

PAWEŁ KWIATKOWSKI

Public international law with regard to the social consequences of the development of genetics

Expansion of the system of human rights to embrace a bioethical perspective is connected to the policy of international organisations focusing on new threats arising from the development of modern genetics. The local consequences of such global challenges – such as genetic discrimination,¹ attempts at improving human beings and violating the integrity of the human being,² or the patenting of the genome³ – required measures of a supra-national character to be taken. These measures were initiated by the United Nations, which laid out the foundations of the direction for the development of domestic systems through declarations, and by the Council of Europe, which passed international legislation to normalise legal issues regarding the social consequences of the development of genetics in the Convention for the protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine. This article focuses on the foundations of international bioethics law, with regard to the social consequences of the development of genetics.

Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights, adopted during the 29th session of the General Conference of UNESCO on 11 November 1997,⁴ is

1 T. Lemke, *Perspectives on Genetic Discrimination*, New York 2013.

2 J. Habermas, *The future of human nature*, Cambridge 2003.

3 M. Ekberg, *Seven risks emerging from life patents and corporate*, “Science Technology and Society” 2005, no. 25.

4 J. Symonides, *Międzynarodowe instrumenty prawne w dziedzinie bioetyki i biotechnologii*, [in] *Prawa człowieka wobec rozwoju biotechnologii*, eds. J. Kondratiewa-Bryzik, K. Sękowska-Kozłowska, Warszawa 2013, p. 21; H. ten Have, M. Jean, *The UNESCO Universal Declaration on the Human Genome and Human Rights. Background principles and application*, Paris 2009; C. Kup-

the first international act to have been devoted to legal issues related to the human genome. This act urges measures to be taken in regard to establishing domestic legislation implementing the principles agreed upon at an international level, and simultaneously requires that the UNESCO Director General be regularly informed of initiatives undertaken in this respect. The principles it formulates apply to human dignity in regard to protection of the human genome, the rights of the individual, research on the genome, the conditions for exercising scientific activity, and international cooperation aimed at implementing the provisions of this legal act.

As established by the provision of Article 1 of the Declaration: “The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity.”⁵ The human genome is susceptible to mutations, and thereby contains potentialities that are manifested in a manner defined by the social and natural environment. Such an understanding of the significance of the human genome gives rise to a catalogue of rights regarding the following:

- Conducting research, providing treatment or making diagnoses affecting the human genome, which in accordance with the provisions of the Declaration requires the independent consent of the person concerned, expressed consciously by this person. In the event of it being impossible to adhere to this form, the Declaration also admits the possibility of authorisation being given in a manner defined in legislation, should there be a direct health benefit for the person concerned. As for the case of research that may result in significant medical benefits for a particular group of people, where the person concerned is incapable of giving consent this authorisation is possible as long as the risks and the related burdens are kept to the minimum – Article 5 letters a, b, d, e.
- The right to decide on whether or not to be informed of the results of genetic examination – Article 5 letter c.
- The prohibition of discrimination on the basis of genetic characteristics – Article 6.
- The legal protection of genetic data stored or processed for research purposes – Article 7.
- The right to compensation for losses sustained as a result of interference in one’s genome – Article 8.
- The right to make use of scientific advances regarding the human genome, while respecting the dignity and human rights of the individual – Article 12 letter a.

puswamy, *The International Legal Governance of the Human Genome*, New York 2009; A. Langlois, *Negotiating Bioethics: The Governance of UNESCO’s Bioethics Programme*, New York 2013. 5 Article 1 A/RES/53/152.

The scope of the rights presented above is connected to the Declaration's assigning adopted precedence to human rights over research on the human genome, which is also reflected in how the purpose of such research is defined. The goal of research regarding the human genome, as determined by the Declaration, is to bring relief from suffering and to improve the state of health of both humankind as a whole and individual human beings. This act indicates the ethical implications of such research, simultaneously indicating the obligation to conduct it and present its findings in an honest and lawful manner. In this respect, the Declaration places responsibility both on the scientists themselves and on those shaping scientific policy. In this context the Declaration formulates countries' obligations in regard to creating the conditions for conducting research on the human genome and the dissemination of its principles. These obligations involve the following:

- ensuring freedom in conducting scientific research regarding the human genome, while simultaneously taking into account the implications of such research in an ethical, legal, social and economic sense – Article 14,
- ensuring freedom in conducting scientific research on the human genome, while simultaneously guaranteeing respect for human rights and freedoms, and the protection of public health, in keeping with the principles presented in the Declaration – Article 15,
- striving to ensure that the findings of scientific research are used for peaceful purposes – Article 15,
- acknowledging the significance of support for ethics committees tackling issues related to the social dimension of research on the human genome – Article 16,
- respecting individuals, families and population groups vulnerable to diseases of a genetic character – Article 17,
- assessing the risks related to conducting scientific work on the human genome and the benefits resulting from this research – Article 19,
- enabling developing countries to make use of scientific achievements related to research conducted on the human genome, and promoting the international dimension of knowledge in this area – Article 19,
- striving to respect the principles of the Declaration and to support the dissemination of scientific knowledge regarding the human genome – Article 20.

The obligations placed on member states should be implemented through education, scientific research and training, and support for forms of propagating information aimed at raising the level of public awareness and the international debate regarding biology, genetics and medicine. This precedence also translates to a prohibition on the reproductive cloning of human beings, simultaneously requiring the cooperation of states and international organisations in detecting such practices. The Bioethics Committee of

UNESCO has the task of disseminating the provisions of the Declaration and analysing the application of the said provisions.

International Declaration on Human Genetic Data

The International Declaration on Human Genetic Data, adopted by the General Conference of UNESCO on 16 October 2003,⁶ formulates the principles that bind “in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived [...] in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research.”⁷

This act gives special status to human genetic data, which it describes by distinguishing their attributes. These attributes are: the ability to define individuals’ genetic predispositions, the ability to influence human offspring, the cultural dimension and the status of human genetic data as an information medium, the significance of which may be identified following genetic testing. This act calls for ensuring the appropriate level of protection both for the data and for the biological samples from which the said data may be obtained. It defines the purposes and procedures in the collection, processing, use and storage of the data. This covers in particular diagnostics, health care, scientific research, forensic medicine and also criminal and other legal proceedings. The Declaration also admits the collection, processing, use and storage of data for purposes other than those numerically listed, establishing as a condition that they are consistent with its provisions and international human rights law. Those procedures related to using human genetic data and proteomic data must meet ethical norms, while policy itself in this area should take into account the opinion expressed by society. Ethics committees play an important role in this policy. These institutions – functioning at national, regional, local and institutional levels – have been ascribed the role of consultants, expressing an opinion in the process of establishing regulations to normalise measures taken in regard to human genetic data, proteomic data, and biological samples, as well as their usage in specific projects.

A condition that has to be met for steps to be taken in respect to human genetic data is that the person concerned gives their consent. This person’s will must be expressed in an informed, voluntary and direct manner, after having received information concern-

6 V.J. Symonides, *op. cit.*, p. 22; A. den Exter *et al.*, *International health law and ethics*, Apeldoorn – Antwerp – Portland 2009, p. 355; J.A. Bovenberg, *Property rights in Blood, Genes and Data. Naturally yours?*, Leiden – Boston 2006, p. 12; G.I. Serour, A.R.A. Ragab, *Ethics of genetic counselling*, [in] *The SAGE Handbook of Health Care Ethics*, ed. R. Chadwick, H. ten Have, E.M. Meslin, London 2011, p. 153.

7 Article 1 of the International Declaration on Human Genetic Data.

ing the purpose of the collection, processing, use and storage of the data, regarding the consequences connected to the said data, and about being able to withdraw consent at any stage of the proceedings. Following the example of the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data also allows for an exception to this rule, linked to reasons of significant importance for the state of health of the person concerned, in the event of the said person being unable to express their conscious consent. The Declaration establishes that such intervention is defined by domestic legislation, and must proceed in keeping with the international system for the protection of human rights, while simultaneously taking into account the overriding character of the individual's interest. The Declaration also attaches authorisations to this interest regarding counselling and the results of examinations. These are: the right to decide whether or not to be informed of the results of examinations, and the right to avail themselves of expert counselling when considering the option of agreeing to undergo genetic testing. Thus not allowing an individual to have access to their own data is in principle forbidden. However, this does not apply in the case of this data being irretrievably unlinked to that person as the identifiable source, or where such access is limited due to a threat to public health or order, or to national security.

The Declaration obliges states to take measures towards protecting the privacy of genetic data through the establishing of domestic legislation consistent with international human rights law. In this context it formulates a set of directives embracing the following:

- a prohibition of the disclosure or rendering accessible of human genetic data, proteomic data or biological samples linked to an identifiable person to third parties – Article 14 letter b,
- a requirement not to link human genetic data, proteomic data or biological samples collected for scientific research purposes to an identifiable person, with the exception of cases where this is essential for the nature of the research, while simultaneously ensuring protection of the privacy of these data and restricting their period of storage to the essential minimum – Article 14 letters c, d,
- a requirement for persons and organisational units responsible for the processing of both data and biological samples to ensure their accuracy, credibility, security and quality – Article 15.

The principles of international collaboration in regard to the circulation of data and samples are defined by three directives:

- a requirement for states to regulate the circulation of human genetic data, proteomic data and biological samples in accordance with domestic and international legislation, and in a manner ensuring fair access to these data – Article 18 letter a,

- a requirement for states to make every effort in regard to fostering the international dissemination of scientific knowledge related to human genetic data and proteomic data – Article 14 letter b,
- a requirement for scientists to make every effort towards establishing collaboration in regard to human genetic data and proteomic data, subject to the restrictions expressed in this Declaration – Article 14 letter c.

This collaboration involves the requirement to share the results of scientific research using human genetic data, proteomic data or biological samples, both with society and the international community, subject to the restrictions contained in domestic legislation and international agreements. The following are example ways of achieving this goal:

- establishing forms of special assistance provided to individual persons and groups participating in the research,
- guaranteeing access to medical care,
- using the research results to ensure new diagnostic methods, means of treatment, and drugs,
- providing support for the health service,
- providing research assistance for developing countries,
- other forms of action in keeping with the principles of this Declaration.

The principles of access, protection of privacy, and demands placed before institutions involved in the processing of human genetic data, proteomic data and biological samples also define the purpose of their use. In order for there to be a change in the purpose of using genetic data, proteomic data and biological samples, there must be sufficient grounds for public interest. As such, the Declaration allows for an exception to the prohibition on changing the purpose of their use. The samples may be used for data generation based on previously-obtained consent expressed in an informed, voluntary and direct manner by the person concerned.

Universal Declaration on Bioethics and Human Rights

The next act of international law tackling issues related to the social consequences of the development of genetic engineering is the Universal Declaration of Bioethics and Human Rights – adopted unanimously on 19 October 2005 during the 33rd session of the UNESCO General Conference.⁸ The Universal Declaration on Bioethics and Human Rights tackles the subject of legal regulations on the social consequences of the development of genetic engineering in the broader context, as one of the issues “related to

8 H. ten Have *et. al.*, *The UNESCO Universal Declaration on the Human Genome and Human Rights. Background principles and application*, Paris 2009; H. ten Have, *Towards global bioethics: UNESCO Universal Declaration on Bioethics and Human Rights*, [in] *Genetic Democracy: Philosophical Perspectives*, ed. V. Launis, J. Räikkä, Berlin 2008.

medicine, life sciences and associated technologies.” The aims for which the Declaration was adopted are, as defined in Article 2:

- establishing a universal framework of principles and procedures for the requirements of drafting legislation, creating policies, and other instruments in the field of bioethics – Article 2 letter a,
- developing guidelines for initiatives undertaken in this scope – Article 2 letter b,
- promoting respect for human dignity – Article 2 letter c,
- protecting human rights – Article 2 letter c,
- calling for scientific research to be subject to ethical principles, while at the same time ensuring the freedom of scientific thought – Article 2 letter d,
- supporting social dialogue regarding bioethical issues – Article 2 letter e,
- promoting equitable access to the findings of scientific research in medicine and rapid sharing of thinking within this field of knowledge – Article 2 letter f,
- protecting the interests of current and future generations of mankind – Article 2 letter g,
- emphasising the role of biological diversity and the importance of its protection – Article 2 letter h.

Achieving these aims is linked to the requirement of observing the following principles:

- the principle of respecting human dignity – Article 3 § 1,
- the principle of the interests and welfare of the individual holding priority over the interests of science or society – Article 3 § 2,
- the principle of maximising the benefits for patients, research participants and other persons concerned, while simultaneously minimising the harm experienced by the above when applying or raising the level of scientific knowledge – Article 4,
- the principle of respecting the autonomy of decisions, with the simultaneous protection of the rights and interests of persons incapable of taking decisions independently – Article 5,
- the principle of the necessity of consent being expressed in an informed manner, voluntarily and directly by the person concerned, after having previously received sufficient information, and prior to prophylactic, diagnostic or therapeutic intervention, while at the same time this consent may be withdrawn at any time and for any reason – Article 6 § 2,
- the principle of the necessity of consent being expressed in an informed manner, voluntarily and directly by the person concerned, after having previously received sufficient information, and prior to scientific research, while at the same time this consent may be withdrawn at any time and for any reason – Article 6 § 2,

- the principle of special protection for persons without the capacity to express consent – Article 7,
- the principle of protection for personal integrity and respect for human vulnerability in the context of advancing and applying scientific knowledge – Article 8,
- the principle of respecting the privacy of the persons concerned – Article 9,
- the principle of confidentiality of information regarding the persons concerned – Article 9,
- the principle of respecting the equality of all human beings – Article 10,
- the principle of non-discrimination – Article 11,
- the principle of due regard being given to the importance of cultural diversity and pluralism – Article 12,
- the principle of solidarity and international cooperation in the Declaration's propagation – Article 13,
- the principle of social responsibility for the promotion of health – Article 14,
- the principle of the right to enjoy the highest attainable standard of health – Article 14,
- the principle of sharing the benefits resulting from scientific research with society and the international community – Article 15,
- the principle of protecting future generations by taking account of the impact of the life sciences – Article 16,
- the principle of protection of the environment, the biosphere and biological diversity – Article 17.

The provisions of the Declaration require support for professionalism, honesty, integrity and transparency in taking decisions and in social dialogue, via the enabling of pluralistic debate. These demands are tied to the functioning of independent and multi-disciplinary Ethics committees, appointed pursuant to the provision of Article 19 of the Declaration, with the purpose of:

- assessing research projects involving human beings in regard to ethical, legal, scientific and social issues,
- offering counselling in regard to the ethical aspects that occur in clinical settings,
- formulating recommendations and guidelines in the scope of this Declaration's regulations, based on the assessment of scientific and technological developments,
- fostering education, debate and social engagement in regard to bioethics.

States have a role to play in regard to promoting the specific provisions of this Declaration – through legislative and administrative initiative, support for educational and training programmes, and international cooperation – while measures within the scope of promotion and dissemination are taken by UNESCO. Pursuant to Article 25 of the

Declaration, this organisation strives to achieve this goal with the assistance of the International Bioethics Committee.

Declaration on Human Cloning

The provisions of the Declaration on Human Cloning adopted by the General Assembly of the United Nations during the 59th session on 23 March 2005⁹ constitute the expression of an initiative calling on states of the international community to undertake measures towards:

- ensuring adequate protection for human life in the application of life sciences – letter a,
- prohibiting all forms of human cloning – letter b,
- prohibiting the application of genetic engineering techniques detrimental to human dignity – letter c,
- preventing the exploitation of women in the application of life sciences – letter d,
- adopting and implementing domestic legislation aimed at putting the above guidelines into effect – letter e.

As a side note to the issues related to human cloning, the Declaration also tackles the matter of research into diseases affecting developing countries to the greatest degree. To this end, the General Assembly called upon the states of the United Nations to take into account such global problems as the HIV virus, tuberculosis and malaria in their policies for financing research in the medical sciences – letter f.

In contrast to the Universal Declaration on Bioethics and Human Rights, the Declaration on Human Cloning was not adopted unanimously, but with 87 voting in favour, 34 voting against, 37 abstaining and 35 absent.¹⁰ As Symonides writes, the lack of consensus between United Nation member states had already revealed itself during the work of the Legal Committee, which began in August 2001.¹¹ At the time France and Germany tabled a motion for the inclusion of a point on the commencement of work on a new convention in the agenda of the General Assembly of the United Nations.¹² This convention was supposed to embrace a prohibition on reproductive cloning. Two key stances emerged in the discussion among country representatives, with the discussion constituting a response to the motion submitted. One was for a prohibition on all forms of cloning, also applying to the research on stem cells that is fundamental to the development

⁹ J. Symonides, *op. cit.*, p. 26; B. Steinbock, *Life Before Birth: The Moral and Legal Status of Embryos and Fetuses*, Oxford 2011, p. 301.

¹⁰ J. Symonides, *op. cit.*, p. 29.

¹¹ *Ibidem*, p. 26.

¹² *Ibidem*, p. 27.

of contemporary genetics, while the other was for a prohibition on reproductive cloning itself¹³. Those in favour of the first approach cited arguments connected to the protection of human dignity and the ineffectiveness of prohibition limited purely to reproductive cloning. Representatives of the countries taking this stance based their reasoning on the conviction that an embryo signifies a human being, a consequence of which is that its protection is subject to the system of human rights. They also emphasised the ineffectiveness of a prohibition limited to reproductive cloning due to the impossibility of verifying whether such a prohibition is observed. Thus such an approach also ruled out the possibility of therapeutic cloning. In addition, as representatives of states supporting this view indicated, the development of scientific research in human cloning may lead to new forms of violation of human rights. These apply to the threats to women, and in particular those from impoverished communities, that might arise from the demand for human egg cells.

On the other hand, the proponents of a prohibition on reproductive cloning cited the goal of the motion tabled by France and Germany for the inclusion in the agenda of the General Assembly of the United Nations of a point regarding measures towards the establishment of a new convention. It applied only to the issue of reproductive cloning and, according to those representing the second stance, this was precisely what should be debated. They pointed out the urgent requirement for such a prohibition to be enacted in the form of a convention, with the purpose of establishing universal legal regulations that would be binding in character, thereby introducing an effective instrument guaranteeing protection in this respect. Due to the inability to reach an agreement, the Legal Committee of the United Nations modified the direction of work, and in March 2005 – after four years of debate – the General Assembly adopted the Declaration on Human Cloning, instead of a binding act of international law. Because of the general character of the norms that the Declaration urges be respected, positions during the sittings of the UN's General Assembly were split, their boundaries marked by the dispute over establishing a prohibition on therapeutic cloning.

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine

Unlike the declarations presented above, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, known as the Convention on Human Rights and Biomedicine,¹⁴ is binding

¹³ *Ibidem*.

¹⁴ A. Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights*, London – Sydney – Portland 2005, p. 75; J. Symonides, *op cit.*, p. 30.

for its signatories. This act, adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature on 4 April 1997,¹⁵ entered into force on 1 December 1999.¹⁶ As with the Universal Declaration on Bioethics and Human Rights, the Convention on Human Rights and Biomedicine is not restricted to issues connected with the social consequences of the development of genetic engineering. Its regulatory scope has a broader perspective – applying to the relations between the system of human rights and the practical application of life and medical sciences. The goal and subject-matter of this international agreement is defined by Article 1, which determines that:

Parties to this Convention shall 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. Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

The general provisions of the Convention emphasise the precedence of the welfare of the individual over the interests of society or science and the legitimacy of taking measures furthering fair access to health care, and also formulate general professional standards regarding interventions in the area of human health. Its different chapters regulate issues connected to the expression of consent by the person concerned for intervention of a scientific or medical nature, privacy and the right to information, the human genome, the conducting of scientific research, the removal of organs and tissues from living donors for transplantation purposes, and a prohibition on the commercialisation of the human body.

The issues related to the concept of a concerned person's consent are regulated by the provisions of Chapter II of the Convention. As Article 5 of the agreement determines, for a medical intervention to be carried out the person concerned must give their free and informed consent, after having been given the appropriate information regarding the purpose and nature of the intervention, as well as the risk related to it. This consent may be withdrawn by the person concerned at any time. An exception to this principle expressed in Article 5 of the Convention is defined in this legal act's Article 8, which determines that in the event of intervention being essential – and when obtaining the required consent is impossible – then the said intervention may be carried out without the required acceptance on the part of the patient. The limits to this exception are defined by the provisions regarding protection of persons incapable of expressing consent,¹⁷

¹⁵ *Ibidem*.

¹⁶ *Ibidem*.

¹⁷ Article 6 CETS no. 164.

establishing protection for persons suffering from mental disorders,¹⁸ and requiring that a patient's wishes expressed beforehand be taken into account should it be impossible to obtain the required consent.¹⁹

Protection of privacy and the right to obtain information is regulated by the provisions of Chapter III of the Convention, which define:

- the right that everyone has to respect for private life in the context of information about their health – Article 10 § 1,
- the right that everyone has to access information regarding their health, although this right may be restricted by domestic law in the interest of the person concerned – Article 10 § 2.

Legal issues connected to the human genome are regulated by the provisions of Chapter IV of the Convention. These provisions prohibit discrimination due to a person's genetic heritage and prohibit the use of techniques of medically assisted procreation where their purpose is only to choose the child's sex, unless such a choice is dictated by the desire to avoid a hereditary disease, the occurrence of which is dependent on the sex. Provisions in this chapter also define the principles for conducting predictive genetic tests and the conditions for the admissibility of interventions on the human genome. The provision of Article 12 of the Convention determines that these tests are subject to counselling and may only be carried out for specified purposes – for health and related scientific research. According to Article 13 of the same act, intervention in the human genome is only permitted for prophylactic, therapeutic or diagnostic purposes, and then on the condition that the intervention will not cause hereditary changes in this person's descendants.

The scope of freedom for scientific research in the field of biology and medicine is determined by the provisions of Chapter V of the Convention. The provision of Article 16 of the Convention defines the catalogue of conditions essential for the admissibility of scientific research on people, which embraces the following:

- no alternative method of research featuring comparable effectiveness,
- the proportionality of the risk borne by the person undergoing such research to the potential benefits deriving from it,
- approval of the research project by the appropriate institution following its independent assessment to define the importance of the purpose of the research and its ethical acceptability,
- informing the person undergoing such research of their rights,
- obtaining and documenting the necessary consent defined in the provision of Article 5 of the Convention.

18 Article 7 CETS no. 164.

19 Article 9 CETS no. 164.

In regard to persons lacking the capacity to express their consent, Article 17 of the Convention stipulates an expanded catalogue of the conditions to be met for the admissibility of scientific research on such people, covering:

- a real and direct benefit to this person's health,
- the impossibility of conducting the research on persons capable of giving consent,
- the consent defined in Article 6 given in writing,
- no objection expressed in other form by the person incapable of giving consent.

The condition for a real and direct benefit to the health of a person incapable of giving consent may be waived as long as the following two demands are fulfilled:

- attaining results bringing significant scientific progress and ensuring benefit to the person subjected to the research or other persons,
- minimal risk to the person undergoing the research.

The provisions of Chapter V of the Convention also define the principles in regard to conducting research on embryos in vitro. Article 18 § 1 of this act established the obligation to ensure appropriate protection for embryos in vitro through a system of domestic law if its regulations admit the possibility of conducting research on them, while § 2 prohibits the creation of human embryos for research purposes.

The final chapters of the Convention – VI, VII, VIII, IX, X and XI – deal with transplantation, taking particular care to ensure proper protection for those persons incapable of giving consent for the removal of organs from their bodies; prohibit the commercialisation of the human body; provide for sanctions in the event of violation of the Convention's provisions; and focus on the relation with other regulations, on the public debate, on the Convention's interpretation and on its protocols.

Conclusion

The extension of international instruments in the field of human rights to embrace a bioethical perspective constitutes a response from international organisations to the social consequences of the development of genetics. Work on the preparation of international standards intensified together with the first scientific publications diagnosing the threats related to technology at the cutting edge of biology and medicine, such as genetic discrimination.²⁰ Global problems that demanded international initiatives were then outlined in the academic discourse. These initiatives led in turn to the formation of universal norms of a declarative nature, as well as legally binding norms for the states of the Council of Europe and the signatories to the Convention. The soft law norms call for the protection

20 P. Billings, M.A. Kohn, M. de Cuevas, J. Beckwith, J.S. Alper, M.R. Natowicz, *Discrimination as a consequence of genetic testing*, "American Journal of Human Genetics" 1992, vol. 50.

of the human genome, for the introduction of principles in the collection, processing, use and storing of human genetic data, for establishing regulations reflecting bioethical standards and for the prohibition of cloning. Regulations of the Council of Europe set out the legally binding standards in the protection of the dignity and identity of a human being in regard to the application of biology and medicine where genetics plays a special role.

Literature

- Billings P., Kohn M.A., Cuevas M. de, Beckwith J., Alper J.S., Natowicz M.R., *Discrimination as a consequence of genetic testing*, "American Journal of Human Genetics" 1992, vol. 50.
- Bovenberg J.A., *Property rights in Blood, Genes and Data. Naturally yours?*, Leiden – Boston 2006.
- Ekberg M., *Seven risks emerging from life patents and corporate*, "Science Technology and Society" 2005, no. 25.
- Exter A. den et al., *International health law and ethics*, Apeldoorn – Antwerp – Portland 2009.
- Have H. ten et al., *The UNESCO Universal Declaration on the Human Genome and Human Rights. Background principles and application*, Paris 2009.
- Have H. ten, *Towards global bioethics: UNESCO Universal Declaration on Bioethics and Human Rights*, [in] *Genetic Democracy: Philosophical Perspectives*, eds. V. Launis, J. Räikkä, Berlin 2008.
- Habermas J., *Przyszłość natury ludzkiej. Czy zmierzamy do eugeniki liberalnej?*, transl. M. Łukasiewicz, Warszawa 2003.
- Kuppuswamy C., *The International Legal Governance of the Human Genome*, New York 2009.
- Langlois A., *Negotiating Bioethics: The Governance of UNESCO's Bioethics Programme*, New York 2013.
- Lemke T., *Perspectives on Genetic Discrimination*, New York 2013.
- Plomer A., *The Law and Ethics of Medical Research: International Bioethics and Human Rights*, London – Sydney – Portland 2005.
- Serour G.I., Ragab A.R.A., *Ethics of Genetic Counselling*, [in] *The SAGE Handbook of Health Care Ethics*, ed. R. Chadwick, H. ten Have, E.M. Meslin, London 2011.
- Steinbock B., *Life Before Birth: The Moral and Legal Status of Embryos and Fetuses*, Oxford 2011.
- Symonides J., *Międzynarodowe instrumenty prawne w dziedzinie bioetyki i biotechnologii*, [in] *Prawa człowieka wobec rozwoju biotechnologii*, eds. J. Kondratiewa-Bryzik, K. Sękowska-Kozłowska, Warszawa 2013.

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, 9 November 1996, CETS no. 164.

Declaration on Human Cloning, 23 March 2005, A/RES/59/280.

International Declaration on Human Genetic Data, 16 October 2003, Resolution of the 32nd General Conference of UNESCO.

Universal Declaration on Bioethics and Human Rights, 19 October 2005, SHS/EST/BIO/06/1.

Universal Declaration on the Human Genome and Human Rights, 11 November 1997, A/RES/53/152.

SUMMARY

Public international law with regard to the social consequences of the development of genetics

The extension of international instruments in the field of human rights to embrace a bioethical perspective constitutes a response from international organisations to the social consequences of the development of genetics. These initiatives led in turn to the formation of universal norms of a declarative nature, as well as legally binding norms for the states of the Council of Europe. The author focuses on the basic principles of: the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data, the Universal Declaration on Bioethics and the Human Rights United Nations Declaration on Human Cloning, and the Convention on Human Rights and Biomedicine – presenting the foundations of international bioethics law with regard to the social consequences of the development of genetics.

Keywords: public international law, international bioethics law, new genetics

PAWEŁ KWIATKOWSKI, University of Gdańsk, Faculty of Law and Administration, Bażyńskiego 8, Gdańsk 80-309, Republic of Poland, e-mail: pawel.kwiatkowski@prawo.ug.edu.pl.