There are two major components to any treatment decision: feasibility and desirability. Whether an intervention is feasible depends on predicting the likely outcome of the intervention. Such predictions are not easy and it should be borne in mind that while a treatment may benefit a failing organ, it will not necessarily bring about a restoration of reasonable health and may even prolong a patient's dying. Whether a treatment is desirable raises the issue of *quality of life*, a term that has no precise, well-defined meaning. Use of the term rests on a distinction be-tween the *condition* of human life and its *meaning and value* which involve the perception of individual worth and well-being. It must be stated unequivocally that no medical treatment can give meaning to life. The best that can be hoped for is to promote the physical function, mental alertness and emotional stability ne-cessary for its attainment.

The financial implications of managing disease and disability in old age are immense and in the last year of life more expensive medical and social resources are consumed than in any other. Hitherto, the financial consequences of medical intervention were kept largely separate from the actual practice of medicine in the U.K. Direct financial responsibility may well be ad odds with what a physician perceives as being in a patient's best interests and lead to a biased decision making. It is interesting that in other circumstances such as in industry and commerce, the law requires safeguards against such *conflicts of interest*. With the present reorganisation of the National Health Service, conflicts of interest appear to be part of the fabric of the system and dilemmas hardly en-countered by the medical practitioner only a few years ago are starting to arise quite often. My perception is that this reorganisation is producing a bewildering, often frustrating, health care environment in which patients' rights are easily overlooked. Physicians must make a conscious effort to fulfil their primary role as a patient's advocate and not accept the provision of substandard health care simply because of his or her budget responsibilities and age alone must never be permitted to become a means by which the costs of health care provision are contained."

Michael Horan*

** Cited from: Horan, M.: Difficult choices in treating and feeding the debilitated elderly. In: Gormally, L. (Ed.): The dependent elderly: Autonomy, justice and quality of care. Cambridge University Press, Cambridge, 1992, p. 16 - 17.*

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WORWAG PHARMA

PÔVODNÉ PRÁCE

ORIGINAL PAPERS

PROTOKOL O TRANSPLANTÁCIÁCH ORGÁNOV A TKANÍV ĽUDSKÉHO PÔVODU K MEDZINÁRODNÉMU DOHOVORU O ĽUDSKÝCH PRÁVACH A BIOMEDICÍNE. STRUČNÝ KOMENTÁR

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1. Predmet, poslanie a obsah Protokolu [1]

Medzinárodný dohovor o ľudských právach a biomedicíne (ETS No. 164, Oviedo, 1997; v platnosti od 1. 12. 1999; ďalej len Dohovor), ku ktorému Slovenská republika (ďalej len SR) pristúpila podpisom (4. 4. 1997) a ratifikáciou (15. 1. 1998) ako jeden z prvých štátov Rady Európy (ďalej len RE), má za cieľ ochranu dôstojnosti a identity všetkých ľudí a zabezpečuje každému rešpektovanie jeho integrity. Predstavuje vhodný rámec na formulovanie dodatočných štandardov na ochranu práv a slobôd darcov, potenciálnych darcov a príjemcov orgánov a tkanív.

Protokol o transplantáciách orgánov a tkanív ľudského pôvodu (ďalej len Protokol; druhý dosiaľ prijatý protokol k spomínanému Dohovoru z viacerých, ktoré sa aktuálne pripravujú) rozširuje ustanovenia Dohovoru na oblasť transplantácie orgánov, tkanív a buniek ľudského pôvodu. Ustanovenia Dohovoru sa v ňom priamo aplikujú, pričom Protokol má za cieľ ich rozpracovanie pre špecifickú oblasť, ktorú pokrýva. Oba dokumenty je potrebné interpretovať a aplikovať vo vzájomnej spojitosti.

Účelom Protokolu je ochrana dôstojnosti a identity každého človeka a zabezpečenie, bez akejkoľvek diskriminácie, rešpektovania jeho integrity a ďalších práv a základných slobôd vo vzťahu k transplantácii orgánov, tkanív a buniek ľudského pôvodu.

Protokol zahŕňa výlučne odber a transplantáciu ľudských orgánov, tkanív alebo buniek u osôb, ktoré sa narodili (či už sú živé alebo mŕtve). Netýka sa transplantácie orgánov, tkanív alebo buniek ľudského zárodku (embrya) alebo plodu (fétu), ani transplantácie orgánov, tkanív alebo buniek zvierat človeku (xenotransplantácií). Obe spomínané oblasti budú predmetom zvláštnych dokumentov, ktoré sú t. č. už v príprave [2].

Reproduktívne orgány a tkanivá (obsahujúce vajíčka, spermie a ich prekurzorové bunky) nie sú zahrnuté do Protokolu, nakoľko transplantácia ľudských orgánov, tkanív a buniek predstavuje odlišnú problematiku od oblasti medicínsky asistovanej reprodukcie človeka a vyžaduje uplatnenie iných regulačných pravidiel.

Krv a prípravky z krvi na použitie v transfúznej medicíne (transfuziológii) sú predmetom špecifických regulačných úprav, ako je napríklad *Odporúčanie R(95)15 o príprave, použití a zabezpečení kvality krvných súčastí*, preto nie sú zahrnuté do tohto Protokolu. Do Protokolu sú však pre prípad transplantácie špecificky zahrnuté krvotvorné (hematopoetické) kmeňové bunky.

Princípy a požiadavky Protokolu platia *mutatis mutandis* aj pre využitie ľudských tkanív a buniek v medicínskych prístrojoch alebo liečivých prípravkoch.

Ľudské orgány, tkanivá alebo bunky sa na účely transplantácie získavajú za týchto okolností:

a) živá osoba, za určitých okolností, dáva súhlas na odber svojho orgánu alebo tkaniva za účelom jeho transplantácie inej osobe;

b) orgány alebo tkanivá môžu byť odobraté zomrelej osobe a implantované druhej osobe;

c) osoba, ktorá sa podrobuje lekárskemu výkonu pre svoj vlastný zdravotný úžitok, môže súhlasiť s tým, aby sa orgán alebo tkanivo odobrané pri tomto výkone implantovalo inej osobe.

Protokol pozostáva z preambuly a jedenástich kapitol, má 34 samostatných článkov.

Preambula obsahuje principiálne východiská uplatnené pri tvorbe Protokolu.

Kapitola I definuje predmet a obsah Protokolu, vrátane definícií niektorých pojmov.

Kapitola II obsahuje všeobecné ustanovenia, vrátane článkov o transplantačnom systéme, profesionálnych štandardoch, informácii pre príjemcu, zdravotných aspektoch a informáciách pre zdravotníckych pracovníkov a pre verejnosť.

Kapitola III je venovaná problematike odberu orgánov a tkanív zo živých osôb. Má za cieľ chrániť živého darcu pred psychologickým a fyzickým rizikom a následkami implantácie ním darovaného orgánu alebo tkaniva, najmä z hľadiska dôvernosti získavaných údajov a záťaže vznikajúcej v súvislosti s požiadavkou sledovateľnosti pôvodu a pohybu (využitia) odobraných orgánov a tkanív.

Kapitola IV obsahuje ustanovenia týkajúce sa odberu orgánov a tkanív od zomrelých. Cieľom je upraviť jednotlivé fázy odberu orgánov alebo tkanív od zomrelých osôb a zabezpečiť, aby sa odber nemohol vykonať, ak zomrelý vyjadril s ním nesúhlas.

Kapitola V upravuje implantáciu orgánov a tkanív odobraných pôvodne pre iný účel než pre účel ich transplantácie. Špecifikuje podmienky, za ktorých je implantácia takéhoto orgánu alebo tkaniva inej osobe možná; zvlášť vyžaduje poskytnutie špecifickej informácie a získanie informovaného súhlasu darcu alebo predpísaného povolenia.

Kapitola VI obsahuje zákaz finančného zisku viazaného na darovanie ľudských orgánov alebo tkanív.

Kapitola VII obsahuje ustanovenia o zabezpečení dôvernosti informácií a ochrany osobne identifikovateľných údajov pred zverejnením a iným zneužitím.

Kapitola VIII - postup v prípade porušenia práv alebo princípov uvedených v Protokole.

Kapitola IX - medzinárodná spolupráca v oblasti transplantácie orgánov a tkanív.

Kapitola X - vzťah Protokolu k Dohovoru a budúca revízia Protokolu (predpokladá sa o 5 rokov od jeho prijatia).

Kapitola XI - záverečné ustanovenia.

Protokol je sprevádzaný **Vysvetľujúcou správou** (Explanatory Report), ktorá bola na požiadanie Pracovnej skupiny vypracovaná pod gesciou Generálneho sekretára RE. Táto správa nie je záväznou interpretáciou Protokolu, avšak obsahuje rozbor najvýznamnejších problémov diskutovaných počas prípravy textu a poskytuje informácie objasňujúce predmet a cieľ protokolu. Má napomôcť lepšiemu pochopeniu jeho ustanovení.

2. História prípravy protokolu

V novembri 1987 sa 3. konferencia európskych ministrov zdravotníctva v Paríži zaoberala problematikou transplantácie orgánov. Jej výsledkom bolo prijatie viacerých smerníc pre túto oblasť, ako aj záverečného vyhlásenia (deklarácie), v ktorom ministri upozornili, že hoci transplantácia orgánov a tkanív predstavuje už zavedenú súčasť zdravotnej starostlivosti, napomáhajúcu záchranu života a zlepšenie jeho kvality, je potrebné zdôrazniť na jednej strane význam špecifických opatrení na podporu darovania orgánov a tkanív pre potreby transplantácie, no na druhej strane aj opatrení, ktoré by zabránili zneužitiu transplantácie a znížili riziko jej neprípustnej komercionalizácie.

Týmto otázkam venoval pozornosť aj Výbor ministrov (Committee of Ministers) RE a Parlamentné zhromaždenie RE, najmä v Rezolúcii (78)29 o harmonizácii legislatívy členských štátov RE týkajúcej sa odberu, implantácie a transplantáce materiálov ľudského pôvodu a v Odporúčaní č. REC (2001)5 o manažmente zoznamov čakateľov a dobách čakania na transplantáciu orgánov.

V roku 1991, v Odporúčaní č. 1160 (Recommendation No. 1160) Parlamentné zhromaždenie RE odporučilo Výboru ministrov pripraviť rámcový dohovor [3] obsahujúcu základný text so všeobecnými princípmi a dodatkové protokoly upravujúce špecifické aspekty. V tom istom roku Výbor ministrov RE požiadal *Ad hoc* výbor expertov pre bioetiku (CAHBI) RE, neskôr zmenený na Riadiaci výbor pre bioetiku (CDBI) o vypracovanie „protokolov ku konvencii, týkajúcich sa, predbežne, transplantácie orgánov a použitia substancií ľudského pôvodu; (a tiež) medicínskeho výskumu na človeku."

CAHBI na svojom 14. zasadnutí v Štrasburgu (November 1991) vymenoval Pracovnú skupinu pre orgánové transplantácie (CAHBI-CO-GT1) a poveril ju prípravou návrhu Protokolu. Pracovná skupina (neskôr pod názvom CDBI-CO-GT1) začala prácu na Protokole na svojom prvom zasadnutí v januári 1992, paralelne s prácami CDBI na príprave Konvencie.

Na druhom zasadnutí CDBI v apríli 1993 Pracovná skupina predložila návrh Protokolu a v júni 1994 zástupcovia ministrov RE súhlasili s deklasifikáciou tohto dokumentu. Keďže v ďalšom sa CDBI sústredil na prípravu textu samotnej Konvencie, práce na Protokole boli pozastavené až do januára 1997. Konvencia bola schválená Výborom ministrov RE 19. novembra 1996 a otvorená na podpis 4. apríla 1997 v Oviede (Španielsko). CDBI, na svojom 11. zasadnutí v júni 1996 rozhodol o obnovení práce na Protokole a jeho prepracovaní vo svetle ustanovení Konvencie.

Text Návrhu Protokolu, posúdený na 15. zasadnutí CDBI (december 1998), bol rozhodnutím Výboru ministrov RE (658. zasadnutie; február 1999; bod 10.1) deklasifikovaný za účelom jeho konzultácií. Konzultujúci, ktorí zahŕňali členské štáty RE, relevantné európske mimovládne organizácie, a najmä Parlamentné zhromaždenie RE (špecificky Výbor pre sociálne, zdravotné a rodinné veci, Výbor pre vedu a technológie a Výbor pre právne veci a ľudské práva) sa podieľali na ďalšom dopracovaní textu. Po dôkladnom posúdení CDBI ukončil text Protokolu a schválil ho na svojom zasadnutí v júni 2000.

Parlamentné zhromaždenie RE vydalo stanovisko k Protokolu 25. apríla 2001 [4]. Zástupcovia ministrov schválili text Protokolu 31. októbra 2001. Protokol bol schválený Výborom ministrov RE 8. novembra 2001 a otvorený na podpis 24. januára 2002.

3. Postoj delegácie Slovenskej republiky

SR sa od počiatku podieľala na príprave textu Protokolu v rámci svojho zastúpenia vo výbore CAHBI (neskôr CDBI). Pripomienky expertov SR, nominovaných na pracovné zasadnutia CDBI, sa uplatnili priamo v diskusii o formuláciách jednotlivých ustanovení Protokolu.

Konečná verzia textu Protokolu nie je v rozpore s platnou legislatívou SR pre oblasť transplantácií orgánov a tkanív, ani so záujmami SR v tejto oblasti.

Pristúpením k Protokolu - jeho podpisom a následnou ratifikáciou - SR pokračuje v doterajšom pozitívnom trende aproximácie svojej legislatívy a jej vývinu v zmysle aktuálnych a progresívnych medzinárodných štandardov.

Pristúpenie k Protokolu je potrebné hodnotiť aj z hľadiska jeho pozitívneho vplyvu na ďalší rozvoj už dosiaľ veľmi intenzívnej medzinárodnej spolupráce SR v oblasti transplantácií orgánov a tkanív a dopadu na zlepšenie zdravotnej starostlivosti o pacientov - potenciálnych príjemcov transplantovaných orgánov a tkanív v SR.

Poznámky

1. Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin. *European Treaty Series - No. 186, Council of Europe*, Strasbourg, 24. 1. 2002, text protokolu v anglickom jazyku je uverejnený v rubrike Dokumenty, s. 9 - 12 (k dispozícii na internetovej stránke Rady Európy: http://conventions.coe.int-/Treaty/en/Treaties/html/186.htm)

2. Protokol o ochrane zárodku a plodu, Odporúčanie o xenotransplantáciách.

3. Dohovor o ľudských právach a biomedicíne RE, ETS No. 164, Oviedo, 1997.

4. Opinion No. 227 (2001).

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PATENT PROTECTION FOR STEM CELL PROCEDURES UNDER THE LAW OF THE EUROPEAN UNION

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Abstract

Stem cell research shows an immense diagnostic and therapeutic potential. The procedures based on human stem cells seem to allow new medical treatments for serious diseases like Parkinson's or Alzheimer's disease, leukaemia or diabetes. However, as no company or inventor would take the risk of immense investments without an adequate legal protection of the possible benefits arising out of their work, intellectual property law plays a pivotal role for the further development of stem cell techniques. Although international patent law knows protection of inventions using biological substances and living matter for about 160 years, patents on stem cells, DNA and other parts of the human body raise specific objections. Nevertheless, from a strictly legal angle, there are no barriers to patents on stem cell procedures. In particular, Art. 6 of the „Directive 98/44/EC of the European Parliament and of the Council of the European Union of July 6, 1998 on the legal protection of biotechnological inventions" - which qualifies inventions as unpatentable where their commercial exploitation would be contrary to *ordre public* or morality - does not hinder patent protection for stem cell research.

Key words: stem cell, patent protection, human cloning, embryo protection, European Court of Justice.

I. Introduction

Patent protection for living matter has already been granted under patent law in the 19th century - for the first time in Finland on 24 July 1843 (1). In 1873, inter alia, *Louis Pasteur* was granted U.S. Patent No. 141,072, containing a *per se* claim to „yeast, free from organic germs of disease, as an article of manufacture"(2). So, in contrast to a widely held opinion (3), the famous US patent granted about 20 years ago to *Chakrabarty* (4) for oil-eating bacteria was not the first patent to be granted

for living organisms or biological substances (5). With this practice in mind, at first sight, recent discussions and disputes on „unjustified patents on life" seem to be somewhat behind the time. However, the significant developments of genetics during the past decades call for reassessments and present a challenge for international patent law. In the following, the requirements for and the barriers to patent protection for biotechnological inventions - with special emphasis to stem cell procedures - according to the law of the European Union should be described in brief.

II. Basic elements of European patent protection

In 1973 a number of European countries signed the European Patent Convention (EPC) which was based on the Strasbourg Convention of 1963. The EPC led to the establishment of the European Patent Office (EPO) as part of the European Patent Organization. Although all the Member Countries of the European Union are also members to the EPC, this document does not present a part of European Union law. Instead, the EPC is part of supranational law.

The European Union presented its first draft of a regulation concerning the legal protection of inventions in the field of biotechnology in 1988. Finally, after a decade of heated debates, on 30 July 1998 the European Co'mmunities' „Directive 98/44/EC of the European Parliament and of the Council of the European Union of July 6, 1998 on the legal protection of biotechnological inventions" (6) came into effect. The so-called Biotechnology Directive serves as a mere framework for the patent laws of the Member States, which subsequently had to adjust their national laws to the provisions of the Directive no later than 30 July 2000. However, more than two years after the end of the transformation period, only Denmark, Spain, Finland, Greece, Ireland and the United Kingdom have met their obligation to transform the Directive (7).

The following considerations are the deciding factors calling for the enactment of this new legal instrument: First of all, as the protection of biotechnological inventions is of fundamental importance for the Community's industrial development (8), the Directive aims at the enhancement of patents on these inventions. Second, an effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology (9). Furthermore, differences in the patent protection offered by the laws and practices of the different Member States could create barriers to trade and hence impede the proper functioning of the internal market (10).

The Directive can be divided into two parts. The first part consists of so-called recitals, which are legally nonbinding. However, as they serve as an interpretative guideline for courts and administrative authorities, the recitals are important for a deeper understanding of the Directive and therefore should be read together with the articles, which present the legally binding elements of the document.

In its Art. 3, the Directive states:

„(1) For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

Therefore, the Directive follows internationally accepted principles of patent law, according to which mere discoveries are not patentable, whereas inventions can be the object of patent protection. At first sight, Art. 3 paragraph 2 seems to be inconsistent with paragraph 1. Antagonists of patents on biotechnological inventions take the view that elements to be found in nature are not new and therefore present mere discoveries. However, Art. 3 paragraph 2 of the Directive does not allow the granting of patents for substances *in situ*. Instead, the provision merely aims at the protection of inventions related to the isolation and synthetic production of naturally occurring substances.

III. Patents on the human body

Art. 5 of the Directive specifies this basic differentiation for patents on the human body:

„(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

Hence, inventions using a gene or another part of the human body have to meet the same requirements of patentability as any other invention. In this connection, recital 21 of the Directive states that an isolated element of the human body should be treated as patentable matter as it can be the object of techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself. However, in order to minimise the risk of „random shots", i. e. patent applications of inventors which do not know the gene's function, Art. 5 paragraph 3 calls for the disclosure of a concrete function (11). A mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention (12). This is also the guiding principle for patents on Expressed Sequence Tags or Single Nuclear Polymorphisms. Furthermore, recital 24 reads:

„[...] in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of protein is produced or what function it performs."

Finally, recital 25 of the Directive contains further information regarding overlapping sequences. According to this provision, for the purposes of interpreting rights conferred by a patent, each sequence will be considered as an independent sequence in patent law terms, if sequences overlap only in parts, which are not essential to the invention.

In addition to these specific requirements for patents on parts of the human body, Art. 6 of the Directive restricts patent protection in several ways. First of all, Art. 6 paragraph 1 reiterates well-known principles of international patent law (13), and qualifies inventions as unpatentable where their commercial exploitation would be contrary to *ordre public* or morality (14). These ethical reservations pay tribute to concerns about potential abuses of biotechnological inventions at the level of application. However, possible conflicts between *ordre public* and the invention as such (and not the invention's application) do not hinder patent protection. This differentiation between the invention and its application achieves an

adequate „filter", as a patent does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes (15).

Art. 6 paragraph 2 of the Directive contains a nonexhaustive list of certain processes, which automatically qualify for an exclusion under Art. 6 paragraph 1. According to this provision the following techniques, inter alia, shall be considered unpatentable:

„(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes; [...]"

Once again, the recitals contain additional information, which are of paramount importance for the provision's interpretation. According to recital 41, a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being. Recital 42 completes Art. 6 paragraph 2 *lit.* c: It provides that the exclusion does not affect inventions for therapeutic or diagnostic purposes, which are applied to the human embryo and are useful to it. The paramount importance of these provisions has to be described in the following.

IV. Stem cell procedures

If one takes into account the requirements and restrictions mentioned above, the patentability of so-called stem cell procedures turns out to be questionable. In general, the term stem cell applies to any cell of the embryo, foetus, or adult human that possesses the capacity to reproduce by cell division for any number of times („immortal" cell) and to differentiate into cells of different degrees of specialisation (differentiation) (16).

In order to be able to fully understand the question raised above, a brief illustration of the scientific foundations of stem cell procedures is helpful: Researchers commonly distinguish between EG cells, ES cells and AS cells. ES cells, i. e. embryonic stem cells, retain the special ability to develop into nearly all of about 210 different cell types (17). Hence, ES cells can be qualified as pluripotent cells. ES cells occur early in embryonic development (until about 16 cells), can easily be isolated and reproduced, and, if placed in appropriate culture conditions, seem to be capable of extensive, undifferentiated proliferation in vitro and retain the potential to create all adult cell types (18).

Embryonic germ cells (EG cells) originate from the primordial reproductive cells of the developing foetus (19). Similar to ES cells, EG cells are not limited to the reproduction of a specific tissue or organ. However, according to latest results of the research, EG cells have fewer properties in common with ES cells than was thought a few years ago (20). Especially, attempts to derive adult cells from EG cells have led to abnormalities.

AS cells, which means adult stem cells, are derived from an adult human being, generally in compliance with the bio-ethical principle of informed consent, i. e. from a donor. Hence, even Pope John Paul II is reported to have judged it morally permissible to conduct research on adult stem cells (21). By now, adult stem cells, inter alia, have been found in or even isolated and grown in culture from brain tissue (22), bone marrow (23), spinal cord (24), blood of the umbilical cord, skin, root of the hairs (25), muscle and intestine (26). In view of this nearly inexhaustible stockpile, antagonists of embryonic stem cell research plead for the exclusive use of AS cells. Nevertheless, nature sets manifold limits to AS cell research. First of all, from embryo to adult, the versatility and abundance of stem cells gradually decreases (27). As a result, AS cells are expected to be only multipotent. That means, AS cells are unable to generate all different cell types. Instead, they have a limited capacity for differentiation. Maybe scientists will be able to re-program them to less differentiated forms of cells. However, at the moment it is quite unclear whether this approach will work (28). In addition, according to some scholars' assessment, the success of AS cell research depends on the findings related to ES cells. In other terms: ES cell research is an indispensable condition for the promising use of AS cells. Finally, AS cells are hard to find and some tissues may not contain them: For many adult cell types it is not known where the stem cells are, or if they even exist (29).

The diagnostic and therapeutical potential and the economic dimension of stem cell research is enormous. Recent developments aim at the use of stem cells in order to enhance the medical treatment of, inter alia, Huntington's, Parkinson's disease, Alzheimer's disease, leukaemia, stroke, heart disease, diabetes, cystic fibrosis, muscular dystrophy, hepatitis, osteoporosis, multiple sclerosis, rheumatoid arthritis, spinal cord injury, or burns (30). Another possible application concerns the use of stem cells as tools or test kits in the filed of clinical trials: Before being tested on humans, drugsį effects could be scrutinized on organs or tissues generated form isolated stem cells. In the long run, stem cell research aims at generating whole organs or tissues. With these possible applications in mind, it is not surprising that the worldwide economic potential of stem cell procedures is estimated at up to $400 billion (31).

Nevertheless, the developments described above require immense investments. An investor, in order to be willing to make these investments, must expect that once commercialisation occurs, he will receive a return on investment (32). Without an adequate protection of intellectual property, stem cell research could be doomed to fail. By now, there have been over 2.000 patent applications involving human and non human stem cells all over the world (33). The question is whether the new Directive allows patents on stem cell procedures: In its Art. 6 paragraph 2, the Biotechnology Directive contains provisions which may lead to barriers to patents on stem cells.

First, Art. 6 paragraph 2 lit. a) could apply to stem cell techniques. As the term cloning circumscribes nothing but the mere duplication of genetic information (34), the production and use of stem cell lines, i. e. sequences of generations of cells obtained by continuous cell division and differentiation, may fall within the scope of Art. 6 paragraph 2 lit. a). However, as already mentioned above, recital 41 of the Directive defines a process for cloning human beings as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being

Hence, Art. 6 paragraph 2 lit. a) does not address cloning procedures aiming at the mere generation of tissue aggregates or whole organs, because they are not designed to reproduce human beings as a whole. For the same reason, the reproductive cloning of animals is not prohibited even if the technique used or its results are applicable to human beings. The provision exclusively aims at the prohibition of patents on human *reproductive* cloning and therefore contains an element of „end product orientation". Not the duplication of human genetic information but the duplication of a human being as a whole is in the provision's centre of interest. Processes that are not intended to *create a human being*, i. e. the mere reproduction of single cells, tissues or organs, which are only *parts of human beings*, do not fall within the scope of this prohibition (35).

Second, embryonic stem cell procedures may be affec-

ted by Art. 6 paragraph 2 lit. c) of the Directive, if human stem cells have to be qualified as „human embryos" (36). For example, for the purposes of the German Embryo Protection Act (Embryonenschutzgesetz)(37) of 1990 (38), every totipotent cell taken from an embryo that has the potential to develop into a human individual is considered to be an embryo (39). However, notwithstanding the differentiation between pluripotent and totipotent stem cells, Art. 6 paragraph 2 lit. c) is not applicable to any stem cells whatsoever. As recital 42 of the Directive states, the exclusion contained in Art. 6 paragraph 2 lit. c) does not affect inventions for therapeutic or diagnostic purposes, which are applied to the human embryo and are useful to it. Therefore, the Directive's definition of „human embryo" calls for the possibility of an individual advantage („useful to it"). As stem cells are usually derived from cadaveric foetal tissue (40), there is no possibility of an individual advantage for the deceased embryo. In addition, single stem cells or even stem cells lines are also unable to profit from therapeutic or diagnostic developments: They are not intended to develop into a human being and therefore fail to show an individual interest. This leads to the result that embryonic stem cells cannot be defined as „human embryos" in the meaning of Art. 6 paragraph 2 lit. c) of the Directive, even if they are totipotent.

In its Opinion No. 16 of 7 May 2002, the European Group on Ethics in Science and New technologies to the European Commission (EGE), which is an independent, multidisciplinary and pluralist instance that serves as an advisor to the Commission, came to the same conclusion (41). However, as the EGE deals with the question how ethical values of European society can be taken into consideration in the scientific and technological development promoted by Community policies (42), its opinion presents an ethical check up or suggestion and no legally binding instrument. In light of the above analysis, it can be said that the Directive does not pose any obstacle to the patentability of stem cell procedures.

V. Recent developments and conclusion

The question of patents on naturally occurring substances, especially on genes and other parts of the human body, stimulated the Dutch government to take a complaint to the European Court of Justice aiming at the rescission of the Directive. The plaintiff invoked various grounds for the Directive's annulment, inter alia, that the Directive was contrary to the principle of subsidiarity, infringed the principle of legal certainty, was incompatible with international obligations, and led to conflicts with fundamental rights. However, on 9 October 2001, the Court dismissed the action in its entirety (43). Although the decision puts the tardy Member States under pressure to fulfil their obligations, i. e. to transform the Directive into national law, it can be taken for granted that it will fail to bring discussions and disputes to an end. Instead, the antagonists of biotechnology patents will continue to deny the *raison d'être* of so-called „patents on life". However, the legal basis for patents on genes and other parts of the human body is solid.

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Biologische Grundlagen und ethisch-rechtliche Bewertung, [1997] 2 Jahrbuch für Wissenschaft und Ethik, 357, 358. **35.** *Cf.* Herdegen/Spranger, in: Herdegen (Ed.), Internationale Praxis Gentechnikrecht, International Law/Comment, Convention on Human Rights and Biomedicine, No. 58 *et seq.* Some scholars state that it is permissible to use cloning techniques within the period of two weeks of embryonic development; *see* S. J. R. Bostyn, One Patent a Day Keeps the Doctor Away ?, [2000] 7 European Journal of Health Law 229, 244. **36.** T. M. Spranger, Legal Status and Patentability of Stem Cells in Europe, 21 Biotechnology Law Report 105 et seq (2002). **37.** In general: Wolfrum/Zeller, Legal Aspects of Research with Human Pluripotent Stem Cells in Germany, [1999] 4 Biomedical Ethics 102. **38.** Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz) of 13 December 1990, entered into force on 1 January 1991, BGBl I, 2746. **39.** Art. 8 (1) of the German Embryo Protection Act. **40.** National Bioethics Advisory Commission (Ed.), Ethical Issues in Human Stem Cell Research, Vol. I, Report and Recommendations of the National Bioethics Advisory Commission, 1999, 45. **41.** Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, No. 16, 7 May 2002. **42.** Cf. EGE Doc. No. IP/02/675. **43.** Case C-377/98 *Netherlands v. European Parliament and Council of European Union* [2001] ECR I-7079.

Abstrakt

Spranger, T. M.: Patentová ochrana postupov s kmeňovými bunkami v zákonodarstve Európskej Únie. [Patent Protection for Stem Cell Procedures under the Law of the Europen Union.] Med. Eth. Bioet., 10, 2003, No. 1-2, p. 3 - 7. Výskum kmeňových buniek vykazuje veľmi významný diagnostický a terapuetický potenciál. Zdá sa, že postupy založené na využití kmeňových buniek by mohli viesť k novým možnostiam liečby závažných ochorení, akými sú Parkinsonova alebo Alzheimerova choroba, leukémia alebo diabetes. Keďže žiadna spoločnosť alebo vynálezca nebude riskovať stratu veľkých vložených investícií bez adekvátnej právnej ochrany možného prínosu svojej práce, zákony zabezpečujúce ochranu intelektuálneho vlastníctva majú zásadný význam pre ďalší rozvoj techník využívajúcich kmeňové bunky. Hoci medzinárodné patentové zákony poznajú ochranu objavov využívajúcich biologické substancie alebo živú hmotu už približne 160 rokov, patenty týkajúce sa kmeňových buniek, DNA alebo iných častí ľudského tela vyvolávajú špecifické námietky. Z výlučne právneho hľadiska však neexistujú žiadne prekážky voči patentom postupov využívajúcich kmeňové bunky. Konkrétne, článok 6 Direktívy 98/44/EC Európskeho parlamentu a Rady Európskej Únie zo 6. júla 1988 o právnej ochrane biotechnologických objavov, ktorá kvalifikuje ako 'nepatentovateľné' tie objavy, ktorých komerčné využitie by bolo v protiklade k verejnému poriadku a morálke, neblokuje patentovú ochranu výskumu kmeňových buniek. ***Kľúčové slová***: kmeňové bunky, patentová ochrana, klonovanie človeka, ochrana embrya, Európsky súdny dvor.

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DÔSTOJNOSŤ STARÝCH ĽUDÍ A ZDRAVOTNÍCKA STAROSTLIVOSŤ

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Abstrakt

Starí ľudia tvoria prevažnú časť klientely väčšiny klinických odborov. Predstavujú veľmi zraniteľnú skupinu a v starobe sú časté situácie, ktoré môžu mať negatívny dopad na ľudskú dôstojnosť. Z viacerých aktuálnych koncepcií ľudskej dôstojnosti je pre pomáhajúce profesie azda najvhodnejšia tá, ktorá vychádza z príslušnosti jedinca k ľudskému rodu. Dôležité je nezamieňať dôstojnosť ako hodnotu a jej prežívanie. Dôstojnosť je východiskom pre poskytovanie adekvátnej starostlivosti „neperspektívnym" pacientom a dôležitou súčasťou starostlivosti o starých ľudí je umožniť im prežívať ich vlastnú dôstojnosť, jej potvrdenie. Zlepší sa tak kvalita starostlivosti bez ďalšieho zvyšovania nákladov, ako i prístup personálu starajúcich sa o starých ľudí k práci. Cieľom prebiehajúceho projektu Európskej únie „Dôstojnosť a starší Európania" je poznať faktory ovplyvňujúce rešpektovanie dôstojnosti starých ľudí a ich prežívanie vlastnej dôstojnosti.

Kľúčové slová: ľudská dôstojnosť, staroba, zdravotnícka starostlivosť.

Hoci starnutie nie je choroba, staroba je spojená s vyšším výskytom chorôb, a tak je starnutie populácie spojené so zvýšenými nárokmi na zdravotnícku a následne i sociálnu starostlivosť. Rastúca technologizácia zdravotníckej starostlivosti a nedostatok zdrojov vytvárajú mnohé etické problémy. Súčasne rastie dôraz na dodržiavanie ľudských práv vo všetkých oblastiach života.

Jednou zo základných podmienok dodržiavania ľudských práv je rešpektovanie ľudskej dôstojnosti. Rada Európy prijala v roku 1997 *Dohovor o* ochrane *ľudských práv a* dôstojnosti *človeka v súvislosti s* aplikáciou *biológie a* medicíny (1). Ľudská dôstojnosť je jednou z ústredných tém európskej kultúry vychádzajúcej z antických a židovsko-kresťanských tradícií. Význam pojmu ľudskej dôstojnosti dokazuje i skutočnosť, že väčšina ústav má v preambule zmienku o ľudskej dôstojnosti a na ľudskú dôstojnosť sa odvoláva aj *Všeobecná deklarácia ľudských práv* Organizácie spojených národov. Napriek tomu máme i v odbornej literatúre viacero správ o tom, že existujú špecifické problémy s rešpektovaním ľudskej dôstojnosti u starých ľudí (2, 3).

Pri práci s pojmom „ľudská dôstojnosť" je závažným problémom, že jeho chápanie je veľmi široké. Dôstojnosť bola dokonca označená ako veľmi elastický resp. značne neurčitý, až vágny pojem (4).

Najčastejšie sa rozlišujú tieto 4 základné prístupy k chápaniu a rešpektovaniu ľudskej dôstojnosti (5):

1. dôstojnosť založená na poznaní a rešpektovaní hodnoty človeka ako takého (Menschenwurde),
2. dôstojnosť človeka založená na jeho sociálnom statuse,
3. dôstojnosť založená na morálnych postojoch,
4. dôstojnosť založená na zásluhách daného človeka.

Pre „pomáhajúce profesie" (medicína, ošetrovateľstvo, psychológia, sociálna práca apod.) je rozhodujúce, aký koncept ľudskej dôstojnosti sa v praxi použije. Pre účely týchto profesií je azda najvhodnejšia koncepcia založená na chápaní a rešpektovaní hodnoty človeka ako takého (Menschenwurde). Relevantná je i dôstojnosť založená na zásluhách.

Podľa Nordenfelta pojem „hodnoty človeka" (Menschenwurde) súvisí s 3 ľudskými vlastnosťami (5): 1. schopnosťou rozmýšľať, 2. možnosťou sa slobodne rozhodovať, 3. autonómiou (možnosťou nezávislého ovplyvňovania behu vecí, ktoré sa človeka týkajú). Podľa Kanta je autonómia základom ľudskej dôstojnosti (6).

V starobe sú však veľmi časté stavy, ktoré vedú ku strate autonómie a rastu závislosti človeka na iných (demencia, stavy po cievnych príhodách apod.). Situáciu starého človeka zhoršujú i ďalšie faktory, ktoré môžu negatívne ovplyvňovať subjektívne prežívanie dôstojnosti - ako sú napr. telesná a duševná integrita a miesto človeka v spoločnosti. Chorý je neraz konfrontovaný s meniacou sa vlastnou identitou (7). Extrémnym prípadom straty všetkých spomínaných atribútov je smrť človeka. Uvedomovanie si straty autonómie niekedy vedie ku strate sebaúcty a úcty k vlastnému životu, čo môže viesť k izolácii a k úvahám o suicídiu resp. eutanázii (8).

Proces liečenia resp. starostlivosti o starých ľudí je procesom, v ktorom personál aktívne presadzuje svoju autonómiu, aby dosiahol zlepšenie resp. udržanie čo najlepšieho zdravotného stavu pacienta. Toto konanie, zamerané v dobrej viere v záujme pacienta, môže niekedy prísť do konfliktu s predstavami pacientov, ktorí môžu mať pocit, že dochádza k obmedzovaniu ich autonómie a v konečnom dôsledku aj k narušovaniu ich dôstojnosti. Riešeniu tohto konfliktu môže napomôcť lepšia informovanosť pacienta a vytvorenie partnerského vzťahu medzi pacientom a lekárom, ako aj medzi pacientom a inými pracovníkmi, ktorí sa podieľajú na zdravotnej a sociálnej starostlivosti (9, 10).

Vo vyššom veku sú časté situácie, ktoré pacientovi znemožňujú vyjadriť svoju vôľu ako prejav jeho vlastnej autonómie. Tento problém čiastočne rieši možnosť pacienta „rozhodnúť dopredu" o spôsobe starostlivosti, ktorú si bude želať, resp. ktorú by odmietol v prípade, keď nebude môcť o sebe priamo rozhodovať (11).

Koncepcia ľudskej dôstojnosti založená na hodnote

človeka danej určitými atribútmi (vlastnosťami) (Menschenwurde) má však určité nedostatky. Ak by sa aplikovala do dôsledkov, potom ľudia v bezvedomí alebo počas anestézy by strácali svoju dôstojnosť a mentálne retardovaní jedinci by ju nikdy nedosiahli. Táto koncepcia nerieši ani problém dôstojnosti mŕtveho ľudského tela.

Riešením tohto problému je priznanie 'vrodenej' ľudskej dôstojnosti každému človeku ako 'príslušníkovi ľudského rodu' alebo 'bytosti stvorenej na obraz Boží' (imago Dei)(5). Tento princíp sa uvádza i vo *Všeobecnej deklarácii ľudských práv* („Všetci ľudia sa rodia slobodní a rovní v dôstojnosti a ľudských právach...“). Uznanie a rešpektovanie dôstojnosti každého jedinca, vychádzajúcej z jeho príslušnosti k ľudskému rodu (12), znamená, že si za každých okolností - bez ohľadu na svoj mentálny alebo zdravotný stav - každý zasluhuje dôstojné a primerané zaobchádzanie. To má hlboký dopad na každodennú starostlivosť o starých, chorých, fyzicky alebo duševne postihnutých (13).

Ďalším problémom je nie celkom adekvátne používanie termínu „dôstojnosť“ v medicínskych textoch, v bežnom odbornom vyjadrovaní. Namiesto termínu dôstojnosť by sa často lepšie hodili iné výrazy - ako napr. „adekvátne“, „dobre“ „s úctou“ apod. (14)

Osobitne závažným problémom je zámena pojmu ľudskej dôstojnosti, jej bezpodmienečného rešpektovania u daného človeka, a možnosti - či pocitu jej prežívania zo strany tohoto človeka. Dôstojnosť je hodnota, ktorú človek subjektívne prežíva. Niektorí autori, ktorí tieto dve skutočnosti presne nerozlišujú, prišli dokonca k záveru, že ľudská dôstojnosť sa stráca pri extrémnej chorobe a utrpení (15). Naopak, napr. Munzarová (16) vo svojom výskume zistila, že študenti medicíny sa domnievajú, že choroba, bolesť ani umieranie nenarušujú ľudskú dôstojnosť daného človeka (pacienta).

Kresťanstvo, ktoré je v našich podmienkach stále silným kultúrnym a morálnym faktorom, tu argumentuje aj 'hodnotou ľudského utrpenia' pričom sa odvoláva na utrpenie Krista. Dôstojnosť, založená na hodnote človeka vychádzajúcej z jeho príslušnosti k ľudskému rodu (prípadne zo skutočnosti, že „človek je dieťaťom Božím“), je základom humánneho prístupu a poskytovania primeranej starostlivosti aj tzv. „neperspektívnym pacientom“. Dôležitou súčasťou tejto celostnej (holistickej) starostlivosti je umožniť chorým a starým ľuďom uvedomiť si a prežiť ich vlastnú dôstojnosť.

Ďalším typom dôstojnosti, ktorá má vzťah k starostlivosti o starých ľudí, je dôstojnosť získaná zásluhami (napr. výchovou detí). Vytvára predpoklady pre určitú satisfakciu. Kríza súčasnej rodiny a realita bežného života mladej a strednej generácie vedie u starých ľudí k zážitku a prežívaniu pocitu nevďačnosti. Doplácanie za lieky a nedostatky zdravotnej starostlivosti vyvolávajú pocit nespravodlivosti, pretože súčasní dôchodcovia „si celý život platili a 'nekonzumovali' zdravotnú starostlivosť - a keď ju potrebujú, nedostáva sa im podľa ich predstáv.“

Starí ľudia sú v podmienkach zdravotnej starostlivosti osobitne *zraniteľní* (17). To viedlo ku vzniku výskumného projektu Európskej komisie „Dôstojnosť a Starší Európania“ [Dignity and Older Europeans]. Prebieha od začiatku roku 2002 v 6 krajinách Európy (Veľká Británia, Švédsko, Francúzsko, Írsko, Španielsko a Slovensko). Jeho cieľom je identifikácia faktorov, ktoré ovplyvňujú dôstojnosť starých ľudí a jej prežívanie, aby bolo možné vypracovať odporúčania na zlepšenie starostlivosti o seniorov. Bližšie informácie možno nájsť na internetovej adrese www.uwcm.ac.uk/study/medicine/geriatric_medicine/international_ research/dignity/index.

Viaceré práce preukázali praktický dopad určitého chápania a prežívania pojmu ľudskej dôstojnosti na konkrétnu starostlivosť o starých ľudí. Rešpektovanie ich dôstojnosti výrazne ovplyvňuje výsledný efekt zdravotnej starostlivosti (18). Akceptovanie ľudskej dôstojnosti pacientov zvyšuje spokojnosť personálu so svojou prácou a zlepšuje poskytovanú starostlivosť, a to bez zvyšovania jej nákladov. Navyše personál, ktorý rešpektoval dôstojnosť starých ľudí, má kladnejší vzťah k svojej práci (19). Výsledky štúdie zo Švédska ukázali, že program zameraný na zdôrazňovanie ľudskej dôstojnosti zmenil náhľad študentov ošetrovateľstva a ich prístup k dementným pacientom. Pod vplyvom programu prestali chápať skupinu pacientov ako anonymnú homogénnu masu a začali ich rozlišovať ako jedinečné ľudské bytosti (20). Významné je i zistenie Molloya a spol. (21), ktorí zistili, že rešpektovanie rozhodnutia obyvateľov domov dôchodcov o liečbe (nešlo o eutanáziu !!) znížilo náklady na starostlivosť o terminálne chorých, pričom neprišlo k zvýšeniu celkovej mortality.

Dôraz na rešpektovanie ľudskej dôstojnosti zverených osôb je podmienkou uplatnenia a ochrany ľudských práv v praxi súčasnej medicíny a zdravotníctva. Vedie ku skvalitneniu poskytovanej starostlivosti najmä u ťažko chorých a nevládnych pacientov, ktorých väčšinu dnes tvoria starí ľudia, a to bez zvyšovania potrebných nákladov.

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Abstract

Krajčík, Š.: Dignity of the Elderly and the Health Care. [Dôstojnosť starých ľudí a zdravotnícka starostlivosť.] Med. Eth. Bioet., 10, 2003, No. 1 - 2, p. 7 - 9. Elderly people are the most numerous group of patients. They are vulnerable and there are many situations that can harm human dignity in the old age. There are several concepts of human dignity present in the contemporary bioethics debate. The most im-portant of them for the caring and helping professions is the concept of human dignity, which is based on the individual's belonging to the human race. It is important to distiguish between the human dignity as

a value, and its perception by the older people. Respect for human dignity forms a basis for offering an adequate care to „perspective-less“ patients. The holistic care must enable patients to percieve their own dignity. Respect for the human dignity improves the quality of care and overall aproach of the personnel who takes care for the elderly people, without increasing the costs of the care. The current project of the European Union „Dignity and Older Europeans“ aimes to learn more about the factors that influence respecting of the human dignity and its perception by the elderly people. ***Key words***: human dignity, old age, health care.

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DOKUMENTY / DOCUMENTS

ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE, ON TRANSPLANTATION OF ORGANS AND TISSUES OF HUMAN ORIGIN

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Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as „Convention on Human Rights and Biomedicine“),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical science, in particular in the field of organ and tissue transplantation, contributes to saving lives or greatly improving their quality;

Considering that transplantation of organs and tissues is an established part of the health services offered to the population;

Considering that, in view of the shortage of organs and tissues, appropriate action should be taken to increase organ and tissue donation, in particular by informing the public of the importance of organ and tissue transplantation and by promoting European co-operation in this field;

Considering moreover the ethical, psychological and socio-cultural problems inherent in the transplantation of organs and tissues;

Considering that the misuse of organ and tissue transplantation may lead to acts endangering human life, well being or dignity;

Considering that organ and tissue transplantation should take place under conditions protecting the rights and freedoms of donors, potential donors and recipients of organs and tissues and that institutions must be instrumental in ensuring such conditions;

Recognising that, in facilitating the transplantation of organs and tissues in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ and tissue procurement, exchange and allocation activities;

Taking into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to organ and tissue transplantation,

Have agreed as follows:

Chapter I - Object and scope

Article 1 - Object

Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

Article 2 - Scope and definitions

1. This Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.

2. The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells.

3. The Protocol does not apply:

a) to reproductive organs and tissue;

b) to embryonic or foetal organs and tissues;

c) to blood and blood derivatives.

4. For the purposes of this Protocol:

– the term „transplantation“ covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage;

– subject to the provisions of Article 20, the term „removal“ refers to removal for the purposes of implantation.

Chapter II - General provisions

Article 3 - Transplantation system

Parties shall guarantee that a system exists to provide equitable access to transplantation services for patients.

Subject to the provisions of Chapter III, organs and, where appropriate, tissues shall be allocated only among patients on an official waiting list, in conformity with transparent, objective and duly justified rules according to medical criteria. The persons or bodies responsible for the allocation decision shall be designated within this framework.

In case of international organ exchange arrangements, the procedures must also ensure justified, effective distribution across the participating countries in a manner that takes into account the solidarity principle within each country.

The transplantation system shall ensure the collection and recording of the information required to ensure traceability of organs and tissues.

Article 4 - Professional standards

Any intervention in the field of organ or tissue transplantation must be carried out in accordance with relevant professional obligations and standards.

Article 5 - Information for the recipient

The recipient and, where appropriate, the person or body providing authorisation for the implantation shall

beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention.

Article 6 - Health and safety
All professionals involved in organ or tissue transplantation shall take all reasonable measures to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ or tissue for implantation.

Article 7 - Medical follow-up
Appropriate medical follow-up shall be offered to living donors and recipients after transplantation.

Article 8 - Information for health professionals and the public
Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissues, including matters relating to consent or authorisation, in particular with regard to removal from deceased persons.

Chapter III - Organ and tissue removal from living persons

Article 9 - General rule
Removal of organs or tissue from a living person may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

Article 10 - Potential organ donors
Organ removal from a living donor may be carried out for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body.

Article 11 - Evaluation of risks for the donor
Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor.

The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 12 - Information for the donor
The donor and, where appropriate, the person or body providing authorisation according to Article 14, paragraph 2, of this Protocol, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks.

They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 13 - Consent of the living donor
Subject to Articles 14 and 15 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body.

The person concerned may freely withdraw consent at any time.

Article 14 - Protection of persons not able to consent to organ or tissue removal
1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 13 of this Protocol.

2. Exceptionally, and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

i. there is no compatible donor available who has the capacity to consent;

ii. the recipient is a brother or sister of the donor;

iii. the donation has the potential to be life-saving for the recipient;

iv. the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body;

v. the potential donor concerned does not object.

Article 15 - Cell removal from a living donor
The law may provide that the provisions of Article 14, paragraph 2, indents ii and iii, shall not apply to cells insofar as it is established that their removal only implies minimal risk and minimal burden for the donor.

Chapter IV - Organ and tissue removal from deceased persons

Article 16 - Certification of death
Organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.

The doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures, or having responsibilities for the care of potential organ or tissue recipients.

Article 17 - Consent and authorisation
Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained.

The removal shall not be carried out if the deceased person had objected to it.

Article 18 - Respect for the human body
During removal the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.

Article 19 - Promotion of donation
Parties shall take all appropriate measures to promote the donation of organs and tissues.

Chapter V - Implantation of an organ or tissue removed for a purpose other than donation for implantation

Article 20 - Implantation of an organ or tissue removed for a purpose other than donation for implantation
1. When an organ or tissue is removed from a person for a purpose other than donation for implantation, it may only be implanted if the consequences and possible risks have been explained to that person and his or her informed consent, or appropriate authorisation in the case of a person not able to consent, has been obtained.

2. All the provisions of this Protocol apply to the situations referred to in paragraph 1, except for those in Chapter III and IV.

Chapter VI - Prohibition of financial gain

Article 21 - Prohibition of financial gain

1. The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

– compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;

– payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

– compensation in case of undue damage resulting from the removal of organs or tissues from living persons.

2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Article 22 - Prohibition of organ and tissue trafficking

Organ and tissue trafficking shall be prohibited.

Chapter VII - Confidentiality

Article 23 - Confidentiality

1. All personal data relating to the person from whom or-gans or tissues have been removed and those relating to the recipient shall be considered to be confidential. Such data may only be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

2. The provisions of paragraph 1 shall be interpreted without prejudice to the provisions making possible, subject to appropriate safeguards, the collection, processing and communication of the necessary information about the person from whom organs or tissues have been removed or the recipient(s) of organs and tissues in so far as this is required for medical purposes, including traceability, as provided for in Article 3 of this Protocol.

Chapter VIII - Infringements of the provisions of the Protocol

Article 24 - Infringements of rights or principles

Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Protocol at short notice.

Article 25 - Compensation for undue damage

The person who has suffered undue damage resulting from transplantation procedures is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 26 - Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

Chapter IX - Co-operation between Parties

Article 27 - Co-operation between Parties

Parties shall take appropriate measures to ensure that there is efficient co-operation between them on organ and tissue transplantation, *inter alia* through information exchange.

In particular, they shall undertake appropriate measures to facilitate the rapid and safe transportation of organs and tissues to and from their territory.

Chapter X - Relation between this Protocol and the Convention, and re-examination of the Protocol

Article 28 - Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 27 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of that Convention shall apply accordingly.

Article 29 - Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee re-ferred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI - Final clauses

Article 30 - Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31 - Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 30.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 32 - Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 33 - Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 34 - Notification

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European

Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:

a. any signature;

b. the deposit of any instrument of ratification, acceptance, approval or accession;

c. any date of entry into force of this Protocol in accordance with Articles 31 and 32;

d. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, this 24th day of January 2002, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

Editorial Note

Text of the Protocol taken from the web page of the Council of Europe: http://conventions.coe.int/Treaty/en/Treaties/html/186.htm, *the Explanatory report to the Protocol can be found at* http://conventions.coe.int-/Treaty/en/Reports/html/186.htm

ETHICS AND BIOMEDICAL RESEARCH

Pontifical Academy for Life*

1. The Ninth General Assembly of the Pontifical Academy for Life took place at the Vatican from February 24-26, 2003. This year it was dedicated to a crucial theme that has a strong social impact, „The Ethics of Biomedical Research For a Christian Perspective."

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, February 24, 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, unmistakably, 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 indispensable 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 favors 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 Truth, Donum Vitae, n. 4). It is therefore the ethical dimension of the human person, which he applies concretely though the judgments 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 his right to life, it must fully respect every person's inalienable dignity as a person, 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, February 24, 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 professionalism, 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, brin-

**At the end of its 9th General Assembly, the Pontifical Council for Life issued the following concluding statement on the „Ethics of Biomedical Research For a Christian Vision." The council, held in the Vatican from February 24-26, highlighted general ethical features that biomedicine has to take into account if it is to serve the human person. The English translation taken from the web page www.zenit.org, document No. ZE03032320.*

ging 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 advanced 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 opinion 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.

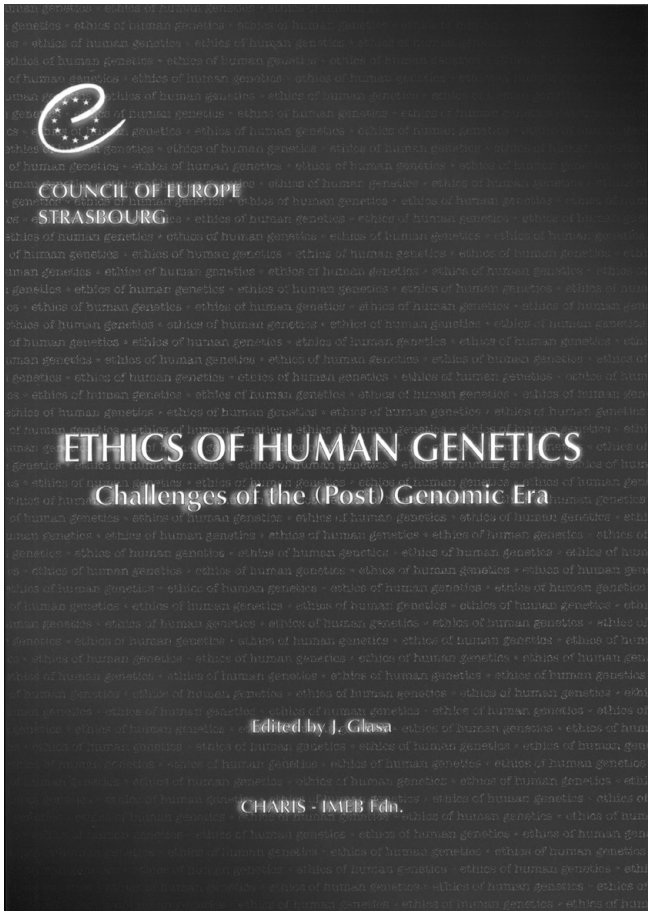
13. To conclude, the Pontifical Academy for Life, with great enthusiasm and a deep sense of responsibility, desires to renew its commitment and dedication to the cause of life, in sincere and respectful collaboration with all who are involved in the field of biomedical research, as the Pope himself said 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 endeavor.

O KNIHÁCH / BOOK REVIEWS

ETHICS OF HUMAN GENETICS CHALLENGES OF THE (POST) GENOMIC ERA

Glasa, J. (Ed.), Charis - IMEB Fdn., Bratislava, 2002, 228 pgs, ISBN 80-88743-51-6

The timely and well-edited volume comprises an interesting selection of the „hot topical issues" of the contemporary human genetics research and its applications in medi-



cine and health care. The collection of papers and essays contained in the book is the result of an international bioethics conference, which has taken place in Bratislava in October 2002. The meeting entitled „Ethics of Human Genetics: Challenges of the (Post) Genomic Era" (the same title has been given to the book) was cosponsored by the Council of Europe (CoE; within the DEBRA Program), European Commission (EC; Directorate General for Research), Ministry of Health of the Slovak Republic (Central (National) Ethics Committee) and other international or local institutions.

The book is organised into six sections. The first part contains the official addresses of the Slovak authorities given at the opening ceremony of the conference (the representative of the Ministry of Health, and the one of the National Council of the Slovak Republic). The second section brings some European perspectives on ethics of human genetics. It starts with the contribution of *P. Zil-galvis* (CoE, Strasbourg) giving the ethical and legal over-view of the European situation from the point of view of the CoE, which is followed by the paper of A. *Bitušíková* and *B. Rhode* (EC, Brussels) outlining some of the key ethical quandaries involved in the preparation of the 6th Framework Program of the EC. Three other papers are completing this section by giving some topical country perspectives - *R. Komel* (Ljubljana) for Slovenia, *B. Belicza* (Zagreb) for Croatia, and *M. Lukáčová* (Bratislava) for Slovakia.

The section „Special Contributions" contains review papers on Human Genome Project by *J. Rogers* (Hinxton, UK), and on human stem cells by *M.-L. Labat* (Paris).

The section on some pressing legal aspects of human genetics is composed of the contributions of *A. McCall Smith* (Edinburgh) on genetic privacy and discrimination, *J. Sándor* (Budapest) on old and new challenges in (genetic) data protection, and of *A. Nomper* (Tartu - Tallin) on Estonian Human Gene Research Act.

The next part of the book is devoted to the problem of genetic prenatal diagnosis. The paper of *A. Dorries* (Hannover) outlines the topic as the doctor's and parents' dilemma. *A. Šipr* (Brno, CZ) approaches the problem from the point of view of respect to parents' autonomy. *M. Šustrová* (Bratislava) reports on the experience and situation of parents and families with children born with disabilities in Slovakia.

The last section of the book, entitled „Exploring New Frontiers" contains a set of papers devoted to the range of 'hot topics' emerging in the human genetics research and application. The paper of *D. Sacchini et al.* (Rome) assesses, from the ethical point of view, the benefits and pitfalls of genetic screening. It is followed by paper of *J. Glasa* (Bratislava) dealing with ethical aspects of pharmacogenetic and pharmacogenomic research. *A. Miah* (Paisley, UK) analyses the ethical problem of 'gene doping', i.e. possible future genetic enhancements in sport. *R. W. Evans* (Castro Valley, CA, USA) brings to the reader's attention the promises and perils of human embryonic stem cell research. *G. Magill* (St. Louis, MO, USA) gives an ethical analysis of the policy implications in the US emerging from the relationship between human genomics and embryonic stem cell research. The report of *A. S. Carvalho et al.* (Porto, Portugal) gives an overview on the press coverage of the problem of cloning in Portugal from the point of view of the public perception of science and its possible applications. Finally, *P. H. Kieniewicz* (Lublin, Poland) gives some reflections - from ethical and theological point of view - on the developments seen in the broad field of human genetics in the „postgenomic era".

The book should be recommended to the broad professional public of medical and health care workers, as well as to the researchers and students of various disciplines of the life sciences area. It will be useful also for the philosophers and theologians, who will find in various chapters of the book an interesting and timely information on both biological - medical and ethical aspects of some of the most pressing issues of the exciting and rapidly growing field of human genetics and its applications.

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Medicínska etika & bioetika - Medical Ethics & Bioethics, založený ako časopis Ústavu medicínskej etiky a bioetiky v Bratislave, spoločného pracoviska Lekárskej fakulty Univerzity Komenského a Inštitútu pre ďalšie vzdelávanie zdravotníckych pracovníkov v Bratislave. Je určený pracovníkom etických komisií v Slovenskej republike, ako aj najširšej medicínskej a zdravotníckej verejnosti. Má tiež za cieľ napomáhať medzinárodnú výmenu informácií na poli medicínskej etiky a bioetiky. Prináša informácie o aktuálnych podujatiach a udalostiach v oblasti medicínskej etiky a bioetiky, pôvodné práce, prehľady, reprinty legislatívnych materiálov a smerníc pre oblasť bioetiky, listy redakcii a recenzie. Príspevky a materiály uverejňuje v slovenskom alebo anglickom jazyku. Vybrané materiály vychádzajú dvojjazyčne. Vedecké práce publikované v časopise musia zodpovedať obvyklým medzinárodným kritériám.

Medicínska etika & bioetika - Medical Ethics & Bioethics, founded as the journal of the Institute of Medical Ethics & Bioethics (Bratislava), a joint facility of the Medical Faculty of the Comenius University and the Postgraduate Medical Institute in Bratislava (Slovak Republic). It aims to serve the informational and educational needs of the members of ethics committees in the Slovak Republic and the broadest medical and health audience as well. It aims also to enhance the international exchange of information in the field of medical ethics and bioethics. The information published comprises news, original papers, review articles, reprints of national and international regulatory materials, letters, reviews. Contributions and materials are published in Slovak or English. Choosen materials are published in both languages. Scientific papers published in ME&B must respect the usual international standards.

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