NGO Parallel Report on the Federal Republic of Germany's Sixth Report on the Implementation of the International Covenant on Economic, Social and Cultural Rights

Submitted to the

UN Committee on Economic, Social and Cultural Rights for consideration in the formulation of the List of Issues during the 61st Pre-Sessional Working Group (9 – 13 October 2017)

September 8, 2017

Submitted by:

International Human Rights Clinic Loyola Law School, Los Angeles

919 Albany Street 90015, Los Angeles, CA, USA Contact: Prof. Cesare Romano <u>cesare.romano@lls.edu</u> Prof. Mary Hansel <u>mary.hansel@lls.edu</u> Associazione Luca Coscioni per la libertà di ricerca scientifica

Via di Torre Argentina 76 00186, Rome, Italy Contact: Prof. Filomena Gallo <u>studiolegalegallo.f@gmail.com</u> <u>segretariocoscioni@gmail.com</u>

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PURPOSE OF THE REPORT

1) The purpose of this "Parallel Report" is to assist the Committee on Economic, Social and Cultural Rights in the formulation of the List of Issues during the 61^{st} Pre-Sessional Working Group (9 – 13 October 2017), leading to the discussion of Germany's Sixth Periodic Reports on its implementation of the Covenant on Economic, Social and Cultural Rights during the 64^{th} Session of the Committee on Economic, Social and Cultural Rights (17 September – 5 October 2018).

2) The Federal Republic of Germany ratified the Covenant on Economic, Social and Cultural Rights (hereinafter "CESCR" or "Covenant") on 17 December 1973.¹ Its last periodic review (5th) was completed in 2011. It is currently undergoing its 6th periodic review.

3) Germany's 6th periodic report, of 16 March 2017, has several lacunae.² Under Article 10 ("Right to Family Life"), it discusses only employment of children and young people and violence against women, but it does not discuss access to Assisted Reproductive Technology (ART), abortion and contraception. Under Article 12 ("Right to Health"), it discusses several issues, including stigmatization and discrimination of people with HIV/AIDS; health protection policy in connection with food containing genetically modified organisms; compulsory medical treatment of people with mental illness; drug use and prevention projects for children and young people; frequency of suicide and impact of suicide prevention measures; situation in nursing homes — shortage of skilled workers; situation with regard to informal care; and risk of malnutrition in schools. However, Germany does not discuss limitations it puts on research on human Embryonic Stem Cells (hESC), abortion and contraception, and Assisted Reproductive Technology, all issues that directly affect the right to health. Finally, under Article 15 ("Right to Benefit from Scientific and religious make-up of the population, and copyrights. However, it is silent on the impact that restrictions on research with human Embryonic Stem Cells (hESC) have on scientists and the public at large. This report complements Germany's report to enable the Honorable

¹ International Covenant on Economic, Social and Cultural Rights, art. 15(1)(b), Dec. 16, 1966, S. Treaty Doc. No. 95-19, 6 I.L.M. 360 (1967), 993 U.N.T.S. 3 [hereinafter CESCR]. *States Party to the International Covenant on Economic, Social and Cultural Rights*, United Nations Treaty Collection, <u>https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en</u> (last visited Jan. 14, 2017).

² U.N. Economic and Social Council, *Sixth Period Reports of States Parties Due in 2016 – Germany*, UN Doc. E/C.12/DEU/6, (16 March 2017).

Committee to get a clearer picture of how Germany is discharging its obligations under these articles of the Covenant.

ABOUT THE AUTHORS OF THIS REPORT AND SOURCES

4) This report has been prepared by the International Human Rights Clinic of Loyola Law School, Los Angeles — directed by Professors Cesare Romano and Mary Hansel — and by the Luca Coscioni Association for Freedom of Scientific Research.

5) The International Human Rights Clinic of Loyola Law School, Los Angeles is committed to achieving the full exercise of human rights by all persons, and seeks to maximize the use of international and regional political, judicial, and quasi-judicial bodies through litigation, advocacy, and capacity-building.³ Loyola Law School, Los Angeles is the school of law of Loyola Marymount University, a Jesuit university.

6) The Luca Coscioni Association for the Freedom of Scientific Research is a non-profit organization comprised of members of parliament, academics, researchers and students, along with representatives of patients and advocacy associations. The Luca Coscioni Association promotes the freedom of scientific research and treatment as well as the civil and political rights of patients and people with disabilities. It was founded in 2002 by Dr. Luca Coscioni, an Italian economist affected by Amyotrophic Lateral Sclerosis, who launched a national campaign to promote freedom of scientific research on embryonic stem cells.⁴ Since its foundation, the Association has been active on a range of issues, including the rights of persons afflicted with illness and disabilities, the right to die, reproductive health, and freedom of scientific research.

7) The World Congress for Freedom of Scientific Research is a permanent forum of activities to promote freedom of scientific research worldwide. Since the founding session of the Word Congress, in October 2004, the Luca Coscioni Association is the Operational Secretariat of the World Congress.

³ See International Human Rights Clinic, Loyola Law School, Los Angeles,

http://www.lls.edu/academics/experientiallearning/clinics/socialcriminaljusticeclinics/internationalhumanrightsclinic/ (last visited Sept. 1, 2017).

⁴ See Luca Coscioni Association, <u>http://www.associazionelucacoscioni.it</u> (last visited Jan. 14, 2017).

8) The Research and Self Determination Index is one of the main projects of the World Congress for Freedom of Scientific Research.⁵ First published in 2014, the Index is a tool for comparative assessment of the degree to which researchers, health care professionals and patients enjoy the right to science around the globe. It measures key legal and regulatory indicators of the right to science in four areas: Assisted Reproduction Technologies (ART); research with human Embryonic Stem Cells (hESC); End-of-Life decisions; and Abortion and Contraception (A&C). For each indicator, points are allocated with highest score allotted to legal environments that recognize the right to science to the greatest degree.⁶ Currently, 46 countries are indexed. At least 80% of data are complete for these countries.

BACKGROUND

9) The Federal Republic of Germany (Germany) is a driving force of the world's economic and scientific progress. It is the second most populous nation of the European continent. It is one of the most developed and industrialized countries in Europe and in the world. The German economy is the fifth largest economy in the world in Parity of Purchasing Power terms and Europe's largest.⁷ In 2014, UNESCO reported Germany spent 2.869% of GDP (about 111 billion USD) on Research and Development (R&D), which put it amongst the top countries in the world in terms of R&D investment.⁸ But this is nothing new. Traditionally, R&D investment has been an integral part of the country's economy. Historically, Germany has been one of the driving forces in the world's development of science and technology. Over the past two centuries, Germany has been the home of some of the most prominent researchers in many natural science disciplines, such as physics, mathematics, chemistry, biology and engineering, as well as in humanities. Before World War II, Germany generated more Nobel laureates in scientific fields than any other country.

10) However, despite its scientific and technological prowess, Germany is still falling short of its obligations under the Covenant. Indeed, the Research and Self Determination Index of the World

⁵ See Research and Self Determination Index, World Congress for Freedom of Scientific Research, <u>http://www.freedomofresearch.org/research-and-self-determination-index</u> (last visited Sept. 1, 2017).

⁶ See id. ("If data are not available, the answer is not included in the calculation.").

⁷ See *The World Factbook*, Central Intelligence Agency, <u>https://www.cia.gov/library/publications/the-world-factbook/geos/print_gm.html</u> (last visited Aug. 30, 2017).

⁸ Research and development expenditure (% of GDP), United Nations Educational, Scientific, and Cultural Organization (UNESCO), Institute for Statistics,

http://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS?locations=DE (last visited Aug. 30, 2017).

Congress for Freedom of Scientific Research, ranks Germany only 25th (out of 46 states ranked), with a score of only 109 points out of a possible total of 194.9

RESEARCH WITH HUMAN EMBRYONIC STEM CELLS (HESC)

Research with human embryonic stem cells (hESC) in Germany

11) Germany scores abysmally low on research with human embryonic stem cells (hESC), with 0 out of 20 points.¹⁰ Indeed, it has some of the most restrictive laws on the matter in Europe.¹¹

12) The Embryo Protection Act (*Embryonenschutzgesetz*), which came into force on 1 January 1991, is the key legislation regulating both research with human embryonic stem cells (hESC) and Assisted Reproductive Technology (ART) in Germany.¹² The Act prohibits the creation of a human embryo "for any purpose other than the bringing about of a pregnancy."¹³ Paragraph 1, entitled "Abuse of Reproductive Techniques", mandates sentencing up to three years and a fine for anyone who: 1) donates an unfertilized oocyte (egg); 2) fertilizes an oocyte for purposes other than achieving pregnancy of the woman from whom the oocyte originates; 3) transfers more than three embryos to a woman during the same In-Vitro Fertilization (IVF) cycle; 4) fertilizes more than three oocytes by gamete intrafallopian transfer within one cycle; 5) fertilizes more oocytes than those that will be transferred in an IVF cycle (prohibition of production of surplus embryos); 6) donates an embryo to another woman; 7) or attempts or carries out surrogacy (maternity for another woman). For (1) through (6), the mere

⁹ See *Germany, Research and Self Determination Index*, World Congress for Freedom of Scientific Research, <u>http://www.freedomofresearch.org/country/de/germany</u> (last visited Aug. 30, 2017).

¹⁰ Id.

¹¹ See *infra*, para. 12-13.

¹² Embryonenschutzgesetz vom 13. Dezember 1990 (BGBI. I S. 2746), das zuletzt durch Artikel 1 des Gesetzes vom 21. November 2011 (BGBI. I S. 2228) geändert worden ist [Act for the Protection of Embryos (The Embryo Protection Act), Federal Law Gazette I 2746 (Dec. 13, 1990), Article 1 amended in Federal Law Gazette I 2228 (Nov. 21, 2011). Available at: <u>https://www.gesetze-im-internet.de/eschg/BJNR027460990.html</u> (last visited Aug. 30, 2017). The human embryo is also protected under the German Constitution (*Grundgesetz*). The Constitution states that "human dignity is inviolable" and that "everyone has the right to life and inviolability of his person." (Art. 1.1). Nonetheless, it also states that freedom to pursue science and research is protected (Art. 5.3). Basic Law for the Federal Republic of Germany, as last amended Dec. 23, 2014, available in English at <u>https://www.btg-bestellservice.de/pdf/80201000.pdf</u> (last visited Aug. 30, 2017).

¹³ Embryonenschutzgesetz, ¶ 2.

attempt is punishable, too.¹⁴ However, the woman is not punishable in the case of (1), (2) and (6), while the surrogate mother is not punishable for (7), if she takes responsibility of the child in the long term.¹⁵

13) The same "three-year-plus-fine" punishment applies also to anyone who causes to develop, sell, acquire or use a human embryo produced extra-corporeally (e.g. *in vitro*), or removed from the womb before the end of its implantation in the uterus, or attempts to do so.¹⁶ In sum, the Act bans the creation and use of human embryos for anything but to achieve pregnancy of the woman from whom the oocyte came and bars any research on them.

14) It should be stressed that the definition of embryo by the Embryo Protection Act is not the scientific definition and it is much more restrictive than the practice of the majority of states where human embryo and ART research are carried out. The Act applies to fertilized eggs just 24 hours after fertilization.¹⁷ However, scientifically there is no embryo until 10-12 days after fertilization, not just 24 hours.¹⁸ Numerous states have acknowledged this scientific fact when regulating research on embryos.¹⁹ To date, Canada, the United States, Iceland, the United Kingdom, Spain, Sweden, Denmark, Netherlands, Slovenia, Switzerland,²⁰ China, India, Japan, South Korea, Singapore, Australia, and New Zealand allow research on zygotes, blastocysts and even embryos up to the 14th day after fertilization.²¹

15) The "14th day rule" was adopted about 30 years ago as an acceptable compromise between those who believe "human life" begins at fertilization, and those who believe the early stages of development do not yet constitute a "human life."²² Since then, it is widely considered to be an acceptable balance

¹⁴ Id., ¶ 1.4.

¹⁵ Id., ¶ 1.3.

¹⁶ Id., ¶ 2.

¹⁷ Id., \P 8.2. ("In the first twenty-four hours after the nuclear fusion, the fertilized human egg is considered viable, unless it is established before the end of this period that it cannot develop beyond the single stage.").

¹⁸ Haywood L. Brown, *Stages of Development of the Fetus*, Merk Manual, <u>https://www.merckmanuals.com/home/women-s-health-issues/normal-pregnancy/stages-of-development-of-the-fetus</u> (last visited Mar. 7 2017).

¹⁹ Insoo Hyun, Amy Wilkerson & Josephine Johnston, *Embryology Policy: Revisit the 14-day Rule*, NATURE, (May 4, 2016), <u>http://www.nature.com/news/embryology-policy-revisit-the-14-day-rule-1.19838</u> (last visited 7 March 2017) (explaining that these states have either codified the 14-day rule into law or have specified it in scientific guidelines).

²⁰ Marc Kaplan, *Call to Re-Examine "14 Day Rule" Limiting In-Vitro Human Embryo Research*, Case Western Reserve University of Medicine (May 4, 2016), <u>http://casemed.case.edu/cwrumed360/news-releases/release.cfm?news_id=302</u> (last visited Sept. 1, 2017) (stating that Switzerland restricts human-embryo research at seven days).

²¹ See id. (explaining that the "14-day rule" limits in vitro human-embryo research to the period before "the earliest point at which an embryo's biological individuation is assured).

²² Id.

between the moral imperatives of religious beliefs and the need to advance science.²³ Moreover, recent developments have raised the question of further extending the possibility of researching on embryos beyond 14 days. Until 2016, culturing human embryos in-vitro had never gone beyond nine-days.²⁴ In 2016, human embryos were sustained in-vitro for 12-13 days.²⁵

16) The Act covers both embryos and stem cells (a.k.a. totipotent cells) derived from embryos.²⁶ A stem cell is an undifferentiated cell of a multicellular organism that is capable of giving rise to indefinitely more cells of the same type, and from which certain other kinds of cells arise by differentiation.²⁷ Scientists primarily work with two kinds of stem cells: embryonic stem cells (i.e. stem cells produced from embryos) and non-embryonic "somatic" or "adult" stem cells.²⁸

17) "Embryonic stem cells," as their name suggests, derive from embryos. They are "formed during the blastocyst phase of embryological development."²⁹ It must be stressed: stem cells used for research do *not* come from eggs fertilized that have been transferred in a woman's body.³⁰ The vast majority of stem cells used in research come from embryos that were developed via IVF (surplus embryos or embryos that are not viable enough to lead to pregnancy), and then were donated to research with the informed consent of the donor(s).³¹

²³ John Harris, It's time to Extend the 14-day Limit for Embryo Research, The Guardian (May 6, 2016),

https://www.theguardian.com/commentisfree/2016/may/06/extend-14-day-limit-embryo-research (last visited Mar. 7, 2017).

²⁴ Id.

²⁵ Kaplan, *supra* note 20.

²⁶ Embryonenschutzgesetz, *supra* note 12. Under Paragraph 8.1, the embryo is defined as "the fertilized, developable human egg from the time of the nuclear fusion, as well as any totipotent cell taken from an embryo, which is able to divide and develop into an individual in the presence of the necessary additional prerequisites." Under Para 8.3 "germline cells in the sense of this law are all cells which lead in a cell line from the fertilized egg to the egg and sperm cells of the human being which originates from it, and the ovum from the introduction or penetration of the sperm cell up to the spermatozoa of the core fusion."

²⁷ Stem Cells Basics I, National Institute of Health (2016), <u>https://stemcells.nih.gov/info/basics/1.htm</u> (last visited Mar. 7, 2017).

²⁸ Id.

²⁹ Harris, *supra* note 23.

³⁰ Stem Cell Basics I, supra note 27.

³¹ Kerstin Bjuresten & Outi Hovatta, Donation of Embryos for Stem Cell Research — How Many Couples Consent?, 18 Hum. Reprod. 6, 1353-1355 (2003), https://academic.oup.com/humrep/article/18/6/1353/2913611/Donation-of-embryos-forstem-cell-research-how (last visited Mar. 7, 2017).

18) An "adult stem cell" is an "[u]ndifferentiated cell, found among differentiated cells in a tissue or organ. The adult stem cell can renew itself and can differentiate to yield some or all of the major specialized cell types of the tissue or organ."³² These type of stem cells can be found in many organs and tissues, including the brain, bone marrow, peripheral blood, blood vessels, skeletal muscle, skin, teeth, heart, gut, liver, ovarian epithelium, and testis.³³

19) However, the number of adult stem cells in each tissue is very small.³⁴ Besides, once removed from the body, their capacity to divide is limited, making the generation of large quantities of stem cells difficult.³⁵ For this reason, "scientists in many laboratories are trying to find better ways to grow large quantities of adult stem cells in cell culture and to manipulate them to generate specific cell types so they can be used to treat injury or disease."³⁶ Research on stem cell lines derived from human embryos is significantly more efficient and faster than the one on adult stem cells.³⁷ Research on human stem cells is believed to be the key to cure many diseases that cause suffering and eventually kill millions each year, such as Alzheimer's, Parkinson's diseases as well as diabetes, and heart disease.³⁸

20) In Germany, because of the Embryo Protection Act, the derivation of new hESC lines from supernumerary IVF embryos (i.e. embryos produced during IVF that were not implanted), and for somatic cell nuclear transfer (SCNT), is prohibited. The derivation of new hESC through Somatic Cell Nuclear Transfer (SCNT) using non-human animal eggs is prohibited, too.³⁹ The rationale for these

- ³³ Id.
- ³⁴ Id.
- ³⁵ Id.
- ³⁶ Id.

³² Id.

³⁷ Harris, *supra* note 23.

³⁸ Stem Cell Basics I, supra note 27.

³⁹ In genetics and developmental biology, Somatic Cell Nuclear Transfer (SCNT) is a laboratory technique for creating an ovum with a donor nucleus. It can be used in embryonic stem cell research, or in regenerative medicine where it is sometimes referred to as "therapeutic cloning." Whether the Embryo Protection Act also prohibits "therapeutic cloning" or whether there is a regulatory gap is subject of a controversial debate amongst legal experts. Heike Trappe, *Assisted Reproductive Technologies in Germany: A Review of the Current Situation, IN Childlessness in Europe: Contexts, Causes, and Consequences* 269-288 (Michaela Kryenfeld and Dirk Konietzka ed., Springer, 2007).

prohibitions is that the creation of embryonic stem cell lines requires the destruction of at least an embryo (but in practice more, as the creation of stem cell lines is still not efficient).⁴⁰

21) Since German scientists are very active on stem cell research but cannot produce stem cell lines from human embryos in Germany, they have to import them. That raises an unresolved logical and ethical dilemma, since the purpose of the prohibition to create human stem cell lines is to protect the sanctity of the life of the embryo. Seemingly, to the German legislator, life is less sacred when it has been created abroad.

22) In Germany, importing embryonic stem cells is regulated by the Stem Cell Act (*Stammzellgesetz*), of 28 June 2002.⁴¹ According to the Stem Cell Act, importing and utilizing cells stem cells is admissible but only if they have been "derived before 1 January 2002 in the country of origin in accordance with relevant national legislation there;" and the embryos from which they were derived "have been produced by medically-assisted in vitro fertilization in order to induce pregnancy."⁴² Moreover, they must "definitely no longer (be) used for this purpose."⁴³ Apart from these stipulations, the Act also lays down that "no compensation or other benefit in money's worth may have been granted or promised" for the donation of these embryos.⁴⁴ Research activities involving stem cells must serve "eminent research aims" and must "have been clarified as far as possible through in vitro models using animal cells or through animal experiments."⁴⁵ Lastly, there must be scientific reasons to believe that "the scientific knowledge to be obtained from the research project concerned cannot be expected to be gained by using cells other than embryonic stem cells."⁴⁶

⁴⁰ Thomas Douglas & Julian Savulescu, *Destroying Unwanted Embryos in Research. Talking Point in Morality and Human Embryo Research*, 10 EMBO Reports 4 (2009), <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2672894/</u> (last visited Mar. 7, 2017).

⁴¹ Stammzellgesetz vom 28. Juni 2002 (BGBl. I S. 2277), das zuletzt durch Artikel 50 des Gesetzes vom 29. März 2017 (BGBl. I S. 626) geändert worden ist [Stem Cell Law of 28 June 2002 (Federal Law Gazette I, p. 2277), amended by Article 50 of the Law of 29 March 2017 (Federal Law Gazette I, p. 626]. English text available at: <u>http://www.ieb-eib.org/en/pdf/stammzellgesetz-stzg-28122002.pdf</u> (last visited Aug. 30, 2017).

⁴² *Id.* at section 4.2

⁴³ Id.

⁴⁴ Id.

⁴⁵ Stammzellgesetz vom 28, section 5.2

⁴⁶ Id.

23) After long controversial discussions, the Parliament of the Federal Republic of Germany voted in favor of amending the German Stem Cell Act on 11 April 2008.⁴⁷ In the process, they agreed to postpone the cut-off date for importing embryonic stem cells from 1 January 2002 to 1 May 2007.⁴⁸

24) Still, because of this restrictive regulation, German researchers face significant problems. Any applications to import stem cell lines for research must be approved by the Central Ethics Commission for Stem Cell Research (*Zentrale Ethik-Kommission für Stammzellenforschung* — *ZES*), which comprises scientists, physicians and experts in ethics.⁴⁹ The German National Ethics Council (*Geschäftsselle des Nationalen Ethikrat*), set up in 2007, advises and issues opinions to the government and public alike on scientific and medical issues that concern society and human health.⁵⁰

25) Patenting research processes and research findings involving embryonic stem cells is also problematic. In 1999, Bonn-based Professor Oliver Brüstle was granted the patent for developing human embryos from neural stem cells. The environmental NGO Greenpeace brought an action against this patent maintaining that it contravened public order and common decency as it involved the destruction of the embryos required. On 5 December 2006, the Federal Patent Court declared the 1999 patent partially null and void on the grounds of the contravention of public order and with reference to the Embryo Protection Act and the Stem Cell Act.⁵¹

26) In the course of the subsequent appeal proceedings, the Federal Court of Justice (*Bundesgerichtshof*) referred the case to the Court of Justice of the European Union (CJEU) to clarify several fundamental questions.⁵² On 18 October 2011, the CJEU ruled that the use of human stem cells obtained from embryos remains "not patentable" in Germany.⁵³ However, the use of embryonic stem cells as such does not constitute a use of embryos, as stem cells do not possess the ability to initiate the process of

⁴⁷ German Parliament, German Stem Cell Act, BT-Drucksache 16/7981, (2008),

http://dip21.bundestag.de/dip21/btd/16/079/1607981.pdf (last visited Aug. 30, 2017).

⁴⁸ *Id.*, Art. 1.

⁴⁹ Central Ethics Committee for Stem Cell Research, Robert Koch Institut,

http://www.rki.de/EN/Content/Institute/Committees/StemCell/StemCell node en.html (last visited Aug. 30, 2017). ⁵⁰ German Ethics Council, <u>http://www.ethikrat.org/welcome?set_language=en</u> (last visited Aug. 30, 2017).

⁵¹ Greenpeace v. Oliver Brüstle, Bundespatentgericht [BPatG] [Federal Patent Court] Dec. 5, 2006, Deutsche Vereinigung für

gewerblichen Rechtsschutz und Urheberrecht [GRUR] 2007, 1049 (Ger.).

⁵² Case C-34/10, Oliver Brüstle v. Greenpeace e.V., 2011 E.C.R. I-9849.

⁵³ Id.

development into a human being.⁵⁴ Patents on the basis of embryonic stem cells are therefore entirely possible if the cell lines used for their production have been obtained without the destruction of an embryo. Hence, procedures that include the use of cell lines obtained from embryos that are no longer viable are also patentable.

27) The CJEU decision was implemented into German national law on 27 November 2012.⁵⁵ Brustle was initially granted the patent, but it was revoked by the European Patent Office on 11 April 2013 on the technicality that such methods of obtaining stem cells without harming or destroying the embryo were not yet public knowledge at the time when he applied for the patent.⁵⁶

Analysis: Research with human embryonic stem cells (hESC) under the Covenant.

28) It is difficult to reconcile Germany's complete ban on embryo research and the obstacles it puts on research with human embryonic stem cells (hESC) with the obligations it has under the Covenant. To wit, Article 15.1.b of the Covenant recites: "The States Parties to the present Covenant recognize the right of everyone ... to enjoy the benefits of scientific progress and its applications." According to the Venice Statement, a document adopted in 2009 by a group of experts convened under the aegis of UNESCO, States have a duty "to respect the freedoms indispensable for scientific research and creative activity, such as freedom of thought, to hold opinions without interference, and to seek, receive, and impart information and idea of all kind."⁵⁷

30) Under Article 15.1.c of the Covenant, "The States Parties to the present Covenant recognize the right of everyone ... [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

31) According to Article 15.2: "The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the

⁵⁴ Id.

⁵⁵ Oliver Brüstle v. Greenpeace e.V., Bundesgerichtshof [BGH] [Federal Court of Justice] Nov. 27, 2012, Docket No. X ZR 58/07.

 ⁵⁶ Stem Cell Network North Rhine Westphalia, *Stem Cell Research Dossier*, German Reference Centre for Ethics (DRZE), http://www.drze.de/in-focus/stem-cell-research/laws-and-regulations?set_language=en (last visited Sept. 3, 2017).
 ⁵⁷ UNESCO, *Venice Statement: The Right to Enjoy the Benefits of Scientific Progress and its Applications*, ¶ 14 (Jul. 16-17, 2009),

http://unesdoc.unesco.org/images/0018/001855/185558e.pdf. (last visited Aug. 30, 2017).

development and the diffusion of science and culture." This general obligation implicitly contains several more specific obligations: first, "conservation of science includes retaining scientific discoveries as well as the data behind them, which must be preserved in a form that allows replication of those discoveries;"⁵⁸ second, "development demands an explicit commitment to the development of science and technology for human benefit;"⁵⁹ and third, "diffusion encompasses the dissemination of scientific knowledge and application both within the scientific community and in society at large."⁶⁰

32) Article 15.3 provides that: "[t]he States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity." The principle that scientific research must be free of constraints is also enshrined in the 2000 Charter of Fundamental Rights of the European Union,⁶¹ of which Germany is a member State. Also, Article 15 of the Convention of Oviedo for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine provides that: "[s]cientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being."⁶²

33) As Farida Shaheed, the Special Rapporteur in the Field of Cultural Rights, remarked: "Freedom of scientific research means ensuring that the scientific enterprise remains free of political and other interference, while guaranteeing the highest standards of ethical safeguards by scientific professions."⁶³ Likewise, the Venice Statement emphasizes that freedom of inquiry is vital for advancing knowledge on a specific subject, procuring data and testing hypotheses for some practical purpose, as well as for

⁵⁸ Margaret W. Vitullo & Jessica Wyndham, American Ass'n for the Advancement of Sci., Sci. and Human Rights Coal., *Defining the Right to Enjoy the Benefits of Scientific Progress and its Application: American Scientist's Perspective* 5 (2013), http://www.aaas.org/sites/default/files/content_files/UNReportAAAS.pdf (last visited Aug. 30, 2017).

⁵⁹ *Id.* at 4.

⁶⁰ Id. at 5.

⁶¹ Charter of Fundamental Rights of the European Union at art. 13, 2000 O.J. art. 13 (C 364),

http://www.europarl.europa.eu/charter/pdf/text_en.pdf. (last visited Aug. 30, 2017).

⁶² Eur. Consult. Ass., Convention of Oviedo for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, ETS Doc. No. 164, (1997)

https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98. (last visited Aug. 30, 2017).

⁶³ Farida Shaheed (Special Rapporteur on Cultural Rights), The Right to Enjoy the Benefits of Scientific Progress and Its Applications, U.N. Doc. A/HRC/20/26 (May 14, 2012)

http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26 en.pdf. (last visited Aug. 30, 2017).

promoting further scientific and cultural activity.⁶⁴ In the preamble to its recommendation on the status of scientific researchers, UNESCO called for measures enabling scientists to work in a spirit of intellectual freedom to pursue, expound and defend the scientific truth as they see it, and to help define the aims and objectives of the programs they are engaged in and the methods adopted.

34) Finally, under Article 15.4: "The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields".

35) Germany has one of the most restrictive laws on these matters in Europe.⁶⁵ A majority of European States engaged in embryo and stem cell research have found a way to better balance the need to protect human life at its earliest stages with the right of everyone to benefit from scientific and technological progress and the right to health.⁶⁶ German's attitude toward research on hESC is not only harmful for Germans, but also for the whole world, as Germany is one of the main driver of world's research and development in biotechnology.

⁶⁴ UNESCO, Venice Statement: The Right to Enjoy the Benefits of Scientific Progress and its Applications, ¶ 8 (Jul. 16-7, 2009), http://unesdoc.unesco.org/images/0018/001855/185558e.pdf. (last visited Aug. 30, 2017)

⁶⁵ In Europe, only in Poland, Lithuania and Slovakia prohibit research with hESC is completely forbidden. Germany, Italy and Ireland allow it but only with imported hESC and under very strict circumstances. Jochen Taupitz, *Legal Aspects of Research with Human Embryonic Stem Cells*, 25 Eur. Rev. 121, 122 (2017).

⁶⁶ France, Spain, Portugal, the Netherlands, Denmark, Norway, Finland, Estonia, Slovenia, Hungary, Czech Republic and Greece allow research with supernumerary embryos and the derivation of hESC from supernumerary embryos. France modified its statute concerning stem cell research and now allows it under special circumstances. Loi 2013-715 tendant à modifier la loi 2011-814 du 7 juillet 2011 relative à la bioéthique en autorisant sous certaines conditions la recherche sur l'embryon et les cellules souches embryonnaires du 6 août 2013 [Law 2013-715 of August 6, 2013 to amend Law No. 2011-814 of 7 July 2011 on bioethics by authorizing under certain conditions research on the embryo and embryonic stem cells], Journal Officiel de la République Française [J.O.] [Official Gazette of France], Aug. 6, 2013. The regulations in the United Kingdom, Belgium and Sweden are even more liberal. They allow the production of embryos for research purposes. The United Kingdom and Belgium allow the derivation of stem cells from embryos created by nuclear transfer, which in fact means therapeutic cloning (Eur. Grp. on Ethics in Sci. and New Techs. Opinion No. 15/2000, at 11). Recently, a new discussion started in the UK as a scientist asked for permission to create a hybrid embryo. R. Trips-Hebert, *Hybrid-Embryonen – Herausforderung für den Gesetzgeber*? [Hybrid Embryos – A Challenge for Legislators?], 42 Zeitschrift für Rechtspolitik [Journal of Legal Policy], at 80 (2009). Austria does not restrict the importation of HESC or their utilization at all. *Id.*

ASSISTED REPRODUCTION TECHNOLOGIES (ART)

ART in Germany

36) Germany scores only 28 out of 56 points on Assisted Reproductive Technologies (ART) in the Research and Self Determination Index.⁶⁷ In Germany, ART is excessively regulated. Surrogacy is prohibited, and only heterosexual, married, couples can benefit from this technology.⁶⁸

37) In Vitro Fertilization (IVF) is a specific Assisted Reproductive Technology by which an egg is fertilized by sperm outside the body. The process involves monitoring and stimulating a woman's ovulation, removing one or more oocyte (ovum/ova - "egg/eggs") from the woman's ovaries, and then letting sperm fertilize them in a liquid in a vial (*in vitro* – "in glass") in a laboratory. The zygote (fertilized egg) is cultured for 2–6 days in a growth medium and is then implanted in the same, or another woman's uterus (in the case of surrogacy), with the intention of establishing a successful pregnancy.⁶⁹

38) Although IVF has been practiced in Germany since the early 1980s,⁷⁰ the country still lacks a comprehensive law that regulates all aspects of aspects of ART. Several laws and regulations have a bearing on it, the most important of which is the above-mentioned Embryo Protection Act.⁷¹ For the sake of protecting the embryo, the Act severely limits ART. The Act limits the number of blastocysts (pre-embryos) that can be produced each IVF cycle. Only three blastocysts can be transferred to the woman's uterus each In-Vitro Fertilization treatment.⁷² Since there is a significant chance none could

⁶⁷ See World Congress for Freedom of Scientific Research: Germany, *supra* note 9.
⁶⁸ Id.

⁶⁹ Mayo Foundation for Medical Education and Research, In vitro fertilization (IVF), <u>http://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/basics/definition/prc-20018905.</u> (last visited Aug. 30, 2017).

⁷⁰ The first "IVF baby" in Germany was born at the university hospital in Erlangen in spring of 1982. Berlin-Institut für Bevölkerung und Entwicklung [Berlin Institute for Population and Development], *Ungewollt kinderlos – Was kann die moderne Medizin gegen den Kindermangel in Deutschland tun?* [Involuntarily childless – What can be done by modern medicine against the shortage of children in Germany?], at 23 (2007).

⁷¹ Id.

⁷² See U. Riedel, Vorgeschichte und Stand der Gesetzgebung [Pre-history and state of legislation], IN Reproduktionsmedizin im internationalen Vergleich – Wissenschaftlicher Sachstand, medizinische Versorgung und gesetzlicher Regelungsbedarf

[[]Reproductive medicine in international comparison – Scientific state of affairs, medical provision, and necessity for legal regulation] 11 (K. Diedrich, R. Felberbaum, G. Griesinger, H. Hepp, H. Kreß, and U. Riedel ed., Frankfurt: Friedrich-Ebert-Stiftung, 2008). ("The core rule related to the realisation of these goals is the so-called 'rule of three': physicians are only allowed to fertilise the egg cells which will be transferred within a single treatment cycle, and the number of embryos which may be transferred in each cycle is limited to three").

lead to a successful pregnancy, this means women are forced to undergo several painful rounds of stimulation and implantation before they can successfully give birth.

39) Embryo cryopreservation is permissible, albeit only for reproductive processes (human pre-embryos and embryos cannot be used for medical research),⁷³ and only for the reproduction of the couple that underwent the treatment. Donation of surplus embryos, to infertile couples or to scientific research, is prohibited.⁷⁴

40) Oocyte cryopreservation, a process in which a woman's eggs (oocytes) are extracted, frozen and stored as a method to preserve reproductive potential in women of reproductive age who decide to pursue pregnancy later in their life, is permissible.⁷⁵ Yet, women cannot donate their eggs.⁷⁶ This denies women who cannot produce viable oocyte the possibility of getting pregnant. The reasoning for the controversial prohibition of egg donation is to avoid ambiguity about who the mother is, and to prevent a separation of the genetic and gestational components, which might result in identity problems for the child.

41) It should be note that, while women cannot donate their eggs, men can donate sperm (although their sperm can be used only as long as they are alive). The donation of sperm cells, including the use of sperm cells which do not come from the female patient's male partner (heterologous or third party donation, including a mixture of sperm cells from different donors), is allowed. The only requirement for using donated sperm is a written declaration of consent by the future parents and the sperm donor. However, sperm donors in Germany are not fully protected from subsequent legal claims demanding financial and other forms of support for any children who are conceived from his donation,⁷⁷ nor are given complete anonymity.⁷⁸

⁷³ Id.

⁷⁴ Id.

⁷⁵ Id.

⁷⁶ Id.

⁷⁷ H. M. Beier et al., *Medizinische und biologische Aspekte der Fertilität* [Medical and biological aspects of fertility], IN Zukunft Mit Kindern: Fertilität und Gesellschaftliche Entwicklung in Deutschland, Österreich und der Schweiz [Future with children: Fertility and social development in Germany, Austria, and Switzerland] 294, 365 (G. Stock, H. Bertram, A. Fürnkranz-Prskawetz, W. Holzgreve, M. Kohli, & U. M. Staudinger eds., Campus Verlag, 2012).

⁷⁸ Two laws are relevant in this context: the Transplantation Law of 2007 (Transplantationsgesetz in der Fassung der Bekanntmachung vom 4. September 2007 (BGBl. I S. 2206), das durch Artikel 2 des Gesetzes vom 18. Juli 2017 (BGBl. I

42) The differences in the regulation of egg cell and sperm donation has been justified by the fact that it is easier to collect male than female gametes.⁷⁹ From an international human rights perspective, it is relevant that ambiguity about the identity of the father of a child has long been tolerated, whereas uncertainty about the identity of a child's mother has not.

43) Surrogacy, a method whereby a woman agrees to carry a pregnancy for another person or persons who will become the newborn child's parent(s) after birth, is not allowed in Germany either.⁸⁰ Surrogacy agreements are not enforceable. Again, this denies women who are infertile or cannot carry to term a pregnancy for health reasons the possibility of having a biological offspring.

44) In Germany, Polar Body Biopsy (PBB), elective Single Embryo Transfer (eSET), and Preimplantation Genetic Diagnosis (PGD), techniques that can be used to detect certain genetic disorders and prevent them from being passed on to the child, are allowed but only within strict limits. The law regulating Preimplantation Genetic Diagnosis (PGD) went into effect on 21 November 2011, but the corresponding by-laws with important details (PIDV) did not become effective until February 2014.⁸¹ PGD can be done only in specially authorized centers, and only after the couple have filed an application which has been approved by an interdisciplinary ethics panel. To

S. 2757) geändert worden ist [Transplantation Act of 4 September 2007 (Federal Law Gazette I, p. 2206), as amended by Article 2 of the Act of 18 July 2017 (Federal Law Gazette I p. 2757)], available at <u>http://www.gesetze-im-</u>

internet.de/tpg/index.html (last visited Aug. 30, 2017) and the section 1600 of the German Civil Code, German Children's Rights Improvement Act (KindRVerbG), 2002, available at

http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl102s1239.pdf (last visited Aug. 30, 2017) ("The former law prescribes that all documents in relation to human tissue have to be stored for at least 30 years ... The second law stipulates that paternity cannot be contested by the male partner or the mother if they have agreed to artificial insemination by a third party donor, but only by the child after she or he reaches the age of majority"). T. Wischmann, *Einführung Reproduktionsmedizin: Medizinische Grundlagen – Psychosomatik – Psychosoziale Aspekte* [Introduction reproductive medicine: Medical foundation – psychosomatic – psychosocial aspects], 121 (Ernst Reinhardt, GmbH & Co KG 2012). This gives children conceived by third party sperm donation the option as adults to gain access to the data of

the former donor, and thus to acquire full knowledge of their ancestry.

⁷⁹ Christoph Revermann & Bärbel Hüsing, Fortpflanzungsmedizin – Rahmenbedingungen, wissenschaftlich-technische Fortschritte und Folgen [Reproductive Medicine – Conditions, Scientific Progress, and Consequences], Büros für Technikfolgenabschätzung beim Deutschen Bundestag [BT] [Bureau of Technology Assessment at the German Bundestag], Arbeitsbericht Nr. 139, at 200 (2010).

⁸⁰ Id. at 166.

⁸¹ Präimplantationsdiagnostikgesetz (PräimpG), BT-DRS. 17/5452,

^{17/6400,} http://dipbt.bundestag.de/dip21/btd/17/064/1706400.pdf (last visited Aug. 30, 2017).

qualify for a PGD procedure, the couple must be able to show that they carry a serious genetic disease, or that the woman is likely to die or miscarry if she becomes pregnant.⁸²

45) Furthermore, in Germany ART is accessible only to married, heterosexual couples.⁸³ According to the Guidelines of the Federal Medical Association, which are binding on all medical professionals in Germany, access to ART services is granted to married couples, but it is granted to cohabiting heterosexual couples only under exceptional circumstances.⁸⁴ Single women are excluded, as well as homosexual couples.⁸⁵ The reasoning for this restriction is that a child's welfare is believed to be best ensured within the legal bonds of matrimony. Some see in this restriction an example of the "power of the norm of heterosexual families with biological children."⁸⁶ Others claim it represents unconstitutional discrimination of same-sex couples and single women.⁸⁷ It is a clear violation of the principle of non-discrimination contained in the Covenant (Art. 2).

46) The question of how to pay for these treatments is one of equality of opportunity, which is relevant for a discussion of obligations under Article 10 of the Covenant. The reimbursement of the costs associated with ART varies between private and statutory health insurance. Overall, the tendency is to limit reimbursement or to deny it.⁸⁸ Since January 2004, the Health Care Modernization Act (*Gesetz zur Modernisierung der gesetzlichen Krankenversicherung - GKV*) applies.⁸⁹ Under the GKV, only 50 % of the treatment costs for a maximum of three treatment cycles is reimbursable.⁹⁰ For couples to qualify for coverage they must be married; additionally, women must be between 25 and 40 years of age and men

⁸⁶ L. Correll, Anrufungen Zur Mutterschaft l[Invocations to motherhood], Münster: Westfälisches Dampfboot, 36 (2010).
⁸⁷ Revermann, *supra* note 79; K.-H. Möller, Rechtliche Regelung der Reproduktionsmedizin in Deutschland [Legal regulation of reproductive medicine in Germany], *in* Reproduktionsmedizin [Reproductive medicine] 583 (K. Diedrich, M. Ludwig, & G. Griesinger, G. eds. 2013)

⁸² *Id.* at \P 3a(2).

⁸³ Richtlinie der bundesärztekammer zur durchführung der assistierten reproduktion [Guidelines on ART of the Federal Medical Association], <u>http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/AssRepro.pdf</u> (last visited Aug. 30, 2017).

⁸⁴ Id.

⁸⁵ Id.

⁸⁸ Revermann, *supra* note 79, at 209.

⁸⁹ Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GKV-Modernisierungsgesetz - GMG), <u>https://www.buzer.de/s1.htm?g=GMG&f=1</u> (last visited Aug. 30, 2017).

⁹⁰ A constitutional complaint about the reduction in reimbursement was rejected by the Federal Constitutional Court. Bundesverfassungsgericht (Federal Constitutional Court). (2009). Pressemitteilung [Press release] Nr.

^{24/2009.} http://www.bverfg.de/pressemitteilungen/bvg09-024.html. (last visited Aug. 30, 2017).

must be between 25 and 50 years of age.⁹¹ For the relatively small share of women and men with private health insurance, the situation is somewhat different. Generally, private insurance provides full coverage for three treatment cycles based on the costs-by-cause principle, which means that in a couple it is the insurance of the person who is affected by fertility disability that has to cover the full costs.⁹²

47) Since the implementation of the GKV, some statutory health insurance providers have individually increased coverage of fertility treatments for their customers.⁹³ A few selected federal states (e.g. Saxony, Saxony-Anhalt, Lower Saxony, Mecklenburg-Western Pomerania, and Thuringia) support state residents who seek fertility treatments by limiting their co-payment to 25%.⁹⁴ This means that a couple's statutory health insurance provider and their place of residence have become significant factors in the size of their ART co-payments. The reduction in reimbursement caused by the GKV has had severe consequences for the great majority of couples with fertility problems.⁹⁵ The number of fertility treatments fell sharply after the passage of the law, and is only slowly returning to previous levels.⁹⁶

Analysis: ART under the Covenant

48) Arguably, under the Covenant (Art. 12 and 15), everyone, without discrimination, has the right to benefit from Assisted Reproductive Technology, and scientist have the right to practice it and improve it through practice and research. ART designates medical techniques within the scientific field of "reproductive endocrinology,"⁹⁷ and, as such, falls under the definitions set forth in the Venice

⁹¹ Jasmin Passet-Wittig et al., The PinK study – Methodology of the baseline survey of a prospective cohort study of couples undergoing fertility treatment 6 (Wiesbaden: Federal Institute for Population Research 2014).

⁹² Revermann, *supra* note 79.

⁹³ Passet-Wittigs, supra note 91, at 7.

⁹⁴ Id.

⁹⁵ See O. Rauprich, Sollen Kinderwunschbehandlungen von den Krankenkassen finanziert werden? Ethische und rechtliche Aspekte [Shall ART treatments be publicly financed? Ethical and legal aspects], IN Umwege zum eigenen Kind: Ethische und rechtliche Herausforderungen an die Reproduktionsmedizin 30 Jahre nach Louise Brown [Detours to a child of one's own: Ethical and legal challenges of reproductive medicine 30 years after Louise Brown] 31, 32 (G. Bockenheimer-Lucius, P. Thorn, & C. Wendehorst ed., 2008) ("The costs associated with fertility treatments are considerable. In Germany, the cost of a standard IVF cycle including medication is about 3000 euros. An Intra-Cytoplasmatic Sperm Injection (ICSI), which is necessary in cases of male subfertility, costs about 3,600 Euro. The rate of success varies according to the age of the woman and other factors ... Based on this, a rough estimate of the cost of a live birth is about 15,000 euro.").

⁹⁶ IR – Deutsches IVF-Register [German IVF registry], Jahrbuch 2013 sowie zurücklie-gende Jahrgänge [Annual 2013 and earlier annuals] (2014).; Trappe, supra note 39, at Section 13.3.5.

⁹⁷ Reproductive Medicine Associates of Connecticut: What is a Reproductive Endocrinologist?, <u>http://www.rmact.com/our-fertility-doctors/what-is-a-reproductive-endocrinologist</u> (last visited Jan. 23, 2015).

Statement and in the Special Rapporteur on Cultural Rights' 2012 Report as "science" and a "benefit of scientific progress."⁹⁸

49) The World Health Organization ("WHO") recognizes infertility as a disability, because it intrinsically limits the major life activity of reproduction.⁹⁹ The WHO emphasized that environmental factors that aid disabled people can allow them to participate in society "on an equal basis with others."¹⁰⁰ IVF is a widely recognized and utilized treatment that effectively helps women overcome disabling fertility issues for over forty years.¹⁰¹

50) The Committee on Economic, Social, and Cultural Rights (CESCR), stated in General Comment 14 that the right to health entails "the right to control one's health and body, including sexual and reproductive freedom."¹⁰² Specifically, the CESCR elaborated that "women and men have the freedom to decide if and when to reproduce," and have a right of access to "appropriate health care-services that will, for example, enable women to go safely through pregnancy and childbirth."¹⁰³

51) In the *Artavia Murillo* case, the Inter-American Court of Human Rights determined that the right to enjoy the benefits of scientific progress (found in Article 14.1.b of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights ("Protocol of San Salvador")), includes accessing medical technology necessary to exercise the right to

⁹⁸ The U.N. Special Rapporteur on Cultural Rights stated in her 2012 Report on the Right to Enjoy the Benefits of Scientific Progress that the term "science" as used in the ICESCR is "knowledge that is testable and refutable, in all fields of inquiry . . . and encompassing all research." *Id.*, ¶ 24. She elaborated that "[t]he 'benefits' of science encompass not only scientific results and outcomes but also the scientific process, its methodologies and tools." *Id.* Consistent with the Special Rapporteur's definition, the Venice Statement says that the right to benefit from scientific research is "applicable to all fields of science and its applications." UNESCO, *Venice Statement: The Right to Enjoy the Benefits of Scientific Progress and its Applications*, §12(a) (Jul. 16-7, 2009).

⁹⁹ WHO Infertility Definitions and Terminology, <u>http://www.who.int/reproductivehealth/topics/infertility/definitions/en/</u> (last visited Jan. 23, 2016); Shorge Sato, *A Little Bit Disabled: Infertility and the Americans With Disabilities Act*, 5 N.Y.U.J. LEGIS. & PUB. POL'Y 223 (2002).

¹⁰⁰ WHO World Report on Disability at 4 (2011), <u>http://whqlibdoc.who.int/publications/2011/9789240685215_eng.pdf</u> (last visited Jan. 23, 2016).

¹⁰¹ Id.

 ¹⁰² United Nations Committee on Economic, Social, and Cultural Rights, General Comment No. 14, *Substantive Issues* Arising in the Implementation of the International Covenant on Economic, Social, and Cultural Rights: The Right to the Highest Attainable Standard of Health at ¶ 8, Doc. E/C. 12/2000/4 (Aug. 11, 2000).
 ¹⁰³ Id. at 20, ¶ 14, n. 12.

private life and reproductive freedom to found a family.¹⁰⁴ This requires access to the best healthcare including assisted reproductive techniques, and prohibits any arbitrary or disproportionate restrictions on accessing this technology.¹⁰⁵

52) In *Artavia Murillo*, the Inter-American Court of Human Rights determined that "reproductive autonomy and access to reproductive health services ... includes the right to have access to the medical technology necessary to exercise this right."¹⁰⁶

53) Since the Embryo Protection Act first went into effect, researchers in Germany have been calling for the passage of a comprehensive law to regulate all aspects of ART.¹⁰⁷ So far, these efforts have been unsuccessful,¹⁰⁸ likely because the proposal of new legislation would incite another round of public debate on the status of embryos and the beginning of human life.¹⁰⁹ On the one hand, the fact that assisted reproduction in Germany is only partially regulated implies that there are no clear instructions to providers on how to manage some important aspects of ART, such as the handling of "supernumerary" embryos. On the other hand, a large number of directives and laws that regulate certain aspects of reproductive medicine have been approved. For instance, the standards of quality and

¹⁰⁴ Artavia Murillo et al. (In vitro fertilization) v. Costa Rica, Preliminary Objections, Merits, Reparations and Costs, Judgment of November 28, 2012, I/A Court H.R., Series C No. 257 (2012), ¶ 146.

¹⁰⁵ Id., ¶¶ 287-284.

¹⁰⁶ Artavia Murillo, *supra* note 105, ¶ 146.

¹⁰⁷ See Taupitz, supra note 65; Diedrich, K., & Griesinger, G., Deutschland braucht ein Fortpflanzungsmedizingesetz [Germany needs a comprehensive law for all aspects of assisted human reproduction], Geburts- und Frauenheilkunde, at 66, 345-348 (2006); Riedel, U., Notwendigkeit eines Fortpflanzungsmedizingesetzes (FMG) aus rechtlicher Sicht [Necessity of a comprehensive law for all aspects of assisted reproduction (FMG) from a legal perspective] (2008), in K. Diedrich, R. Felberbaum, G. Griesinger, H. Hepp, H. Kreß, & U. Riedel (Eds.), Reproduktionsmedizin im internationalen Vergleich – Wissenschaftlicher Sachstand, medizinische Versorgung und gesetzlicher Regelungsbedarf [Reproductive medicine in international comparison – Scientific state of affairs, medical provision, and necessity for legal regulation], Frankfurt: Friedrich-Ebert-Stiftung, at 88-11 (2014); DIR- Deutsches IVF-Register (German IVF registry), Jahrbuch 2013 sowie zurückliegende Jahrgänge [Annual 2013 and earlier annuals], http://www.deutsches-ivf-register.de. (last visited 30 August 2017).

¹⁰⁸ Riedel, U., Vorgeschichte und Stand der Gesetzgebung [Pre-history and state of legislation] (2008), in K. Diedrich, R. Felberbaum, G. Griesinger, H. Hepp, H. Kreß, & U. Riedel (Eds.), Frankfurt: Friedrich-Ebert-Stiftung, Reproduktionsmedizin im internationalen Vergleich – Wissenschaftlicher Sachstand, me-dizinische Versorgung und gesetzlicher Regelungsbedarf [Reproductive medicine in international comparison – Scientific state of affairs, medical provision, and necessity for legal regulation], at 11-21 (2008).

¹⁰⁹ Taupitz, supra note 65; Spiewak, *Medizin – Die Ausweitung der Grauzone* [Medicine – The extension of the twilight zone], *Die Zeit* at 30 (Jul. 16, 2009).

safety for egg cells, sperm cells, oocytes, and embryos were established in the Tissue Act of 20 July 2007.¹¹⁰

54) For more than two decades, German physicians of reproductive medicine have been calling for a reasonable policy on egg donation to support the 3–4 % of women under age 40 who are unable to conceive for genetic or other reasons.¹¹¹ They have also argued that, because of legal restrictions, the types of treatment they can offer their patients are not keeping up with the most recent developments in medical science and technology. For example, physicians have asserted that the prohibition on embryo selection, and thus of the elective transfer of a single embryo, often results in unwanted multiple pregnancies.¹¹²

ABORTION AND CONTRACEPTION (A&C)

Abortion and Contraception in Germany

55) On Abortion and Contraception, Germany scores surprisingly low in the Research and Self Determination Index: only 53 out of 82 points.¹¹³

<u>Abortion</u>

56) "Abortion" means the termination of pregnancy by the removal or expulsion from the uterus of a fetus or embryo prior to viability. The German Criminal Code (paragraph 218) states that abortion is a

¹¹⁰ Heike Trappe, Assisted Reproductive Technologies in Germany: A Review of the Current Situation, ch. 13 at 271 (2015).

¹¹¹ H. Kentenich & G. Griesinger, Zum Verbot der Eizellspende in Deutschland: Medizinische, psychologische, juristische und ethische Aspekte [On the proscription of egg cell donation in Germany: Medical, psychological, legal, and ethical

aspects], JOURNAL FÜR REPRODUKTIONSMEDIZIN UND ENDOKRINOLOGIE, 10 at 273 (2013).

 ¹¹² Taupitz, supra note 65; Beier, H. M., van den Daele, W., Diedrich, K., Dudenhausen, J. W., Felberbaum, R., & Gigerenzer, G., et al., *Medizinische und biologische Aspekte der Fertilität* [Medical and biologial aspects of fertility] (2012), *in* G. Stock, H. Bertram, A. Fürnkranz-Prskawetz, W. Holzgreve, M. Kohli, & U. M. Staudinger, Frankfurt/New York: Campus, *Zukunft mit Kindern: Fertilität und gesellschaftliche Entwicklung in Deutschland, Österreich und der Schweiz* [Future with children: Fertility and social development in Germany, Austria, and Switzerland], at 294–391, 364 (2012).
 ¹¹³ Germany, World Congress for Freedom of Scientific Research, supra note 9.

crime.¹¹⁴ Those who attempt to abort a fetus face up to three years in prison or a fine.¹¹⁵ In severe cases, where the perpetrator acts without the consent of the pregnant woman or frivolously endangers her life or health, the sentence ranges from six months to five years in prison.¹¹⁶ While the attempt to abort a fetus by a third party is unlawful, a woman who unsuccessfully *attempts* to end her pregnancy will not be prosecuted.¹¹⁷ However, if the pregnant woman does abort the fetus, she faces up to one year in prison or a fine.¹¹⁸

57) While abortion is a crime, under the Criminal Code, termination of pregnancy (*schwangerschaftsabbruch*) or an abortion (*abtreibung*) is not a prosecutable crime if performed: 1) "on demand", with pretermination counselling; or without counselling but the circumstances must be verified: 2) on "medical grounds" (*medizinische indication*); or 3) "criminal grounds" (*kriminologische indication*). ¹¹⁹

¹¹⁴ "(1) Whosoever terminates a pregnancy shall be liable to imprisonment not exceeding three years or a fine. Acts the effects of which occur before the conclusion of the nidation shall not be deemed to be an abortion within the meaning of this law; (2) In especially serious cases the penalty shall be imprisonment from six months to five years. An especially serious case typically occurs if the offender: 1. acts against the will of the pregnant woman; or 2. through gross negligence causes a risk of death or serious injury to the pregnant woman; (3) If the act is committed by the pregnant woman the penalty shall be imprisonment not exceeding one year or a fine; (4) The attempt shall be punishable. The pregnant woman shall not be liable for attempt." Translation of the German Criminal Code in the version promulgated on 13 November 1998, Federal Law Gazette [Bundesgesetzblatt] I p. 3322, last amended by Article 1 of the Law of 24 September 2013, Federal Law Gazette I at 3671 and with the text of Article 6(18) of the Law of 10 October 2013, Federal Law Gazette I at 3799, https://www.gesetze-im-internet.de/englisch_stgb/englisch_stgb.html.

¹¹⁵ Id., ¶ 218.1.

¹¹⁶ Id., ¶ 218.2.

¹¹⁷ Id., ¶ 218.4.

¹¹⁸ Id., ¶ 218.3.

¹¹⁹ "Section 218a, Exception to liability for abortion. (1) The offence under section 218 shall not be deemed fulfilled if: 1. the pregnant woman requests the termination of the pregnancy and demonstrates to the physician by certificate pursuant to section 219(2) 2^{nd} sentence that she obtained counselling at least three days before the operation; 2. the termination of the pregnancy is performed by a physician; and 3. not more than twelve weeks have elapsed since conception. (2) The termination of pregnancy performed by a physician with the consent of the pregnant woman shall not be unlawful if, considering the present and future living conditions of the pregnant woman, the termination of the pregnant woman and if the danger to the life or the danger of grave injury to the physical or mental health of the pregnant woman and if the danger cannot reasonably be averted in another way from her point of view. (3) The conditions of subsection (2) above shall also be deemed fulfilled with regard to a termination of pregnancy performed by a physician woman unlawful act has been committed against the pregnant woman under sections 176 to 179, there is strong reason to support the assumption that the pregnancy was caused by the act, and not more than twelve weeks have elapsed since conception. (4) The pregnant woman shall not be liable under section 218 if the termination of pregnancy was performed by a physician after counselling (section 219) and not more than twenty-two weeks have elapsed since conception. "*Id*, ¶ 218.a.

58) On demand: A pregnant woman wanting to abort for any reason other than medical or criminal must have counselling for the unwanted pregnancy (*schwangerschaftskonfliktsberatung*). The consultation prior to an abortion is to be performed by a state-recognized social service agency that advises women on pregnancies (*Schwangerschaftskonfliktstelle*). The agency issues a certificate to the doctor who is to perform the abortion and it serves to exempt the doctor and woman from being prosecuted. The doctor who performs the abortion is not eligible to advise his/her patient. The abortion must take place within 12 weeks of conception, which is calculated as 14 weeks from the first day of the woman's last period. Written confirmation in the form of a certificate (*heratungsschein*) from a recognized center is required to prove that counselling has been undertaken. There must be at least three days between the counselling and the operation. Mandatory counseling for unwanted pregnancy can make women feel guilty, ashamed or very uncomfortable, which is at odds with the obligation of all states party to the Covenant to encourage reproductive autonomy and freedom.

59) On medical grounds (*medizinische indikation*): Abortion may be carried out after the 12th week of pregnancy only where the life of the pregnant woman is in danger, or her physical or mental health is threatened by the pregnancy (it must be proved that the danger to the woman can only be averted by a termination), or where there is known or anticipated damage to the unborn child due to chromosomal disorders or similar issues.

60) On criminal grounds (*kriminologische indikation*): Where a woman is pregnant as a result of rape, termination must take place within 12 weeks of conception. Abortion of a pregnancy due to a rape or for medical reasons after the first trimester is a crime.¹²⁰ In case of pregnancy due to rape, there is no obligation to attend counselling. However, an independent doctor must verify that there are medical or criminal grounds for an abortion and provide a medical certificate (*ärztliches Attest*) stating this. This independent doctor may not be the one to perform the abortion.

61) Abortion on criminal or medical grounds is paid by health insurance (*Krankenkasse*) and the state (*Bundesland*). In all other cases, the woman must pay for the operation. These costs include the actual abortion and any essential medical costs where there is follow-up treatment. All other expenses, for example the examination to establish pregnancy and any complications as a result of the abortion, must

¹²⁰ Id.

be covered by private medical insurance (*Krankenversicherung*). In cases where a woman has no or limited income or does not have statutory medical insurance, the state might cover the costs.

62) Paragraph 218 of the German Criminal Code is outdated; it has been in place since 1871.¹²¹ Complete decriminalization of abortion is necessary to ensure that Germany complies with its international legal obligations.¹²² Although the Criminal Code provides for five main conditions and exceptions whereby the woman and doctor will not be prosecuted, abortion is still a crime in Germany. This criminalization constitutes an unreasonable limitation of rights under the Covenant. There are many reasons women make the difficult decision to have an abortion that go beyond those provided under the exceptions in the German Criminal Code. Particularly for adolescent girls, it can be dangerous to carry a pregnancy to full term. In fact, the risk of death from abortion through the middle of the second trimester is lower than the risk of death in childbirth.¹²³ Additionally, women may not be financially stable enough to feed and take care of a baby, or it may be discovered that the fetus has crippling developmental abnormalities. Whatever the reason, the woman should be in charge of her decision without the interference of the government. As the German Criminal Code stands, for instance, those who truly had a natural miscarriage should not live in fear that they will be accused of intentionally ending the pregnancy and be prosecuted.

Contraception

63) Germany fares better on contraception, but could make further progress towards ensuring greater reproductive autonomy of women.

¹²¹ Paragraph 218 of the German Criminal Code has undergone several amendments since. After German unification it was necessary to align the West German law with the East German law. East Germany did not restrict or criminalize abortion during the first trimester. In 1992, the German Bundestag voted to amend paragraph 218 to adopt the former East German law, the so-called *Fristenregelung*, but included a compulsory consultation prior to the procedure. After an action introduced by several deputies of the CDU/CSU and the Bavarian state government, the law was struck down as unconstitutional by the Federal Constitutional Court in 1993. The law was reworked in 1994 and 1995, with the result that today abortion remains generally unlawful but not punishable under certain circumstances.

¹²² It should be noted that no international legal instrument prohibits abortion, and in at least one case, the denial of access to a legal abortion was held to be a human rights violation. *See* U.N. HRC, KL v. Peru, Comm. No. 1153/2003 ¶ 2.1, U.N. Doc. CCPR/C/85/D/1153/2003 (Oct. 24, 2005).

¹²³ Rachel N. Pine, *Achieving Public Health Objectives through Family Planning Services*, 1 Reproductive Health Matters 2 (November 1993) at 79, available at <u>http://www.rhm-elsevier.com/article/0968-8080(93)90010-Q/abstract</u> (last visited Jan. 26, 2017).

64) All usual methods of contraception (*Verhütungsmittel*) are easily available in Germany. One can buy condoms at any pharmacy. However, hormonal contraceptives (the birth control pill, implants, injections), IUDs (intra-uterine devices, such as the spiral), and diaphragms are available only if prescribed by a gynecologist.

65) Doctors prescribing birth control pill to girls under the age of fourteen require parental consent. Doctors may determine whether young women between fourteen and sixteen years old are mature enough and do not require parental consent for the prescription of birth control. Young women sixteen or older do not require parental consent for any form of birth control.

66) Until 2015, emergency contraception, drugs that can prevent pregnancy up to five days after intercourse, commonly known as "morning after pill" (*Pille danach*), was available, but only with prescription. Since March 2015, following a January 2015 EU Commission decision, Levonorgestrel and Ulipristal pills can be bought without prescription (over-the-counter) and women older than fourteen years do not need parental consent.¹²⁴ Mifepristone, also known as RU-486, an oral medication typically used to bring about an abortion and is more than 95% effective during the first 50 days of pregnancy, is also only available through prescription.

67) Germany could do much better to ensure accessibility to contraception. Pharmacies/pharmaceutical companies are neither allowed to advertise for the pill nor sell it via mail order or the internet.¹²⁵ Health insurance typically covers birth control if a medical prescription is required and the woman is under twenty years of age. However, once a woman is twenty, her health insurance does not cover any form of birth control unless it is considered medically necessary. Free access to contraception is a fundamental aspect of women's autonomy. The fact that contraception is not covered by health insurance for women older than twenty, puts women who cannot afford paying for their own contraception at risk of unwanted pregnancy. This means that in Berlin, for example, women have to pay €50-266 per year for the pill, depending on the brand and package size; €180-195 plus extra insertion fees for a hormonal

¹²⁴ Bundesrat stimmt rezeptfreier "Pille danach" zu, Suddeutsche Zeitung (Mar. 6, 2015),

http://www.sueddeutsche.de/gesundheit/verhuetung-bundesrat-stimmt-rezeptfreier-pille-danach-zu-1.2381202. (last visited Aug. 26, 2017).

¹²⁵ Bundestag gibt "Pille danach" frei, Apotheke Adhoc (Feb. 27, 2015),

http://www.apotheke-adhoc.de/nachrichten/politik/nachricht-detail-politik/bundestag-gibt-pille-danach-frei-apothekeotc-levonorgestrel-verhuetung-ulipristal/. (last visited Aug. 26, 2017).

implant, which lasts for three years, or up to €400 for an IUD, which lasts five to ten years and is up to twenty times more effective than the pill or condoms.¹²⁶ Emergency contraception, aka the "morning after pill," costs up to €35 for one dose.¹²⁷

Analysis: Abortion and Contraception under the Covenant

68) The right to benefit from scientific progress includes the right to benefit from scientific procedures and methods that help improve health and safety, including controlled, medical abortion procedures. Access to legal and safe abortion procedures falls within the rights Germany has undertaken under the Covenant of Economic, Social, and Cultural Rights. Article 10 of the Covenant provides: "The widest possible protection and assistance should be accorded to the family ... particularly for its establishment". The Covenant demands that States respect the decision to become or not become a parent — including under what conditions conception should occur. As this honorable Committee remarked in General Comment 14, on Article 12 of the Covenant, "reproductive health means that women and men have the freedom to decide if and when to reproduce."¹²⁸ The right to health entails "the right to control one's health and body, including sexual and reproductive freedom."¹²⁹ Specifically, "women and men have the freedom to decide if and when to reproduce," and have a right of access to "appropriate health-care services that will, for example, enable women to go safely through pregnancy and childbirth."¹³⁰

69) The "right to reproductive autonomy" is well-established in international human rights law. According to the Programme of Action of the International Conference on Population and Development, held in Cairo in 1994, "[r]eproductive rights embrace certain human rights that are already recognized in national laws, international human rights documents, and other relevant UN consensus

¹²⁶ Mary Katharine Tramontana, The cost of sex, Exberliner (May 2, 2016),

http://www.exberliner.com/features/lifestyle/the-cost-of-sex/ (last visited Aug. 26, 2017).

¹²⁷ Id.

¹²⁸ U.N. Committee on Economic, Social, and Cultural Rights, General Comment No. 14, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social, and Cultural Rights: The Right to the Highest Attainable Standard of Health*, ¶ 14, n. 12, U.N. Doc. E/C. 12/2000/4 (Aug. 11, 2000).

¹²⁹ *Id.* at ¶ 8.

¹³⁰ Id. at ¶ 14, n. 12.

documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children"¹³¹

70) Likewise, Article 16.1.e of the Convention on the Elimination of Discrimination against Women guarantees men and women equal rights to "decide freely and responsibly on the number and spacing of their children..."132 In its General Recommendation No. 24 (Women and Health), the CEDAW Committee stressed the importance of the right to reproductive autonomy, stating that this right is violated when the means by which a woman can exercise the right to control her fertility are restricted.¹³³

71) In Costa and Pavan v. Italy, as well as in Evans v. UK, ¹³⁴ Dickson v. UK, ¹³⁵ and S.H. and Others v. Austria, ¹³⁶ the European Court of Human Rights found that the decision to become or not become a parent is an

¹³¹ Programme of Action of the International Conference on Population and Development, Cairo, 1994, ¶ 7.3, U.N. A/CONF.171/13/Rev.1 (1995),

http://www.unfpa.org/sites/default/files/pub-pdf/programme of action Web%20ENGLISH.pdf. (last visited 27 February 2017).

¹³² "States Parties shall . . . ensure, on a basis of equality of men and women . . . (e) The same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights." U.N. General Assembly, Convention on the Elimination of All Forms of Discrimination Against Women art. 16.1.e, Dec. 18 1979, U.N.T.S. 1249,

http://www.refworld.org/docid/3ae6b3970.html. (last visited 15 March 2017).

¹³³ U.N. Committee on the Elimination of Discrimination Against Women (CEDAW), CEDAW General Recommendation No. 24: Article 12 of the Convention (Women and Health), ¶ 21 and 31(b), A/54/38/Rev. 1 (1999), http://www.refworld.org/docid/453882a73.html. (last visited 15 March 2017).

¹³⁴ See ECHR Case of Evans v. United Kingdom, (No. 6339/05), Judgement of 4 October 2007, ¶ 7172, where the ECHR indicated that "private life [...] incorporates the right to respect for both the decisions to become and not to become a parent" and, regarding the regulation of the practice of IVF, clarified that "the right to respect for the decision to become a parent in the genetic sense, also falls within the scope of Article 8."

http://hudoc.echr.coe.int/webservices/content/pdf/001-72684?TID=ihgdqbxnfi. (last visited 14 March 2017).

¹³⁵ See ECHR Case of Dickson v. United Kingdom (No. 44362/04), Judgement of 12 December 2007, ¶ 66 (the Court indicated, with regard to the technique of assisted reproduction that "Article 8 is applicable to the applicants' complaints in that the refusal of artificial insemination facilities concerned their private and family lives which notions incorporate the right to respect for their decision to become genetic parents."), http://hudoc.echr.coe.int/webservices/content/pdf/003-2204926-2350295?TID=ihgdgbxnfi. (last visited 14 March 2017).

¹³⁶ See ECHR Case of S.H. and others v. Austria (No. 57813/00), Judgement of 3 November 2011, ¶ 82 (the Court referred explicitly to the right of access to assisted reproduction techniques, such as IVF, indicating that "the right of a couple to conceive a child and to make use of medically assisted procreation for that purpose is also protected by Article 8, as such a choice is an expression of private and family life."), http://www.ieb-eib.org/en/pdf/cedh-shothers-c-austria-20100401.pdf (last visited 14 March 2017); see also ECHR, Case of P. and S. v. Poland (No. 57375/08), Judgment of 30 October 2012, ¶ 96 (the ECHR indicated that, "[w]hile the Court has held that Article 8 cannot be interpreted as conferring a right to abortion, it has found that the prohibition of abortion when sought for reasons of health and/or well-being falls within the scope of the right to respect for one's private life and accordingly of Article 8."),

http://www.grocjusz.edu.pl/Materials/ archiwum/archiwum2012/js 16.11.2012.pdf. (last visited 14 March 2017).

"expression of private and family life," and is therefore protected under Article 8 of the European Convention of Human Rights, which is similar to Article 10 of the Covenant.¹³⁷

72) Finally, in *Artavia Murillo*, the Inter-American Court of Human Rights held that the right "to decide freely and responsibly on the number and spacing of their children is violated when the means by which a woman can exercise the right to control her fertility are restricted. Thus, the protection of private life includes respect for the decisions both to become a mother or a father, and a couple's decision to become genetic parents."¹³⁸

RECOMMENDATIONS

73) We recommend this honorable committee to include at least one of the following questions in the List of Issue it will prepare for Germany.

- i. Please, explain how the *Embryonenschutzgesetz* of 1991 and the *Stammzellgesetz* of 2002 can be reconciled with the duty Germany has under Article 15.1.b of the Covenant to ensure everyone benefits from progress in science and technology.
- ii. Please, explain how the *Embryonenschutzgesetz* of 1991 and the *Stammzellgesetz* of 2002 can be reconciled with the duty Germany has under Article 15.2 of the Covenant to take steps to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
- iii. Please, explain how the *Embryonenschutzgesetz* of 1991 and the *Stammzellgesetz* of 2002 can be reconciled with the duty Germany has under Article 15.3 to respect the freedom indispensable for scientific research and creative activity.
- iv. Please, explain how the *Embryonenschutzgesetz* of 1991 and the *Stammzellgesetz* of 2002 can be reconciled with the duty Germany has under Article 10 to guarantee everyone's right to health.

¹³⁷ Costa and Pavan v. Italy (No. 54270/10), Judgement of 28 August 2012, art. 8, ¶ 56-57 of the European Convention recites: "1. Everyone has the right to respect for his private and family life, his home and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others." European Convention for the Protection of Human Rights and Fundamental Freedoms, 213 U.N.T.S. 222, *entered into force* Sept. 3, 1953, *as amended by* Protocols Nos 3, 5, 8, and 11 *which entered into force* on 21 September 1970, 20 December 1971, 1 January 1990, and 1 November 1998 *respectively*.

¹³⁸ Artavia Murillo, supra note 106, ¶146.

- v. Please, explain the rationale for prohibiting research on stem cell lines derived from human embryos that have been created in Germany, while the same is allowed for lines that have been created before 1 May 2007, and imported lines.
- vi. Please, explain how the prohibition of egg donation can be reconciled with the duty not to discriminate and with the duty to ensure the right to health of infertile women.
- vii. Please, explain how the prohibition of embryo selection, and of the elective transfer of a single embryo, often resulting in unwanted multiple pregnancies, can be reconciled with the right of women to health and to reproductive autonomy.
- viii. Please, explain how denying access to Artificial Reproductive Technology to homosexual couples, as well as single women, and restricting it to exceptional circumstances for unmarried couples, is compatible with the duty to ensure everyone's right to health, without discrimination.
- ix. Please, report on what steps has Germany taken, or intends to take, to ensure respect of the "right to reproductive autonomy".
- x. Please, report on what steps has Germany taken, or intends to take, to decriminalize abortion.
- xi. Please, report on what steps has Germany taken, or intends to take, to make contraception more available and affordable.