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Bucharest, Sep. 09, 2023

To: Romanian MEPs
Ref.: EU SoHo platform vote, Sept 12th

Dear MEP,

We would like to draw your kind attention on the vote, next week (Tuesday Sept 12th), in the EP plenary session on the so-called EU SoHO Platform (2022/0216(COD) Standards of quality and safety for substances of human origin intended for human application)[1]. This Regulation "concerning quality and safety standards for substances of human origin intended for human application (or SoHO regulation for Substance Of Human Origin)" aims at **sharing cells, blood and tissues within member states in a harmonized and standardized way, run by the EC.**

In our opinion, this document includes dangerous provisions on the ethical, regulatory and sanitary levels.

Ethics - The legal rules concerning free donation, non-availability of the human body, authorization of creation, use and modification of gametes and embryos differ upon Member States. **This regulation would establish the rule of the highest bidder** within the EU. The Commission expresses itself as follows: "*The growing demand from commercial companies (such as egg banks for in vitro fertilization, or plasma collectors for the manufacture of medicines) is increasing pressure on donations and, hence, the need to establish solid measures for the protection of donors."* We understand it as a recognition and support of the existence of a European fertility market, which is **a moral scandal**.

Regulatory - In the Legal Basis part of the regulation, it is specified that Member States remain decision-makers regarding ethical issues, such as in vitro fertilization, but that the Commission is responsible for its implementation. We thus sense the desire to establish and strengthen the competence of the EU in the field of health. Moreover, according to the Treaty on the Functioning of the EU in its article 168, public health is an area which falls above all within the competence of the Member States, the European Union can only complement their action. The takeover of national health and bioethics policies by the EC tends to widen, as demonstrated by the implementation of the Covid Certificate by the Commission.

[1] https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2022%2f0216(COD)

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Sanitary - According to researchers, increasing the flow of human cells, blood and tissues could lead to the appearance of new prion diseases and viruses unknown to national health surveillance organizations.

Call to action

We respectfully suggest that you vote for 2 **additional amendments (one from ID, one from ECR)** to remind the EP plenary that human substances are not disposable and interchangeable body parts, embryos and fetuses are not raw material and should not be subject to any trade.

Amdt 242 ID

Recital 3 a (new) (3a) The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) known as the Oviedo Convention signed on 4 April 1997 and ratified by the 27 Member states, and the Additional Protocol to that Convention (ETS No.186) of 24 January 2002, prohibit use of the human body and its parts as a source of financial gain, as well as advertising of the need for organs or tissues, or their availability, with a view to offering or seeking a profit or comparable advantage.

Amdt 243 ECR

Recital (15a) new - It is imperative that neither human embryos nor human foetuses be used for diagnostic, therapeutic or raw material purposes.

Thank you very much for your attention,

Bogdan I. Stanciu
President