

CUATRECASAS, GONÇALVES PEREIRA

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Sociedad Española de Fertilidad (SEF)
Sr. D. Agustín Ballesteros Boluda
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Asociación para el Estudio de la Biología de la Reproducción (ASEBIR)
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Asociación Española de Andrología, Medicina Sexual y Reproductiva (ASESA)
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Barcelona, on December [...], 2015

Ref.: Legal warning notice about on-line SEF Bulletin signed by you all and with title: "NOTA sobre el ofrecimiento de "Inseminación en casa" que realizan algunos bancos de semen", dated November 10, 2015.

Dear Mr. Ballesteros, Ms. Boada and Mr. Prieto,

On behalf of our client, the Danish company "Cryos International Denmark ApS", domiciled in Vesterbro Torv 1-3, 5., 8000 Aarhus C., Denmark (Cryos), we hereby contact you in relation to your e-mail/circular letter "Sociedad Española de Fertilidad" dated 10th November 2015 (attached), with title "NOTA sobre el ofrecimiento de "Inseminación en casa" que realizan algunos bancos de semen".

Our client strongly disagrees with the content of that circular letter, and before initiating legal actions, we amicably ask you to document your claims or to recall and correct your wrongful and harmful allegations.

Cryos is a licensed tissue establishment that fulfils the highest security requirements, and who legally conducts its business in and from Denmark, having all necessary permits and public licenses to do it. Any attempt, as it result from you bulletin, to perform illegal and harmful publicity about the company or illegal market protectionism, will be brought to justice by all means, including claims of compensation for damage and loss.

To this extent, the express mentioning of "Cryos" and the several breaches you allege against us could be considered as a serious infringement by you of the Unfair Competition Act (*Ley 3/1991, de 10 de enero, de Competencia Desleal*), General Advertising Act (*Ley 34/1988, de 11 de noviembre, General de Publicidad*), and our right to honor (*Ley Orgánica 1/1982, de 5 de mayo, de protección civil del derecho al honor, a la intimidad personal y familiar y a la propia imagen*)

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Consequently, continuance of your statements will legitimize Cryos to exercise what legal actions are deemed convenient pursuant the provisions of article 32 of Unfair Competition Act in relation to articles 1, 5.g), 9 and 18 of the same Law, and articles 3.e) and 6 of General Advertising Act; particularly, in connection with rectification of erroneous information and compensation for damages (article 32.1.4th and 5th of Unfair Competition Act), as well as article 7.7 and 9 of Right to Honor Act 1/1982.

With reference to your mail/circular letter, at least the following statements are wrong, and therefore should be documented or immediately recalled:

*"The offer for home insemination from sperm banks like Cryos is a serious reproductive health problem in Spain, **because it deprives the patients from crucial health guarantees received in assisted reproduction techniques¹ as medical supervision², evaluation of the sperm quality before insemination³, that it takes place in an authorized centre, that fulfils all standards for quality and security according to Spanish and EU legislation⁴, and the existence of a responsibility insurance in case of injuries⁵.**"*

Rather on the contrary:

1. Home insemination does not deprive patients from any crucial health guarantees. On the contrary, Cryos ensures supply of donor sperm according to the EU-tissue directive's requirement for quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells including traceability; and furthermore Cryos [recommend on its website](#) to search for medical care whenever it is needed. However, in many countries, certain patients are denied medical care or they are denied the particular kind of donors they demand. This is actually the cause for home insemination in most cases, not the opposite.
2. Home insemination does not require medical supervision as an assisted reproduction technique carried out in a clinic does. Home insemination is unassisted.
3. The donor sperm is indeed evaluated, that is what Cryos does as an authorized tissue establishment. The donors are selected and the sperm processed in accordance with the Directive 2004/23/EC of the European Parliament and of the Council and meet all requirements. The donor sperm Cryos delivers is identical whether it is delivered for assisted treatment or for unassisted treatment (home insemination). Cryos evaluates the quality of the sperm in all cases.
4. Home insemination is not taking place in an authorized center and therefore it is not applicable for Spanish legislation you mention in your letter. As for the EU-legislation, the Directive 2004/23/EC applies, and Cryos guarantees that the donors and the sperm meet all requirements as per 3 above.
5. As for the responsibility and insurance, Cryos confirms that legal liability related to its products is covered by Cryos, and this applies independently to whom the sperm is delivered. As home insemination is not a treatment, there are no requirements or need for an insurance for responsibility, as well as no such insurance is required for other kinds of products used by private individuals.

Further statements are also wrong and should be documented or immediately recalled:

"The mentioned offer is illegal in Spain as it seriously violates the Spanish law 14/2006 for assisted reproduction and the Royal Decree 9/2014 introducing the EU legislation".

As Cryos is a licensed tissue establishment (license attached), it is also licensed to distribute in all EU-countries, including Spain. Thus, your statement is in clear conflict with this license, granted by the Danish Health Authorities.

It is not correct to affirm, as you do, that the mentioned offer is illegal according to the Spanish law 14/2006 for assisted reproduction, and the Royal Decree Law 9/2014.

Mainly, because these laws are not applicable for Cryos, who is a Danish entity/tissue establishment. The EU Tissue Directive or Danish regulation, which are those Cryos must apply to, do not mention to whom delivery shall take place or whom can be inseminated with the sperm or that treatment shall be performed assisted or not.

There are certainly different regulations in force nationally for assisted medical treatment, but as Cryos has no treatment at all, these rules are not applicable to Cryos.

Therefore, Cryos can legally distribute sperm to both private individuals and clinics all over EU.

Furthermore, these laws are not applicable for private persons in Spain, as they are not performing an assisted treatment when doing home insemination.

Regarding your four statements with reference to the specific legislation:

"1.- Performing any kind of techniques of assisted reproductive technique can only take place in clinics or health centres duly authorized by the competent health authority (Art. 4.1 of Law 14/2006). Only in this way can it be performed by competent professionals who can ensure that the treatment is appropriate and does not pose serious health risks to the patient or its progeny, and that it is practiced in the most proper way."

However, this statement is incorrect as "home insemination" is unassisted, so the mentioned Spanish laws do not cover it.

"2.- Violation of anonymity requirement of donor gametes, which are designed to protect private life / the privacy for both donors and patients themselves (Art. 5.5 of Law 14/2006)."

Again, "home insemination" is unassisted, so the mentioned Spanish laws do not cover it.

You shall therefore document that the law are applicable for unassisted treatment, or otherwise recall your statement.

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"3.- Violation of the rule that it is the doctor / medical team that must choose the donor, which also guarantees that it is the most appropriate donor for the receiving couple (art. 6.5 of lov14 / 2006). The fact that patients choose donor characteristics, promotes trade of gametes, which goes against what is stated in the Spanish and European regulations."

Once again, "home insemination" is unassisted, and the mentioned Spanish laws do not cover it. We also request you to inform to which specific European Regulations you refer to. We can inform that Cryos does not sell the donor sperm, but the process, handling, testing, etc. cf. Cryos' [Terms of Agreement pkt. 25](#) (attached) and that this complies with a decision from the Danish Minister of Health.

"4.- From the moment, when samples of sperm are sent to patients' homes, traceability and biosecurity measures are no longer guaranteed, which are mandatory requirements throughout the European region and allows to reconstruct the origin of the cells, when there is a health problem (Decree 9 / 2014)."

This statement is not correct. Cryos maintains traceability cf. The EU-Tissue directive in 30 years from last use. This is the same whether Cryos delivers to a clinic, a tissue center or directly to the recipient, so we consider there is no lack of traceability and biosecurity at all.

We look forward to receive your documentation and the basis for all your statements, or an immediate official recall.

Finally, our client would be very happy to initiate a serious dialogue with you afterwards to clarify any potential questions you could have.

We are all part of the Spanish market, and will without doubt be so in the future, so it would be an advantage for all of us to get along and keep a good tone.

We look forward to receive your answer before next January 15, 2016, in order to reach an amicable solution of the matter.

Sincerely yours,

Juan Carlos Hernanz
Attorney