

Commercialization of Human Reproductive Material: Legal Situation in Albania

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Abstract

The industry of assisted reproductive technology, which is growing on a global scale, has created a tense situation between certain individuals' economic interests and human dignity. Individuals who donate sperm or eggs claim to have the right to monetary remuneration for goods and services, arguing that if a person has the right to sell his/her own blood or body tissues, then that person should also have the right to sell his/her own reproductive material. However, commercialization of those cells that have the potential to become human beings in the future poses a serious threat to the dignity and other moral values of mankind. This paper will address whether human gamete purchase and sale at a price should be legally and ethically acceptable, or their donation should be in full awareness and voluntarily. The second part deals with the legal situation in the state of Albania comparing it to the legislation in force in the state of Kosovo.

Keywords: assisted reproductive technology, human reproductive material, commercialization, donation, dignity, monetary compensation.

Introduction

Assisted reproductive technology emerged as one of the most widely adopted and successful medical technologies in the last century. While giving hope to millions of couples suffering from infertility, it has also raised new legal, ethical, cultural and social dilemmas that society is facing increasingly each and every day. In particular, genetic experiments, laboratory cryopreservation techniques, the right of an individual to genetic offspring, informed consent, and gamete or embryo donation constitute aspects of human procreation which are and tend to become more and more subject of future discussion and debate.

In the last decade, there has been a decline in the number of gamete donors in developed countries as a result of legislation restricting monetary reimbursement of gamete donors, which has, in turn, led to a loss of incentives for many future donors, who also face numerous problems and concerns linked with their donation. Concerns such as the process being time-consuming, lack of monetary remuneration, and risk of medical complications due to superovulation drugs in the case of oocyte donation have also contributed significantly to the decrease in the number of volunteer donors. In some countries this situation has worsened even further as a result of the abolition of donor anonymity, thus discouraging even altruistic donors (Heng, 2007). On the other hand, the recent spread and development of the Internet has enabled donors to

sell their gametes in the open virtual market to the highest bidder, thus turning egg and sperm sale and “donation” into a lucrative business.

The United Kingdom’s Human Fertilization and Embryology Authority has placed its emphasis on altruistic donation and encouraging voluntary gamete donors to come forward. In addition, according to the World Medical Association Resolution on the Non-commercialization of Human Reproductive Material, monetary compensation given to individuals for their economic costs, expenses or inconveniences associated with the retrieval of donated reproductive materials should be distinguished from payment for the purchase of reproductive materials (WMA Resolution on the non-commercialisation of human reproductive material, 2014).

1. “Legitimacy” and Ethics of Gamete Trade

The rapid advances in biomedical technology have led to a growth in the assisted reproduction industry, which tends to be poorly regulated. Despite the fact that many governments have laws prohibiting commercial transactions involving reproductive material, most of them have not been successful in universally preventing the sale of human oocytes, sperm and embryos on the Internet and elsewhere. The market value of human material, including cells, tissues, and cellular tissue, can be lucrative, creating a potential conflict among physicians and other parties between economic interests and professional ethical obligations (WMA Resolution on the non-commercialisation of human reproductive material, 2014).

There is a well-established principle that a person may not be purchased or sold. To a certain extent, this principle concerns the human body, either the body of a living person or the body of a person who is already dead. Despite the fact that people are not regarded as “commodities subject of trading”, perceiving why an embryo should be considered in the same manner is somewhat complicated. It can be argued that liberal economic theory accepts the principle that each commodity has a price. For this reason, a person’s organ which is used for another person’s benefit should be paid at a price proportional to the benefit. However, not everything that benefits an individual or society, whether it is an item or service, necessarily has a price, and the usefulness of an item is not measured by its price, even though it is necessary to have a market price, a price that is generally set taking into account how rare that item is, or based on the cost of its production. In this light, the human body is legally considered as “*Res Extra Commercium*” (Mahomed, Nöthling-Slabbert, & Pepper, 2013).

The principle of non-commercialization of the human body is incorporated into various national and international conventions, statements and resolutions that emphasize the protection of human rights and dignity. Article 21 of the Convention on Human Rights and Biomedicine provides that: “*The human body and its parts shall not, as such, give rise to financial gain*” (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, 1997). The 2006 World Medical Association Statement on Human Organ Donation and Transplantation, and World Medical Association Statement on Organs and Tissues (2012) call for a ban on the sale of organs and tissues intended for transplantation. The World Medical

Association Statement on Assisted Reproductive Technologies (2006) also states that it is inappropriate to offer financial benefits with the intent to encourage donation of human reproductive material (WMA Resolution on the non-commercialisation of human reproductive material, 2014). One should not confuse the sale of clinical assisted reproductive services, which is legal, with the sale of human reproductive materials, which is usually illegal, and drawing a distinction between the two is of paramount importance. Moreover, due to the special nature of human embryos, the commercialization of gametes is unlike the commercialization of other human cells and tissues because sperm and eggs may develop into a future child if fertilization is successful.

Donor insemination was first reported by Addison Hard in 1909, where a fertile male offered his sperm to an infertile couple (AT & RC, 1965). Provision of a fertile woman oocytes to an infertile one dates back a little more than a decade later. The data on the origin and history of donor insemination indicate that sperm and oocytes were previously supplied without monetary exchanges. For this reason, it is appropriate to describe the first provider as a "donor". It is a legal requirement that prior to the donation of human reproductive material, the donor must give his/her informed consent, and he/she must do so free from pressure or coercion. The use of genetic material, especially for reproduction, without a person's informed consent is deemed a serious violation of that person's autonomy (Pennings, 2000). This requires that the donor be considered as having full capacity to act, and has been provided all the available information about procedures and outcome. There should be no incentive or other unnecessary pressure to donate, nor compensation offers. The fact is that payments for such services are made with the intent to incentivize sperm and ovarian suppliers since, nowadays, when infertility problems are on the rise, it has become increasingly necessary for clinics to have spare reserves of such gender cells in order to cover the needs of the couples who approach those clinics for artificial fertilization. Free of charge and genuine donations only occur when gender cells are provided by family members, such as a brother or sister of a couple having fertility issues. Gynecologists, therefore, justify donor payment as the only way to encourage donors and meet the needs of people seeking a third party's gametes in order to conceive offspring.

In a study conducted in Britain about the stands towards the compensation of "sperm donors", the respondents' responses were divided into three groups: general public responses, responses of the students who were also the potential donors, and responses of patients with fertility problems (H, GW, & IT, 1998). The majority of the public were not in favor of compensation, i.e. 58% were against compensation and 38% were for it, 67% of the potential donors were in favor and 29% were against it, and 52% of the potential recipients were in favor of compensation and 43% were against it (H, GW, & IT, 1998). As noted from the responses, the largest percentage of respondents were in favor of compensation, a stand that should be viewed as carrying considerable weight when deciding whether or not to allow compensation in such donation cases. Other countries have also witnessed similar debates. In 1996, the Canadian government decided to prohibit "the purchase or sale of eggs, sperm and embryos". According to them, reproductive material should not be commercialized because such practices violate the principles of respect for human life and dignity. This prohibition shall constitute a stage

that over time will facilitate the transition from the current commercial system to an altruistic system (Network, 1996). Medical groups had expressed considerable concern over this proposal. The Canadian Fertilization and Andrology Society (CFAS), in its written submission to the Permanent Parliamentary Health Committee, stated that legitimate donor expenses should be reimbursed. In an earlier statement the Society had highlighted CFAS's concern that if sperm donors were not compensated for their donation, supplies would not meet the needs of infertile patients (K, et al., 2006). There is a tendency to shift the argument base from payment to compensation as a form of remuneration for donors. However, the debate remains, in essence, the same: without a kind of monetary remuneration, compensation or payment, medical clinics will face a shortage of reproductive cell supply.

Rapid technological and scientific developments in the field of assisted human reproduction have prompted the governments of different countries to set up inquiry commissions/committees charged with making policy and legislative recommendations. The European Commission has explored to what extent the existence of a common European Community policy could be possible. Governments' initial requirements responded in general to the concerns raised by Patricia Baird who argues that "individual decisions regarding use of reproductive technology may be personally beneficial, yet have undesirable collective consequences" (PA, 1996). Focus on and concern with collective outcomes should be the proper scope of action for governments. Baird argues that government must act "... to protect the interests of citizens" and that it does so "... by ensuring regulation and accountability in the relevant domain" (PA, 1996). She also argues that the distribution of collective resources, determination of justice on service access issues, and the impact of the commodification and commercialization of human dignity provide collectively the authority for state engagement in this field (PA, 1996).

Some policies can be more widely accepted by physicians than others. Proposals to prohibit payment for gamete donations, as shown above, have brought about widespread opposition in the society. It is fair to say that committees and commissions are mostly concerned with principles, while physicians are mostly concerned with pragmatics. Researchers Denis and Hall have discussed gamete recruitment issues, taking into account the move towards prohibiting payments, and argue that a system based on the outsourcing of providers should be considered as a substitute for monetary remuneration. What supporters of donor payment fail to realize or do not accept is that a non-payment gamete donation system has been operating successfully in France for over 20 years (R.Daniels & J.Hall, 1997). Radin argues that market inalienability is grounded in non-commodification of things important to personhood (Radin, 1986). Is it possible to show respect for a person when we have purchased and sold key components of his or her personhood? This matter raises questionable issues related to personhood and gametes as integral components of personhood, where scholars such as Robertson argue that paying gamete providers is ethically acceptable because recipients' needs have priority: "...The ethical objections to payment must be balanced against the need to pay women to assure an egg supply for needy recipients and to treat donors fairly" (Robertson, 1989). This position is in line with his views on the central importance of autonomy.

Although all countries prohibit the purchase and sale of children and, by analogy, trading in embryos, it happens that in some states this prohibition is not applicable to gametes, which are seen as a trade designed to meet the needs of recipients and perhaps those of gamete providers or clinicians. This view constitutes additional ground against commodification rather than justifying it. However, as can be seen, when the legislations of different countries have decided to prohibit or allow payment as a form of remuneration to donors, they have relied on ethical clarifications that are divided into two different approaches, i.e. either support or prohibit such a commercialization strictly. Finally, it should be noted that free market benefits all parties: those willing to donate their gametes and receive the compensation they want, and, on the other hand, the desperately needy individuals who are willing to pay in order to have such gametes and undergo assisted reproduction.

2. Legal Situation in Albania and Kosovo

In Albania, the applicable Law No. 8876 on Reproductive Health, dated 04.04.2002, and Instruction No. 268 on Assisted Medical Reproduction Techniques, dated 10.07.2003, do not contain any specific provisions that would regulate explicitly if obtaining reproductive cells or embryos from a donor is made against a payment or through voluntary donation. Article 40 of the Law on Reproductive Health provides that *"Artificial fecundation shall mean the experimental fertilization of female eggs with the sperm of the male of a couple, outside of the body of a woman. Participation therein shall be conditioned by a written consent of the woman who (donates) the eggs and the male who (donates) the sperm."* [Brackets added by the writer, R. K.] As can be seen, this provision makes reference to the meaning of artificial fecundation and informed consent which must be given in writing by the couple participating in this assisted reproductive procedure. The last section of the provision contains the term "donation", implying that eggs and sperm cells should be donated voluntarily rather than upon payment. However, it may happen that the same terminology is used to cover up or camouflage profit-making actions which, although prohibited and by no means moral and dignified, bring considerable economic gains. In this regard, Article 4, paragraph 13, of the Albanian Law No. 10454 on the Transplantation of Cells, Tissues and Organs, dated 21.7.2011, provides that *"Reproductive Cells" shall include all tissues and cells intended to be used for replication through assisted techniques*", thus also covering those reproductive cells that are used for assisted reproduction techniques, and making a legal regulation of their management. Further on, the wording of Article 5 (a), *"removal of tissues, cells and organs for transplantation purposes shall be performed solely for a recipient's therapeutic benefit"*, places emphasis on the recipient's therapeutic benefit, and avoids monetary benefit, a fact that is also reinforced by the word *"solely"* thereby giving the wording an imperative intent. Moreover, further below this Article prohibits monetary benefit from donation very explicitly. Specifically, Article 5 paragraph c) sets forth a mandatory provision that *"donation of tissues, cells and organs shall be based on voluntary and unpaid donation...."* wherefrom it is very obvious that giving/taking certain monetary remunerations or payments to/from persons who decide to donate/receive reproductive cells and, analogously, embryos is legally prohibited. Likewise,

according to Article 6, paragraph 1(c) of the Law No. 9947 on Industrial Property, dated 07.07.2008, the use of a human embryo for industrial or commercial purposes may not be patented because it is considering as an invention the commercial use of which runs contrary to public order, morality or public health and people's lives (Law On .9947, dated 7.7.2008 On Industrial Property, (As amended by law no. 10/2013, dated 14.2.2013, nr.55/2014, dated 29.5.2014, no. 17/2017, dated 16.2.2017),).

In the legislation of the neighboring country, Kosovo, monetary benefits from such donations are explicitly prohibited by the Law on Reproductive Health. A specific article of that Law prohibits certain well-defined assisted reproduction activities, including "illegal donations of embryos" as part of those activities (Ligji mbi Shëndetin Riprodues, Ligji Nr. 02/L-76, Article 23 par3). Not only this. Article 4, paragraph 3 of the Administrative Instruction No. 06/2013 on Medically Assisted Conception, lays down explicitly that "*The donation of gender cells shall be made on the basis of voluntary and unpaid donation...*", thereby considering the payment for that kind of service as unlawful. Such a prohibition is also foreseen in Article 19 which states that "*the donation of gender cells shall be based on voluntary donation and without compensation*". Further on, paragraph 2 of the same Article states that "*An agreement on the donation of gender cells entered into contrary to paragraph 1 of the present Article shall be invalid and unlawful.*" Likewise, Article 27 provides specifically that "*Trade and public announcement of any kind involving gender cells and embryos shall be prohibited.*"

Although unpaid donation is preferred both morally and legally, in a world where money determines healthcare, it is difficult to establish strict standards, which often leads to deviant practices based on the interests of individuals or clinical services. Kosovo also found itself in such a situation in 2015, when some of its physicians became the focus of a media scandal related to compensation and substantial profits from trading in sperm and ovaries in collaboration with "Newborn Clinic" in Skopje, North Macedonia. Although the laws in force provide for severe punishments, the North Macedonia hospital invited, through a letter signed by the medical director of the Clinic in question, a large number of physicians from Kosovo, mainly gynecologists, to refer to that Clinic patients who were interested in the "donation" of sperm, and as an incentive, every Kosovo physician would be paid 250 Euro or, in the case of "donation" of oocytes, 300 Euro for each patient referred (A.Selimi, 2015). The Head of the Committee on Assisted Conception in Kosovo stated that, although not openly, the physicians who cooperate in such cases apparently receive payments for their cooperation, despite the fact that this is unlawful.

Conclusion Since human body products can be purchased and sold, the question arises whether it is morally acceptable to commercialize human gametes, too. If individuals can buy and sell blood or tissue, then should they also be allowed to buy and sell their gametes? Commercialization of human reproductive material can be objected to on the ground that gametes are different from other cells and tissues because sperm and eggs contain half of the human genome and, when combined, they can form an embryo which, if developed, becomes a person. Furthermore, it can also be argued that the purchase and sale of reproductive material may have an adverse impact on social values, such as respect for human life and dignity. Moreover, gamete commercialization can create a market for the exploitation of poor women

who, being in dire straits, would be willing to sell their eggs very cheaply. Taking into account this kind of development, which is likely to become a real threat to human dignity and values, it would be wise to set up an appropriate legal arrangement as a proactive and adequate response, including the threat of criminal sanctions, to activities such as the sale and purchase of gametes, or other prohibited activities that conflict directly with societal values, and are potentially detrimental to the interests of individuals and society.

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