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**REPORT No. 204/19**

**PETITION 126-10**

REPORT ON ADMISSIBILITY

G.F.C.C. AND OTHERS

PERU

Electronically approved by the Commission on December 6, 2019.

**Cite as:** IACHR, Report No. 207/19, Petition 126-10. Admissibility. G.F.C.C. and others. Peru. December 6, 2019.

**I. INFORMATION ABOUT THE PETITION**

<b>Petitioner:</b>	Legal Defense Institute (IDL)
<b>Alleged victim:</b>	G.F.C.C. and others <sup>1</sup>
<b>Respondent State:</b>	Peru <sup>2</sup>
<b>Rights invoked:</b>	Articles 4 (life), 5 (humane treatment), and 19 (rights of the child) of the American Convention on Human Rights, <sup>3</sup> in relation to its Articles 1.1 (obligation to respect rights) and 2 (domestic legal effects); Article XI (health and well-being) of the American Declaration of the Rights and Duties of Man; <sup>4</sup> and article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights <sup>5</sup>

**II. PROCEDURE BEFORE THE IACHR<sup>6</sup>**

<b>Filing of the petition:</b>	February 2, 2010
<b>Notification of the petition to the State:</b>	August 16, 2011
<b>State's first response:</b>	September 10, 2014
<b>Additional observations from the petitioner:</b>	March 14, 2012; December 29, 2017
<b>Additional observations from the State:</b>	January 30, 2018
<b>Notification of the possible archiving of the petition:</b>	October 14, 2016
<b>Petitioner's response to the notification regarding the possible archiving of the petition:</b>	December 29, 2017

**III. COMPETENCE**

<b>Competence <i>Ratione personae</i>:</b>	Yes
<b>Competence <i>Ratione loci</i>:</b>	Yes
<b>Competence <i>Ratione temporis</i>:</b>	Yes
<b>Competence <i>Ratione materiae</i>:</b>	Yes. American Convention (deposit of instrument of ratification on July 28, 1978); American Declaration (ratification of OAS Charter on February 12, 1954); Protocol of San Salvador (deposit of instrument of ratification on June 4, 1995)

**IV. DUPLICATION OF PROCEDURES AND INTERNATIONAL *RES JUDICATA*, COLORABLE CLAIM, EXHAUSTION OF DOMESTIC REMEDIES AND TIMELINESS OF THE PETITION**

<b>Duplication of procedures and International <i>res judicata</i>:</b>	No
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<sup>1</sup> Diana Mercedes Canessa Garay, mother of G.F.C.C., a minor, and Johana Pilar Sánchez Turriate, mother of J.A.F.C.S., a minor.

<sup>2</sup> Pursuant to the provision of Article 17.2.a of the IACHR Rules of Procedure, Commissioner Francisco José Eguiguren Praeli, a Peruvian national, did not participate in the discussion or voting on this matter.

<sup>3</sup> Hereinafter "American Convention" or "Convention."

<sup>4</sup> Hereinafter "American Declaration" or "Declaration."

<sup>5</sup> Hereinafter "Protocol of San Salvador."

<sup>6</sup> The observations submitted by each party were duly transmitted to the opposing party.

<b>Rights declared admissible</b>	Articles 5 (humane treatment), 11 (privacy), 13 (freedom of expression and thought), 19 (rights of the child), 24 (equal protection), and 26 (economic, social, and cultural rights) of the American Convention in relation to its Articles 1.1 and 2; article XI (health and well-being) of the American Declaration
<b>Exhaustion of domestic remedies or applicability of an exception to the rule:</b>	Yes. August 6, 2009
<b>Timeliness of the petition:</b>	Yes. February 2, 2010

## V. ALLEGED FACTS

1. The petitioner claims that in February 2005, G.F.C.C. and J.A.F.C.S., ages nine and nineteen months then, were subjected to an experiment consisting in the administration of a transgenic rice-based oral rehydration solution supplemented with human proteins found in breastmilk, to treat diarrhea.<sup>7</sup> Allegedly, the mothers were not provided with complete information on the side effects of this treatment, whilst it was the first time the experiment was being performed on human beings. The petitioner submits that the mothers of G.F.C.C. and J.A.F.C.S. were deceived with the promise of receiving preferential treatment, including free diapers and other gifts; and that because of their low economic background, they were persuaded into making a misguided wrong. It argues that if the mothers had had adequate information, they would never have accepted this medical treatment and that it was thanks to the Peruvian Medical Association's complaint that they learned that their children had been subjected to a clinical trial. It alleges that this experiment involved grave violations of, *inter alia*, the Declaration of Helsinki<sup>8</sup> and that Peruvian officials failed to properly evaluate the research project before it was conducted in children.<sup>9</sup> The petitioner requests that the State grant the alleged victims a comprehensive health insurance policy for life, as well as pecuniary reparation since it is unknown what future side effects the clinical trial may have on the alleged victims.

2. According to the petition, the facts were brought to the attention of local authorities on June 2, 2006, when the Peruvian Medical Association filed a complaint with Provincial Criminal Public Prosecutor's Office No. 5 of Lima, for abuse of power, bribery, and neglect of child. The petitioner states that on June 13, 2006, it demanded the authorities to take the statement of the alleged victims' mothers and that on July 11 and 13, 2006, under article 14 of the Federal Law on Health, it requested a copy of the children's medical record. On July 21, 2006, the Public Prosecutor's Office took the statement of the mothers. On December 20, 2007, the Public Prosecutor's Office decided not to file a criminal complaint, on considering that the facts reported did not fit in the criminal concepts of crime against life, physical safety, and health; neglect of persons by exposure to life-threatening risk or serious and imminent damage to health; or crime against public administration and abuse of power to the detriment of the alleged victims. The petitioner appealed the refusal on December 27, 2007 and August 22, 2008. On December 20, 2007, the Superior Criminal Public Prosecutor's Office No. 3 of Lima revoked the prosecutor's resolution. However, on December 30, 2008, the Provincial Prosecutor's Office again decided not to file a criminal complaint and dismissed the matter. On January 8, 2009, the Peruvian Medical Association appealed this refusal, claiming that the resolution challenged had been passed without the authorities' undertaking all the procedures necessary to clarify the facts—given the existence of serious contradictions and inconsistencies and the authorities' failure to verify if the experiment was conducted under international and Peruvian norms. On June 18, 2009, the

<sup>7</sup> The petitioner indicates that the research was led by Ventria Bioscience, University of California, Davis, from the United States, and the Peruvian Nutrition Research Institute ("IIN"). It submits that after an evaluation from the IIN Ethics Committee, the project was approved by resolution of January 20, 2003. Likewise, the executive director of the technology research and development division of the National Institute of Child Health issued an opinion in favor of the project by a resolution dated January 22, 2003.

<sup>8</sup> Declaration passed in 1964, by the World Medical Association (WMA), as a statement of ethical principles for medical research on human subjects, including research on identifiable human material and data.

<sup>9</sup> The record includes a report prepared by the Ombudsman's Office, which observed that the National Institute of Child Health has not questioned the lack of observance of some ethical principles mentioned in the Helsinki Declaration and that the Ministry of Health has given imprecise information to the public, on the clinical study. It submits that the Peruvian authorities approved a consent form that was inadequate as it did not contain complete and relevant information on the treatment and the research project.

Superior Criminal Public Prosecutor's Office of Lima found the appeal inadmissible and on July 24, 2009, the Attorney General's Office resolved not to file a preliminary investigation. This decision was notified to the petitioner on August 6, 2009.

3. The State alleges the petitioner's lack of exhaustion of domestic remedies. It claims that it was not the alleged victims that submitted the complaint, but the Peruvian Medical Association. It contends that the facts that were the subject matter of the Association's complaint are not the same as those raised in this petition to the IACHR. It argues that the complaint refers to Supreme Decree 013-2005-SA, authorizing the import, distribution, and use of pharmaceuticals and other similar products as long as they were not for sale. While the initial petition refers to the said decree, this is not strictly related to the approval of the clinical test. It further submits that the resolution passed by prosecutor's office concerned the former minister of health only and did not refer to other officials allegedly responsible for the delayed irregular approval of the clinical trial. It believes that although the children are the harmed party in the investigation, in a strict sense, remedies were not filed or exhausted by their mothers and/or legal representatives. It also contends that the petitioner did not pursue internal mechanisms to obtain compensation or comprehensive health insurance, which petitioner requests in the petition to the IACHR.

4. The State moreover alleges that the facts raised in this petition do not violate any of the rights invoked by the petitioner. It contends that without proving real harm to the child's health or safety, or their mothers', this petition is based simply on general allegations regarding purported damage in that the documentation provided did not specify the risks involved in the research project. The State argues that it has adopted a series of measures to prevent risks to children's life and health in clinical trials. It also highlights that, according to the consent form, the mothers had the opportunity to ask any question they had to the professionals leading the clinical trial. It also indicates that there is no prohibition on conducting clinical trials in children.

5. The State invokes the exception of competence given the matter of the alleged violation of the right to health, claiming that only those rights recognized in articles 8 and 13 of the Protocol of San Salvador may be enforceable in the IACHR system of individual petitions. Likewise, it alleges that the right to health may not be analyzed under the American Convention, as this recognizes civil and political rights, not economic, social, and cultural rights; that the Convention sets forth obligations for Member States to adopt different types of measures for the progressive fulfillment of those rights, instead. Therefore, it argues that the right to health may not be enforced before the inter-American human rights system.

## **VI. ANALYSIS OF EXHAUSTION OF DOMESTIC REMEDIES AND TIMELINESS OF THE PETITION**

6. The Commission believes that domestic remedies shall be deemed exhausted once the filing of adequate and useful remedies for protecting the alleged rights is proven, despite the fact that these remedies were filed by and granted to a legal entity, and that the claims raised in the internal proceedings coincide with the alleged violations brought to the attention of the inter-American system. In this regard, the I/A Court H.R. has established that the existence and action of a legal entity acting on behalf of a natural person, the alleged victim of a human rights violation, should not pose an obstacle, hindrance, or excuse for the State not to fulfill its obligations.<sup>10</sup> The Commission observes that the complaint filed by the Peruvian Medical Association before Provincial Criminal Prosecutor's Office No. 5 of Lima refers to the situation of the child alleged victims as the people injured, meaning that the State had the opportunity to remedy the matter reported to the domestic authorities. It also observes that the alleged victims' mothers requested that the medical records of their underaged children be attached to the file of the complaint and that authorities take their statements. On June 18, 2009, the Superior Criminal Public Prosecutor's Office of Lima dismissed the appeal, and by a resolution of July 24, 2009, the Attorney General's Office ruled not to file a preliminary

<sup>10</sup> I/A Court H.R., Advisory Opinion. OC-22/16 of February 26, 2016. Entitlement of legal entities to hold rights under the Inter-American Human Rights System (Interpretation and scope of Article 1(2), in relation to Articles 1(2), 8, 11(2), 13, 16, 21, 24, 25, 29, 30, 44, 46 and 62(3) of the American Convention on Human Rights, as well as of Article 8(1)(A) and (B) of the Protocol of San Salvador). Series A No. 22, para. 40 (available in Spanish).

investigation and to close the case. The Commission observes that although the State alleges the lack of exhaustion of domestic remedies, it does not specify the adequate and useful remedies to exhaust. Accordingly, the Commission finds that since this ruling exhausted the domestic remedies, the petition meets the requirement in Article 46.1.a of the Convention. As to the date of filing, the Attorney General's decision was notified on August 6, 2009, and the petition to the IACHR was filed on February 2, 2010. In view of this, the Commission finds that the petition meets the requirement set forth in Article 46.1.b of the Convention.

7. Regarding the claim for damages, the Commission has repeatedly established that a claim before the contentious-administrative jurisdiction is not an adequate means to assess the admissibility of a petition of this nature, for it is inadequate to provide measures of full reparation and justice to the family.

## VII. ANALYSIS OF COLORABLE CLAIM

8. In view of the elements of fact and law submitted by the parties, and the nature of the matter brought to its attention, the Commission believes that, if proven, the pleadings concerning the alleged victims' participation in the clinical trials without free, prior, and informed consent; and the lack of protocols and frameworks of ethical standards to protect this population from any risk involved in the application of clinical trials or research all may establish violations of articles 5 (humane treatment), 11 (privacy), 13 (freedom of expression and thought), 19 (rights of the child), 24 (equal protection), and 26 (economic, social, and cultural rights) of the American Convention, in accordance with its Article 1.1 (obligation to respect rights) and 2 (domestic legal effects).

9. As regards to the allegations of violations of Article XI (health and well-being) of the American Declaration, the IACHR has previously established that once the American Convention enters into force with respect to a State, it is that instrument, and not the Declaration, that becomes the specific source of law to be applied by the Inter-American Commission, provided that the petition alleges violations of rights of identical substance upheld by both instruments. Thus, considering that Article 26 of the American Convention refers broadly to the economic, social and cultural rights, and that these rights should be analyzed in relation to the OAS Chart and other relevant legal instruments, the IACHR deems that where a specific violation of the Declaration is alleged in relation to the general content of said article 26, the analysis of its interplay and common scope should be made at the merits stage.

10. As to the claim about a possible violation of Article 4 (life) of the American Convention, the Commission notes that the petitioner has not provided enough allegations or evidence to *prima facie* establish a possible violation.

11. As for the allegation regarding the violation of article 10 of the Protocol of San Salvador, the IACHR notes that under article 19.6 of the same treaty, its competence to determine violations in an individual petition is limited to articles 8 and 13. With respect to the other articles, pursuant to Article 29 of the American Convention, the Commission may consider them to interpret or apply the American Convention or other instruments applicable.

## VIII. DECISION

1. To declare the instant petition admissible in relation to Articles 5, 11, 13, 19, 24, and 26 of the American Convention, in accordance with its Articles 1.1 and 2, and Article XI of the American Declaration; and

2. To declare the instant petition inadmissible in relation to Article 4 of the American Convention; and

3. To notify the parties of this decision; to continue with the analysis on the merits; and to publish this decision and include it in its Annual Report to the General Assembly of the Organization of American States.

Approved by the Inter-American Commission on Human Rights on the 6<sup>th</sup> day of the month of December, 2019. (Signed): Esmeralda E. Arosemena Bernal de Troitiño, President; Joel Hernández, First Vice President; Antonia Urrejola, Second Vice President; Margarete May Macaulay, Luis Ernesto Vargas Silva, and Flávia Piovesan, Commissioners.