

**NGO Parallel Report on the
Italian Republic's 6th 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 66th Pre-Sessional Working Group (9–13 March 2020)*

Submitted by:

*International Human Rights Center
Loyola Law School, Los Angeles*

919 Albany Street
90015, Los Angeles, CA, USA

Contact: Prof. Cesare Romano
cesare.romano@lls.edu

*Associazione Luca Coscioni
per la libertà di ricerca scientifica*

Via di S. Basilio, 64
00187 Roma, Italy

Contact: Filomena Gallo
segretariocoscioni@gmail.com

Science for Democracy

Rue Ducale 41
B-1000 Brussels, Belgium

Contact: Marco Perduca
info@sciencefordemocracy.org

PURPOSE OF THE REPORT

1) The purpose of this Parallel Report is to assist the Committee on Economic, Social and Cultural Rights in its review of the Italian Republic's upcoming Sixth Periodic Report on the implementation of the International Covenant on Economic, Social and Cultural Rights (ICESCR or "the Covenant"). Italy ratified the International Covenant on Economic, Social and Cultural Rights on 15 September 1978.¹ Its first periodic review was completed in 1982. It is currently undergoing its 6th periodic review. The 66th Pre-Sessional Working Group will meet from 9 March 2020 to 13 March 2020.

2) This Report focuses on Italy's Law 40/2004, entitled Rules on Medically Assisted Procreation (*Norme in materia di procreazione medicalmente assistita*).² Although Italy's 6th periodic report has not yet been submitted, we anticipate it will not address, or not sufficiently address, the question of the compatibility of Law 40/2004 with the Covenant. Indeed, Italy's previous reports failed to make any mention of Law 40/2004 and its impact on Italy's capacity to discharge its obligations under the ICESCR. Moreover, the Honorable Committee addressed the question of the incompatibility of Law 40/2004 with the ICESCR recently in the context of an individual communication (S.C. and G.P. v. Italy, CESCR Comm. No. 22/2017).³

ABOUT THE AUTHORS OF THIS REPORT AND SOURCES

3) This report was prepared by Adam Peterson, J.D. Candidate 2020, and Sheyda Semnani, J.D. Candidate 2020, of the International Human Rights Center of Loyola Law School, Los Angeles, under the supervision of Professors Cesare Romano, Rajika Shah, and Hannah Robinson, in cooperation with the Luca Coscioni Association for the Freedom of Scientific Research.

4) The International Human Rights Center 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.⁴ Loyola Law School, Los Angeles is the school of law of Loyola Marymount University, a Jesuit university.

5) 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

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 ICESCR].

² Law No. 40 of 19 February 2004, published in Official Gazette No 45, February 24, 2004, <http://www.camera.it/parlam/leggi/04040l.htm> (site last visited 4 April 2019) [hereinafter Law 40/2004, or "the Law"]. A rough translation in English can be found in the website of the European Institute of Bioethics, at <http://www.ieb-cib.org/en/pdf/loi-pma-italie-english.pdf> (site last visited 19 April 2019).

³ Committee on Economic, Social and Cultural Rights, *SC and GP v. Italy*, Comm. No. 22/2017 (7 March 2019).

⁴ See *International Human Rights Clinic*, Loyola Law School, Los Angeles, <https://www.lls.edu/academics/experientiallearning/clinics/internationalhumanrightsclic/> (last visited March 1, 2019).

campaign to promote freedom of scientific research on embryonic stem cells.⁵ Since its foundation, the Association has been active on a range of issues, including the rights of persons afflicted with illness and disabilities, reproductive health, and freedom of scientific research.

6) Filomena Gallo is the National Secretary of the Luca Coscioni Association. She is an attorney and former professor of Law, Ethics and Biotechnology in Human Life Sciences at the University of Teramo, in Italy. Over the years, with the support of the Luca Coscioni Association and other Italian patients' associations, Gallo has led a pool of specialized lawyers to represent successfully plaintiffs in 27 of the 38 decisions pronounced by national courts in the field of ART. Also, three of the five decisions pronounced by the Constitutional Court to date, finding several of the prohibitions imposed by Law 40/2004 unconstitutional, concerned cases in which Filomena Gallo was involved as legal representative of one or both plaintiffs.

BACKGROUND

7) The Italian Republic ("Italy") is a country in Western Europe, with a population of about 62 million.⁶ About 80% of the population is Christian, an overwhelming majority of which is Roman Catholic.⁷ Though Catholicism has not been the official State religion in Italy since 1984,⁸ it still wields considerable influence in Italian politics.⁹

8) Prior to 2004, Italy was one of the few countries in Europe that did not regulate various human fertilization procedures.¹⁰ On 19 February 2004, the Italian Parliament adopted Law 40/2004, a statute drafted and pushed through by the most conservative members of Italy's political spectrum, to regulate Artificial Reproductive Technologies (a.k.a. Assisted Reproductive Technologies or "ART"). It entered into force on 10 March 2004.

9) In its original version, Law 40/2004 allowed resort to ART only to adult couples composed of two living persons, of different gender, married or cohabiting, potentially fertile, when all other means to cure infertility had been exhausted. Because Law 40/2004 limited access to ART to infertile couples meeting these requirements, *fertile* couples who were carriers of one or more genetic disorders could not resort to Preimplantation Genetic Diagnosis (PGD), a technique that can be used prior to implantation to check whether the embryos produced by couples with high genetic risk present genetic defects.¹¹ In addition, Law 40/2004 restricted the number of

⁵ See Luca Coscioni Association, <http://www.associazionelucacoscioni.it> (last visited Jan. 14, 2017).

⁶ CIA World Factbook, Italy, <https://www.cia.gov/library/publications/the-world-factbook/geos/it.html>.

⁷ Id.

⁸ Italy Profile – Timeline, BBC News (7 Feb. 2019), <https://www.bbc.com/news/world-europe-17435616>.

⁹ See Mary Rogers Bundren, "The Influence of Catholicism, Islam and Judaism on the Assisted Reproductive Technologies ("ART") Bioethical and Legal Debate: A Comparative Survey of ART in Italy, Egypt and Israel," 84 U. Det. Mercy L. Rev. 715, 731 (Summer 2007) [hereinafter Bundren, A Comparative Survey].

¹⁰ Andrea Boggio, "Italy Enacts New Law on Medically Assisted Reproduction," 20 Hum. Reprod. 5, 1153, 1153 (March 2005), <https://academic.oup.com/humrep/article/20/5/1153/2356855> (last visited April 24, 2019).

¹¹ Law 40/2004, Art. 13.3.b. See also John A. Robertson, "Protecting Embryos and Burdening Women: Assisted Reproduction in Italy," 19 Hum. Reprod. 8, 1693, 1695 (Aug. 2004), <https://academic.oup.com/humrep/article/19/8/1693/2356367/> Protecting-embryos-and-burdening-women-assisted, (last visited April 24, 2019) [hereinafter Robertson, Protecting Embryos].

gametes that could be fertilized for reproductive purpose to three.¹² It prohibited cryopreservation of embryos,¹³ and it required the implantation in utero of all fertilized embryos in one single act.¹⁴ Finally, it banned the use of donor gametes, thus preventing infertile couples from having children.¹⁵

10) As we will explain, over time, many of these restrictions have been declared unconstitutional and in violation of international human rights standards, thanks to litigation in national and international fora, most of which brought by the organizations presenting this Report. However, several restrictions that cannot be reconciled with Italy's obligation under the ICESCR and other human rights treaties remain. To wit, first, Law 40/2004 still bars access to ART treatments to homosexual couples.¹⁶ In June 2019, the Constitutional Court upheld the exclusion of homosexual couples from access to ART.¹⁷ Moreover, it denies singles access to ART, and bans maternal surrogacy.¹⁸ Second, Law 40/2004 is silent as to whether consent to have embryos implanted in utero can be withdrawn after fertilization.¹⁹ Third, it prohibits scientific research on embryos, unless carried out for the health of the embryo itself and where no other alternative exists, it prohibits the destruction of embryos, even when they are destroyed during scientific research and it prohibits the creation of embryos ad hoc for research.

11) Law 40/2004's overly restrictive provisions have undesirable consequences that go against the rationale of Law 40/2004 itself. For example, while ART is meant to increase pregnancies and protect the health of women, studies comparing data from 2003, before Law 40/2004 was enacted, and 2005, after the law was enacted, showed that pregnancy rates dropped in women using ART.²⁰ In addition, by requiring all fertilized embryos to be implanted, the law increased the risks of multiple simultaneous pregnancies, which poses greater health risks to women than single pregnancies.²¹ This was confirmed by the 2011 annual report prepared by the National Registry on ART and submitted by the Minister of Health to Parliament.²² Despite the report, the Italian Parliament has never shown intention to amend the Law.

12) Law 40/2004 forced, and still forces, couples to seek medical care out of the country. Immediately after the enactment of Law 40/2004, the number of Italian couples that went abroad for treatment increased by nearly

¹² Law 40/2004, Art. 14.2.

¹³ Id., Arts. 14.1, 14.2.

¹⁴ Id., Arts. 14.1, 14.2, 14.3.

¹⁵ Id., Art. 4.3. Gametes are the cells used during sexual reproduction to produce a new individual organism; in other words, the egg or the sperm.

¹⁶ Id., Arts. 4.1, 5.

¹⁷ Constitutional Court of Italy, Press Release (18 June 2019), available at https://www.cortecostituzionale.it/documenti/comunicatistampa/CC_CS_20190618200704.pdf.

¹⁸ Law 40/2004, Art. 13.

¹⁹ Id., Art. 6.3.

²⁰ Emanuela Turillazzi and Vittorio Fineschi, "Assisted Reproductive Technology: Official Data on the Application of the Italian Law," 16(1) RBM Online 5, 7 (2008), [https://www.rbmojournal.com/article/S1472-6483\(10\)60393-8/fulltext](https://www.rbmojournal.com/article/S1472-6483(10)60393-8/fulltext).

²¹ Ibid.; see also Robertson, *Protecting Embryo s*, at 1693-94.

²² Italian Minister of Health, *Relazione del Ministro della Salute al Parlamento sullo stato di attuazione della legge contenente norme in materia di procreazione medicalmente assistita (legge 19 febbraio 2004, n. 40, articolo 15)*, http://old.iss.it/binary/rpma/cont/Relazione_202009.pdf (last visited July 24, 2019).

200%.²³ By 2005, it was four times higher.²⁴ More recently, a study by the European Society of Human Reproduction and Embryology based on a survey of 46 clinics in six European countries, found that 31.8% were Italian patients.²⁵ 70.6% of those Italians mentioned legal reasons as the predominant motive for cross-border reproductive care.²⁶

13) In 2005, the Luca Coscioni Association and Radicali Italiani, with the support of other organizations, political parties and individuals, campaigned to gather signatures to hold a referendum to repeal, in whole or in part, Law 40/2004.²⁷ Under Article 75 of the Italian Constitution, 500,000 citizens who have the right to vote, or five Regional Councils (*Consigli Regionali*) can request the holding of a referendum to repeal a law or parts of it. The Court of Cassation checks the compatibility of the request to abrogate a law with the Constitution, as well as the fulfilment of the formal requirements to gather signatures. It should be noted that Italy has a long and unfortunate story of deliberately and arbitrarily hindering referenda, an issue that is currently under consideration, via an individual communication, by the Human Rights Committee.²⁸

14) The promoters gathered 1,090,000 signatures in support of a referendum to repeal Law 40/2004, more than double the 500,000 signatures threshold. Still, the Court of Cassation rejected the request to hold a referendum repealing, in its entirety, Law 40/2004. The promoters gathered also between 702,000 and 740,000 signatures to hold referendum to repeal only specific parts of the Law, specifically the articles that increase risks for women's health; those governing the rights of the newborn; the prohibition of using donor gametes; and the

²³ Irene Riezzo et al., "Italian Law on Medically Assisted Reproduction: Do Women's Autonomy and Health Matter?," 16(44) BMC Women's Health 1, 3 (2016).

²⁴ Giulia Zanini, "Abandoned by the State, Betrayed by the Church: Italian Experiences of Cross-Border Reproductive Care," 23(5) RBM Online 565, 566 (2011), [https://www.rbmojournal.com/article/S1472-6483\(11\)00473-1/fulltext](https://www.rbmojournal.com/article/S1472-6483(11)00473-1/fulltext) [hereinafter Zanini, Abandoned by the State].

²⁵ Id.

²⁶ Id.

²⁷ On July 13, 2004, four referendum questions aimed at partially repealing Law 40/2004 on medically assisted procreation were submitted to the Italian Court of Cassation. Three of them (i.e. those on the risks for women's health; the prohibition of using donor gametes; and the prohibition of using embryonic stem cells for scientific research purpose) were expression of a multi-partisan agreements that brought together representatives of the most diverse political forces. They were signed by: Antonio Del Pennino, Barbara Pollastrini, Gavino Angius, Cesare Salvi, Enrico Morando, Chiara Moroni, Cinzia Dato, Loredana De Petris, Francesco Nucara, Katia Zanotti, Lanfranco Turci, Natale D'Amico, Pierluigi Mantini, Lalla Trupia, Vittoria Franco, Maria Teresa Amici, Beatrice Magnolfi; the representatives from the Radical Party Daniele Capezzone, Rita Bernardini and Michele De Lucia; the reporters Antonio Polito e Arturo Diaconale; professor Cinzia Caporale, Tommaso Frosini and Costanza Pera; the Secretary of the Associazione Luca Coscioni, Marco Cappato and the board member Rocco Berardo; the leaders of the CGIL Morena Piccinini, Maria Gigliola Toniollo, Paolina Agnello Modica, Elisabetta Leone and Elisabetta Castellano and the representatives from associations "Madre Provetta", "Lega Italiana Fibrosi Cistica", "Centri Cecos", "Tribunale per i diritti del malato", "L'Altra Cicogna", "Amica Cicogna", "Hera (genitori talassemici)", Gerardo Tricarico, Monica Soldano, Stefano Inglese, Paola Costantini, Laura Pisano, Claudia Livi, Filomena Gallo, Giuseppe Consolo and Antonino Guglielmino. The fourth referendum question, aimed at repealing those rules leading to a greater risk for women's health and the rules governing the rights of the newborn, was signed by Katia Zanotti, Barbara Pollastrini, Maura Cossutta, Vittoria Franco, Lalla Trupia, Luana Zanella, Beatrice Magnolfi and Massimo Villone, representatives from left wing parties; the leaders of the CGIL Morena Piccinini, Maria Gigliola Toniollo, Elisabetta Leone and Elisabetta Castellano; and the President of the "Madre Provetta" association, Monica Soldano. During the following days, the Committees for the promotion of the referendum were officially established, supported by other representatives from the political and cultural world, including MPs Alfredo Biondi and Dario Rivolta and Sen. Lino Jannuzzi.

²⁸ See Human Rights Committee, *Staderini and De Lucia v. Italy*, Comm. No. GSO2015ITA (17) (July 2015).

prohibition to donate to national research supernumerary embryos, as well as embryos that are not suitable anymore for reproduction. These questions were cleared by the Court of Cassation and put to vote. Under the Italian Constitution and laws, for a referendum to pass, it takes a double majority: a majority of eligible voters must cast a vote, and a majority of the votes cast must be in favor. Although about 75% of the 12 million votes cast were in favor of the abrogation of Law 40/2004, only 26% of the population voted, defeating the referendum.²⁹

15) The campaign against the most troubling parts of Law 40/2004 continued in court, where it was challenged for being in violation of the Italian Constitution. The litigation strategy produced positive results. On 8 May 2009, the Constitutional Court declared unconstitutional, insofar as it imposes the creation of a maximum of three embryos per IVF cycle, and the duty to transfer them to the uterus simultaneously, and Article 14.3, insofar as it does not provide that the transfer of embryos should be made without prejudice to the health of the woman.³⁰ Also, the Court found violations of Italian constitutional principles of reasonableness and equality and the right to health.³¹

16) On 14 May 2014, the Court declared Article 4.3, Article 9 Sections 1 and 3, and Article 12.1 of Law 40/2004 unconstitutional insofar as they ruled out recourse to heterologous IVF.³² It ruled that these provisions violated the constitutional principles of inviolable rights, equality, family, and health.³³

17) The Court addressed the issue of access to ART and PGD for immune carriers of genetic disorder in two judgments of 2015. First, on 14 May 2015, the Court found Article 1 (Sections 1 and 2) and Article 4.1 unconstitutional, since they exclude fertile people who are carriers of transmittable genetic disorders from ART, and, therefore, from resort to PGD to have the genetic characteristics of their embryos studied before being implanted in utero.³⁴ Notably, the Court referred to a decision from the European Court of Human Rights in deciding that Law 40/2004 unreasonably balanced the interests of the State and the individual.³⁵

18) In a second case, decided on 21 October 2015, the Constitutional Court held Articles 13.3(b) and 13.4 of Law 40/2004 to be unconstitutional because they criminalized embryo selection, even when the selection was aimed at avoiding the transfer of embryos suffering from inheritable genetic disorders that met the criteria for therapeutic abortion.³⁶

19) In 2012, the Constitutional Court had been called, as a matter of urgency, to determine the compatibility of articles 6.3 (regarding the revocation of consent before fertilization) and 13 (regarding the prohibition of research on embryos) of Law 40/2004 with the Constitution. Four years later, on 22 March 2016, it declared the

²⁹ Ian Fisher, "Italian Vote to Ease Fertility Law Fails for Want of Voters," N.Y. Times (June 14, 2005).

³⁰ Constitutional Court of Italy, Judgment No. 151 (8 May 2009).

³¹ *Id.* at paras. 5.3, 5.4.

³² Constitutional Court of Italy, Judgment No. 162 (14 May 2014).

³³ *Id.*

³⁴ Constitutional Court of Italy, Judgment No. 96 (14 May 2015).

³⁵ *Costa and Pavan v. Italy*, App. No. 54270/10, Eur. Ct. H.R., Judgment (28 Aug. 2012).

³⁶ Constitutional Court of Italy, Judgment No. 229 (21 October 2015).

case inadmissible because it deemed the claim concerning the irrevocability of the consent moot.³⁷ However, the Court found that the case had multiple ethical and juridical implications related to the balance between the right to enjoy the benefits of scientific progress and its applications (and the related benefits) and the rights of the embryo, and that these issues divide jurists, scientists and society. The Court stated that it is the task of the legislator to strike a balance between rights of the embryo and right to enjoy the benefits of scientific progress and its applications, not of the Constitutional Court itself. Accordingly, it called on the legislature to consider “the views and calls for action (...) deeply rooted at any given moment in time within the social conscience”.³⁸ Once again, the Court took note of decisions by the European Court of Human Rights, demonstrating that the Court welcomes guidance from human rights bodies; in this case, it waited to rule on the case until the European Court of Human Rights had ruled on a similar matter.³⁹

20) The same case was brought before this Honorable Committee by the organizations presenting this Report. On 7 March 2019, this Committee found Italy in violation of Article 12 of the Covenant because “Law 40/2004, as interpreted in the authors’ case, restricts the right of women undergoing the treatment to waive their consent, leading to possible forced medical interventions or even pregnancies for all women undergoing in vitro fertilization treatments. It considers that, even if, presumably, this restriction on the right to withdraw one’s consent affects both sexes, it places an extremely high burden on women. ... [T]he possible consequences on women are extremely grave, constituting a direct violation of their right to health and physical integrity”.⁴⁰ It also stated that “Law 40/2004 imposes a restriction on the authors’ right to health as it prevents their access to a health treatment that is otherwise available in the State party”.⁴¹

21) The striking down of several provisions of Law 40/2004 over the years by Italian courts, at times with the assistance of international human rights bodies, has led to increased access to and overall improvement in women’s health. Compared to the years immediately after Law 40/2004 was enacted, in Italy now more couples resort to ART, there are more pregnancies, and the number of born-alive infants has increased.⁴²

³⁷ Constitutional Court of Italy, Judgment No. 84 (22 Mar. 2016).

³⁸ Id. at para. 11.

³⁹ *Parrillo v. Italy*, App. No. 46470/11, Eur. Ct. H.R., Judgment (27 Aug. 2015). Though *Parrillo* found that Art. 13 of Law 40 was reasonable legislation given the wide margin of appreciation the European Convention of Human Rights grants States, there are several distinguishing features that separate that case from the rights at issue in this Report. First, the ECHR was analyzing Article 8 of the European Convention (right to privacy). While this Report does look to Article 10 of the Convention (right to family life), it also analyzes Articles 12 (right to health) and Article 15 (right to science). Furthermore, the ECHR noted that the *Parrillo* case involved a situation where the applicant (Parrillo) was not sufficiently connected to the issue brought before the court, because her right to donate embryos to science was not connected to her right to family life. The ECHR thus limited its ruling to the facts of the case, refusing to examine Law 40 “in the abstract.” *Parrillo*, at para. 191. Because this Committee is not analyzing a specific case, but Italy’s obligations as a whole under the Covenant, it need not be so limited.

⁴⁰ *SC and GP v. Italy*, Comm. No. 22/2017, para. 10.3.

⁴¹ Id. at para. 11.1.

⁴² A. Malvasi et al., “Review 2014-2017, How Medically Assisted Reproduction Changed in Italy: A Short Comparative Synthesis with European Countries,” 168(4) *La Clinica Terapeutica* e248, e249 (July-August 2017).

22) However, there are still very problematic aspects of Law 40/2004 that remain. These include: A) The denial of access to ART by homosexual couples is a discrimination on the basis of sexual orientation prohibited by the Covenant; B) The lack of a provision that makes it clear that consent to *in vitro* insemination and/or transfer *in utero* of the resulting fertilized egg can be revoked at any time before transfer takes place is a violation of the Right to Health, protected by the Covenant, as recognized by this Honorable Committee in *SC and GP v. Italy*, Comm. No. 22/2017; C) the prohibitions of destruction of embryos, research on supernumerary embryos, access to ART for single persons and access to maternal surrogacy are not legitimate limitations of the rights contained in the Covenant under Article 4 because they are arbitrary, unreasonable and disproportionate.

A) LAW 40/2004 DISCRIMINATES AGAINST HOMOSEXUAL COUPLES

23) Article 5 of Law 40/2004 violates Article 2.2 of the Covenant. Article 5 of Law 40/2004 states: “those who can have access to medically assisted procreation techniques are couples of heterosexual adults, married or living together, of a potentially fertile age, both alive.” In other words, homosexual couples cannot resort to artificial reproductive technology in Italy to conceive.

24) We believe that, by only allowing access of ART to heterosexual couples, Law 40/2004 violates Article 2.2 of the Covenant. Pursuant to Article 2.2, “[t]he State Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.” Article 10 states: “The widest possible protection and assistance should be accorded to the family.” When read in conjunction, Articles 10 and 2.2 guarantee that all individuals have the right to a family, including those that are not part of a heterosexual couple.

25) General Comments No. 22 and No. 20 provide further guidance. General Comment No. 22 recognizes that the “full enjoyment of the right to sexual and reproductive health remains a distant goal for millions of people ... such as lesbian, gay, [and] bisexual ... persons.”⁴³ It goes on to state that “[l]aws, policies and programmes ... are required to prevent and eliminate discrimination, stigmatization, and negative stereotyping that hinders access to sexual and reproductive health” for marginalized groups.⁴⁴ Pursuant to General Comment No. 20, “[s]tate parties should ensure that a person’s sexual orientation is not a barrier” to any of the Covenant’s rights.⁴⁵ Finally, the “failure to ensure formal and substantive equality in the enjoyment of the right to sexual and reproductive health constitutes a violation of this right.”⁴⁶

⁴³ Committee on Economic, Social and Cultural Rights, *General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Art. 12 of the Covenant)*, 2 May 2016, E/C.12/GC/22, para. 2.

⁴⁴ *Id.* at para. 30.

⁴⁵ Committee on Economic, Social and Cultural Rights, *General Comment No. 20 (2009) on Non-Discrimination in Economic, Social and Cultural Rights (Art. 2.2 of the Covenant)*, 2 July 2009, E/C.12/GC/20, para. 32.

⁴⁶ *Id.* at para. 55.

26) Arguably, under the Covenant (Arts. 2, 3, 10, 12, and 15), everyone, without discrimination, has the right to benefit from Assisted Reproductive Technology, and scientists have the right to practice it and improve it through practice and research. ART designates medical techniques within the scientific field of “reproductive endocrinology,”⁴⁷ and, as such, falls under the definitions set forth in the Venice Statement and in the Special Rapporteur on Cultural Rights’ 2012 Report as “science” and a “benefit of scientific progress.”⁴⁸

27) 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 private life and reproductive freedom to found a family.⁴⁹ This requires access to the best healthcare including assisted reproductive techniques, and prohibits any arbitrary or disproportionate restrictions on accessing this technology.⁵⁰ Furthermore, “reproductive autonomy and access to reproductive health services ... includes the right to have access to the medical technology necessary to exercise this right.”⁵¹

B) LAW 40/2004 PROHIBITS WITHDRAWAL OF CONSENT AFTER FERTILIZATION

28) Law 40/2004, and in particular its Article 6.3, is in violation of Article 12 (right to health) of the Covenant. Article 6.3 of Law 40/2004 recites: “[t]he willingness [sic] of both parties to have access to medically assisted reproduction techniques is given in writing together with the physician in charge of the facility, in a manner determined by decree of the Ministers of Justice and Health. ... The will [sic] may be revoked by each of the persons mentioned in this paragraph until the time of fertilization.” During IVF procedures, fertilization of the oocyte takes place in vitro, days, weeks and even years before the fertilized egg is transferred in utero. However, Law 40/2004 as worded, does not specify that consent can be withdrawn after fertilization and before transfer in utero. The object and purpose of Law 40/2004, which is the protection of “human embryos” justifies the conclusion that Law 40/2004 actually prohibits withdrawal of consent to transfer in utero after fertilization. Indeed, in its views in the case of *S.C. and G.P. v. Italy* (CESCR Comm. No. 22/2017) this Honorable Committee determined that “the prohibition on withdrawing one’s consent to the transfer of an embryo constitutes a

⁴⁷ *Reproductive Medicine Associates of Connecticut: What is a Reproductive Endocrinologist?*, <http://www.rmact.com/our-fertility-doctors/what-is-a-reproductive-endocrinologist> (last visited April 26, 2019).

⁴⁸ See UNESCO, Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications (July 2009) (“Venice Statement”); Report of the Special Rapporteur in the Field of Cultural Rights, Farida Shaheed, on The Right to Enjoy the Benefits of Scientific Progress and its Applications, Human Rights Council, A/HRC/20/26 (14 May 2012). Farida Shaheed stated in her 2012 Report 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.” Report, at para. 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 states that the right to benefit from scientific research is “applicable to all fields of science and its applications.” Venice Statement, para. 12(a).

⁴⁹ *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), para. 146.

⁵⁰ *Id.* at paras. 287-284.

⁵¹ *Id.* at para. 146.

violation of the right to health, as it can lead to forced medical interventions or even forced pregnancies.”⁵² The Committee noted that the problem stems from ambiguities in Law 40/2004, and emphasized that “States should update their regulations regularly to harmonize them with their human rights obligations.”⁵³

29) Furthermore, the Committee found that when a law on its face disproportionately affects women, the State is responsible for showing that the law “does not maintain, but alleviate[s], the inherent disadvantage that women experience in exercising their right to sexual and reproductive health.”⁵⁴ The Committee found that since Law 40/2004 does not allow women to waive their consent, even if the restriction is imposed on both sexes, “it places an extremely high burden on women.”⁵⁵

C) LAW 40/2004 ARBITRARILY, DISPROPORTIONALLY AND UNREASONABLY HINDERS SCIENTIFIC RESEARCH

30) Article 13 of Law 40/2004 violates Article 12, 15.1.b, 15.2., 15.3 of the Covenant. It allows research on human embryos only if there are no available alternative means and only for diagnostic and therapeutic purposes that will protect the health and development of the specific embryo itself.⁵⁶ Lastly, it prohibits the destruction of human embryos that have been created through ART and have not been implanted in utero.⁵⁷

31) These prohibitions and limitations significantly hinder scientific research in Italy and deny the world the contribution of Italian scientists to the advancement of medicine, violating Article 12, 15.1.b, 15.2 and 15.3 of the Covenant. Italian scientists are concerned that, because of Law 40/2004, they are “dependent on science done abroad,” and, at the same time, they are “not sure this will entitle [Italy] to benefit from such research.”⁵⁸ They work under constant threat of calls for excommunication and political vitriol, making it difficult to conduct research freely.⁵⁹

32) Major lines of biological and human health research rely on the availability of embryos for studies and experiments and for the creation of cell lines. There are primarily two types of stem cells that scientists use for research: adult stem cells that are derived from cells in a tissue or organ, and human embryonic stem cells (“hESC”), which are derived from embryos (but not from fertilized eggs that have been transferred into a woman’s body).⁶⁰ Human embryonic stem cells have several advantages over adult stem cells for scientific research: they can become all types of cells since they are pluripotent (capable of giving rise to several cell types),

⁵² *SC and GP v. Italy*, Comm. No. 22/2017, para. 11.2.

⁵³ *Id.* at para. 11.4.

⁵⁴ *Id.* at para. 8.2.

⁵⁵ *Id.* at para. 10.3.

⁵⁶ Law 40/2004, Art. 13.1.

⁵⁷ Thomas Douglas & Julian Savulexcu, “Destroying Unwanted Embryos in Research: Talking Point in Morality and Human Embryo Research,” 10(4) *EMBO Reports* 307, 307 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2672894/>.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

whereas adult stem cells are limited to the cell types of their original tissue.⁶¹ Furthermore, hESC are easily grown in culture, whereas adult stem cells are difficult to isolate and create from their originating tissue.⁶² These distinctions are important because large numbers of stem cells are necessary for both research and certain types of stem cell replacement therapies.⁶³ Stem cells are important for scientific research because they offer great potential in treating debilitating diseases such as Alzheimer's, Parkinson's, diabetes, and various heart diseases.⁶⁴

33) This is just one possible example of the many ways in which human embryos help medical research and help fulfilling the human right to health, but, as science progresses, there are many other instances where researchers need to be able to utilize fertilized germline cells. For instance, genome editing of human germline cells, which includes zygotes, blastocyst and fertilized eggs up to 14 days after fertilization, holds much promise to free individuals and, potentially, humanity from hundreds of inheritable genetic disorders.⁶⁵ Research on human germline genome modification for therapeutic purposes advances faster, bringing a cure to severe genetic diseases closer, where scientists are allowed to work with embryos.⁶⁶

34) Although the rights protected in the Covenant are, in general, not absolute and may be restricted, any limitation must be: in accordance with the law, including international human rights standards;⁶⁷ compatible with the nature of the rights protected by the Covenant;⁶⁸ in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society;⁶⁹ and not be arbitrary or unreasonable or discriminatory.⁷⁰

35) We believe Law 40/2004 arbitrarily, disproportionately and unreasonably hinders scientific research in Italy because: i) It implicitly defines embryos unscientifically, arbitrarily and unreasonably; ii) it prohibits, arbitrarily, disproportionately and unreasonably, experimentation on embryos unless necessary for the health of the specific embryo in question; and iv) it prohibits the destruction of embryos and, therefore, it prohibits, disproportionately and unreasonably, research on supernumerary embryos.

⁶¹ National Institutes of Health, *Stem Cell Basics V*, 2016, <https://stemcells.nih.gov/info/basics/5.htm>.

⁶² Id.

⁶³ Id.

⁶⁴ National Institutes of Health, *Stem Cell Basics I*, 2016, <https://stemcells.nih.gov/info/basics/1.htm>.

⁶⁵ See, e.g., ETH Zurich, "Genetic Disease Healed Using Genome Editing," Science Daily, <https://www.sciencedaily.com/releases/2018/10/181008183347.htm> (last visited 19 April, 2019) (describing how gene editing cured phenylketonuria, a genetic metabolic disorder, in mice).

⁶⁶ See, e.g., Ludovica Poli, *The Regulation of Human Germline Genome Modification in Italy* (forthcoming book chapter; copy on file with the authors). Human genome modification has enormous therapeutic potential, but the vague, restrictive nature of Law 40 makes this type of research difficult (and potentially illegal) in Italy. *Id.* at 11.

⁶⁷ CESCR, Art. 4.

⁶⁸ Id.

⁶⁹ Id..

⁷⁰ The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, UN Commission on Human Rights, E/CN.4/1987/17 (Jan. 8, 1987), Principle 49.

i) Law 40/2004 Defines “Embryos” Unscientifically

36) First, Law 40/2004 is arbitrary and unreasonable because it does not define “human embryo”, the very object that it intends to protect and regulate, at all. The legislative history, rationale and overall purpose of Law 40/2004, as interpreted by Italian courts over the years, is that, according to Law 40/2004, an embryo exists immediately after fertilization of the egg. Before there are sperm and eggs, separate, which are not protected life (for sure the sperm, less clearly so the egg). The very moment a sperm enters the egg and fertilization takes place, there is an embryo, with all the legal consequences that derive from that. This is unscientific and unreasonable. Law 40/2004 approaches the various stages of embryonic development simplistically. It treats the process of the creation of life as magic, as if it happens suddenly.

37) In reality and scientifically, embryonic development is an analogic process. It happens in stages, each with a specific biological sense and meaning. It is not a sudden event. Syngamy (i.e. the union of gametes), occurs only about 20 hours after the sperm has entered the egg. The fertilized egg cell that results from syngamy is called “zygote”, not an “embryo”.⁷¹ The development of the zygote into an embryo proceeds through specific recognizable stages of “blastula”, “gastrula”, and “organogenesis”. About 3-4 days after fertilization, a “morula” is formed, a mass of 16 totipotent cells in a spherical shape. About 5 days after fertilization, when a fluid-filled cavity opens up in the morula, there is a “blastula” or “blastocysts”. During gastrulation, the cells of the blastula undergo coordinated processes of cell division, invasion, and/or migration to form three tissue layers (endoderm, ectoderm, and mesoderm). Because the zygote and blastocyst have the potential to split and become twins prior to becoming embryos, the scientific consensus is that it is only after they become embryos does “individuality” begin.⁷² Scientifically, an embryo exists only about ten to twelve days after fertilization.⁷³ The “primitive streak”, where the embryo elongates and marks where the spinal cord will grow, does not begin until around fourteen days after fertilization.⁷⁴

38) These are important distinctions that are taken into consideration by many countries around the world that share Italy’s ethical and religious views of human life and its formation and that do not restrict research on human embryos to the extent Italy does. Indeed, it is possible to protect human life and the religious and ethical values that underpin it without distorting the meaning of what a human embryo is. For instance, Germany, which shares with Italy a very conservative view on artificial reproductive technology, prohibits research with embryos, too.⁷⁵ However, it has explicitly recognized that the embryo exists only after syngamy (i.e. the union of gametes), which occurs only about 20 hours after fertilization.⁷⁶

⁷¹ Id.

⁷² Id.

⁷³ Brown, “Stages of Development of the Fetus,” *Merkel Manual*.

⁷⁴ Id.

⁷⁵ See, in general, Boggio A./Romano C./Almqvist J. (eds.), Human Germline Genome Modification and the Right to Science: A Comparative Study of National Laws and Policies, Cambridge University Press, 2019 (forthcoming).

⁷⁶ Robertson, *Protecting Embryos*, at 1694.

39) It is difficult to see how the restrictions contained in Law 40/2004, relying on an undefined, or ill defined, “human embryo” concept, can meet the principle of legality enshrined in Article 4 of the Covenant.

ii) Law 40/2004 Prohibits Research on human embryos unless it is done for diagnostic and therapeutic purposes that will protect the health and development of the specific embryo itself

40) Law 40/2004 prohibits research on human embryos unless it is done for diagnostic and therapeutic purposes that will protect the health and development of the specific embryo itself.⁷⁷ That is a disproportional limitation of the freedom of scientific research, one that is scientifically absurd and it ignores the way in which science advances. Scientists cannot learn how to cure a disease in this human embryo unless they have tried it on several other human embryos. Computer simulations and work on embryos of other species can only advance research so far. Again, this limitation is unscientific and unreasonable, and not admissible under Article 4 of the Covenant. It is a violation of Articles 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 development and the diffusion of science and culture”) and 15.3 (“The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity”) of the Covenant.

iii) Law 40/2004 Prohibits the Destruction of Embryos and, Therefore, Research on Supernumerary Embryos

41) Third, Law 40/2004 prohibits the destruction of embryos. However, research often necessitates manipulation of the embryo, which might lead to, or require, its destruction.⁷⁸ While many countries prohibit the creation of embryos ad hoc for research, they do allow research on so-called “supernumerary embryos”. These are embryos that are not viable and/or affected by genetic disorders, or are healthy but will not be implanted because the IVF procedure has resulted in more than wanted or needed (IVF procedures tend to produce multiple embryos to give doctors the chance to select for implantation only those that are actually health and viable).

42) In 2016, the Constitutional Court ruled on the prohibition to donate to national research supernumerary embryos, as well as embryos that are not suitable anymore for reproduction.⁷⁹ The decision originated from a request by the Tribunal of Florence (*Tribunale di Firenze*) raising the question of the constitutionality of the articles of Law 40/2004 prohibiting the donation of supernumerary embryos to scientific research (art. 13) and the prohibition to withdraw consent to ART after the fertilization of the egg (art. 6). The Constitutional Court rejected the request. The Court highlighted that, based on current case-law, “the protection of the embryo cannot be weakened (where and) due to the sole fact that it is an embryo affected by a genetic malformation”, given the obligation to respect the woman’s right to health and the needs of a pregnancy. It also explained that it is the

⁷⁷ Law 40/2004, Art. 13.1.

⁷⁸ Thomas Douglas & Julian Savulescu, “Destroying Unwanted Embryos in Research: Talking Point in Morality and Human Embryo Research,” 10(4) EMBO Reports 307, 307 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2672894/>.

⁷⁹ Constitutional Court, Judgment No. 84/2016.

legislature, not the judiciary, the branch of government that is responsible for regulating the matter and for striking a reasonable balance between the respect for human life and the needs of scientific research. Still, so far, the Parliament has not taken any steps in this regard, nor shows any sign of intending to do so in the near future.

43) In Italy, since the judgment of the Constitutional Court on 8 May 2009 that lifted the cap on the number of embryos that can be produced during an IVF cycle, and the 14 May 2015 judgment that lifted the ban on Pre-Implantation Genetic Diagnosis thus allowing fertile couples carriers of genetic disorders to access PGD, there is a considerable and growing number of supernumerary embryos. However, because of Law 40/2004, these embryos cannot be researched on nor be disposed of. They are kept in cryopreservation *sine die*. In essence, Law 40/2004 protects embryos by condemning them to a frozen limbo in perpetuity. That is an absurd and unreasonable result, one that is hard to defend not only legally but also ethically.

44) The prohibition to carry out research on embryos and creating embryos for research is not only arbitrarily implemented, but it is also a disproportionate measure to achieve any legitimate goals Italy might have. Indeed, there are other and better ways to balance religious and ethical concerns with the duty to promote science and the right to benefit from its progress.

45) Spain is predominantly Catholic, and yet has laws that allow supernumerary embryos to be donated for scientific research, as long as they have been frozen for five years.⁸⁰ Switzerland forbids the production of embryos solely for research, but allows supernumerary embryos to be used for the production of embryonic stem cell lines.⁸¹

46) Many states around the world allow research on supernumerary embryos. In Europe, these include, besides Switzerland and Spain, at least Belgium, Finland, France, Greece, the United Kingdom, Sweden, Denmark, the Netherlands, and Slovenia.⁸² Outside of Europe, Australia, Mexico, Canada, the United States, Iceland, China, India, Japan, South Korea, Singapore, Australia, and New Zealand can be indicated as examples of countries that allow research on supernumerary embryos.⁸³

47) Most of these countries allow research on human embryos during the first 14 days of their development in vitro. The “fourteenth day” rule was adopted about thirty years ago in the United Kingdom, first to strike a balance between those who believe human life begins at fertilization and those who believe the early stages of development do not constitute protected human life yet.⁸⁴ The global community widely considers the 14-day

⁸⁰ Bionews, *Spain Approves Rules for Stem Cell Research*, 8 Nov. 2004, https://www.bionews.org.uk/page_89471.

⁸¹ The New Atlantis, *Overview of International Human Embryonic Stem Cell Laws, Appendix E*, <https://www.thenewatlantis.com/publications/appendix-e-overview-of-international-human-embryonic-stem-cell-laws> (last visited Apr. 1, 2019).

⁸² Dossiers of the European Institute of Bioethics, *Embryo Research – European Overview*, <https://www.ieb-cib.org/fr/pdf/dossier-en-embryo-research.pdf> (last visited 19 April 2019).

⁸³ See Insoo Hyun et al., “Embryology Policy: Revisit the 14th Day Rule,” 533 *Nature* 169, 171 (12 May 2016), <https://www.nature.com/news/embryology-policy-revisit-the-14-day-rule-1.19838> (last visited 26 April 2019).

⁸⁴ *Id.*

limit to be a reasonable, justifiable and proportional balance between the need to allow research to progress and the need to protect predominant ethical values and religious beliefs in those societies.⁸⁵

48) Though many of these countries recognize the religious imperatives that Italy has, they adhere to the provisions of the Covenant more closely by allowing research on supernumerary embryos. Italy's practice is significantly off line with the practice of all developed countries. Italy should allow research on supernumerary embryos and, if it has to find a temporal limit within which this research is to be carried out, 14 days is the current prevailing international standard.

49) The absolute prohibition of the destruction of human embryos is also arbitrary. Although Law 40/2004 prohibits destroying embryos facially because they are human life and, thus, must be preserved, at the same time, Italy does not prohibit research on embryos created for research abroad. Indeed, Italian scientists routinely work on embryonic stem cell lines imported from abroad.⁸⁶ They participate in cooperative international research projects on hESCs funded by the European Union,⁸⁷ even though the Italian government does not fund research on hESCs because that entails the destruction of embryos.⁸⁸ If the alleged rationale of Law 40/2004 is to protect the sanctity of human life, enshrined in a human embryo, it is not clear why embryos created outside Italian territory are not sacred life as much as those created in Italy. "Foreign embryos" can be used, researched on, and possibly destroyed in the process, while the same cannot be done with embryos created within Italian territory. The different treatment is arbitrary, rendering this restriction incompatible with Article 4 of the Covenant.

RECOMMENDATIONS

50) The rights protected in the Covenant are not absolute and may be subject to such limitations as permitted by Article 4 of the Covenant. However, Article 4 is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States. Consequently, a State party imposing a restriction on the enjoyment of a right under the Covenant has the burden of justifying such serious measures in relation to each of the elements identified in Article 4.

51) We believe that Law 40/2004 falls short of fully allowing Italy to fulfill its obligations as set forth in Article 2, Article 10 (right to family), Article 12 (right to health) and Article 15(1)(b) (right to benefit from progress in science and technology), Article 15.2 (duty to develop and diffuse science), and Article 15.3 (freedoms

⁸⁵ John Harris, "It's Time to Extend the 14-Day Limit for Embryos Research," *The Guardian* (6 May 2016).

⁸⁶ Barbara Forrest, "Three Courageous Italian Scientists – An Example for Louisiana," World Congress for Freedom of Scientific Research (19 Apr. 2010), <https://www.freedomofresearch.org/three-courageous-italian-scientists-an-example-for-louisiana-by-barbara-forrest/> (last visited 26 April 2019); see also Horizon 2020 Program, The EU Framework Programme for Research and Innovation, <https://ec.europa.eu/programmes/horizon2020/> (last visited 1 April 2019); Jacopo Pasotti & Ned Stafford, "It's Legal: Italian Researchers Defend their Work with Embryonic Stem Cells," 442 *Nature* 229, 229 (20 July 2006), <https://www.nature.com/articles/442229a> (last visited 19 April 2019).

⁸⁷ See Horizon 2020 Program, The EU Framework Programme for Research and Innovation, <https://ec.europa.eu/programmes/horizon2020/> (last visited 19 April 2019).

⁸⁸ Lorenzo Beltrame, "The Italian Way to Stem Cell Research: Rethinking the Role of Catholic Religion in Shaping Italian Stem Cell Regulations," 17 *Developing World Bioethics* 157, 160 (Jan. 2016), <https://doi.org/10.1111/dewb.12104> (last visited 26 April 2019).

indispensable for scientific research). We also believe Law 40/2004 is inconsistent with the Italian Constitution, namely Article 9.1 (“The Republic promotes the development of culture and of scientific and technical research”), Article 33.1 (“The Republic guarantees the freedom of the arts and sciences, which may be freely taught”), and Article 32 (“The Republic safeguards health as a fundamental right of the individual”).

52) The bar for homosexual couples to have access to ART in Italy is unjustifiable. It cannot be considered a limitation in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, or necessary for the promotion of the general welfare in a democratic society.

53) As this Honorable Committee recently held in *S.C. and G.P. v. Italy* (CESCR Comm. No. 22/2017), the impossibility to withdraw consent to transfer in utero after fertilization is inconsistent with the Covenant. Italy has an obligation to amend Law 40/2004 to allow consent to be withdrawn at any moment by both parents and, in certain circumstances, unilaterally by the woman.

54) Law 40/2004 is arbitrary, unreasonable and disproportional in its approach to human embryos and research on them. It does not define the object that it intends to protect and regulate (i.e. the human embryo), and the implicit definition identified through jurisprudence is not grounded in science.

55) Italy’s Constitutional Court, as well as international human rights bodies, including this Honorable Committee, have determined on several occasions that provisions of Law 40/2004 do not comport with the Italian Constitution and international human rights standards. Although Law 40/2004 has been chipped away by numerous decisions over the years, it still stands, containing several provisions that remain in violation of the Italian Constitution and the Covenant.

56) Therefore, we ask the Honorable Committee as it prepares the List of Issues to ask Italy to explain:

- What steps does Italy intend to take to allow homosexual couples access to ART?
- What steps does Italy intend to take to allow withdrawal of consent to transfer in utero of fertilized ova at any time?
- What steps is Italy taking to implement the Committee’s recommendation in *S.C. and G.P. v. Italy* (CESCR Comm. No. 22/2017)?
- What steps is Italy taking to examine and revise Law 40/2004, taking into account the evolution of society and scientific progress, particularly in the areas of biotechnology?
- What steps does Italy intend to take to address the need to regulate the donation of supernumerary embryos no more suitable for reproductive purpose to national research, also in light of judgment 84/2016 of the Constitutional Court?