

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

**STATE COUNCIL
COURT OF ADMINISTRATIVE LITIGATION
FIRST CHAMBER**

Presiding Judge: Doctor Rafael E. Ostau de LafontPianeta

Bogota, Capital District, five (5) June two thousand and eight (2008)

File number: 11001 0324 000 2002 00251 01

Claimant: CARLOS HUMBERTO GOMEZ ARAMBULA

The Court will decide, in the only instance, the case herein referenced, brought as an action to invalidate against the National Institute for Control of Medicines and Food (INVIMA), for having granted a health certificate allowing for the importation and sale of a certain pharmaceutical product.

I. THE CLAIM

Private citizen CARLOS HUMBERTO GOMEZ ARAMBULA, bringing a claim to invalidate under Article 84 of the CCA [Translator's note: Acronym is not defined in the text], requests that the State Council, following an ordinary proceeding, carry out the following:

1. Petition

Declare Resolution No. 266285, dated 14 September 2000, through which INVIMA granted the Association for the Well Being of Colombian Families, or PROFAMILIA (Asociación Probienestar de la Familia Colombiana), a health certificate allowing for the importation and sale of the pharmaceutical product POSTINOR 2 for a period of 10 years, to be invalid.

2. Statements and Omissions in the Claim

In summary, the actor refers to the effects of POSTINOR 2 during pregnancy and the formation of human life, in the sense that this drug acts after fertilization of an egg and prior to implantation, in such a way that it prevents the mucus lining of the uterine wall from accepting the already fertilized egg, and as a result causes the death of the human life resulting from the union of the masculine spermatozoid and the feminine egg prior to its arrival to the mother's uterus, and then deliberately suppresses a human life in its initial phases, thereby violating the right of all persons to life, which attaches from the moment of conception and lasts until the moment of natural death.

The claim argues that this product does not avoid an encounter between the spermatozoid and the egg, given that it has been scientifically demonstrated that, moments after the sexual act, a large number of spermatozoids will already have reached the Fallopian tubes, where they meet with the egg. As a result, the action of the drug must always be after the spermatozoids meet with the egg, and will always prevent the implantation of the human embryo in the mother's uterus.

3. Laws violated and manner of the violation

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

The claim argues that the following laws are violated by the resolution, for the reasons set forth below: Articles 1, 2, 11, 13, 14 and 16 of the Political Constitution, Article 3 of the Universal Declaration of Human Rights, Article 6 of the International Covenant on Civil and Political Rights, as approved by Law 74 in 1968, Article 4 of the American Convention on Human Rights, or the Pact of San Jose, as approved by Law 16 in 1972, the Preamble to the Convention on the Rights of the Child, as approved by Law 12 in 1991, Article 91 of the Civil Code, and Article 3 of Decree 2737 of 1989, and the Code regarding Children.

3.1 Respect for human life is the primary condition for the existence and development of the community, and any attack thereon leads to the so-called “Culture of Death”, in which abortion is justified, given that the defense that human life is a right that society and the State must protect, and is guaranteed under the Political Constitution and the other legal standards listed above as having been violated, and is the base for all other rights.

3.2 The legal use of abortion drugs presupposes a step toward the dissemination of the aberrant mentality that considers the “right to abortion” to be an achievement, and the sale of POSTINOR 2 will increase its commission or frequency, and will as a result eliminate the mental barrier that exists in respect of this unlawful act.

3.3 As support for its allegations, the claimant cites to and comments on various legal texts and jurisprudence, including decisions T-179 of 1993, C-133 of 1994, and SU-491 of 1993, and ends with a quote from the encyclical letter written by Pope John Paul the Second on March 25, 1995, affirming that even if a child is not wanted, there is no reason to kill that child, but instead that the child could be put up for adoption. For the protection of such children, the State has created institutions such as the ICBF.

II. THE RESPONSE TO THE CLAIM

1. The Association for the Well Being of Colombian Families, or PROFAMILIA, acting as an interested third party in these proceedings, as a beneficiary of the law in question, is opposed to the allegations set forth in the claim and argued that the facts on which the claim is based are not true, given that POSTINOR 2 is classified as an emergency contraceptive, as it is not meant to be used on a regular basis. The drug is instead an emergency treatment that is exclusively to be used within 72 hours following unprotected sex, in order to prevent pregnancy, rather than terminating a pregnancy, given that the egg loses its capacity to develop into an embryo, according to scientific reports in respect of the drug’s function. After the drug takes effect, there is no egg available to be fertilized.

As a defense, the interested third party argues that the action to invalidate must be based on strictly legal grounds, without any religious, moral or theological connotations, and in this case the claimant is bringing a claim on religious and theological grounds in order to classify POSTINOR 2 as an abortion drug that facilitates a culture of death. With all due respect to these arguments, they cannot be presented in a court of law.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

The interested third party argues that the claimant confuses the terms “fertilization” and “conception”, which have different scientific meanings, and in respect of which there exists extensive discernment, in various senses of the words. In this regard, the interested third party notes that “conception” is the moment of implantation in the uterine wall, which is not a synonym for “fertilization”, which generally occurs within a few hours of ovulation, in the middle third of the Fallopian tube. Medical science defines the beginning of a pregnancy as the moment in which the fertilized egg implants itself in the endometrium (the mucosal lining covering the uterus), and occurs within a period of 6 or 7 days after intercourse.

In addition, the interested third party presents an extensive argument in respect of the fact that emergency contraception supports women’s sexual and reproductive rights, and the emergency contraception provided by POSTINOR 2 does not cause an abortion.

The interested third party concludes by stating that the approval of the resolution in question does not violate any of the legal standards invoked by the claimant, and should not be invalidated as a result. The interested third party requests that the third party’s claims be denied.

2. The legal representative of INVIMA is also opposed to the pretensions of the claim, given the fact that the resolution in question was passed in full observance of the applicable constitutional and legal framework, and argues that POSTINOR 2 is not an abortion drug, and as a result does not result in the death of a human life, but is instead an emergency contraceptive that prevents pregnancy. Its principal active ingredient is levonorgestrel, a substance that is found in innumerable contraceptive pills.

In defense of the resolution in question, the legal representative of INVIMA argues that it had the authority to issue it, under Articles 2 and 4, numerals 1 and 5, of Decree 1290 of 1994, and the resolution was issued in keeping with the procedures outlined in Decree 677 of 1995 for new medicines such as POSTINOR 2, with the strict complexity and rigor as applied to other medications. As a result, no legal standard whatsoever was violated.

3. The citizen Beatriz Helena Quintero Garcia, holding identity card No. 32.483.584, of Medellin, and recognized as a party to the proceedings, presented a brief in which, without specifying her position in respect of the petitions of the claimant, in summary, argues that in support of the right to material equality, it is hardly possible that there not be available a variety of options to allow women to have the opportunity to control their fertility and to use birth control, while respecting individual rights, psychosocial practices of different persons, and their physical particularities. One way to allow women to regulate their own fertility is through the use of chemical contraceptive methods, such as Postinor 2 (page 172 of the record of the proceedings).

4. Another brief was presented by the citizen Maria Ximena Castilla Jimenez, supporting the arguments of the respondent, the Ministry of Health and INVIMA and the arguments made by PROFAMILIA. The brief argues that abortion is not equivalent to murder, that each woman’s body is her own, and that the cited jurisprudence is not applicable to the case at hand.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

5. The National Medical Association (pages 203 to 205 of the record of the proceedings), the Chilean Institute of Reproductive Health (pages 221 and 222 of the record of the proceedings), Pio Ivan Gomez Sanchez (pages 257 to 260 of the record of the proceedings), the Center for Reproductive Rights (pages 265 to 273 of the record of the proceedings), Efrain Otero Ruiz (pages 345 to 347 of the record of the proceedings), and the International Federation of Family Planning / Western Hemisphere Region (pages 350 and 351 of the record of the proceedings) also presented briefs challenging the claim, presenting arguments similar to those raised in the response to the claim, and in agreement with the classification of the drug POSTINOR 2 as an emergency contraceptive due to the principal active ingredient that it contains, levonogestrel, which, prior to preventing the implantation of the fertilized egg in the uterine wall, prevents ovulation. Such briefs are recognized by the Court in their entirety.

III. EVIDENCE

In addition to the evidence presented by the actor as required by law, various documents relevant to the issue were presented to the Court as evidence, including in respect of the administrative procedural history of the resolution and a report from the National Institute of Legal Medicine and Forensic Science regarding the issue *sub judice* (page 200 of the record of the proceedings).

IV. CONCLUDING ARGUMENTS

The legal representatives of PROFAMILIA and INVIMA in this opportunity reiterated and complemented the arguments they presented in their respective responses to the claim.

V. BRIEF OF THE PUBLIC OMBUDSMAN

The representative of the Public Ombudsman, Corporate Delegate, stated that, according to scientific documents, POSTINOR 2 causes the ovaries to lose the ability to ovulate adequately, and as such, has a contraceptive effect. The drug does not cause any change in the receptive capacity of the endometrium or in the capacity of the mucosal lining of the uterus to receive and to allow the implantation of a fertilized egg. In this sense, this product does not interrupt pregnancy, but prevents it. The authorization of the registration of this drug does not create a violation of the right to life, given that contraceptives are permitted in order to guarantee the fundamental rights of women. In this regard, the representative cites to decision C-355 of 2005, and concluded by stating that the issuance of the resolution in question does not violate the rights aforementioned. As such, the representative requested that the claimant's arguments be denied.

VI. LEGAL ANALYSIS

1. The act giving rise to the claim

The act giving rise to the claim is Resolution No. 266285, dated 14 September 2000, through which INVIMA granted the Association for the Well Being of Colombian

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

Families, or PROFAMILIA, a health certificate allowing for the importation and sale of the pharmaceutical product POSTINOR 2 for a period of 10 years.

The resolution indicates in the section regarding the drug's PRINCIPAL ACTIVE INGREDIENT that "EACH TABLET CONTAINS 0.75 MG OF LEVONORGESTREL".

In the section of the resolution entitled "Indications for Use", it is stated that, "THIS IS A PHARMACEUTICAL INDICATED FOR USE AS AN EMERGENCY CONTRACEPTIVE MEASURE, WHICH CAN AVOID PREGNANCY, AS LONG AS USED WITHIN 72 HOURS OF UNPROTECTED INTERCOURSE".

From the section of the resolution entitled "MEDICAL CONTRAINDICATIONS", the following should be highlighted:

"FOR PATIENTS WHO ARE NOT ALREADY PREGNANT, THE USE OF THIS DRUG HAS NO OTHER MEDICAL CONTRAINDICATIONS WHATSOEVER".

"THIS DRUG IS RECOMMENDED FOR USE IN THE EMERGENCY SITUATIONS ENUMERATED ABOVE, AND SHOULD NOT BE USED AS A REGULAR MEANS OF BIRTH CONTROL. SPECIALIZED USE. MEDICINE FOR EXCLUSIVE DISTRIBUTION BY PROFAMILIA".

The act in question is a specific administrative resolution, and was issued within an administrative procedure initiated in exercise of the right to petition for a private interest, by the petitioner, the Association for the Well Being of Colombian Families, or PROFAMILIA. This procedure gave rise to the right under the authorized registration—that is, to import the product in question.

However, given that the act in question deals with an act of registration, it is therefore susceptible to challenge through the action to invalidate brought by the claimant, as per Article 84, final paragraph, of the CCA, which states that, "The invalidation of service circulars and acts of certification and registration may also be requested".

2. Examination of the evidence

2.1 The principal question of the sub lite

The central factual issue of the sub lite consists in establishing whether or not the product authorized by the health certification in question is a contraceptive or an abortifacient, and whether or not it endangers human life. The abortifacient nature of the drug, as presumed in the claim, leads the claimant to the conclusion that POSTINOR 2 is an abortion drug because it prevents not fertilization, but always the implantation in the uterine wall of the fertilized egg.

From this, the legal issue that this Court must rule on, considering all the evidentiary elements related to the facts and the relevant laws and legal standards, is, concretely, if the challenged act was or was not issued on false pretenses—that is, if the resolution was issued based on the fact that the pharmaceutical product in question is an

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

emergency contraceptive (EC) and if, as a result, it does or does not violate the higher applicable laws (supra, the Constitution and other legal norms) invoked by the claimant.

2.2 Classification of POSTINOR 2

2.2.1 Regarding the challenged act

In the resolution herein challenged, as per the transcript of the resolution in which the question at issue is formulated, the product is described as a CONTRACEPTIVE, as long as it is administered within 72 hours following intercourse, and is as result referred to as an EMERGENCY CONTRACEPTIVE (EC).

This classification is based on the drug's principal active ingredient, which is LEVONORGESTREL (LNG), in a dose of 0.75 mg.

The principal active ingredient is a compound or a mix of compounds that has a pharmacological effect—that is, it has the effects of a pharmaceutical or a medicine. The dictionary of the Royal Academy of the Spanish Language defines it as a substance that is contained in a pharmaceutical or a drug, and which as a result gives such ingredient its particular medicinal properties.

It is accepted that levonorgestrel is a biologically active synthetic form of progesterone, and as such has anti-estrogen properties, for which it is used as an oral contraceptive.

The drug levonorgestrel acts by preventing ovulation, without having an important effect on the endometrium, and it is not effective after the implantation of the zygote or egg (the cell resulting from the union of the masculine gametes with the feminine gametes in sexual reproduction of organisms) has begun, as will be explained below.

2.2.2 Regarding the evidence and literature available in respect of this issue

From the material presented into evidence and the official information or documentation available on the subject it can be inferred, without a doubt, that POSTINOR 2, due to its active ingredient, is a contraceptive, as it provides for the possibility of preventing the fertilization of an egg in the majority of cases (at least 75 %) in which it is administered within the 72 hours following unprotected intercourse, in a dose of two (2) pills, taken at the same time or at an interval of 12 hours between the two doses.

This preventative effect results from the action of the drug's principal active ingredient to negate or retard the migration or ascent of the spermatozoid into the uterus, making it more difficult for the spermatozoid to come into contact with the egg, after ovulation, as well as retarding the process of ovulation when ovulation has not taken place at the time of the intercourse, and throughout the time period that the spermatozoid are able to survive in the uterine environment.

Once fertilization has occurred, the active ingredient does not have the capacity to act directly upon the fertilized egg, and after the implantation or fixing of the fertilized egg

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

in the endometrium, the drug cannot have any effect upon such implantation. That is, the drug does not have any effect on a pregnancy or on a fetus.

Therefore, as a result, it has not been demonstrated that the drug interrupts or affects pregnancy, or, that is to say, that it has an abortifacient or harmful effect on the fertilized egg, and less so, once the fertilized egg has already been implanted in the uterine wall.

The above is based on the following evidence:

2.2.2.1 At the claimant's request and as evidence in the proceedings, an opinion was obtained from the Colombian Institute of Legal Medicine and Forensic Science in respect of whether POSTINOR 2:

- a) Acts after the union of the spermatozoid and the egg.
- b) Prevents the implantation or attachment of the human embryo to the mother's uterus.
- c) Harms or causes the death of the human embryo.

The response from the aforementioned institution is quoted below:

"The drug POSTINOR is used medically as an emergency contraceptive administered in a dose of 2 tablets daily.

The drug uses a synthetic hormonal compound (Levonorgestrel 0.75 mg), which acts on several levels. First, the drug reduces vaginal and cervical mucus, which makes it difficult for the spermatozoid to reach the middle third of the Fallopian tube, where fertilization takes place. Second, the drug reduces the contractility within the Fallopian tubes, making it more difficult for the spermatozoid to reach the egg. Finally, levonorgestrel changes the surface of the endometrium, making it hostile to implantation.

Levonogestrel causes no direct harm to the human embryo.

It should be noted that in studies undertaken on women who have used this method of contraception, highly sensitive pregnancy tests have shown negative results, indicating that no pregnancy occurred, and as a result, that no abortion occurred." (Page 200 of the record of the proceedings.)

2.2.2.2 The World Health Organization (WHO) has classified levonorgestrel in a double dose of 0.75 mg, or a single dose of 1.5 mg, as an emergency contraceptive (EC).

This is noted, for example, in the Informational Bulletin on Family Planning from October 2005¹, which states that, "It has been demonstrated that emergency

¹ From the WHO web page.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

contraceptive pills (ECP) that contain levonorgestrel prevent ovulation, and do not have any observable effects on the endometrium (the inner lining of the uterus) or on progesterone levels, when administered after ovulation”, and notes that ECP are not effective once the implantation process has occurred, and that they do not cause abortion. (Underlined text not in the original.)

The Global Manual for Family Planning Providers, 2007 Edition, prepared by the WHO,² states that Emergency Contraceptive Pills are, “Pills that contain only progestin, or progestin and estrogen together”, and “act fundamentally to avoid or to delay the release of eggs from the ovaries (ovulation). They are not effective if a woman is already pregnant”. (page 45)

In answer to the question, what pills can be used as emergency contraceptive pills? The handbook indicates, along with three others and in the primary list, “a particular ECP that contains the progestin levonorgestrel”. (Underlined text not in the original.) And regarding when to take it, the handbook indicates that, “The pills may prevent pregnancy if taken within 5 days after having unprotected sex”.

Regarding the dosage for ECP that contain only estrogen – progestin, the manual indicates that the recommended dosage is 1.5 mg of levonorgestrel in a single dose, although as an alternative it is possible to administer 0.75 mg of levonorgestrel in one dose, followed by a second dose in the same amount 12 hours later. For the patient, one dose is easier to take and works as well as 2 doses (page 50).

Regarding effects other than contraceptive effects, the manual states the following:

“Correcting misunderstandings (see also questions and answers, p. 54)

Emergency contraceptive pills:

- Do not cause abortion
- If the patient becomes pregnant, the pills do not cause birth defects
- The pills are not dangerous to women’s health
- The pills do not promote high-risk sexual conduct
- The pills do not cause infertility in women (p. 48)

Do ECP interrupt a pregnancy that has already begun?

² The cited manual from the WHO contains, “Guidance based on evidence developed thanks to global collaboration”. The manual is described as “A Family Planning Cornerstone of the WHO”, and was prepared with the help of its Department of Reproductive Health and Research, the Bloomberg School of Public Health at Johns Hopkins, and the U.S. Agency for International Development, Office for World Health. Taken from the WHO web page, Publications, Reproductive Health, version in the Spanish language.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

No. ECP will not work if a woman is already pregnant. If taken before the woman ovulates, the ECP will work to avoid the release of the egg from the ovary, or to delay its release, for 5 to 7 days. At that point, the spermatozoid in the reproductive tract of the woman will have died, given that spermatozoid can survive there for about 5 days.

Do ECP cause birth defects? Does it harm the fetus if a woman takes ECP by accident when she is pregnant?

No. There is strong evidence to show that ECP do not cause birth defects and do not harm the fetus if a woman is already pregnant when she takes the ECP, or if the ECP are not able to prevent the pregnancy.” (p. 54)

2.2.2.3 In, “Medical criteria for eligibility for use of contraceptives”, 3rd edition, 2005, a specialty publication also by the WHO,³ levonorgestrel is also classified as a single dose contraceptive, either administered in a dose of 0.75 mg or 1.5 mg as an ECP, which if taken within 72 hours after unprotected intercourse, reduce the risk of pregnancy by at least 75 % (p. 14).

2.2.2.4 In the Medical Bulletin of the IPPF (the International Federation for Family Planning, for its initials in Spanish), Volume 36, Number 6, from December 2002, Spanish language version, introduced into the proceedings as evidence and appearing on pages 135 and 136 of the record of the proceedings, pills containing 0.75 mg of levonorgestrel (LNG) are listed under “Emergency contraceptive pills”, as they prevent pregnancy. Regarding the manner in which the pills act to prevent pregnancy, the bulletin describes the following effects:

A. The window of opportunity for use of ECP

ECP can prevent sperm from reaching the egg, or, if the two gametes do come into contact, can prevent fertilization within the six fertile days of a woman’s menstrual cycle—those in which intercourse can result in pregnancy—occurring between ovulation and the five days prior. This preventative effect is viable because in the majority of cases, the sperm must wait between one and five days in the feminine genital tract before coming into contact with the egg. This interval, and the lack of efficiency in fertilization in humans⁴, provides an opportunity in which to intervene in the migration and function of the sperm and / or in the process of ovulation.

In this regard, it should be noted in fine that there is no direct evidence in favor or against the hypothesis that ECP prevent pregnancy by intervening in events that occur after fertilization of the egg.

B. Regarding action in respect of the migration and function of the sperm

The pills interfere with the sustained migration of the sperm by increasing the PH of the uterine fluid, which immobilizes the sperm, and increase the viscosity of the cervical mucus, which impedes the sperm from reaching the uterine cavity.

³ From the WHO web page, Health Issues.

⁴ This lack of efficiency is reflected by the data provided by the WHO in the Planning Manual previously cited, which show that only 8 of 100 women who have unprotected sex one time during the second or third week of their menstrual cycles are likely to become pregnant. (p. 46)

C. Effects on the process of ovulation

EC pills taken during the follicular phase have the capacity to interfere with the ovulation process, either by suppressing peak levels of the hormone lutein, follicular rupture, or luteinization.

2.2.2.5 The National Academy of Medicine, in a communication dated 20 September 2004, addressed to all members, which appears at pages 203 to 205 of the record of the proceedings, stated that, “The emergency hormonal contraceptive acts by inhibiting ovulation, which has been observed in women, as well as in tests on monkeys and rats.

2.2.2.6 Dr. Pio Ivan Gomez Sanchez⁵, the author of a relevant treatise on the subject, classifies treatments with progestin only based on 1.5 mg doses of levonorgestrel as emergency contraception, which is achieved if the drug is ingested immediately, by taking two 0.75 mg tablets, within 72 hours of having unprotected sex. The author notes that some people prefer to use a first dose of a 0.75 mg tablet, followed by another equal dose 12 hours later. The author explains that this method works, “Depending on the point of her menstrual cycle during which the woman takes hormonal EC, the drug can either inhibit or delay ovulation, modify the endometrium, or prevent fertilization, preventing the movement of sperm within the Fallopian tubes”.

The author adds that, “Emergency contraception does not cause an abortion, and in fact this type of contraception avoids pregnancy. The beginning of the gestation period has been defined as the moment at which the fertilized egg implants itself in the endometrium. This implantation occurs between 5 and 7 days after fertilization. Emergency contraceptives work prior to this implantation, and not after the process has already begun”.

2.2.2.7 Although the foregoing considerations would be sufficient in order to deal with the claimant’s arguments, it is convenient to complement them with some conceptual and practical specifications relevant to the matter at hand, in particular related to the arguments that the claimant attempts to make regarding the abortifacient nature of POSTINOR 2, and which are summarized by the argument that because the drug takes effect after the fertilization of the egg, which occurs almost immediately after having unprotected sex, the drug therefore takes action after conception has taken place, when there is already a human life at stake, given the fact that the egg is fertilized, and the drug prevents it from implanting into the wall of the endometrium.

In this regard, the Court finds that, as PROFAMILIA, the entity that will benefit from the resolution in question and a third interested party in these proceedings, argues, the actor confuses several of the phenomena that occur during the human reproductive cycle, given that the claimant does not distinguish between fertilization, conception and gestation. Regarding this issue, there is evidence that in addition to the inefficiency that characterizes the process of human reproduction, as shown by the fact that 8% of women who have unprotected sex will become pregnant, as stated above, and ignoring gametogenesis, which is the product of the

⁵ Gomez Sanchez Pio Ivan, “Autonomy of the human body – Contraceptives – a Tool (“AUTONOMIA DE LOS CUERPOS – Anticoncepcion – unaherramienta”), First Ed., 2007, Bogota, DC, Colombia, pages 195 to 199.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

masculine gametes (sperm) and the feminine gametes (egg), for which a series of events must successfully take place, beginning with insemination, followed by fertilization, the activation of the sperm, the conception or fixing of the fertilized egg in the wall of the endometrium, in order for a pregnancy to occur, and for gestation to follow. Up to that point, the process can take between 12 and 16 days after the sexual act.

These events in turn take place during various points, and require specific conditions in order to be successful. All of this indicates that neither fertilization nor conception occur spontaneously, instantly, and much less automatically. As such, intercourse itself is not enough to immediately result in conception, as can be appreciated from the content and characteristics of these events, as described below:

- Insemination or semination, which, in the words of Dr. Edward Hughes⁶, is the “introduction of the semen into the vagina”, and results in the first successful stage of coitus.
- The capacity of the sperm to fertilize the egg, which takes between 48 and 72 hours. The Medical Bulletin of the IPPF previously cited explains that the migration of the sperm occurs in two phases. Those involved in the second phase, which takes place over several days, are those sperm that have the capacity to fertilize the egg, and are those that go through an activation process, as such: “The sperm that are not activated attach to the epithelium of the Fallopian tubes for a few hours until they are activated, and then they become very mobile and resume their journey. Once activated, the sperm are not viable for much time, and as such, in order to continuously maintain an active population of sperm capable of fertilizing the egg within the Fallopian tubes until the time of ovulation, it is essential that fresh cohorts of sperm continue migrating toward the cervix”. (page 135 of the record of the proceedings)
- The fecundation, fertilization or singamia, which the aforementioned Welsh author describes as the process that begins with the fertilization or penetration of the secondary layer of the egg by the sperm, and completes the union of the masculine and feminine nuclei.

According to Dr. C. Simon Valles and E. EscuderoVelando⁷, it can be said that this stage, of fecundation or fertilization, is a sequence of coordinated phenomena, which takes approximately 24 hours, and consists of i) contact between the two gametes, which occurs in the region of the ampulla (the distal third) of the Fallopian tube; ii) penetration of the sperm into the cytoplasm of the egg, and activation during its maturity, for which, it must travel through two important cellular levels that surround the egg (the radiata and the zonapellucida);

⁶ Edward C. Hughes, “Terminology in Obstetrics and Gynecology”, Salvat Editores, Barcelona, 1975, p. 242.

⁷ C. Simon Valles and E. EscuderoVelando, “Establishment of gestation: gametogenesis, fertilization and development of the egg until the formation of the three germinal sheets. Implantation.” (“Establecimiento de la gestacion: gametogenesis, fecundacion y desarrollo del huevo hasta la formacion de last res hojasgerminales. Implantacion.”), Chapter 21 in the TREATY ON GYNECOLOGY, OBSTETRICS AND REPRODUCTIVE MEDICINE (TRATADO DE GINECOLOGIA, OBSTETRICA Y MEDICINA DE LA REPRODUCCION), Vol. 1, Ed. MedicaPanamericana, Madrid 2003, p. 198

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

iii) the cortical reaction, which is the closure of the egg in order that no additional sperm may penetrate it; iv) formation of the feminine and masculine pro nuclei; and v) the correct fusion of both pro nuclei (masculine and feminine). The result will be a single cell embryo (the zygote) with 46 chromosomes, which will later begin to divide.

- Development of the embryo, which is the process through which the embryo, in its blastocyte phase⁸, fixes itself to the endometrium of the mother's uterus in order to continue its development, and which generally occurs within the middle and superior thirds of the posterior uterine wall, at a specific moment in the menstrual cycle, referred to as the window for implantation, and which occurs between the sixth and tenth days following ovulation. This occurs in four phases: apposition, adhesion, rupture of the epithelial barrier, and invasion⁹.

In this context, *conception* is defined as the "implantation of the blastocyte. It is not synonymous with fertilization" (underlined text added), and pregnancy is the "condition in which a woman is found after conception and until gestation ends", in the words of Dr. Edward Hughes¹⁰.

In turn, gestation is to gestate, and according to the Dictionary of the Royal Academy, to gestate means, "Said of a female: To carry and to sustain in her womb the embryo or fetus until the moment of birth".

In this respect, abortion, medically and legally, is the "interruption of a pregnancy by natural causes and deliberately caused", according to its definition in the previously cited dictionary, which also states that, "this is the medical and legal definition".

In this regard, the publication *Medicine Plus, Health Information for You*, from the Service of the National Library of Medicine of the United States of America and the National Institutes of Health, states that, "[Abortion] is a procedure to terminate a pregnancy by extracting the fetus and the placenta from the uterus of the mother".

This being the case, for an abortion to occur, it is a necessary condition that conception has taken place, or that the woman is pregnant, and given that POSTINOR 2 does not have any effect after conception or pregnancy, but acts prior to the occurrence of either condition, it is not possible that it be considered an abortion drug. It is not even proven that it has any effect whatsoever on the embryo or fertilized egg.

⁸ *Medicine Plus, Health Information for You*, from the Service of the National Library of Medicine of the United States of America and the National Institutes of Health, states the following: BLASTOCYTE: The zygote continues to divide, creating an internal group of cells with an outer layer, during which the organism is referred to as a "blastocyte". The internal group of cells will become an embryo, while the external group will become the membranes that will feed and protect it. The blastocyte reaches the uterus around the fifth day, and is implanted in the uterine day on approximately the sixth day. At this point in the mother's menstrual cycle, the uterine lining has grown and is ready to support the fetus. The blastocyte adheres strongly to the uterine lining, which provides it with nutrition from the mother's bloodstream.

⁹ *Id.*, p. 200 to 202.

¹⁰Edward C. Hughes, *Op. Cit.* p. 341 and 373, respectively.

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

2.2.3 Given the above, there is no action that would result in a violation of the legal standards that were cited by the claimant, in respect of their guaranteeing and protecting the right to life of all persons and including those persons who are not yet born, given that these standards protect human life as a fundamental human right of natural persons, and do not protect life in the abstract. This is due to the fact that rights do not exist in any form except as refers to actual subjects, and as such are identified as rights (of all persons, of women, of children, etc.).

A contrary finding would suggest that the right to life would have to be considered to be threatened or violated even in respect of any risk to the elements that act together to create human reproduction, such as the masculine and feminine gametes, before their union or fusion, given that they are in and of themselves procreative elements, but at that point the law does not recognize any subject for the right to attach to. Indeed, in the case that the egg were to be fertilized and not implanted, this could constitute a problem for religious, ethical or moral interests, but in those areas the problem is beyond the reach of this jurisdiction, as there is no relevant law to address it, either at international law or within the Colombian domestic legal system.

From the foregoing it can be seen that the superior or essential thing that must be protected is human life, which begins just at the moment of conception, which, as stated above, occurs when implantation does, and is equivalent to a pregnancy. The Constitutional Court has so found in the decisions cited by the claimant itself.

In Decision C-355 of 2005, the Court stated that, “life and the right to life are distinct phenomena. Human life occurs in different stages and is manifest in different forms, which each have a distinct form of legal protection”.

C-133 of 1994, previously cited, also indicates that,

“It is true that our Political Constitution expressly recognizes the inviolable right to life that belongs to all members of the human race. However, this does not mean that this extends to latent **human life** in the form of an unborn child, which does not enjoy constitutional protection. In fact, if the essential value to be protected by our higher laws is human life, then it follows that where life exists, so then does the consequent duty of the State to protect it.

In other words, the Constitution **does not only protect the product of conception** that takes place at birth, and which results in the existence of a natural legal person, in the terms as regulated by law, but also **the process itself of human life, which begins at conception**, is developed and perfected through the fetus, and acquires an individual identity at birth”. (bold text not in the original)

The foregoing is in agreement with Article 4.1 of the American Convention on Human Rights, which states that, “Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life”. (underlined text not in the original) Article 6 of the International Covenant on Civil and Political Rights, also states that, “1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”

2.3 Conclusions

Translation provided by the Lawyers Collective (New Delhi, India) and partners for the
Global Health and Human Rights Database

Under these procedural circumstances, the Court finds that the material that was presented into evidence during the course of the suit brought before it, and which form part of the record of the proceedings, and the official information regarding the state of knowledge regarding the subject matter, particularly the opinion of the Colombian Institute of Legal Medicine and Forensic Science, to the extent that it states that, "levonorgestrel does not cause any direct harm to the human embryo", support the factual basis for the resolution herein challenged, and in particular, regarding the contraceptive nature of POSTINOR 2, belie the claimant's characterization of the drug as an abortifacient. The claimant, in fact, has presented no scientific evidence or information from a recognized authority on the subject matter, and including the scientific proof that the claimant requested by presented contradicts or undermines the characterization of the drug in question as an abortifacient, as stated in the claim. As a result, there is no apparent demonstration of any violation of the right to life, or, equally, of any of the laws cited by the claimant.

As the claimant has not proven the elements of its claim, the claim must as a result be dismissed, and the Court effectively will dismiss the claim in the resolution of this sentence.

In light of the foregoing, the State Council, Court of Administrative Litigation, First Chamber, administering justice in the name of the Republic and as authorized by law,

FINDS:

The petition of Mr. CARLOS HUMBERTO GOMEZ ARAMBULA that the Court declare Resolution No. 266285, dated 14 September 2000, through which INVIMA granted the Association for the Well Being of Colombian Families, or PROFAMILIA, a health certificate allowing for the importation and sale of the pharmaceutical product POSTINOR 2 for a period of 10 years, to be invalid, is hereby denied.

This decision, being final, and the appropriate formalities having been complied with, case files are to be archived.

To be copied, relevant parties notified, decision to be published, relevant parties informed, and the decision to be enforced.

The foregoing resolution was read, discussed and approved by the Court in its session on 5 June 2008.

MARCO ANTONIO VELILLA MORENO

Presiding Judge

CAMILO ARCINIEGAS ANDRADE

RAFAEL E. OSTAU DE LAFONT PIANETA

MARTHA SOFIA SANZ TOBON