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Britta van Beers, Charlotte de Kluiver, and Rick Maas

I INTRODUCTION

When it comes to medical law and medical ethics, the Netherlands has a reputation of being pragmatic and progressive, emphasizing values such as tolerance, pluralism and personal autonomy.[1] The Dutch legal framework for euthanasia, which made the Netherlands the first country in the world to legalize it, is generally regarded as a prime example of this legal and ethical tradition.

This approach is also reflected on an academic level. Until recently, Dutch scholars regarded self-determination as the central principle of medical law and medical ethics. In this vein, Henk Leenen's classic *Handbook on Health Law* (*Handboek gezondheidsrecht*) traditionally described self-determination not only as a central legal principle but even as a patient's individual right.[2] This focus on personal autonomy originated in the 1970s, when medical law and medical ethics were emerging academic disciplines in the Netherlands. In that era, a paternalistic attitude from medical professionals towards their patients was not uncommon. To counterbalance the power of the medical profession, Dutch legal scholars and ethicists called for the recognition of patients' right to self-determination. This idea proved to be influential: it was crucial for the recognition of patients' rights in Dutch medical contract law.

However, during the past decade, the traditional focus on self-determination has been reconsidered. Dutch medical law and ethics scholars have started to also pay attention to values and principles other than the one of self-determination, such as the principles of protection, equality and

[1] Rendtorff and Kemp, *Basic Ethical Principles in European Bioethics and Biolaw* (Centre for Ethics and Law 2000) 209–216.

[2] E.g. HJJ Leenen and JKM Gevers, *Handboek gezondheidsrecht* (4th edn, Boom Juridisch 2000) 33.

human dignity.[3] Similarly, in more recent editions of Leenen's *Handbook*, self-determination is no longer described as a right or as the cornerstone of health law, but only as one of several guiding principles of medical law and ethics.[4]

How can this shift in focus be explained? One of the most important reasons is the emergence of biomedical technologies and their accompanying regulatory frameworks. Indeed, consistent with emerging international regulation, such as the Council of Europe's Oviedo Convention (1997),[5] the Dutch legislature adopted a restrictive and prohibitive approach to biomedical technologies, as exemplified by the Embryo Act (2002)[6] and other biomedical laws. As we will discuss at length below, according to current Dutch law, human embryos and gametes cannot be sold;[7] embryos cannot be created for scientific purposes;[8] and preimplantation genetic diagnosis is only allowed under strict conditions for very serious diseases.[9] More to the point, the Embryo Act prohibits human germline genome editing of cells with which impregnation might take place.[10]

As the *travaux préparatoires* and explanatory memoranda to these laws make clear, the legal restrictions and prohibitions are underpinned by values such as respect for human life, non-commercialization and human dignity.[11] The Dutch legislature takes these principles to be of such importance that they can outweigh other important values in these contexts, such as self-determination and scientific progress. However, the tensions between these principles remain. Whenever the Dutch legal order is challenged by new biomedical developments, the tensions between these values and principles resurface.

[3] E.g. AC Hendriks, *In beginsel. De gezondheidsrechtelijke beginselen uitgediept* (inaugural Leiden) (NJCM boekerij 2005); AC Hendriks, BJM Frederiks and MA Verkerk, 'Het recht op autonomie in samenhang met goede zorg bezien' (Tijdschrift voor Gezondheidsrecht 2008), 2–18; BC van Beers, *Persoon en lichaam in het recht. Menselijke waardigheid en zelfbeschikking in het tijdperk van de medische biotechnologie* (dissertation VU) (Boom Juridische uitgevers 2009).

[4] HJJ Leenen and others, *Handboek gezondheidsrecht* (6th edn, BJu 2014).

[5] Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (opened for signatures on 4 April 1997, entered into force 12 January 1999) ETS No. 164 (Oviedo Convention).

[6] Act of 20 June 2002 Relating to the Use of Gametes and Embryos (*Wet houdende regels inzake handelingen met geslachtscellen en embryo's*) (Embryo Act).

[7] E.g. Act of 24 May 1996 relating to providing Organs (*Wet houdende regelen omtrent het ter beschikking stellen van organen*) (Organ Donation Act), art. 2; Embryo Act, art. 27.

[8] Embryo Act, art. 24.a.

[9] Ibid., arts. 26.1 and 26.2.

[10] Ibid., art. 24.g.

[11] See parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 3, 16, 41–49, 64.

The rise of gene-editing tool CRISPR/Cas9 offers a striking illustration of that dynamic. Since CRISPR/Cas9 took the life sciences by storm, human germline genome editing has become a topic of heated debates in Dutch politics and academia. These debates make clear that the Dutch prohibitive approach to germline editing is under increasing pressure and that personal autonomy and self-determination are returning to the discussion. For example, over the past few years, several organizations, politicians and academics have proposed to lift the ban on germline editing as soon as the technology is safe for introduction in the clinic, with the purpose of enabling prospective parents to use the technology for therapeutic purposes.[12] In these discussions, personal autonomy is often invoked as an important argument.[13]

In this chapter we first discuss the general regulatory and institutional framework (Section II). We then focus on the most important legal provisions within the regulation of human germline editing (Section III). Finally, we offer an overview and analysis of current public and political debates on this technology in the light of the tensions between self-determination and reproductive autonomy on the one hand and human dignity and respect for human life on the other (Section IV).

II THE REGULATORY FRAMEWORK

This section outlines the Dutch legal framework and the institutional environment regulating research involving human gametes and embryos. First, we describe the broad legal framework within which research on human germline genome modification takes place in the Netherlands. Subsequently, we turn to the specific national legal framework, of which the 2002 Act Relating to the Use of Gametes and Embryos (the Embryo Act) is the most important one. While discussing the relevant legislation, we will also describe the relevant regulatory authorities and advisory bodies.

1 *The General Legal Framework*

The broad legal framework within which research on human germline genome modification takes place in the Netherlands comprises the Constitution and international law as incorporated by the Constitution, including EU law, some provisions of the Civil Code and the Criminal Code and the legal doctrine of progressive legal protection.

[12] See, in this chapter, Section IV 'Current perspectives and future possibilities'.
[13] *Id*.

a The Constitution, International Law and EU Law

The Constitution of the Kingdom of Netherlands contains several provisions regarding the place of international law (treaties, customary international law and acts of international organizations) in the Dutch legal system.[14] Under the Constitution, the Dutch government has a general obligation to 'promote the development of the international legal order'.[15] The States General (*Staten-Generaal*), the Kingdom's bicameral Parliament, approves the ratification and denunciation of treaties.[16] Under Article 91.3, treaties that conflict with the Constitution or lead to conflicts with it must be approved by the Houses of the States General by two-thirds majority. Article 92 provides: 'Legislative, executive and judicial powers may be conferred on international institutions by or pursuant to a treaty, subject, where necessary, to the provisions of Article 91.3.' Lastly, ratified treaties and 'resolutions by international institutions which may be binding on all persons by virtue of their contents' have binding legal effect within the Dutch legal system[17] and displace statutory regulations in force within the Kingdom.[18]

In general, the Netherlands can be regarded as a law-abiding member of the international community, hosting on its territory several major international courts and tribunals. It is a member of all major international organizations, both global and regional. It is a member of the United Nations and its specialized agencies, including the United Nations Economic, Social and Cultural Organization (UNESCO). Within Europe, it is also a member of the European Union and the Council of Europe. By virtue of Article 92 of its Constitution, binding legal instruments adopted by those organizations are part of its national legal system.

The Netherlands ratified the International Covenant on Economic, Social and Cultural Rights on 11 December 1978, which is, therefore, part of its legal system.[19] So far, it has just signed but not ratified the Optional Protocol giving individuals access to the Committee on Economic, Social and Cultural Rights to claim violations of their rights under the Covenant.[20]

[14] Constitution of the Kingdom of the Netherlands of 24 August 1815 (*Grondwet voor het Koninkrijk der Nederlanden van 24 augustus 1815*) (Constitution), arts. 93 and 94.
[15] Ibid., art. 90.
[16] Ibid., art. 91.
[17] Ibid., art. 93.
[18] Ibid., art. 94.
[19] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR).
[20] Optional Protocol to the International Covenant on Economic, Social and Cultural Rights (adopted 10 December 2008, entered into force 5 May 2013), A/RES/63/117.

Within the Council of Europe, as every member, the Netherlands is party to the European Convention on Human Rights and subject to the jurisdiction of the European Court of Human Rights.[21] Among the relevant provisions of the European Convention on Human Rights, Article 8 (the right to respect for private and family life) deserves special mention in the context of reproductive medicine. For over a decade, the European Court of Human Rights has ruled that the right to private life also protects certain reproductive rights and interests, including 'the right to respect for both the decisions to become and not to become a parent',[22] 'the right of a couple to conceive a child and to make use of medically assisted procreation for that purpose'[23] and 'the desire to conceive a child unaffected by [a] genetic disease [. . .] and to use assisted reproductive technologies and PGD to this end'.[24]

However, the Netherlands is not party to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Oviedo Convention), even though the Netherlands signed it already in 1997.[25] In 2016, the Dutch government decided not to ratify it, mainly because of the prohibitions contained in Article 13, which bans human germline editing, and Article 18.2, which bans the creation of human embryos for research purposes.[26] Relying heavily on two legislative evaluation reports,[27] the government concluded that these prohibitions could hold back further advances in reproductive medicine, more specifically research into early embryonic development and preclinical research into safety of reproductive techniques.[28] The decision not to ratify the Oviedo Convention was heavily criticized in Dutch legal literature.[29] Some authors argued that the Convention is a comprehensive document, with respect to patients' rights, privacy, human dignity, equitable access to healthcare and non-discrimination, and that by failing to ratify it, the Netherlands had put itself outside of the international

[21] Convention for the Protection of Human Rights and Fundamental Freedoms, ETS No. 5 (European Convention on Human Rights, as amended) (ECHR).

[22] *Evans* v. *United Kingdom* app no 6339/05 (ECHR [Grand Chamber], 10 April 2007) para 71.

[23] *S.H.* v. *Austria* app no 57813/00 (ECHR [Grand Chamber], 3 November 2011) para 82.

[24] *Costa & Pavan* v. *Italy* app no 54270/10 (ECRM 28 August 2012) para 57.

[25] Parliamentary document on the Embryo Act 14, 33508, 9, p. 31; 2012/13, 33508, 3, 13; 2012/13, 33400 VII, 83, 11.

[26] Ibid.

[27] HB Winter and others, *Evaluatie Embryowet en Wet donorgegevens kunstmatige bevruchting* (ZonMW 2012); E.T.M. Olsthoorn-Heim, *Evaluatie Embryowet* (ZonMW 2006).

[28] Parliamentary document 2014/15, 34000 XVI, 106.

[29] M Buijsen, 'Ratificatie van het Biogeneeskundeverdrag: kwestie van menselijke waardigheid' (2015) S&D 4.

legal order on biomedicine, healthcare and ethics.[30] Nevertheless, as we discuss below, the current Dutch legislation on research on human gametes and embryos still corresponds, in large lines, with the provisions of the Oviedo Convention, including the bans on human germline editing and on the creation of embryos for research purposes.

Finally, the Netherlands is a member of the European Union. As such, and by virtue of Article 93 of its Constitution, it is bound by all EU legislation, as well as case law of the Court of Justice of the European Union.[31] Among relevant EU legal instruments, one must mention Regulation 536/2014,[32] on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and Regulation 1394/2007, on advanced therapy medicinal products.[33]

b The Civil Code and Criminal Code

The Civil Code (*Burgerlijk Wetboek*)[34] and the Criminal Code (*Wetboek van Strafrecht*)[35] contain provisions that must be taken into account when discussing the general legal framework for the regulation of acts affecting embryos and fetuses in the Netherlands. Article 1.2 of the Civil Code states: 'A child of which a woman is pregnant, is regarded to have been born already as often as its interests require so. If it is born lifeless, it is deemed to have never existed.' This legal fiction, known as the '*nasciturus* fiction', dates back to Roman law and many European legal orders of the Romano-Germanic tradition have incorporated it in their civil codes. It does not imply legal personhood of unborn life, nor does it aim to determine the legal status of various types of unborn human life. Instead, once the child is born, one may, for the purposes of the law, act as if the child was born at an earlier moment than it actually was,

[30] JCJ Dute, 'Buiten de (mensenrechten)orde? Over het niet ratificeren van het Biogeneeskundeverdrag door Nederland' (2015) *Magazine for Health law* (TVG) 39, 394, at 401; COGEM/Health Council of the Netherlands, *Editing Human DNA: Moral and Social Implications of Germline Genetic Modification* (Bilthoven 2017), p. 42.

[31] Case C-26/62 *Van Gend en Loos* [1963] ECR; Case C-6/64 *Costa/ENEL* [1964] ECR.

[32] On EU laws regulating human germline genome modification, see, in this volume, Part 2, Section II, Chapter 6. EU Regulation No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, OJ L 158, 27.5.2014,1–76.

[33] EC Regulation No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance), OJ L 324, 10.12.2007, 121–137.

[34] 1992 New Dutch Civil Code (*Nieuw Burgerlijk Wetboek van 1992*) (Civil Code).

[35] Criminal Code of 3 March 1881 (*Wetboek van Strafrecht van 3 maart 1881*) (Criminal Code).

if 'its interests require so'. In other words, the *nasciturus* fiction is used to protect several legal interests of an already born child. For instance, in accordance with its Roman law roots, Article 1.2 of the Civil Code is most commonly invoked for the purposes of inheritance law, to enable a child to be recognized as the beneficiary of an inheritance, even if the child was not born yet at the time of the deceased's death. More to the point, recently, the legal fiction has been used to justify prenatal child protective measures, giving rise to much discussion among legal scholars, as this new interpretation does seem to imply prenatal protection.[36] Another example is the discussion about the duty of care of healthcare providers towards unborn human life. In 2005, the Dutch Supreme Court was confronted with the question whether an embryo can be considered a 'patient' under Dutch law. The Court ruled that this could be the case if the embryo is in vivo and the pregnant woman has explicitly entered into a treatment contract on behalf of her unborn child on the basis of the Civil Code.[37]

The Criminal Code is relevant mainly because of the criminal law provisions on abortion. According to Article 82.a of the Criminal Code: 'taking the life of a person or of an infant at birth or shortly afterwards shall include: the killing of a fetus which might reasonably be expected to have the potential to survive outside the mother'.[38] In other words, once a fetus has reached the stage when it could survive outside the womb (the so-called viability limit), abortion is a crime. This criminal law provision has led to the enactment of the 1981 Termination of Pregnancy Act (*Wet Afbreking Zwangerschap*). According to the Act, abortion can be performed by a certified clinic or hospital at any point between conception and viability, which was originally set to be at 24 weeks of the pregnancy.[39] Although medical technology has advanced in the meantime, making it possible to keep children alive who are born already after 22 weeks of pregnancy,[40] in 2011, the Minister of Health decided that the

[36] P Vlaardingerbroek and others, *Het hedendaagse personen- en familierecht* (Deventer 2011), pp. 26–27; See, for an interesting analysis of both this judicial interpretation and the ensuing academic discussions, LT Haaf, 'Unborn and Future Children as New Legal Subjects: An Evaluation of Two Subject-Oriented Approaches – The Subject of Rights and the Subject of Interests', 18 *German Law Journal* 5, 1091–1119.

[37] *Baby Kelly* [2005] Dutch Supreme Court, ECLI: NL: HR: 2005: AR5213.

[38] Translation provided by Legislationline, 'Criminal Codes: Netherlands' www.legislationline.org/documents/section/criminal-codes/country/12/Netherlands/show accessed 26 October 2018.

[39] Act of 1 May 1981 concerning regulations on the termination of pregnancy [*Wet van 1 mei 1981, houdende regelen met betrekking tot het afbreken van zwangerschap*].

[40] A Reerink, 'Wel/niet levensvatbaar' (NRC Handelsblad, 3 februari 2011) www.nrc.nl/nieuws/2011/02/03/welniet-levensvatbaar-11993573-a4276l9 accessed 26 October 2018.

traditional limit of 24 weeks would be maintained.[41] During the first 24 weeks, the mother can request abortion, but only within the limits of the Termination of Pregnancy Act.[42] Abortion outside the limits established by the Termination of Pregnancy Act and after viability is a crime punished under Article 82.a of the Criminal Code.

In sum, within Dutch law, and the Dutch Civil Code and Criminal Code in particular, embryos and fetuses are not regarded as legal subjects with independent legal rights. However, unborn human life, even in its earliest stages, is not treated as just a legal object either.

c The Legal Doctrine of Progressive Legal Protection

Dutch health law scholars have developed the legal doctrine of 'progressive legal protection' as a theoretical framework to explain the legal status of unborn life.[43] It posits that as unborn life develops over time, it becomes increasingly worthy of legal protection. There are several embryonic development phases that are deemed legally relevant.

The first phase, between fertilization (either in utero or in vitro) and nidation (i.e. the organic process whereby a fertilized egg becomes implanted in the lining of the uterus of placental mammals), is called the *status potentialis*. At this early stage, the guarantees and requirements of the Termination of Pregnancy Act do not apply yet.[44] Moreover, the Embryo Act makes it clear that during this early phase, the interests and values of others (e.g. patients who might benefit from research, or the parents) can outweigh those of the embryos in vitro.[45]

The second phase is the *status nascendi*, which starts once nidation is completed.[46] Within the *status nascendi* phase, because of the aforementioned criminal law provisions relating to abortion, one can distinguish two separate sub-

[41] 'Abortusgrens blijft staan op 24 weken' (Volkskrant, 19 April 2011) www.volkskrant.nl/mensen/abortusgrens-blijft-staan-op-24-weken~bbbf9c18/ accessed 26 October 2018.

[42] TPA, art. 2–5.

[43] HJJ Leenen and others, *Handboek gezondheidsrecht* (6th edn, BJu 2014) 139; AM te Braake, 'De juridische status van het embryo: een stevig aangemeerde leer' (1995) 19: 2 *Tijdschrift voor Gezondheidsrecht* 32.

[44] Termination of Pregnancy Act, art. 1.2.

[45] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 5 (Explanatory memorandum).

[46] According to Leenen's *Handbook on Health Law*, nidation constitutes the beginning of pregnancy, although this remains contested among health law scholars. HJJ Leenen and others, *Handboek gezondheidsrecht* (6th edn, BJu 2014), s 4.3.2; W van der Burg, 'De juridische "status" van het embryo: een op drift geraakte fictie' (1994) 7 *Tijdschrift voor Gezondheidsrecht* 386, 386–401.

stages: before and after viability.[47] During this phase, the embryo still does not have the status of a legal subject. This remains the case even when the embryo is beyond the viability limit and abortion is no longer allowed.

The doctrine of progressive legal protection explains some features of the Dutch regulatory framework with regard to unborn life, such as the difference in legal protection before and after the viability limit. However, recent technological developments have created dilemmas that cannot be adequately resolved by resorting to the idea of progressive legal protection. The Embryo Act created various categories of embryos and fetuses with various legal regimes of protection that cannot be explained in terms of different stages in biological development. For example, the Embryo Act created different regimes of protection for embryos in vitro that are intended to be implanted for pregnancy and for those that are not.[48] It also distinguishes between embryos that are left over from IVF treatments and embryos that were deliberately created for research purposes, an act that is prohibited. As the Minister of Health stated during the parliamentary discussions that led up to the Embryo Act: 'To us the intention with which embryos are created are decisive for the degree to which acts with embryos are to be permitted.'[49] Accordingly, several legal scholars argue that the doctrine of progressive legal protection has severe limitations[50] and fails to offer a satisfying theoretical framework to explain the status of embryos in an era of biomedical technologies.[51] In sum, the Embryo Act demonstrates that not only the stage of biological development matters for the Dutch legal framework surrounding acts with embryos and fetuses but also the intentions with which these entities were created and the circumstances in which they were placed.[52]

2 *The Specific Regulatory Framework*

a The Embryo Act

The Act Relating to the Use of Gametes and Embryos (*Wet houdende regels inzake handelingen met geslachtscellen en embryo's*), better known as 'the

[47] HJJ Leenen and others, *Handboek gezondheidsrecht* (6th edn, BJu 2014) 134.
[48] Embryo Act, arts. 16 and 10 respectively.
[49] Parliamentary document *Handelingen II* 2001/02, 336.
[50] W van der Burg, 'De juridische "status" van het embryo: een op drift geraakte fictie' (1994) 7 *Tijdschrift voor Gezondheidsrecht* 386, 386–401.
[51] BC van Beers, 'De mysterieuze status van het embryo' (2005) 13 *Nederlands Juristenblad* 678, 678–685; BC van Beers, *Persoon en lichaam in het recht. Menselijke waardigheid en zelfbeschikking in het tijdperk van de medische biotechnologie* (dissertation VU) (Boom Juridische uitgevers 2009) 244–250.
[52] Ibid.

Embryo Act', is the most important national law with respect to research with human embryos. As its official name makes clear, it regulates the use of both human embryos and gametes. It was adopted on 20 June 2002, after a long deliberative and legislative process. The bill was drafted under a government consisting of political parties with different political outlooks: a conservative liberal political party (VVD), a liberal-democratic party (D66) and the labour party (PvdA). Policy formation under this government was a balancing act, and it shows in the Embryo Act.[53]

The Embryo Act strikes a difficult balance between, on the one hand, limiting the use of embryos for research or medical purposes in accordance with the principles of human dignity and respect for human life, and, on the other hand, supporting scientific research to promote the health of those who are ill and the welfare of infertile couples.[54] Moreover, the Explanatory Memorandum mentions the welfare of the future child as an important perspective that was taken into consideration by the legislator. Thus, the overarching idea underlying the Embryo Act is that respect for human life and dignity calls for caution and restraint when human embryos are involved.[55] Even if instrumental use of embryos is allowed, embryos still have a certain special legal standing that distinguishes them from mere objects. Therefore, embryos can only be used for certain purposes and under strict conditions. As the Explanatory Memorandum to the Embryo Act explains: 'Exactly because we give much weight to the principle of respect for human life, we subject the use of gametes and embryos to certain conditions and restrictions, and restrict the purposes for which gametes and embryos may be used.'[56]

The Act defines an 'embryo' as a 'cell or coherent whole of cells with the capacity to grow into a human being'.[57] A fertilized egg certainly qualifies as such. However, how this definition relates to other embryo-like entities remains unclear. For instance, as the Act is worded, the creation of human–animal hybrids and synthetic embryos, as long as they do not have 'the capacity to grow into a human being', does not fall under the scope of this law. Although some have bemoaned the vagueness of the definition of embryo,[58] it is not unlike, nor certainly less precise than, the one provided for by the

[53] BC van Beers, 'De mysterieuze status van het embryo' (2005) 13 *Nederlands Juristenblad* 678, 683.

[54] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 5–6 (Explanatory memorandum).

[55] Ibid. 5.

[56] Ibid. 6.

[57] Embryo Act, art. 1.c.

[58] HB Winter and others, *Evaluatie Embryowet en Wet donorgegevens kunstmatige bevruchting* (ZonMW 2012); E.T.M. Olsthoorn-Heim, *Evaluatie Embryowet* (ZonMW 2006).

legislation of several other states around the world. The definition of 'fetus' contained in the Embryo Act is more peculiar: an 'embryo in the human body'.[59] In this chapter, however, we use the term 'embryo' to refer to all types of unborn life, both in vitro and in vivo.

The Act permits, under strict conditions, the scientific use of embryos that are left over after an IVF treatment (so-called surplus embryos), but, in any event, not beyond 14 days after fertilization.[60] The creation of embryos for research is prohibited.[61] The first condition is consent of the individuals who underwent the fertility treatment.[62] Article 8 limits the range of options that these individuals have when choosing the destiny of the surplus embryos: they can donate them to others who wish to become pregnant (par. 1.a); to scientists for research (par. 1.b and c); or they can opt for destruction (par. 3).[63] A second requirement is that research on embryos must take place in accordance with a protocol that provides a complete description of the planned research.[64] The research protocol must be approved by a national oversight body called the Central Committee on Research Involving Human Subjects before the scientific research involving the surplus embryos can move forward.[65] A similar procedure applies to research involving 'fetuses'[66] and gametes.[67]

We will discuss how the Embryo Act regulates human germline editing in more detail below.[68] For now, it suffices to say that it prohibits germline modification of nuclear DNA for reproductive purposes,[69] reproductive cloning,[70] sex selection[71] and bringing together human and animal gametes for the purpose of creating a hybrid.[72] Finally, it bans selling embryos and gametes.[73] In case of violation of these prohibitions, the Act provides for criminal sanctions varying from a fine to imprisonment.[74]

[59] Embryo Act, art. 1.d.
[60] Ibid., art. 25.b.
[61] Ibid., art. 24.a.
[62] Ibid., art. 8.
[63] Ibid., art. 24.c, prohibiting using embryos for purposes other than the ones mentioned in Article 8.
[64] Ibid., art. 3.1.
[65] For more information about this committee, see infra Section II.2.c.
[66] Embryo Act, art. 3.3.
[67] Ibid., art. 3.1.
[68] See, in this chapter, Section III, 'Substantive Provisions'.
[69] Embryo Act, art. 24.g.
[70] Ibid., art. 24.f.
[71] Ibid., art. 26.1.
[72] Ibid., art. 25.a.
[73] Ibid., art. 27.
[74] Ibid., arts. 28 and 29 sanctioned with a prison sentence of one year maximum.

b Regulation Preimplantation Genetic Diagnosis 2009

In the Netherlands, preimplantation genetic diagnosis (PGD) is only allowed for couples that are at a high risk of giving birth to children with a severe, hereditary disorder. The legal framework consists of a general law, the Special Medical Procedures Act (*Wet op de Bijzondere Medische Verrichtingen*), that allows for the creation of administrative decrees to regulate certain special medical procedures, such as PGD.[75] For PGD the following decree is currently in force: Regulation Preimplantation Genetic Diagnosis 2009.[76] Based on this decree, the PGD National Indications Committee (*Landelijke Indicatiecommissie PGD*) was called into existence to draft guidelines on the question as to which genetic disorders are serious enough to justify PGD.[77] Section 2 of the Special Medical Procedures Act gives the power to the Ministry of Public Health to license permits to hospitals to perform PGD. So far, only the Maastricht University Medical Centre has been licensed to do so.

c Medical Research on Human Subjects Act, the Central Committee on Research Involving Human Subjects, and the Minister of Health, Welfare and Sport

The Medical Research on Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* – WMO), adopted in 1998, regulates medical research on human subjects.[78] It establishes various regulatory bodies, including the Central Committee on Research Involving Human Subjects (*centrale commissie voor medisch-wetenschappelijk onderzoek*),[79] the governmental body in charge of implementing the Medical Research on Human Subjects Act as well as the Embryo Act.[80] It is composed of up to 15 doctors and persons who are experts in the field of embryology, pharmacology, pharmacy, nursing, behavioural sciences, legal science, the methodology of scientific research and ethics, as well as a person who specifically assesses the scientific research from the perspective of the subject.[81]

[75] Preimplantation Genetic Diagnosis.
[76] 2009 Regulation Preimplantation Genetic Diagnosis (*Regeling preïmplantatie genetische diagnostiek*) (Regulation PFD) 2009.
[77] PGD, 'What is PGD?: PGD National Indications Committee' (PGD Nederland) www.pgdnederland.nl/en/pgd-national-indications-committee accessed 26 October 2018.
[78] Act of 26 February 1998, regarding rules on medical scientific research on humans (*Wet van 25 februari 1998, houdende regelen inzake medisch-wetenschappelijk onderzoek met mensen*).
[79] Medical Research Act, art. 14.
[80] https://english.ccmo.nl, accessed 24 November 2018.
[81] Medical Research Act, art. 14.

All research that falls under the scope of the Medical Research on Human Subjects Act or the Embryo Act must be reviewed by the Central Committee. The Central Committee protects subjects taking part in medical research by reviewing the research against the statutory provisions and taking into account the interests of medical progress. The Central Committee reports to the Minister of Health, Welfare and Sport.[82] The Minister can suspend research on human subjects in case of unacceptable risks for the research subjects' health.[83] In case of scientific research on medicine concerning gene therapy, somatic cell therapy, xenogeneic cell therapy or medicine that contains genetically modified organisms (GMOs), research is only allowed after explicit consent of the Minister and/or the Central Committee.[84]

The Central Committee also reports annually to the Minister of Health on the application of the Embryo Act 'with special attention being paid to new developments concerning actions involving germ cells and embryos, insofar as these are apparent from the submitted research protocols'.[85] The Minister of Health sends their annual report to the two chambers of the States General and gives its opinion on the new developments identified by the Central Committee.[86]

d The Environmental Management Act and the Commission on Genetic Modification

The Environmental Management Act (*Wet Milieubeheer*) was adopted in 1979 to govern general subjects of environmental protection.[87] It establishes many bodies, the most relevant for this chapter being the Commission on Genetic Modification (*Commissie genetische modificatie* – COGEM).[88] The Commission is composed of 20 members, appointed by the Minister of Infrastructure and Water Management. It operates under the umbrella of the Ministry of Health. It advises the Minister of Health on notifications and applications for a licence relating to the production of or activities involving GMOs and on safety measures to be taken to protect public health and the

[82] Embryo Act, art. 4.
[83] Medical Research Act, art. 3.a.
[84] Ibid., art. 13i.4.
[85] Embryo Act, art. 4.1.
[86] Ibid., art. 4.2.
[87] Act of 13 June 1979 regarding rules on several general topics relating to environmental hygiene (*Wet van 13 juni 1979, houdende regelen met betrekking tot een aantal algemene onderwerpen op het gebied van milieuhygiëne*) (Environmental Management Act) [amended last in 2018], preamble.
[88] Environmental Management Act, art. 2.26.

environment.[89] It advises the administrative authority authorized to approve licences relating to research establishments working on GMOs.[90] It also advises the administrative authority in charge of monitoring the production of or activities involving GMOs on matters related to its monitoring tasks.[91] And, finally, it informs the relevant ministers when the production of or activities involving GMOs have ethical or social implications which the Commission considers to be important.[92]

e The Health Act and the Health Council

The Health Act (*Gezondheidswet*) was adopted in 1956 and is the general statute regulating public health in the Netherlands.[93] It establishes the Health Council (*Gezondheidsraad*), an advisory body composed of about 100 members, appointed by the Crown and operating under the umbrella of the Ministry of Health.[94] Government ministers can use the advice of the Health Council to substantiate policy decisions.[95] The Health Council informs the Minister of Health, Welfare and Sport periodically of the current state of public health and health-related research.[96] The Health Council also has an independent and 'alerting' function: it can give unsolicited advice[97] by issuing advisory reports on health-related scientific developments.[98]

3 *Funding*

In the Netherlands, research on gene editing and human embryos is publicly funded by two organizations: the Netherlands Organization for Scientific Research (*Nederlandse Organisatie voor Wetenschappelijk Onderzoek* – NWO)[99] and the Organization Health Research Netherlands (*Organisatie*

[89] Environmental Management Act, art. 2.27.1.a.
[90] Environmental Management Act, art. 2.27.1.b.
[91] Environmental Management Act, art. 2.27.1.c.
[92] Environmental Management Act, art. 2.27.2.
[93] Act of 18 January 1956, on new legal regulations on the organization of health care (*Wet van 18 januari 1956, houdende nieuwe wettelijke voorschriften met betrekking tot de organisatie van de gezondheidszorg*) (Health Act) [amended last in 2018].
[94] Health Act, art. 21.
[95] Health Act, art. 22.
[96] Ibid.
[97] Website Health Council: www.healthcouncil.nl/task-en-procedure/legal-task, accessed 24 November 2018.
[98] Website Health Council: www.healthcouncil.nl/task-en-procedure/independence, accessed 24 November 2018.
[99] NWO (2018) www.nwo.nl accessed 7 November 2018.

ZorgOnderzoek Nederland – ZON).[100] The NWO was established in 1987 by the Act on the Netherlands Organization for Scientific Research (*Wet op de Nederlandse organisatie voor wetenschappelijk onderzoek*).[101] Its task is furthering the quality of scientific research and stimulating new developments in scientific research in general.[102] The ZON focuses specifically on research and development in the fields of health, prevention and care. It was established in 1998 by the Act on the Organization of Health Research in the Netherlands (*Wet op de organisatie ZorgOnderzoek Nederland*).[103]

Funding for health research comes from the Netherlands Organization for Health Research and Development (*Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie*),[104] an organization in which NWO and ZON collaborate. ZonMw is tasked to solve problems and challenges in health care and research and promote the actual use of scientific knowledge.[105] Currently, no research into human gene editing is funded in the Netherlands by either NWO or Horizon 2020.[106]

III SUBSTANTIVE PROVISIONS

Having presented the regulatory environment in general terms, it is now possible to explain the Dutch legal rules on germline genome modification. For the regulation of human genome germline editing, two provisions of the Embryo Act are essential: the prohibition on creating human embryos for research (Article 24.a) and the prohibition on genetically modifying human embryos and gametes (Article 24.g). These prohibitions mirror the prohibitions contained in Articles 18.2 and 13 of the Oviedo Convention, even though the Netherlands has not ratified it.

[100] ZonMw (2018) www.zonmw.nl accessed 7 November 2018.

[101] Act of 7 July 1987 on the regulation of the Dutch Organization of Scientific Research (*Wet van 7 juli 1987, houdende herziene regeling van de Nederlandse organisatie voor zuiver-wetenschappelijk onderzoek*) (*Act on the Netherlands Organization for Scientific Research*) [amended last in 2017].

[102] NWO Act, art. 3.1.

[103] Act of 14 February 1998, on the Act on the Organization of Health Research in the Netherlands (*Wet van 14 februari 1998*) (*Act on the Organization of Health Research in the Netherlands*) [amended last in 2011]; ZON Act, art. 2.1.

[104] ZonMw, 'ZonMw in the Netherlands' (ZonMw 2018) www.zonmw.nl/en/about-zonmw/zonmw-in-the-netherlands/ accessed 24 October 2018.

[105] ZonMw in English (2018) www.zonmw.nl/en/ accessed 7 November 2018.

[106] According to the latest project lists on: European Commission, 'Examples of EU funded projects' (European Commission) http://ec.europa.eu/budget/euprojects/search-projects_en last accessed 7 November 2018 and NWO, 'Research & Results' (NWO 2018) www.nwo.nl/en/research-and-results accessed on 7 November 2018.

1 The Prohibition to Create Human Embryos for Research Purposes

Research on embryos can be done with surplus embryos if certain conditions are met, namely: (i) the research must be likely to lead to new insights in the field of medical science;[107] (ii) it cannot be conducted in any another manner but by using surplus embryos;[108] (iii) its methodology must be convincing;[109] (iv) the donor couple must give informed and written consent, after a 'sufficient time of reflection';[110] (v) cells grown from an embryo, as well as reproductive cells and embryos, cannot be used for purposes other than those for which they may be made available;[111] and (vi) the embryo must not be allowed to develop outside the human body for more than 14 days.[112]

However, scientists cannot create embryos for research purposes. Article 24. a of the Embryo Act prohibits 'deliberately creating embryos and using deliberately created embryos for scientific research and other purposes than initiating a pregnancy'. The ban is phrased in such a way that Dutch scientists are also not allowed to import and use embryos that have been created for research purposes abroad, as confirmed by the Explanatory Memorandum of the Embryo Act.[113] As will be discussed below, this prohibition forms the main legal obstacle for research involving human germline editing.

It should be noted that the legislator had in mind at least four considerations when drafting the ban. The first was the need to respect human life, demanded both by the Dutch legal system and by prevailing societal attitudes. According to the government, 'the creation of embryos for research purposes constitutes a graver interference with the principle of respect for human life than in case of using embryos that already existed, such as embryos that are left over from IVF'.[114] The second was the need to ensure that scientific research is not unduly hindered.[115] The third was taking into consideration the views on the matter of the public. The government observed in that context 'that, outside scientifically oriented circles, there hardly is public support within society for the creation of embryos for scientific purposes'.[116] And, finally, the fourth was keeping the

[107] Embryo Act, art. 10.a; Medical Research (Human Subjects) Act, arts. 14.1 and 16.
[108] Embryo Act, art. 10.b; Medical Research (Human Subjects) Act, arts. 14.1 and 16.
[109] Embryo Act, art. 10.c.
[110] Embryo Act, art. 8; Medical Research (Human Subjects) Act, arts. 14.1 and 16.
[111] Embryo Act, arts. 24.d and 24.h.
[112] Embryo Act, art. 24.e; Medical Research (Human Subjects) Act, arts. 14.1 and 16.
[113] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 57–58 (Explanatory memorandum).
[114] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 24 (Explanatory memorandum).
[115] Ibid. 25–26.
[116] Ibid. 27.

Netherlands in line with prevailing international and European standards.[117] At the time, only the United Kingdom permitted creating embryos for research purposes.

At the same time, the government underlined that scientific and societal developments in this field usually take place at a rapid pace. To enable the Embryo Act to respond to these developments, the ban on the creation of embryos for other purposes than a pregnancy should, according to the government, not be written in stone. Therefore, the ban can be lifted by mere Royal Decree, an act of the government that does not require a parliamentary vote.[118] Should that day arrive, the government has already made it clear that it will follow the so-called not allowed, unless approach,[119] namely, embryos will not be created ad hoc for research unless: (i) the scientific research leads to new and fundamental insights in infertility, artificial reproduction, transplantation medicine, or hereditary or congenital disorders; (ii) the specific research cannot be conducted without creating embryos, for example by using surplus embryos from IVF;[120] and (iii) the same requirements already in place for research on surplus embryos are met.[121]

2 *The Ban on Human Germline Genetic Modification*

Article 24.g of the Embryo Act prohibits 'deliberately modifying the genetic material of the *nucleus* of human germ cells with which a *pregnancy* will be established'.[122] These words suggest that human genetic modification is prohibited only for *reproductive* purposes, and only where *nuclear* DNA is concerned. In other words, Article 24.g does not prohibit *research* on germline editing. It also does not prohibit modification of *mitochondrial* DNA for either reproductive or research purposes. Therefore, in theory, scientists in the Netherlands can modify the genome of both human embryos and gametes for research purposes. Moreover, the technology of so-called human nuclear genome transfer[123] (also

[117] Ibid. 27–28.
[118] Embryo Act, art. 33(2).
[119] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 30 (Explanatory memorandum).
[120] See first draft of the Embryo Act, art. 11 (Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 1–2).
[121] Embryo Act, arts. 5, 6 and 7.
[122] Emphasis added.
[123] Nuclear genome transfer is a procedure that can be used to prevent passing on mitochondrial diseases to future children in the following way: one removes the nuclear DNA from eggs that originate from a woman with dysfunctional mitochondrial DNA and transfers the resulting nuclear DNA into the enucleated eggs from a third party who donated her eggs for this procedure.

known as 'mitochondrial replacement therapy')[124] is not explicitly prohibited, even for reproductive purposes.

However, even though the Embryo Act does not explicitly prohibit scientific research involving human germline editing or nuclear genome transfer, the prohibition of the creation of human embryos for research contained in Article 24.a makes this kind of research practically impossible. As Dutch scientists have emphasized repeatedly, surplus embryos cannot be used for this kind of research; it takes embryos that have been created ad hoc.[125] As a result, the Embryo Act contains, what could be called, a de facto prohibition on research in the field of human germline editing, since the creation of research embryos is indispensable for the most important types of research in this field.

What the Embryo Act does not prohibit, de jure or de facto, is research involving human germline editing or nuclear genome transfer that does not involve the creation of embryos for research purposes, such as editing the nuclear DNA of gametes for research purposes. Additionally, the Embryo Act, at least in theory, does not impede the introduction of nuclear genome transfer in clinical contexts. In practice, this will not be authorized, as long as research involving nuclear genome transfer cannot take place in the Netherlands. This was confirmed by the Dutch Minister of Health in answer to questions from Members of Parliament about the technology.[126]

Originally, the ban on human germline editing was repealable through a simple Royal Decree, just like the prohibition of the creation of embryos for research.[127] However, in response to the EU Clinical Trials Directive, which states that 'no gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity',[128] and which came into force during the parliamentary discussion of the Act, the government changed its

[124] We agree with Baylis that the term 'mitochondrial replacement' is misleading, and will therefore, like the Dutch Health Council and COGEM (see COGEM/Health Council of the Netherlands, *Editing Human DNA: Moral and Social Implications of Germline Genetic Modification* (Bilthoven 2017)), use the term 'nuclear genome transfer' instead (see F Baylis, 'Human Nuclear Genome Transfer (So-Called Mitochondrial Replacement): Clearing the Underbrush' (January 2017) 31:1 Bioethics 7, 7–19.

[125] As evidenced in a report commissioned by the Dutch government: J Eeuwijk and others, *Onderzoek naar speciaal kweken*, (Pallas 2015).

[126] Parliamentary document *Kamerstukken II* 2016/17, 29 323, no 105, 12–13.

[127] See first draft of the Embryo Act, art. 32.3 (parliamentary document *Kamerstukken II* 2000/01, 27 423, no 1–2).

[128] Article 9.6 of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, [2001] OJ L 121, 34–44.

mind and amended the text of the proposed law accordingly.[129] As a result, a parliamentary vote is now needed in order to lift the ban on germline modification.

In its Explanatory Memorandum, the government stressed the need for further ethical reflection on human germline modification. Questions that need to be addressed include 'the question whether human dignity implies the right to inherit a genetic pattern that has not been modified as a result of intentional human interventions, or that germline therapy would, on the contrary, be required by that same principle'.[130] Furthermore, the government mentioned the irreversibility of human germline modification and the possible risk that human diversity would decrease as a result. Nevertheless, the government raised these questions without offering any answers. When it came to, for example, the ban on reproductive cloning, contained in Article 24.f of the Embryo Act, the government was much more outspoken: 'we completely share the fundamental argument that cloning human individuals violates human dignity'.[131]

IV CURRENT PERSPECTIVES AND FUTURE POSSIBILITIES

As discussed in the previous section, two bans dominate the national legislative and policy framework for human germline editing: the ban on intentionally modifying the genetic material of the nucleus of human germline cells for reproductive purposes and the ban on the creation of embryos for research purposes. So far, political debates in Parliament have tended to focus on the latter. The rise of CRISPR/Cas9 gave new impetus to the debate, but the issue has so far remained unresolved. A change of government in September 2017, with a different position on medical-ethical issues than the previous government, has further complicated the discussion.[132] A discussion of the debate will shed light on current perspectives and future possibilities for the evolution of the regulatory framework for embryo research and human germline genome modification in the Netherlands.

[129] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 5, 99–100.

[130] Parliamentary document *Kamerstukken II* 2000/01, 27 423, no 3, 45 (Explanatory memorandum).

[131] Ibid. 42.

[132] The previous government consisted of a conservative liberal political party (VVD) and the labour party (PvdA). The current government consists of a conservative liberal political party (VVD), a liberal-democratic party (D66), a center-right Christian-democratic party (CDA) and another Christian-democratic party (ChristenUnie).

Following up on the findings and recommendations of two evaluation studies on the Embryo Act that had been published since this legislation came into force,[133] in May 2016, the Minister of Health, Mrs Edith Schippers, sent a letter to Parliament proposing to lift the ban on creating embryos for research.[134] According to Schippers, who is a prominent member of the People's Party for Freedom and Democracy (*Volkspartij voor Vrijheid en Democratie* – VVD), a conservative-liberal political party, important scientific research is hindered by the prohibition. The Minister proposed to lift the ban only for some types of research. She stressed that, although the principle of respect for human life is an important one, other interests should also be taken into account. Through a revision of the Embryo Act, she aimed to offer relief to 'infertile couples and couples who risk passing on hereditary diseases to their offspring'. Describing her approach to research embryos as a 'not allowed, unless' policy,[135] she proposed to replace the existing blanket ban with a provision that allows the creation of embryos for certain types of research under certain conditions:

1. the research must be designed to generate new insights in the field of infertility, assisted reproductive technologies and hereditary or congenital deficiencies and must be directly relevant to clinical practice;
2. the research cannot be performed by using surplus embryos;
3. the research design and research activities must meet the relevant quality standards for scientific research;
4. the medical objective must outweigh the objections to creating embryos specifically for scientific research.[136]

In her letter, she identified three types of research that would fulfil these conditions: in vitro maturation (IVM), in vitro gametogenesis (IVG) and nuclear genome transfer (NGT). The 2016 letter to Parliament made headlines, received much media attention and led to diverging reactions.[137] In

[133] HB Winter and others, *Evaluatie Embryowet en Wet donorgegevens kunstmatige bevruchting* (ZonMW 2012); E.T.M. Olsthoorn-Heim, *Evaluatie Embryowet* (ZonMW 2006). Schippers had commissioned an inquiry into the matter. The resulting report had concluded that the legal ban on the creation of embryos for research purposes hampered clinically relevant developments in the field of medical technologies. J Eeuwijk and others, *Onderzoek naar speciaal kweken* (Pallas 2015) 15.

[134] Parliamentary document 2015/16, 29 323, no 101.

[135] Parliamentary document *Kamerstukken II* 2015/16, 29 323, no 101, 4.

[136] Ibid. 5.

[137] Eg G de Wert, 'Embryowet blijft te beperkt', (NRC Handelsblad, 31 May 2016) www.nrc.nl/nieuws/2016/05/31/embryowet-blijft-te-beperkt-1623987-a1557164 accessed 7 November 2018; BC van Beers, 'Debat over embryo's hoort op hoogste politieke niveau' (Volkskrant, 2 June 2016) www.volkskrant.nl/columns-opinie/debat-over-embryowet-hoort-op-hoogste-politieke-niveau~b5

a subsequent 2017 letter to the Parliament,[138] she also added human germline genome editing to the list. The 2017 letter made clear that Schippers considered human germline genome editing viable as soon as it is proven safe for clinical applications. However, to prove safety, clinical research is needed, and, according to her, this research should take place also in the Netherlands. Thus, she proposed to include germline genome editing in the list of types of research for which the ban on creating embryos should be lifted. The Minister stressed the importance of a public debate on the matter, although, in her view, it should focus on the question as to *how* to regulate the use of this technology, and not as to *whether* this technology is desirable in the first place. Indeed, she was 'optimistic that a regulatory framework – comparable to the existing regulatory framework for preimplantation genetic diagnostics (PGD) – could work well and could warrant that only morally and socially acceptable applications of germline modification would take place'.[139] As discussed, in the Netherlands, PGD is permitted only for serious hereditary diseases. Apparently, according to Schippers, human germline modification does not raise additional issues compared to PGD, apart from the safety issues. The Minister's position is that human germline editing should be available for prospective parents as soon as the technology no longer poses any health risks, and as long as it is only used for the elimination of serious hereditary diseases.

Barely a month later, the Dutch Health Council and the Netherlands Commission on Genetic Modification issued a joint advisory report on human germline genetic modification with exactly the same recommendation: lift the ban on creating embryos for research and on human germline genome modification for therapeutic purposes as soon as the technology is safe for introduction in the clinic.[140] In the report's chapter on the ethical dimensions of the issue, the two bodies discussed the ethical concerns about producing embryos for research, instead of using surplus embryos. The Netherlands Commission on Genetic Modification and Health Council argued that the fear of 'instrumentalization' of embryos could not justify a blanket ban on creating embryos for research. They emphasized that germline modification

b712fb/ accessed 7 November 2018; W Dondorp, G de Wert and S Repping, 'Instrumenteel gebruik van embryo's is al lang geaccepteerd' (Volkskrant, 9 June 2016) www.volkskrant.nl/columns-opinie/instrumenteel-gebruik-van-embryo-s-is-allang-geaccepteerd~b796f9bb/ accessed 7 November 2018; NOS, 'Embryo's zijn mensen, die kweek je niet' (NOS, 27 May 2016) nos.nl/artikel/2107661-embryo-s-zijn-mensen-die-kweek-je-niet.html accessed 7 November 2018.

[138] Parliamentary document *Kamerstukken II* 2016/17, 29 323, no 110, 2.

[139] Ibid.

[140] COGEM/Health Council of the Netherlands, *Editing Human DNA: Moral and Social Implications of Germline Genetic Modification* (Bilthoven 2017).

would be able to eliminate serious diseases, also in the few cases in which PGD would no longer be an option.

Additionally, they discussed several arguments that have been raised against human germline editing based on human dignity, designer babies and slippery slopes, and equality and justice, and offered counterarguments for each, finding that using human germline editing to eliminate grave diseases does not conflict with human dignity but rather respects it, as the future child and future generations will be permanently rid of unhealthy genes. Moreover, both organizations argued that if the Dutch legislator does not prohibit the use of NGT, then it should also not prohibit the use of germline editing to prevent serious diseases.

Both Schippers's proposal and the advisory report were discussed in media at length.[141] Both positive[142] and negative[143] reactions were expressed by several ethicists and legal scholars. Moreover, several important organizations and institutions responded. The Dutch Council of State (*Raad van State*), a constitutionally established advisory body to the Dutch government and States General, was very critical. In its advisory report on the Minister's proposal, it wrote that it is not convinced of the necessity of lifting the ban on creating embryos to enable research in the field of reproductive technologies.[144] Moreover, it stressed the importance of the principle of respect for human life and human dignity, and pointed out that Schippers's policy could have certain negative side effects for society.

Similarly, the Rathenau Instituut, a government-sponsored organization that performs research relating to the societal aspects of science, innovation and new technologies, expressed concerns about these developments. In

[141] E.g. M Keulemans, 'Gezondheidsraad adviseert: legaliseer het genetisch bewerken van embryo's', (Volkskrant, 28 March 2017) www.volkskrant.nl/wetenschap/gezondheidsraad-adviseert-legaliseer-het-genetisch-bewerken-van-embryo-s~b53e7492/ accessed 24 November 2018.

[142] E.g. A Bredenoord, quoted in: D Waterval, 'Nederland is volwassen genoeg om aanpassing DNA te reguleren', (Trouw, 29 March 2017) www.trouw.nl/home/-nederland-is-volwassen-genoeg-om-aanpassing-dna-s-te-reguleren-~a53c82f9/ accessed 24 October 2018; Y Buruma, 'Genetische modificatie. Fundamentele vragen voor het recht' (2017) 1754 NJB 32, 2310; EJ Oldekamp and MC de Vries, 'Nieuwe procreatietechnieken. Achterhaalde juridische kaders?' in *Nieuwe techniek, nieuwe zorg. Preadviezen* (Handelingen Vereniging voor Gezondheidsrecht. Deel 2018–1) (Den Haag: Sdu 2018) 15–88.

[143] D Pessers, 'De aanbidding van het DNA' (De Groene Amsterdammer, 6 September 2017) www.groene.nl/artikel/de-aanbidding-van-het-dna last accessed 24 October 2018; B van Beers, 'We zijn blij met de assemblage van onze iZoon: Designbaby's of de voortplanting van de toekomst' (2018) 6 De Groene Amsterdammer 42; T Vaessen, 'D66 maakt weg vrij voor industriële fabricage van baby's' (Financieele Dagblad, 22 December 2017) fd.nl/weekend/1229975/d66-maakt-weg-vrij-voor-industriele-fabricage-van-baby-s accessed 24 October 2018.

[144] Raad van State, 'Advice W13.16.0202/III' (4 November 2016) www.raadvanstate.nl/adviezen/zoeken-in-adviezen/tekst-advies.html?id=13060 accessed 24 October 2018.

a report entitled 'Rules for the Digital Human Park',[145] the Rathenau Instituut called for a broader discussion, in which more collective values and interests also would be involved, such as the rights and interests of future generations, human dignity and the protection of the human genome as the common heritage of humanity. Clearly, the authors were inspired by German philosopher Peter Sloterdijk's famous essay *Rules for the Human Zoo*.[146] Like Sloterdijk, they argued that new technologies, such as germline editing and persuasive technologies, could evolve into practices of breeding and taming human beings. Hence, according to them, the possible prospect of a self-domestication of the human species offers an important perspective for debates on germline modification.

Both Schippers's letters and the report written by the Health Council and the Netherlands Commission on Genetic Modification remained undiscussed in Parliament for a long time. The reason is that in March 2017 elections took place. Parliamentary discussions on 'controversial' topics like human germline editing were postponed until the new government was sworn in September 2017. Schippers did not return as Minister of Health. She was succeeded by Mr Hugo de Jonge, a member of Christian Democratic Appeal (*Christen-Democratisch Appèl* – CDA). The coalition agreement, which serves as the basis for the current government, immediately made clear that Minister De Jonge will not continue Schippers's line of policy with regard to human gene editing and creating embryos for research.[147] The coalition agreement emphasized the need for further public debate about these issues before further political decisions are made.[148] This was confirmed through several letters that De Jonge sent to Parliament in 2017 and 2018.[149]

Overall, in current debates on germline genome editing two conflicting ethical perspectives seem to dominate in the Netherlands. The report 'Rules

[145] R Van *Est and others*, Regels voor het digitale mensenpark. 'Telen' en 'temmen' van de mens via kiembaanmodificatie en persuasieve technologie (Den Haag: Rathenau Instituut 2017). An English version was published earlier: *Rules for the digital human park. Two paradigmatic cases of breeding and taming human beings: human germline editing and persuasive technology* (11th Global Summit 2016) www.globalsummit-berlin2016.de/programme/GlobalSummit2016DiscussionPapers.pdf accessed 24 October 2018.

[146] P Sloterdijk, 'Rules for the Human Zoo: A response to the Letter on Humanism' (2009) 27 *Environment and Planning D: Society and Space* 12.

[147] The coalition agreement was translated in English, see 'Confidence in the Future', www.kabinetsformatie2017.nl/documenten/verslagen/2017/10/10/coalition-agreement-confidence-in-the-future, accessed 24 October 2018.

[148] 'Confidence in the Future', 22.

[149] Parliamentary documents *Kamerstukken II* 2017/2018, 34 775 XVI, no 46; Amendment Parliamentary documents 2017/18, 1141, 1; Parliamentary documents *Kamerstukken II* 2017/2018, 34 990, no 1.

for the Digital Human Park' calls these two opposing views the 'human rights regime' and the 'medical ethics regime'.[150] The 'human rights regime' goes back to the legal-ethical approach that underpins the founding international conventions and declarations in the field of biolaw. The Council of Europe's Oviedo Convention and UNESCO's Universal Declaration on the Human Genome and Human Rights, each in its own way, embody the thought that biomedical developments touch on the question of what it means to be human and 'that the misuse of biology and medicine may lead to acts endangering human dignity', to quote the Oviedo Convention's recital.

This approach can be distinguished from the 'medical ethics regime', which the Rathenau Instituut's report describes as follows: 'The basic question in this regime is whether a particular intervention in the human body satisfies criteria of safety, informed consent, and, in the context of reproductive medicine, also parental rights and reproductive freedom. In these terms, human germline engineering may be deemed ethically acceptable, especially when a particular intervention may alleviate potential suffering of a (future) human individual.'[151] This line of thinking can, for example, be recognized in the international calls for a moratorium on human gene editing from scientists working in the field. These groups' prime concerns are that 'the precise effects of genetic modification to an embryo may be impossible to know until after birth' and 'potential problems may not surface for years'.[152] Their main recommendations are more research and better education of the public by experts 'about this new era of human biology'.[153]

The Embryo Act shares the same legal-ethical outlook as the Oviedo Convention when it comes to human germline editing and research into human germline editing. However, this prohibitive 'human rights regime' approach is under increasing pressure. Instead, the 'medical ethics regime' approach, which focuses on the prevention of clinical risks and the principle of self-determination, is becoming more dominant in this context. Schippers's letters can serve as a good illustration of the current tendency to focus on safety risks instead of the legal-ethical principles that are at stake. By proposing to lift the ban on research embryos without first investigating whether IVM, IVG, NGT and germline editing are the way forward in the first place, Schippers seems to presuppose that the only possible moral objection against these technologies is that they are not clinically safe yet. Yet, this approach ignores some of the most

[150] *Rules for the Digital Human Park* (n 145) 16–17.
[151] Ibid. 16.
[152] E Lanphier and others, 'Don't edit the human germline' (2015) 519 *Nature* 411.
[153] D Baltimore and others, 'A prudent path forward for genomic engineering and germline gene modification' (2015) 348:6230 *Science* 38.

important questions raised by the prospect of germline genome editing. Interestingly, the European Group on Ethics in Science and New Technologies (EGE), which is an independent advisory body of the President of the European Commission, warns exactly about this tendency in a 2016 statement on gene editing:

> The EGE cautions against reducing the debate to safety issues and the potential health risks or health benefits of gene editing technologies. Other ethical principles such as human dignity, justice, equity, proportionality and autonomy are clearly at stake and should be part of this necessary reflection towards the international governance of gene editing.[154]

This brings us to a second line of critique on the manner in which the public debate on germline editing currently plays out in the Netherlands. From a human rights perspective, the legal principle of human dignity is of central importance to the debate on germline editing. Yet, in many of the policy documents, little reflection is offered on human dignity. A striking example is the position paper on genome editing that was written by the Royal Netherlands Academy of Arts and Sciences. This paper does not make any mention of human dignity.[155] Instead, the Academy's main concerns about human germline applications are about various types of health risks.

The report of the Health Council and the Netherlands Commission on Genetic Modification does engage with the principle of human dignity, albeit quite briefly. However, its interpretation is strikingly one-dimensional. It is common among scholars of bioethics and biolaw to distinguish between two dimensions of, or perspectives on, human dignity: human dignity as 'empowerment' and human dignity as 'constraint'.[156] The first perspective understands respect for human dignity as respect for personal autonomy and self-determination. The second interprets human dignity as a principle that protects individuals against dehumanization, objectification or commodification (even if these individuals consent to their dehumanizing treatment). What seems to underlie the ban on germline editing in the Oviedo Convention is mainly the second view of human dignity.[157] The Convention's Explanatory Report, in

[154] European Group on Ethics in Science and New Technologies, 'Statement on gene editing' (2016) ec.europa.eu/research/ege/pdf/gene_editing_ege_statement.pdf accessed 24 October 2018.

[155] Royal Netherlands Academy of Arts and Sciences, *Position paper on genome editing* (Koninklijke Nederlandse Akademie Van Wetenschappen, November 2016) www.knaw.nl/en/news/publications/genome-editing/@@download/pdf_file/Genome%20Editing%20Position%20Paper%20KNAW%20November%202016.pdf accessed 24 October 2018.

[156] Brownsword/Beyleveld, *Human Dignity in Bioethics and Law* (Oxford University Press 2001).

[157] For a further discussion, see BC van Beers, 'Imagining future people in biomedical law: From technological utopias to legal dystopias within the regulation of human genetic modification

its comments on Article 13, identifies as its ultimate fear the use of 'intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities'.[158]

The Health Council and the Netherlands Commission on Genetic Modification, on the contrary, only highlight the other dimension of human dignity: empowerment. According to the report, if human germline editing is used to prevent suffering by removing the genetic cause of a disease, it should be considered a form of respect for human dignity.[159] From their perspective, dignity is primarily about alleviating suffering.

Since Schippers presented her ideas on germline editing, the political composition of the government has changed. It remains to be seen how this will affect the political debate on germline editing in the Netherlands. It is clear that this government is more cautious in its approach and prefers to await further public and political debate about the issue. How the current government intends to stimulate this debate is still unknown. It would be our suggestion that, in order to make this debate more inclusive and balanced, both the human rights perspective and the medical-ethical perspective should be properly represented. This means that not only the safety risks of the technology but also the legal and ethical principles that are at stake must be discussed; that not only scientists but also citizens should be heard; that not only individual but also collective interests and values should be addressed in the discussion; and that human dignity should not only be understood as respect for autonomy but also as protection against dehumanization.

technologies', in M Ambrus, R Rayfuse and W Werner (eds.), *Risk and the Regulation of Uncertainty in International Law* (Oxford: Oxford University Press) 117–140.

[158] Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Explanatory Report), para 89.

[159] COGEM/Health Council of the Netherlands, *Editing Human DNA: Moral and Social Implications of Germline Genetic Modification* (Bilthoven 2017) 55.