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A Human Rights Approach to Risk: The Case of Human Germline Editing

BY JESSICA ALMQVIST*

I. INTRODUCTION

The new human genome editing tools (CRISPR) have the potential of improving the protection of the human right to health.¹ Not only can these tools be used to treat and cure diseases, such as cancer or diabetes; in the future, they may also be used to prevent genetic and other diseases and disorders in offspring. In this light, the tools have the potential to prevent human suffering, which is a core concern in international human rights law.² However, clinical applications of these new tools pose several risks of harm. When it comes to modifications of human somatic cells, these risks are limited to the patient undergoing the treatment.³ In the case of human germline editing, the risks are not so limited since the effects are inheritable and can be passed onto future generations.⁴ There is currently a great deal of scientific uncertainty about the actual biological consequences of human germline editing not only for the offspring whose genome has been modified, but also future generations. A key question that arises is how to manage risk in this kind of scenario.

This article will center on the question of how to manage risks posed by human germline editing, including for the purpose of permitting genetic modifications of future offspring. As will be explained, international law entails a series of legal obligations, including in the area of human rights, that frames and constrains regulatory decisions on how to

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1. International Covenant on Economic, Social and Cultural Rights art. 12, *opened for signature* Dec. 16, 1966, 993 U.N.T.S. 3 (entered into force Jan. 3, 1976) [hereinafter ICESCR].

2. Roberto Adorno and Cristiana Baffone, *Human Rights and the Moral Obligation to Alleviate Suffering*, SUFFERING AND BIOETHICS (Ronald M. Green and Nathan J. Palpant eds., 2014).

3. NAT'L ACADS. OF SCI., ENG'G, AND MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 83 (The Nat'l Acads. Press ed., 2017).

4. *Id.* at 111–12.

respond to the risks posed by clinical human germline editing. Since these obligations protect different interests, some of which are in direct competition with one another, there is a need for balancing these interests and obligations. While difficult decisions must be made, the idea of ‘side-stepping’ some interest that a state is legally obliged to protect will not be a satisfactory response and is incompatible with international law.

Part II will explain how risk assessment and management has come to be integrated into international law in the form of legal obligations placed on states to act with due diligence and precaution. Part III will discuss the role of the “precautionary principle” in responding to risk scenarios. In this context, this article will highlight the contributions and shortcomings of this principle. This article will stress a basic problem that arises where the principle leaves the door open for different interpretations, some of which ignore existing human rights obligations. Part IV will identify several rights that come under pressure by sweeping bans of clinical human germline editing. Part IV argues that such bans downplay the benefits of continued scientific research for the progressive realization and fulfillment of the human right to health. This article will further argue that the bans also ignore the rights to science and to scientific freedom. In conclusion, any reasonable response to the challenges and opportunities posed by future clinical applications of CRISPR must consider not only state obligations of due diligence and precaution, but also obligations to respect, protect and fulfill these rights. The focus on these interests and obligations does not preclude that there may be additional interests and obligations to take into account, including equality and non-discrimination.⁵

II. RISK ASSESSMENT AS A DUE DILIGENCE OBLIGATION

The need to assess and manage risk is an ongoing concern in our societies. As Stephen Townley put it, “[r]isk has become a preoccupation of states, businesses, and individuals,” which has come to be reflected in different areas of international law.⁶ This has changed our understanding of the role of international law in society. For example, there is an emergent theory of “proactive law” that seeks broadly to “[shift] the focus of

5. See, e.g., Britta van Beers, *Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era*, J. OF L. AND THE BIOSCIENCES (2020).

6. Stephen Townley, *The Rise of Risk in International Law*, 18 CHI. J. INT’L L. 594, 596 (2018).

attention from dispute-resolution to . . . legal risk management.”⁷ The emerging approaches to risk in international law build on the principle of due diligence and the concept of due diligence obligations.⁸ As Timo Koivurova noted, many fields of international law have seen

the emergence of primary obligations that require States to exercise due diligence, that is, to endeavour to reach the result set out in the obligation. A breach of these obligations consists not of failing to achieve the desired result, but failing to take the necessary, diligent steps towards that end.⁹

Due diligence obligations have their origin and have been advanced mostly in the field of international environmental law.¹⁰ Yet the same obligations extend to the protection of public health, even if the significance of these obligations has not received the same degree of wide international *legal* attention as their significance in the field of environmental protection.¹¹ A special branch of international law in which due diligence obligations have come to occupy an important place is international human rights law. As Frédéric Mégret explains, according to this body of law, the state needs to protect individuals from human rights violations.¹² This means that the state “needs to proactively ensure that persons within its jurisdiction do not suffer from human rights violations at the hands of third parties or even broad phenomena such as preventable environmental catastrophes.”¹³ In this context, the due diligence obligations have become key for insisting that the state must enforce laws that require private actors, such as business enterprises, to respect human rights, and to provide an effective remedy for victims of human rights violations perpetrated by such actors.¹⁴ To be certain, the state is not responsible for all

7. Gerlinde Berger-Walliser & Paul Shrivastava, *Beyond Compliance: Sustainable Development, Business, and Proactive Law*, 46 GEO. J. INT’L L. 417, 438 (2015); see also George J. Siedel & Helena Haapio, *Using Proactive Law for Competitive Advantage*, 47 AM. BUS. L. J. 641, 656–67 (2010).

8. Townley, *supra* note 6, at 598.

9. TIMO KOIVUROVA, *Due Diligence*, in OXFORD PUB. INTERNATIONAL LAW: MAX PLANCK ENCYCLOPEDIAS OF INTERNATIONAL LAW, ¶ 3 (2015).

10. *Id.*

11. See, e.g., Brigit Toebes, *International Health Law: An Emerging Field of Public International Law*, 55 INDIAN J. INT’L L. 299, 299–328 (2015).

12. FRÉDÉRIC MÉGRET, INTERNATIONAL HUMAN RIGHTS LAW 97 (Daniel Moeckli et al. eds., 2018).

13. *Id.*

14. See, e.g., OFF. OF THE HIGH COMM’R FOR HUM. RTS., GUIDING PRINCIPLES ON BUSINESS AND HUMAN RIGHTS: IMPLEMENTING THE UNITED NATIONS “PROTECT, RESPECT AND REMEDY” FRAMEWORK 3, U.N. Doc. HR/PUB/11/04 (2011), https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf.

adverse interferences in individual rights by private actors,¹⁵ but the state is “liable for those failures that can be traced to its shortcomings in protecting individuals from others for example because it has adopted a law that made the violation possible, or because it has failed to do something that would have prevented the violation from happening.”¹⁶ In other words, the state is responsible for taking measures to prevent harm to the population, including those that private actors cause.¹⁷

A recurrent theme in the field of biomedicine is the importance of risk assessment and management, including research, treatment and diagnostics affecting an individual’s genome. As expressed in the UNESCO Declaration of the Human Genome and Human Rights, which was adopted in 1997, “[r]esearch, treatment or diagnosis affecting an individual’s genome shall be undertaken only after rigorous and prior assessment of the potential *risks* and benefits pertaining thereto and in accordance with any requirement of national law.”¹⁸ According to Article 19 of the same declaration, “[i]n the framework of international co-operation with developing countries, states should seek to encourage measures enabling: (i) assessment of the *risks* and benefits pertaining to research on the human genome to be carried out and abuse to be prevented.”¹⁹ In the more recent UNESCO Declaration on Bioethics and Human Rights that was adopted in 2005, the importance of risk assessment and management is reaffirmed.²⁰ Specifically, the Declaration on Bioethics and Human Rights proclaims that “[a]ppropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.”²¹

Having referred to these two declarations, the call for risk assessment and management in research, treatment and diagnostics affecting an individual’s genome is not limited to public policy or what is sometimes referred to as soft law.²² Risk assessment and management has also been

15. *Id.* at 3.

16. MÈGRET, *supra* note 12, at 97–98 (citing *X and Y v. The Netherlands* 8 EHHR 235 (1986); *Young, James and Webster v. UK* 4 EHHR 38 (1982)).

17. OFF. OF THE HIGH COMM’R FOR HUM. RTS., *supra* note 14, at 3.

18. UNESCO 29 C/Res. 16, Universal Declaration on the Human Genome and Human Rights, art. 5(a) (Nov. 11, 1997) (endorsed by the UN General Assembly on December 9, 1998 at its 53rd session) (emphasis added).

19. *Id.* art. 19(a) (emphasis added).

20. See UNESCO 33 C/Res. 36, Universal Declaration on Bioethics and Human Rights (Oct. 19, 2005).

21. *Id.* art. 20; see also *id.* art. 7(b) (also mentioning risk).

22. See, e.g., C.M. Chinkin, *The Challenge of Soft Law: Development and Change in International Law*, 38 INT’L & COMP. L.Q. 850 (1989); see also, e.g., Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance*, 54 INT’L ORG. 421 (2000).

integrated into and manifested in treaty law. A good example is the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (commonly referred to as the Oviedo Convention), which was adopted in 1997 and states that parties are obliged to assess and manage risk in different scenarios.²³ In line with Article 16(ii), research on a person may only be undertaken if several conditions are met, among them, that “the risks which may be incurred by that person are not disproportionate to the potential benefits of the research.”²⁴ Furthermore, the need to assess risks and prevent possible harm is a central element of the EU Regulation on Clinical Trials, which mentions risk forty times.²⁵ To illustrate:

The assessment of [an] application for a clinical trial should address in particular the anticipated therapeutic and public health benefits (relevance) and the risk and inconvenience for the subject. In respect [to] the relevance, various aspects should be taken into account, including whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment of medicinal products, and the authorization [provided before their] placing on the market, and whether surrogate end-points, when they are used, are justified.²⁶

The outcome of a risk assessment may also have motivated, at least in part, the introduction of the rule included in Article 13 of the Oviedo Convention, which states, “An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.”²⁷ A risk assessment may also lie behind the formulation of Article 90 of the EU Regulation on Clinical Trials: “No gene therapy clinical trials may be carried out which result in modifications to the subject’s germline genetic identity.”²⁸ Until the current risks

23. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine art. 16, *opened for signature* Apr. 4, 1997, E.T.S. No. 164 (entered into force Dec. 1, 1999).

24. *Id.*

25. See Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use and Repealing Directive 2001/20/EC, 2014 O.J. (L 158) 1 [hereinafter Regulation (EU) 536/2014] (building on Recommendation of the Organization for Economic Cooperation and Development (OECD) on the Governance of Clinical Trials of 10 December 2012, which introduces different risk categories for clinical trials).

26. *Id.* at recital 13.

27. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, *supra* note 23, art. 13.

28. Regulation (EU) 536/2014, *supra* note 25, art. 90.

associated with clinical applications have been reduced, their presumed significance will lie at the heart of the recent global moratoriums on human germline editing for the purpose of creating genetically modified children.²⁹

As Eric Lander et al. pointed out, “[f]or germline editing to even be considered for clinical applications, its safety and efficacy must be sufficient.”³⁰ While techniques have improved in recent years, human germline interventions are still not seen as safe or effective enough to justify any use in the clinic.³¹ In particular, “the risk of failing to make the desired change or of introducing unintended mutations (off-target effects) is still unacceptably high.”³² Likewise, “[n]o clinical application of germline editing should be considered until its long-term biological consequences [for individuals and the human species] are sufficiently understood.”³³ According to the drafters of the moratoriums on heritable gene editing, attempting to modify the risk of a common disease is fraught with challenges.³⁴ It is also necessary to consider the risk that “the introduction of genetic modifications into future generations could have permanent and possibly harmful effects on the species.”³⁵

III. THE ROLE OF THE PRECAUTIONARY PRINCIPLE IN RISK MANAGEMENT

Whether or not precautionary measures, including the imposition of bans, are needed to reduce risks created by human activities has been debated over decades. Now there is an upsurge of academic literature on this topic.³⁶ This debate revolves around the question of whether or not to regulate a human activity that could potentially harm or damage the environment or human health, even if it is scientifically unclear what the probability that such harm or damage will actually occur and, if so, how

29. See, e.g., Joint Press Release of CCNE, DER, & NCOB, *Joint Statement of Ethics Councils from France, Germany and the United Kingdom on the Ethics of Human Germline Intervention*, DEUTSCHER ETHIKRAT (Mar. 3, 2020), <https://www.ethikrat.org/en/press-releases/2020/joint-statement-of-ethics-councils-from-france-germany-and-the-united-kingdom-on-the-ethics-of-human-germline-intervention/> (last accessed Feb. 14, 2021) [hereinafter *Joint Statement of Ethics Councils*].

30. Eric Lander et al., *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165, 166 (2019).

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 167.

36. See, e.g., Neil Pierce, *Public Health and the Precautionary Principle*, in THE PRECAUTIONARY PRINCIPLE: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN 49 (Marco Martuzzi & Joel A. Tickner eds., 2004).

significant it would be.³⁷ In a fundamental sense, the risks are “[u]nknown” in reference to the “*potential* peril about which we lack information either on the likelihood of the harm materializing or knowledge of the effect it would have if it did.”³⁸ These scenarios thus differ from risks that are “known” because we are informed about the probability of occurrence of harm as well as the magnitude of the resulting harm.³⁹ For example, the risk of allowing the disposal of toxic waste near people’s homes or allowing the contamination of drinking water is not only known, but has a high probability of causing significant harm, such as cancer.⁴⁰

The possible need for precaution in relation to activity that could potentially cause harm or damage to the environment or people’s health has led to the introduction and development of the precautionary principle.⁴¹ According to the European Commission, this principle is meant to guide regulators on whether or not to intervene in cases where “scientific information [about the risks involved] is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous.”⁴² It reflects the simple truism, “better safe than sorry.” As attractive as this guide may be, there is no agreement on how to interpret the principle.⁴³ In fact, it has generated a whole array of different interpretations, some of which are at odds with international law.

As Richard Stewart explains, the precautionary principle is open to a range of interpretations of what this principle actually means.⁴⁴ Under the weakest interpretation, the principle asserts that “uncertainty regarding the adverse environmental effects of an activity should not automatically bar adoption of measures to prohibit or otherwise regulate the activity.”⁴⁵ In this light, it provides what seems to be a reasonable justification to not simply wait to regulate a human activity that may be harmful until there is conclusive, sufficient, and certain scientific

37. *Id.* at 49.

38. Townley, *supra* note 6, at 597.

39. *Id.*

40. *E.g.*, R D Morris, *Drinking Water and Cancer*, 103 ENV’T HEALTH PERSPS., 225 (1995).

41. *See, e.g.*, Kriebel et al., *The Precautionary Principle in Environmental Science*, 109(9) ENV’T HEALTH PERSPS., 871 (2001).

42. *Communication from the Commission on the Precautionary Principle*, at 7, COM (2000) 1 final (Feb. 2, 2000).

43. *Id.* at 2.

44. Richard Stewart, *Environmental Regulatory Decision Making Under Uncertainty*, in 20 INTRODUCTION TO THE LAW AND ECONOMICS OF ENVIRONMENTAL POLICY: ISSUES IN INSTITUTIONAL DESIGN 71 (Timothy Swanson ed., 2002).

45. *Id.* at 71–72.

evidence about the existence of a risk that must be managed or minimized. By contrast, under the strong interpretation, it asserts that “uncertainty provides an affirmative justification for regulating an activity or regulating it more stringently than in the absence of uncertainty.”⁴⁶ The strong interpretations of the principle encourage regulators to assess the risks of a human activity that could potentially cause significant harm in terms of “worst case” scenarios,⁴⁷ which, according to the Cambridge Dictionary, refers to “the most unpleasant or serious thing that could happen in a situation.”⁴⁸ For this reason, the strong version provides grounds for sweeping regulatory interventions, including bans, without considering the costs of regulating that activity, which are seen as irrelevant.⁴⁹ Based on this interpretation of the principle’s meaning, the burden of proof is reversed and those who wish to avoid regulation must provide the evidence that their activity is safe.⁵⁰

Both versions—weak or strong—are problematic since they can give rise to extreme and undesirable outcomes. At one extreme, the strong version risks legitimizing a policy that hinders scientific progress and applications of new technology.⁵¹ The strong version threatens to make society too risk averse, which in turn may lead to paralysis.⁵² In comparison, the weak version of the principle seems rather unobjectionable.⁵³ As Cass Sunstein explains, the weak version simply states a truism which in and by itself is “uncontroversial and necessary only to combat public confusion or self-interested claims of private groups demanding unambiguous evidence of harm, which no rational society requires.”⁵⁴ Indeed, insofar as the principle counteracts the tendency to demand certainty about risks, it is sound.⁵⁵ Nevertheless, this version is problematic since it fails to provide clear guidance about whether or not to regulate a human activity that could potentially cause harm. It merely indicates that scientific uncertainty about risk does not ‘automatically’ preclude regulation.⁵⁶

46. *Id.* at 72.

47. *Id.*

48. *Worst-case scenario*, *DICTIONARY.CAMBRIDGE.ORG*, <https://dictionary.cambridge.org/us/dictionary/english/worst-case-scenario> (last visited Jan. 3, 2021).

49. Stewart, *supra* note 44, at 72.

50. *Id.*

51. Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1035 n.147 (2003).

52. *Id.* at 1020–28.

53. *Id.* at 1016.

54. *Id.*

55. *Id.* at 1007.

56. *Id.* at 1014.

International law, which upholds the precautionary principle as a legal one, does not resolve the problem of different interpretations, but rather it reproduces different versions.⁵⁷ A weak version is found in the UN Framework Convention on Climate Change (1992),

[w]here there are threats of serious or irreversible damage, lack of full scientific uncertainty should not be used as a reason for postponing ... [precautionary] measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.⁵⁸

The so-called Wingspread Statement (1998) goes a bit further, demanding that “[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”⁵⁹ It also adds that “the proponent[s] of an activity, rather than the public, should bear the burden of proof” that it will not pose threats of harm to human health or the environment.⁶⁰

The Convention on Biological Diversity, adopted in 1992, instead expresses a strong version of the principle. According to the Convention, each state party shall, as far as possible:

[e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health.⁶¹

Stronger versions of the principle are also at play in the field of EU law. The precautionary principle lies at the heart of many regulations and directives passed by the EU. It is recognized as a general principle of EU law, which is used not only to interpret acts, but also as a ground for the

57. According to international law scholars, the principle is not only treaty-based but also grounded in customary international law. See, e.g., Owen MacIntyre & Thomas Mosedale, *The Precautionary Principle as a Norm of Customary International Law*, 9 J. OF ENV'T. L. 221 (1997).

58. United Nations Framework Convention on Climate Change art. 3, *opened for signature* June 4, 1992, 1771 U.N.T.S. 107 (entered into force Mar. 21, 1994).

59. *Precautionary Principle: The Wingspread Statement*, COLLABORATIVE ON HEALTH AND THE ENV'T, <https://www.healthandenvironment.org/environmental-health/social-context/history/precautionary-principle-the-wingspread-statement> (last visited Feb. 14, 2021).

60. *Id.*

61. United Nations Conference on Environment and Development: Convention on Biological Diversity art. 8(g), *opened for signature* June 5, 1992, 1760 U.N.T.S. 79 (entered into force Dec. 29, 1993).

invalidation of acts that contravene this principle.⁶² It is expressly enshrined in the context of environmental matters, which includes protecting human health.⁶³ Even if it is only mentioned explicitly in this context, the principle is broader in scope since it is also intended to ensure high levels of protection for health, consumer safety, and the environment in all of the EU's spheres of activities.⁶⁴ These goals translate into a requirement placed on competent authorities to take appropriate measures to prevent specific potential risks to public health and safety, including food safety and the environment, by giving precedence to this requirement over economic interests.⁶⁵

As previously mentioned, there is no consensus on whether the principle authorizes or requires regulatory intervention in risk scenarios, nor whether there are any methods to analyze or assess risk of harm in scenarios where there is no scientific certainty. There is also no formula to calculate the probability that harm will occur or to determine its magnitude. Indeed, there is no precise agreement on the meaning of the principle, not even within EU law, where it is acknowledged to be malleable.⁶⁶ A good example of this malleability is demonstrated in the judgment related to genetically modified organisms using CRISPR, which the EU Court of Justice decided in 2018.⁶⁷ In the case, the court insisted that CRISPR posed potential risks for the environment or human health and therefore the EU directive concerning GMO was applicable.⁶⁸ Yet the court's interpretation contradicted the opinion of the Advocate General, who argued that CRISPR must be seen as excluded from the scope of the EU directive. In his words, "[a] mere fear of a risk induced by something new, or a vaguely and generally asserted risk of a risk where it cannot be conclusively stated that the new thing is safe, is an insufficient trigger for the precautionary principle."⁶⁹

62. PAUL CRAIG & GRÁINNE DE BÚRCA, *EU LAW: TEXT, CASES, AND MATERIALS* 111 (6th ed. 2015).

63. Consolidated Version of the Treaty on the Functioning of the European Union art. 191(1), May 9, 2008, 2008 O.J. (C 115) 47 [hereinafter TFEU].

64. *Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN>; Case C-528/16, *Confédération Paysanne v. Premier Minister*, ¶¶ 49–53 (July 25, 2018).

65. *See id.* at 49–53.

66. SCI. FOR ENV'T POL'Y, *FUTURE BRIEF: THE PRECAUTIONARY PRINCIPLE: DECISION-MAKING UNDER UNCERTAINTY* 4 (2017), https://ec.europa.eu/environment/integration/research/newsalert/pdf/precautionary_principle_decision_making_under_uncertainty_FB18_en.pdf.

67. Case C-528/16, Judgment, CURIA.

68. *Id.* ¶ 60.

69. Case C-528/16, Opinion of Advocate General Bobek, ECLI:EU:C:2018:20, ¶ 53 (Jan. 18, 2018).

Be that as it may, the question raised in this article is if the precautionary principle should guide decisions on how to regulate new biotechnology and, if so, what would it require. As we have seen, the principle is most immediately associated with and has thrived in the field of environmental protection. It also extends to public health. As noted by Neil Pierce, “The primary goals of public health are preventing disease and promoting health in populations. The concepts of precaution and prevention have therefore always been at the heart of public health practice.”⁷⁰ To date, exactly how the precautionary principle would influence the regulatory framework for clinical germline editing has not been examined with great detail. The few contributions on the topic seem to reproduce rather than resolve the disagreement about how the principle should be interpreted.

Notably, Matthias Braun and Peter Dabrock stress that a core characteristic of the precautionary-based approach is that it must not conflict with or prohibit innovation.⁷¹ As they put it, “[i]t lies within the precautionary principle that precaution and innovation cannot be framed as opposing and mutually exclusive poles.”⁷² Therefore, any regulatory intervention must acknowledge and reconcile these goals, as well as adjust to the fluid and dynamic nature of CRISPR as a biotechnological invention by resorting primarily to soft law instruments.⁷³ According to another contribution, the principle recommends placing somewhat greater weight on avoiding threats to future generations than on achieving short-term benefits.⁷⁴ At the same time, competing stances are also upheld. Harald König once said a moratorium on human germline editing could prevent states from adapting their regulatory frameworks to their own needs, interests, values, ethical views and moral stances.⁷⁵ To illustrate, in some societies, “the importance of having a genetically related child could outweigh the technology’s biological risks.”⁷⁶ In other words, in his view, the risks involved are not sufficiently grave to outweigh the possible benefits. A somewhat similar position stresses that a degree of uncertainty is

70. Pierce, *supra* note 36, at 49.

71. Matthias Braun & Peter Dabrock, *Mind the Gaps! Toward an Ethical Framework for Genome Editing*, 19 EMBO REP. 197, 200 (2018).

72. *Id.*

73. *Id.*

74. Julius J. Koplin, et al., *Germline Gene Editing and the Precautionary Principle*, 34 BIOETHICS 49, 49 (2019).

75. Harald König, *Germline-Editing Moratorium—Why We Should Resist It*, 568 NATURE 458 (April 23, 2019).

76. *Id.*

inherent in emerging biotechnological inventions and tools.⁷⁷ In the end, it is a matter of determining when the technology is considered ‘safe enough’ to move along the translational pathway.⁷⁸

IV. RECONCILING PRECAUTIONARY MEASURES WITH HUMAN RIGHTS OBLIGATIONS

Those who downplay the significance of the risks of harm that could be caused by clinical applications of human germline editing tools stress the benefits that such applications could bring. Indeed, there are several potential beneficiaries of these kinds of interventions: the couples who want a genetically related child without passing on genetic disease as well as the child who will be born without such disease. As indicated by Bartha Knoppers and Erika Kleiderman, the calls for global moratoria on clinical applications of heritable genome editing are troubling since they do not foster the best interests for the health of children nor do they align with their right to benefit from the advancement of science.⁷⁹ In a more long-term perspective, the technology could potentially “endow children with ‘protective’ genes that reduce the risk of common diseases, such as heart disease, cancer and diabetes,” which could potentially benefit not only the genetically modified children but also their descendants.⁸⁰ Also, the Nuffield Council on Ethics stresses the potential benefits of the emerging tools to prevent medical diseases or disorders of future offspring.⁸¹

From this perspective, a regulatory framework for scientific research and possible future applications of human germline editing tools should be designed not merely to avert potential risks of harm. Such a framework may be consistent with and justified on the basis of existing legal obligations to act with due diligence and precaution. It may, however, not be compatible with the legal obligation to ensure respect, protection and fulfillment of human rights, including the rights to health, science and scientific freedom. According to the International Covenant on Economic, Social and Cultural Rights, the right to science entails the right to enjoy the benefits of scientific progress and its applications. The same treaty says that states must undertake to “respect the freedom

77. Erika Kleiderman, Vardit Ravitsky & Bartha Maria Knoppers, *The ‘Serious’ Factor in Germline Modification*, 45 J. OF MED. ETHICS 508, 510 (2019).

78. *Id.*

79. Bartha Knoppers & Erika Kleiderman, *Heritable Genome Editing: Who Speaks for “Future” Children?*, 2 CRISPR J., 285 (2019).

80. Koplin, *supra* note 74, at 50.

81. NUFFIELD COUNCIL ON ETHICS, GENOME EDITING AND HUMAN REPRODUCTION: SOCIAL AND ETHICAL ISSUES (2018).

indispensable for scientific research.”⁸² Freedom of research is both individual and collective, negative and positive. Individually, this freedom entails the right of everyone, including scientists and patients, to participate in the scientific enterprise. Collectively, it is the right of scientists to govern the scientific enterprise, including the right to self-regulation, but also a right to policies that support science, to research funding and infrastructure.⁸³ The covenant also states that the right to health is “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”⁸⁴ The right to health is especially stressed as a right of children. As proclaimed in the International Convention on the Rights of the Child (1989), state parties “recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health,” which extends to the obligation of state parties to combat disease.⁸⁵

Even if the enjoyment of individual human rights can be restricted, any such restriction must be prescribed by law and “must be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.”⁸⁶ Pursuant to human rights doctrine, the promotion of the general welfare entails and legitimizes measures meant to protect different public goods, including public health and safety of the state’s population.⁸⁷ At the same time, since such restrictions must be prescribed by law, they cannot be done arbitrarily.⁸⁸ Such restrictions must be “compatible with the nature of these rights,” which means that the *core* of the individual rights to health and science must be protected at all times.⁸⁹ The compatibility requirement seems to pose significant restraints on regulatory decisions on how to manage risks of harm when the risks of harm are scientifically uncertain. Regulatory decisions are also restrained when the risks must be weighed against potential benefits that would strengthen the protection and progressive

82. ICESCR, *supra* note 1, art. 15(1).

83. For a definition of the right to science, see Andrea Boggio, Cesare Romano & Jessica Almqvist, HUMAN GERMLINE GENOME MODIFICATION AND THE RIGHT TO SCIENCE, A COMPARATIVE STUDY OF NATIONAL LAWS AND POLICIES 73–74 (2020).

84. *Id.* art. 12.

85. G.A. Res. 44/25, Convention on the Rights of the Child, art. 24 (Nov. 20, 1989).

86. ICESCR, *supra* note 1, art. 4.

87. OLIVIER DE SCHUTTER, INTERNATIONAL HUMAN RIGHTS LAW: CASES, MATERIALS, COMMENTARY 341 (2013).

88. *Id.*

89. Comm’n on Hum. Rts., The Limburg Principles on the Implementation of the International Covenant on Economic Social and Cultural Rights, ¶ 56, U.N. Doc. E/CN.4/1987/17, annex (Jan. 8, 1987) (“The restriction ‘compatible with the nature of these rights’ requires that a limitation shall not be interpreted or applied so as to jeopardize the essence of the right concerned.”).

realization of human rights, including the rights to health and to science. In particular, strong versions of the precautionary principle when applied to managing risks that are scientifically uncertain and which must be weighed against benefits, seem incompatible with the protection of these rights.

As noted in the General Comment no. 25 of the UN Committee on Economic, Social and Cultural Rights, the application of the precautionary principle “is sometimes controversial, particularly in relation to scientific research itself, as limitations on the freedom of scientific research are compatible with the Covenant only in the circumstances set out in article 4.”⁹⁰ Nevertheless, this principle “is more broadly applied for the use and application of scientific outcomes.”⁹¹ Therefore, it “should not hinder and prevent scientific progress, which is beneficial for humanity.”⁹² In this light, this principle does not and should not hinder continued scientific research aimed at improving genome editing tools in order to reduce the current risks of harm associated with clinical applications of such tools. Considering the potential benefits to the right to health, state parties must “Ensure access to those applications of scientific progress that are critical to the enjoyment of the right to health and other economic, social and cultural rights.”⁹³

When it comes to the question whether or not future clinical applications of genome editing tools are consistent with a human rights framework it must first of all be recalled that individual rights and freedoms are often at play in decision-making on risks, “decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health.”⁹⁴ Despite this, those who discuss what measures must be taken do not necessarily consider the range of individual rights and freedoms that come under pressure as a result of these decisions.

International human rights law ordinarily generates three types of obligations. Firstly, there is the duty to *respect* human rights, which essentially refers to a negative obligation not to take any measures that results in a violation of a given right. Secondly, there is the duty to *protect*

90. UN Comm. on Econ., Soc. and Cultural Rts. [CESCR], General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights (Article 15 (1)(b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights) ¶ 57, U.N. Doc. E/C.12/GC/25 (Apr. 30, 2020) [hereinafter General Comment No. 25 (2020)].

91. *Id.*

92. *Id.*

93. *Id.* ¶ 52.

94. *Communication from the Commission on the Precautionary Principle*, at 2.

human rights, which requires states to provide health care and education to their populations and safeguard the benefits from scientific progress and developments for everyone. The latter presupposes that states are willing not only to allocate resources and invest in science, including innovation, but also to integrate the results of scientific progress into healthcare and educational settings. Finally, there is the duty to fulfill human rights, which means that the state is obliged to take positive steps that lead to the greater enjoyment of rights. Even if all rights generate duties to protect and fulfill additional economic, social and scientific rights, these are paradigmatic of rights that the state can hardly guarantee unless it actively adopts legislative and other measures to protect and fulfill them.⁹⁵

From a human rights standpoint, individual rights and freedoms do not function as mere side-constraints on the democratic decision-making of how to manage risks. That is, such rights and freedoms do not merely *limit* the scope and subject matter of such decisions. Rather, rights will also *guide* and *inform* such decision-making.⁹⁶ Despite this, those who discuss what measures must be taken do not necessarily consider the range of individual rights and freedoms that come under pressure as a result of these decisions. This is so since the question of how to guarantee a particular right, such as to health or to science, can require the allocation of resources and investments in scientific research on new technology that can strengthen the protection and progressive fulfilment of these rights. Therefore, any decision-making on whether or not to invest in future scientific research on human germline editing must consider and weigh the importance of protecting people and future generations from the impact of potentially harmful technology, even if the effects of that technology are uncertain. It furthermore requires protecting people from decisions that effectively prevent or deprive them from benefiting from emerging technology that has the potential of significantly improving the enjoyment of their right to health. In controversial cases, such as clinical human germline editing, a human rights approach stresses the importance of participation and transparency. Both the risks and the potential of genome editing tools “should be made public in order to enable society,

95. Off. of the High Comm’r for Hum. Rts., CESCR General Comment on No. 3: The Nature of States Parties’ Obligations (Art. 2, ¶ 1, of the Covenant), U.N. Doc. E/1991/23 (Dec. 14, 1990), <https://www.refworld.org/pdfid/4538838e10.pdf>.

96. *See generally*, JEREMY WALDRON, LAW AND DISAGREEMENT (1999) (discussing the role of rights in the democratic decision-making process).

through informed, transparent and participatory public deliberation, to decide whether or not the risks are acceptable.⁹⁷

V. CONCLUSION

Whatever decisions are made on the future regulation of human germline editing, whether as a field of scientific research or as an emerging technology with benefits for human health, it must be in line with a series of legal obligations. These obligations entail both acting with due diligence and precaution as well as with respect to protect and fulfill human rights. Per international human rights law, rights can be restricted if deemed necessary to promote the general welfare of society, including for the sake of protecting the health and safety of populations writ large. At the same time, the core significance of each human right, including to health, must be protected and reconciled with measures to prevent risks of harm.

The precautionary principle provides an important justification for regulating activities that pose significant risk of harm to the environment and public health, even if there is no scientific certainty about the probability that harm will actually occur or how grave it will be. From a legal standpoint, in its weak version, it clarifies that the state may well act with due diligence and precaution in the context of scientific uncertainty. In its strong versions, the principle not only permits but requires states to make risk assessments and even to impose sweeping bans. A strong reading of the principle, however, comes into conflict with human rights obligations generated by the right to science and rights of scientists. A society that mainly cares for due diligence and precaution will end up stifling scientific freedom and, as a result, scientific progress, which is a condition for the progressive realization of the right to health. Against this background, it is concluded that the precautionary principle—as valuable as it might be in a society that struggles with environmental degradation and climate change—must not be interpreted in such a way that it impedes continued scientific progress aimed at developing new tools that could be used to protect basic human rights.

97. General Comment No. 25 (2020), ¶ 57.