Draft General Comment on Article 15
Recommendations to the Committee on Economic, Social and Cultural Rights
from scholars in medical law and bioethics from Swedish universities

Summary of Recommendations

The Committee on Economic, Social and Cultural Rights has published a comprehensive Draft General Comment on Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Draft Comment proposes that Article 15 obligates State Parties to support scientific research and innovation and to combat pseudoscience, but otherwise to refrain from the regulation of scientific activities unless it is necessary and proportionate to prevent certain harms. With this general restrictive approach to regulation, however, the Draft Comment raises several concerns in matters of medical law and ethics. It does not adequately set forth the relationship of Article 15 to established rights in UN treaties that obligate State Parties to thoroughly regulate medical practices, experimentation, and research. It also does not adequately recognize the complex national legal and ethical frameworks that are widely respected as essential to preventing and redressing unique harms that medical interventions often pose to human beings. It also lacks any analysis of the relationship of Article 15 to the right to health in several UN treaties. It is, therefore, recommended that the Draft Comment should be revised as follows:

1. The Final Comment should clarify in detail the scope and limitations of Article 15 in connection with all UN treaties that impose binding obligations on State Parties to regulate medical interventions in both medical practice and research.

2. The Final Comment should recognize that State Parties have obligations under international law beyond the UN Framework to regulate biomedical interventions in order to ensure that individuals actually benefit from safe, effective, and ethically sound medical care and research.

3. Regarding the national implementation of Article 15, the Final Comment should formally recognize that Article 15 does not alter any obligations under established international and national frameworks to ensure safe, effective and ethically sound medical care and research. If the Committee intends material changes to this regulatory framework, it should carefully specify and distinguish these intended changes in the Final Comment.

I. Basic Premises and Normative Content (Draft Comment Parts I & II)

A. The Role of Non-Binding Instruments in Interpretation of Article 15 (paras. 1-15)

The Draft General Comment sets forth its basic premises by drawing substantially on the work of UNESCO to underscore how science benefits human rights. As UNESCO has explained, in order to ensure that individuals actually “benefit” from science within the meaning of Article 15, regulation is often needed to prevent harms from scientific advances, as required by the right to health under Article 12 of the ICESCR and other human rights instruments.¹ The Draft Comment, however, only endorses the Universal Declaration of Human Rights (UDHR) and the Universal Declaration on Bioethics and Human Rights in defining the normative content of Article 15, even

¹ UNESCO, The right to enjoy the benefits of scientific progress and its applications (2009), p. 5.
though these instruments do not create binding obligations on State Parties to the ICESCR. The Comment also does not clarify whether these instruments are effectively intended to have any binding effect on State Parties’ obligations under Article 15.

The Final Comment should, therefore, clarify what weight State Parties must give to the UDHR and Universal Declaration on Bioethics and Human Rights in implementing Article 15. It should also explain how these instruments should be weighed against any binding obligations under UN treaties that State Parties to the ICESCR have also ratified. Of particular note, the Draft Comment makes no reference to the International Covenant on Civil and Political Rights (ICCPR), which makes many of the UDHR obligations not only binding on State Parties but prevents State Parties from derogating from these obligations, even in times of emergency. As these rights impose obligations that may affect the promotion of scientific advances, the Comment should recognize that non-derogable rights may often take precedence. The Final Comment should also clarify how State Parties to the ICESCR should implement Article 15 in connection with the right to health in the UN framework. As explained below, the Draft Comment’s lack of detailed analysis of State Parties’ obligations and powers to protect individuals from scientific harms from health-related interventions creates significant potential for normative conflict in national and international law.

B. Interdependence with Other Rights (para. 19)

The Draft Comment currently does not recognize that three UN treaties specifically obligate State Parties to protect human beings from health-related harms in the field of medical sciences. While it quotes from the Committee’s General Comment no. 14 regarding how science can advance human health, it does not thoroughly address how scientific advances may undermine the right to the highest attainable standard of health protected under Article 12 of the ICESCR. Article 12 recognizes that State Parties must ensure that health care is safe and effective by setting standards for medical practitioners and other health professionals and assuring the quality of medicinal products. It also clarifies that the right to health is directly connected to the right to privacy, as protected in multiple UN treaties. Pursuant to Article 24 of the Convention on the Rights of the Child (CRC), the Committee on the Rights of the Child has explained that the right to health obligates State Parties to ensure that pediatric care is based on the best available evidence and that medicines are child-specific. Article 25 of the Convention on the Rights of Persons with Disabilities (CRPD) specifies that the right to health obligates State Parties to ensure that health care does not create further disabilities.

The Draft Comment also does not elaborate on the relationship of Article 15 of the ICESCR to the ICCPR, particularly the right to life (Article 6) or freedom from torture, or cruel, inhuman, or degrading treatment and the freedom from medical and scientific experimentation without free consent (Article 7). These rights are directly extended to children in the ICCPR (Article 24) and to persons with disabilities through the CRPD (Articles 5, 10 and 15). The CRC also protects these rights and freedoms (Articles 6, 24, and 37) and requires State Parties to ensure that

---

2 Human Rights Committee, General Comment No 29: art 4: Derogations during a State of Emergency, CCPR/C/21/Rev.1/Add.11, para 7.
3 Committee on Economic Social and Cultural Rights, General Comment No. 14, The right to the highest attainable standard of health (2000), para. 12.
4 Committee on the Rights of the Child, General Comment no. 15, on the right of the child to the enjoyment of the highest attainable standard of health, para. 116.
children are protected in clinical research according to ethical guidelines set forth by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO). While the Human Rights Committee has not elaborated on the full scope of the concept of “experimentation” addressed by Article 7 of the ICCPR, several Special Rapporteurs have noted that numerous medical interventions on vulnerable groups are of dubious scientific character and violate the freedom from torture and cruel, inhuman and degrading treatment. Because all of these rights are non-derogable, State Parties cannot favour scientific experimentation and other claimed innovations in ways that undermine these rights.

The ESCR Committee must clarify the scope of Article 15 in terms of these rights. At a minimum, the Final Comment should recognize that any Parties’ efforts to implement Article 15 do not relieve them of their other obligations under UN treaties to protect the full array of rights that are related to biomedical interventions. The Final Comment should, if necessary, formally remain open to a future Joint Comment with other UN committees on the relationship of Article 15 to the right to health and all non-derogable rights.

II. Elements of the Right

A. The Possibility of Limitations on the Rights ( paras. 20-49)

The Draft Comment currently addresses the permissibility of regulation of medical science in broad terms in ways that are not adequately grounded in medical ethics, national law, or treaties outside the UN framework. It notes only that “some” regulation may be necessary to protect people’s “dignity, identity and integrity” and the right to “free and informed consent to medical interventions”. It also, however, provides that State Parties should ensure the “innocuous character” of “new scientific applications” but should rely deferentially on “agreed scientific knowledge, in dialogue with the scientific community”. It asserts that “limits on scientific activity or on the access to its benefits ... are at the same time necessary and risky” and requires that all regulation must be “necessary” and “proportionate”. This is also a concern as it asserts that State Parties must ensure individuals the “complete freedom” to “best choose the treatment they want” and protect “the people from researches [sic] or tests” only if they “contravene the basic principles of the medical profession”. The Draft Comment offers no authority for such tests or for the legitimacy of such limits and standards for the regulation of medical practice and clinical research.

Prior to the opening of the ICESCR for signature, the World Medical Association’s Declaration of Helsinki in 1964 recognized that “[d]octors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries” and may combine “clinical research with

---

5 Ibid. para 85.
7 Draft Comment, para. 29.
8 Ibid. 25.
9 Ibid. 28, 30 & 32.
10 Draft Comment, para. 48.
professional care” only if it is “justified by its therapeutic value of the patient”. While the Declaration originally proposed that an individual doctor “must be free” to use professional judgment for new therapeutic measures, the WMA has eliminated that language and increased the duties of medical professionals to submit their research to special protections for participants. Today, the CIOMS/WHO Guidelines go much further in requiring researchers to comply with the law in several areas, including requiring researchers to compensate for injuries that their research may cause, as well as to be subject to ethical review committees for research approval, and to protect vulnerable groups of individuals, such as children and persons with disabilities.

The Draft Comment also does not reflect the well-recognized importance of national law to protections of persons receiving medical care or undergoing research, which State Parties are obligated to enforce under other international instruments. The European Convention on Human Rights, for example, obligates 47 nations to require “high professional standards” and have regulatory frameworks to protect the life and safety of patients. It also requires those states to ensure that criminal and civil penalties are in place when patients die in health care, and that tort law and discipline redress medical negligence. The Convention on Human Rights and Biomedicine currently obligates 29 of these nations to make quality assessments to ensure that medical interventions are assessed in light of scientific progress and eliminate those that are not state of the art in light of current scientific knowledge. It requires that all biomedical interventions “must be performed in accordance with the law in general”, guided by professional standards, but with numerous mandatory legal protections for persons undergoing biomedical research, including compensation for harms or access to court to stop rights violations.

The Draft Comment does not clarify the impact that the Committee’s proposed interpretation of Article 15 will have on this framework. The Final Comment, therefore, must more clearly and carefully distinguish the established global and national frameworks of medical law and medical ethics from general regulation of the “natural and social sciences”.

B. Pseudoscience and Scientific Misconduct (paras. 48-49).

The Draft Comment provides that State Parties have positive obligations under Article 15 to “establish protective measures in relation to messages from certain pseudoscience which, often due to purely economic interests, create ignorance and false expectations among the most vulnerable parts of the population”. The Draft Comment does not, however, recognize that many false scientific claims are generated in established medical research and clinical practice, which makes the scientific harms they cause all the more dangerous. The Comment notes, for example, that many parents “decide not to vaccinate their children on grounds the scientific community considers false”. The Comment does not acknowledge, however, that the claims about the links between autism and vaccines spread rapidly precisely because distorted data was published in

---

11 WMA, Declaration of Helsinki 1964, preamble and II.2.
12 WMA, Declaration of Helsinki (2013), para. 10, 14, 18, 23 & 37.
14 Ibid.
The Lancet and then used to advance those claims. The scientific misconduct behind this flawed science has aptly been described as “the most damaging medical hoax of the last 100 years”.16

The Committee should clarify any obligations and limitations that it intends to place on State Parties regarding scientific misconduct. In recent well-known cases of unlawful experimentation in Sweden and China, the experiments were not only facilitated by the falsification of documents and data but prevented oversight of the activity until the activity reached the level of crimes.17 The Final Comment should, therefore, clarify the authority of State Parties to investigate and prevent scientific misconduct before it leads to further harms to individuals, particularly when that misconduct takes place at State Parties’ facilities and is financed by those State Parties.

III. National Implementation of the Right (paras. 84-88)

The Draft Comment concludes that State Parties have a “wide margin” of discretion in establishing a normative framework for the implementation and realization of Article 15, though throughout the Comment it requires that such regulations must be “necessary” and “proportionate”. These two standards of validity of regulation are in tension other as a matter of law, with the former of these standards generally requiring considerable deference to national legal orders to determine which regulations are appropriate, especially in matters that require complex factual and scientific inquiries. In this light, if the Committee intends material changes to current regulatory schemes for medical science and research and protections for human rights in this field, it should more clearly specify those intended changes in the Final Comment.

Jameson Garland
LL.D., Doctor of Medical Law
Uppsala University
Department of Law
corresponding author
Jameson.Garland@jur.uu.se

Heidi Howard,
PhD (molecular genetics)
& Msc (Bioethics)
Uppsala University
Center for Research Ethics and Bioethics

Santa Slokenberga
LL.D., Doctor of Medical Law
Lund University
Department of Law

Kavot Zillén
LL.D., Doctor of Medical Law
Stockholm University
Department of Law

Therése Fridström-Montoya
LL.D., Doctor of Public Law
Uppsala University
Department of Law

17 For scientific misconduct behind the unlawful use of experimental implants in Sweden, see Michael Day, Disgraced tracheal transplant surgeon is handed 16 month prison sentence in Italy, 2019 BMJ 16676. For unlawful gene editing of children in China, see Caroline Johnson, Chinese scientist who claimed to create gene-edited babies sentenced to 3 years in prison, Washington Post, 30 December 2019.