

## Criminal Liability of fertility institutions and centers -comparative study-

### المسؤولية الجنائية لمؤسسات ومراكز الإخصاب -دراسة مقارنة-

Ayadi Sara, Faculté of law University Badji Mokhtar Annaba , Algeria,  
ayadi.sara08@gmail.com

Send Article Date: 23 /08/2023

Date of acceptance of the article: 27/08/2023

#### Abstract:

In recent times, the field of reproductive medicine has witnessed significant advancements. These advancements have led to interventions in the creation of embryos through non-natural methods, Which is referred to as assisted reproductive technology.

These developments have prompted legal intervention to regulate these medical practices, imposing a set of restrictions to ensure their legitimacy and proper implementation. In addition to holding individuals accountable for these practices, there has been an acknowledgment of the criminal responsibility of both natural and legal persons involved. This responsibility extends to the facilities where these interventions take place, specifically referring to fertility centers or medical clinics where artificial reproduction procedures are carried out. Legislation has appropriately introduced criminal liability for legal persons in these cases, as it enhances protection for the fetus and the sanctity of reproduction.

**key words:** Legal person, criminal responsibility, fertility centers, assisted reproductive technology.

#### ملخص:

في الآونة الأخيرة شهد مجال الطب الإنجابي تطورات كبيرة، أدت هذه الأخيرة إلى التدخل في العملية الإنجابية بممارسات وتقنيات غير طبيعية عرفت بالمساعدة الطبية على الإنجاب. لتلزم هذه التطورات التشريعات القانونية بالتدخل لتنظيمها من خلال وضعها لمجموعة من الضوابط والقيود التي تضمن مشروعيتها وتنفيذها السليم. إضافة إلى ذلك الإقرار بالمسؤولية الجنائية للأشخاص المتدخلة في هذه العملية عن كل خرق لهذه الضوابط أو اللجوء إلى أحد الممارسات الغير مشروعة منها.

لم تقتصر المسؤولية الجزائية على الأشخاص الطبيعية فقط، بل امتدت لتشمل الأشخاص المعنوية أيضا، والمتمثلة في مؤسسات ومراكز الإخصاب والعيادات الطبية التي تتم على مستواها الممارسات المتعلقة بالإنجاب الاصطناعي.

وقد اعترف التشريعات القانونية بالمسؤولية الجزائية للشخص المعنوي في هذه الحالة لضمان أكبر قدر من الحماية للجنين وللعملية الإنجابية وذلك بالنظر لقدوسيتها.

**الكلمات المفتاحية:** الشخص المعنوي، المسؤولية الجنائية، مراكز الإخصاب، المساعدة الطبية على الإنجاب.

### **Introduction:**

Medical assistance to reproduction is defined as medical activity or practice that enables reproduction outside the natural pathway, in cases where there is an obstacle preventing it.

This includes medical interventions for artificial conception, either within the uterus – as in artificial insemination – or outside of it – through in vitro fertilization. These practices are regulated by criminal laws to ensure their legitimacy and to prevent unauthorized medical interventions in the reproductive process, with penalties for any harm to embryos or human gametes. However, in addition to holding individuals accountable, legal systems also recognize the criminal responsibility of legal entities, like organizations, to ensure greater protection against unlawful practices and negative exploitation of scientific advancements in this field.

The recognition of corporate criminal responsibility has been a topic of debate among legal scholars, with some supporting and some opposing it. However, many modern legislations acknowledge the criminal responsibility of legal entities, imposing appropriate penalties. Recognizing and reinforcing the criminal responsibility of legal entities is considered a priority due to the broader purposes and motivations behind medical and scientific practices in this domain, which extend beyond personal interests and therapeutic goals to delve into the exploration of human origins and the pursuit of understanding hidden realms.

This has led to the emergence of a new type of industry and commerce involving human products and derivatives, necessitating the regulation of legal entities engaged in medical practices related to human embryos within licensed specialized centers often referred to as fertility or reproductive centers. In this study, I will attempt to explore these centers and investigate whether there is established criminal responsibility in this domain.

## **FIRST REQUIREMENT: LEGAL REGULATION OF MEDICAL CENTERS RELATED TO EMBRYOS AND HUMAN CLONES.**

Before delving into these centers, it is important to define the legal entity. There have been various definitions provided for it, including: "A group of individuals or a collection of funds recognized by the law as an independent entity distinct from the legal entity of its constituent individuals, managers, or owners, such as a state, association, company, or institution."<sup>1</sup>

It is also defined as: "A group of individuals or funds that come together and collaborate to achieve a specific project or purpose, recognized with legal personality."<sup>2</sup>

In the realm of experimental and biomedical medicine, the legal entity is represented by research centers and institutions that are defined as: "A group of natural individuals specialized in the medical field, carrying out specific medical tasks on behalf of or for the account of the center or institution."<sup>3</sup>

### **FIRST SECTION: CONCEPT OF MEDICAL CENTERS RELATED TO EMBRYOS AND HUMAN CLONES**

We will attempt to understand the meaning of these centers, along with their tasks and obligations, through studying the established laws that govern them in both Western and Arab contexts.

#### **Firstly: their definition**

Article 1 of **the Lebanese Law** for Licensing Fertility Centers defines these centers as: "Licensed centers by the Ministry of Public Health where assisted reproductive technologies are performed, including all clinical and biological interventions aimed at achieving pregnancy without natural conception."

Similarly, Article 1, Paragraph 3, of **the Saudi Law** on the Regulation of Fertilization Units and Embryos and the Treatment of Infertility defines them

**The Tunisian legislator** also addresses this framework. Article 17, under the second section of licenses and practice methods, from the Law No. 93 of 2001 related to reproductive medicine states: "Reproductive medical procedures are conducted in public health institutions or specially licensed private health institutions, by virtue of a decision from the Minister responsible for public health, after obtaining the opinion of the committee referred to in Article 16 of this law."

**As for the Algerian legislator**, according to Article 372 of the Health Law, clinical and therapeutic biological activities related to medical assistance for reproduction can be performed by authorized practitioners within institutions, centers, or laboratories specifically licensed by the Minister responsible for health to perform such activities. Based on what has been mentioned above, these centers

can be defined as: "**Public or private medical centers, whether independent or affiliated with a healthcare institution, licensed by the legal authority - often the Minister of Health - to carry out biological and clinical practices within the scope of medical assistance for reproduction and related activities, distinguished by their specialization, human and material resources, and technical structure.**"

From this, we can deduce several characteristics of these centers:

1. These centers can be either public or private, with a predominant trend towards private centers, particularly in our Arab world due to the specialized equipment, facilities, and capabilities required, which may be challenging for public institutions to provide.

2. They can stand alone as specialized entities focused on reproduction, conception, and practices related to human embryos. Alternatively, they might be affiliated with healthcare institutions that deal with various medical practices and treatments while holding a specific license for medical assistance for reproduction.

3. These centers are established through legal authorization granted by the competent authority, usually the Ministry of Health.

4. The authorization is based on the specialized human, material, technical, and structural capabilities these centers possess.<sup>4</sup>

5. These centers are responsible for all biological and clinical practices related to assisted reproductive techniques, therapeutic or scientific experiments stemming from medical assistance for reproduction.

### **Secondly: Licensing the Establishment of These Centers**

Licensing is a fundamental requirement for establishing these centers, and it is essential for them to carry out their tasks related to medical assistance in reproduction, therapeutic experiments, or non-therapeutic procedures involving human embryos. This license must be obtained from the relevant legal authority. This principle is emphasized by most laws.

According to **French legislation**, under Article L2131-1, paragraph 7 of the Public Health Code, medical biological tests aimed at prenatal diagnosis are conducted in licensed and authorized biological laboratories by the Ministry of Health. Article L2131-1, paragraph 1, which pertains to pre-implantation diagnosis, states that: "...the physician should perform this diagnosis in a specialized and licensed center, authorized by the Agency of Biomedicine..."<sup>5</sup>

In the United Kingdom, the authority responsible for granting licenses is the Human Fertilization and Embryology Authority (HFEA), which is empowered to issue licenses and oversee ethical considerations in scientific.

Based on these licenses, the framework for scientific practices permissible within the laws of this authority is determined for research purposes.

On the Arab level, Article 4 of the Bahraini Law on the Use of Medical Techniques for Artificial Insemination and Fertility states that no natural person can establish, operate, or manage a healthcare institution in this field without obtaining a license from the competent authority.<sup>6</sup>

Similarly, the Saudi legislator also underscores the importance of licensing. According to their law, these centers cannot be established without obtaining a license from the Ministry of Health, based on a recommendation from the supervisory committee.<sup>7</sup>

In this context, Article 19 of the Tunisian Law on Reproductive Medicine states that: "Reproductive medicine must be practiced in licensed institutions within a separate and functionally independent unit. This unit shall be under the administrative responsibility of a qualified obstetrician licensed for this purpose. The designated physician shall serve as the coordinator of the mentioned unit. This license is granted by virtue of a decision from the Minister responsible for public health, following consultation with the committee referred to in Article 16<sup>8</sup> of this law."

Article 18 outlines some procedures for granting the license, which involve the applicant submitting a technical and administrative file. Afterward, the competent authorities within the Ministry of Public Health conduct an on-site inspection to verify the institution's compliance with the legislative and regulatory provisions applicable in this field.

In Lebanon, the Law on Assisted Reproduction established a committee known as the Supervisory and Oversight Committee for Assisted Reproduction Centers. Among its tasks is overseeing the licensing conditions and criteria for assisted reproduction centers, as well as making recommendations for granting licenses after ensuring compliance with the licensing requirements.<sup>9</sup>

The Lebanese legislator emphasizes the necessity of obtaining a license as a condition for establishing these centers in Article 4 of the same law, stating that no center can be established within the republic without obtaining a license from the ministry in accordance with the legal conditions and regulations stipulated.

Furthermore, it is highlighted that even if centers obtain establishment licenses, they must also obtain a license to practice assisted reproductive techniques.<sup>10</sup>

As for the stance of the Algerian legislator, Article 372 of the Health Law stipulates that licenses for institutions, centers, and laboratories applying assisted reproductive techniques shall be granted by the Minister of Health. However, this article does not specify the procedures for granting such licenses. This leads us to

refer to the provisions governing clinical studies since assisted reproductive practices are classified as clinical studies. Therefore, after analyzing Articles 381 to 384, we can deduce the stages or procedures for obtaining the license as follows:

1. The practitioner must conduct the clinical study upon the request for the license.

2. The practitioner<sup>11</sup> prepares a protocol focusing on the completed clinical study. The physician-researcher (who is presumed to be the applicant for the license) signs this protocol after obtaining approval and committing to respect the study's conditions.

3. The license application<sup>12</sup>, including a medical and technical file, along with the practitioner's statement of completing the clinical study on human subjects, is submitted to the Minister of Health.

4. The license application is reviewed by the Minister of Health within three months, after consulting the Medical Ethics Committee<sup>13</sup>.

## **THE SECOND SECTION: OVERSIGHT OF PRACTICES IMPLEMENTED IN THESE CENTERS**

Considering the medical therapeutic and non-therapeutic practices carried out in these centers, such as insemination, embryos, or human gametes, implementing oversight becomes crucial and necessary. This is due to the fact that these practices offer a fertile ground for both legitimate and illegitimate research and experiments. Additionally, these practices are considered sacred and hold sanctity. The pursuit of scientific advancement in this field may lead physician-researchers to neglect their scientific, ethical, and professional responsibilities. This could result in the pursuit of research that is not permissible or disregarding certain regulations and constraints that ensure the legitimacy of therapeutic or non-therapeutic medical experiments on human embryos and gametes.

From this context, the importance of monitoring the operations of these centers and the physicians working within them becomes evident, as they play a crucial role in ensuring compliance with scientific, legal, and ethical regulations and restrictions, fearing civil or criminal accountability.

Consequently, we will attempt to understand how legislative regulations govern the oversight bodies for these centers, both in Western and Arab countries. Regarding the Algerian legislative stance, it demonstrates a commitment to oversight functions for healthcare institutions in general, including private centers and institutions, such as reproductive medical centers and practices involving human embryos, as reflected in several legal articles.

One aspect of oversight for healthcare institutions involves the establishment of a specialized inspection authority, as per Article 189 of the Health Law. This law

institutes qualified inspector practitioners in external services under the Ministry responsible for health. These inspectors are authorized to investigate violations of laws and regulations in the field of health. Article 191 grants them a range of authorities within the scope of their oversight responsibilities, including:

- Monitoring the compliance of healthcare professions with legal and regulatory provisions.

- Ensuring the compliance of healthcare premises and facilities with standards and conditions.

- Overseeing structures, institutions, and any other places where healthcare activities are conducted.

The Algerian legislator also emphasizes subjecting these centers and institutions to oversight Article 310 of the Health Law states that private healthcare structures and institutions are subject to monitoring and evaluation by the competent departments and bodies under the Ministry responsible for health. To enhance oversight of healthcare centers, especially in the field of clinical trials, a ministerial decision dated July 31, 2006, was issued.

This decision focuses on the supervisory role of administrative bodies in clinical trials. Article 25 of this decision mandates the creation of local ethical committees at the level of each specialized healthcare structure. These committees are independent bodies composed of physicians, healthcare specialists, legal experts, and representatives of patient rights associations. They are tasked with overseeing medical trials within their area of expertise.

Regarding the issue of oversight for centers and institutions involved in assisted reproductive techniques and related practices, the Algerian legislator affirms this in Article 373 of the Health Protection and Promotion Law. This article states that institutions practicing assisted reproductive techniques are subject to oversight by specialized health services<sup>14</sup>. Furthermore, the Algerian legislator establishes the Medical Ethics Committee for clinical studies within external health departments, responsible for providing opinions on clinical studies, including studies involving human embryos.<sup>15</sup>

These principles are reinforced by the ministerial decision concerning clinical trials, which underscores the role of this committee. Article 24 of this decision mandates that all clinical trial projects undergo prior oversight by the Ethics Committee, which must provide its opinion within one month of receiving the application.

The Tunisian Law on Reproductive Medicine also addresses the issue of supervision, whereby the responsible physician practicing reproductive medicine is required to document their work in a register maintained within the units of reproductive medicine. The data to be included in this register are specified by the

Minister of Health<sup>16</sup>. This obligation to document information and data related to each reproductive procedure signifies a form of oversight over physicians, compelling them to adhere to all regulations and conditions. This register is subject to scrutiny by relevant authorities, which makes physicians vigilant in avoiding errors and mistakes that could lead to accountability. Moreover, these units are subject to inspection by inspectors affiliated with the specialized departments of the Ministry of Health. These inspectors are specialized in detecting violations and conducting investigations.

The Saudi legislator also addresses the issue of supervision over fertility units, as evidenced by certain articles in the Law on Units for Assisted Reproduction, Embryos, and Infertility Treatment. Article 14 stipulates that units for assisted reproduction and infertility treatment are obligated to submit an annual report to the supervisory committee, including comprehensive statistics and information about the cases examined and treated. The supervisory authority over these units consists of technical committees established by the supervisory committee.<sup>17</sup>

The Saudi legislator's emphasis on supervision is further highlighted in Article 27 of the same law, which mandates units for assisted reproduction to document all information and data, including treatment sessions and outcomes, and to retain them for a period of ten years, to be presented to relevant authorities upon request. This reflects a form of subsequent oversight on the activities of these units.

Additionally, the Lebanese Law on Licensing Assisted Reproduction Centers, in Article 2, establishes a supervisory and oversight committee for assisted reproduction centers, responsible for conducting oversight on these centers<sup>18</sup>. This oversight is conducted through performance evaluation reports to assess their compliance with quality standards.

## **THE SECOND REQUIREMENT: THE CONDITIONS OF CRIMINAL LIABILITY FOR REPRODUCTION CENTERS AND THE IMPOSED PENALTIES**

Article 51 of the Algerian Penal Code states that: "Except for the state, local communities, and moral persons subject to public law, a moral person shall be criminally liable for offenses committed on its behalf by its organs and legal representatives, when the law provides for this." Based on this article, it can be inferred that the Algerian legislator limits criminal liability to private moral persons, excluding the state, local communities, and moral persons subject to public law.

Similarly, the French legislator, under Article 121/2 of the Penal Code, stipulates that: "Moral persons, excluding the state, shall be criminally liable for offenses committed on their behalf and by their members or representatives, in



accordance with the rules set out in Articles 121/4 and 121/7, under the conditions provided for in the law and regulations. However, local authorities shall only be criminally liable for offenses committed during the exercise of activities that may be subject to delegation in the management of a public facility through agreement."<sup>19</sup>

From this, we can deduce the conditions for establishing criminal liability for private moral persons, based on the content of these articles:

1. The offense must be committed for their benefit and interest.
2. The offense must be committed by their organs and legal representatives.
3. The existence of the legal text regarding the criminal liability of a legal entity for the relevant crime.

Since medical research centers related to embryos and human fetuses are considered legal entities – often belonging to the private sector – they also bear criminal responsibility for therapeutic and non-therapeutic practices related to embryos and human fetuses, as well as for medical assistance with reproduction, provided that the necessary conditions are met. Afterward, they are subject to the prescribed punishment as stipulated by the law, which we will explain further.

### **FIRST SECTION: CONDITIONS FOR THE CRIMINAL RESPONSIBILITY OF FERTILITY AND EMBRYO-RELATED RESEARCH CENTERS.**

Before addressing the conditions for criminal responsibility of these medical centers, it should be noted that, in accordance with Article 51 of the Penal Code, private medical centers or institutions alone are subject to criminal provisions and liable for criminal responsibility if they commit any of the crimes defined by law.

The Algerian legislator has regulated the establishment and organization of these institutions through Executive Decree No. 07-321<sup>20</sup> dated October 22, 2007, which governs private hospital institutions and their operation. These are institutions involved in medical treatment and care, including gynecology and obstetrics, as well as diagnostic activities, and they possess legal personality.

#### **Firstly: The crime must be committed by one of the members, officials, or representatives of these centers.**

The crime must be committed by legal or authorized representatives of the legal entity. The term "members," "legal representatives," or "officials" refers to entities specified by law or the fundamental structure of the legal entity authorized to act on its behalf. This includes the president, director, board of directors, general assembly of participants and members, and the body is also referred to as the collective formation or regulatory council of the legal entity.<sup>21</sup>

Legal representatives refer to natural persons who have legal or contractual authority to act on behalf of the legal entity. They are elected or appointed representatives entrusted with the legal function of representing the legal entity<sup>22</sup>.

Article 65 bis 2 of the Algerian Code of Criminal Procedure defines the legal representative as follows: "The legal representative of a legal entity is the natural person authorized by law or the bylaws to represent it."

There are those who argue that the distinction between a member and a representative is that a member is an individual or group of individuals responsible for making decisions on behalf of the legal entity, whereas a representative merely holds a functional role and decisions taken by them do not directly stem from the legal entity itself.<sup>23</sup>

Returning to the context of medical centers for fertility and embryo-related research, considering the nature of these centers, the practices implemented within them, largely carried out by specialized doctors, raises the question: **What is the status of a doctor performing medical practices within the center?**

According to the definitions provided earlier for a member and a representative, and based on Article 51 of the Algerian Penal Code, we cannot classify a doctor as either a member or a representative of these centers; rather, they are considered employees or workers within these centers.

Consequently, it is inconceivable for these centers to bear criminal responsibility for violations committed by affiliated or employed doctors because they are not classified as members or representatives of the centers. In the event of violations or crimes committed by them, they alone would bear criminal responsibility.

However, certain specific laws related to fertility and infertility treatment add another category of natural persons for whom the legal entity assumes criminal responsibility for their actions.

The Bahraini law on the use of assisted reproductive techniques and artificial insemination, in Article 18, states that "the legal person shall be criminally liable if any crime stipulated in this law is committed by a natural person in its name or on its behalf, by one of its devices, representatives, or employees." Here, criminal responsibility is attributed to members, representatives, or employees, and based on this, we can say that the centers' responsibility arises from the violations or crimes committed by doctors as employees within these centers.

**Secondly: for a crime to be attributed to the legal entity.**

It is not enough for the act to have been committed materially; there must also be an element of attribution, which means that the criminal conduct and its effects must be attributed to the legal entity itself. Therefore, the legal entity's criminal responsibility cannot be established if one of its members commits a crime for their personal benefit.

Some practices committed by natural persons can be attributed to the legal entity in the following cases:

1. Unlawful acts discussed and decided upon by the legal entity's legal members on its behalf.

2. Criminal acts committed by natural persons, such as directors or members of the management, as representatives of the legal entity, using tools provided by the legal entity.

3. Criminal acts by individual members benefiting the legal entity, whether directly or indirectly, whether the interest is immediate or future. Based on this,

4. the criminal responsibility of medical centers for fertility and embryo-related research arises when members or representatives of these centers commit violations to achieve material or moral benefits for these centers<sup>24</sup>.

However, this raises questions about the nature of the violations committed by the members and representatives, given the specialized nature of practices carried out within these centers, typically performed by specialized doctors. This question will be addressed in the second section of this issue.

## **THE SECOND SECTION: NATURE OF CRIMES WARRANTING CRIMINAL RESPONSIBILITY OF FERTILITY AND EMBRYO-RELATED RESEARCH CENTERS AND THE IMPOSED PENALTIES EXAMINING FOR THERE.**

related research centers raises questions about the nature of violations or crimes committed by members or representatives of these centers that would justify attributing criminal responsibility to them.

First, it is important to note that according to Article 51 of the Algerian Penal Code, and in addition to the conditions required to establish the criminal responsibility of a legal entity, there must be an explicit legal provision indicating that the legal entity is criminally responsible for the violation committed by a member or representative.

In other words, if there is no provision explicitly attributing criminal responsibility to the legal entity for a specific crime, then the legal entity cannot be punished for the crime committed by a member or representative.

As for the practices carried out by specialized doctors, whether related to medical assistance for reproduction or the implementation of therapeutic or non-therapeutic experiments, it is assumed that a doctor should only engage in these practices after ensuring the presence of the legal conditions and regulations. However, the question arises: Who is responsible for verifying these conditions, the practicing doctor, or a specialized entity within the center?.

Returning to **Algerian legislation**, it mentions the conditions that must be respected, but it does not specify who is responsible for ensuring their fulfillment and compliance. Is it the centers, institutions, or the specialized doctor who will perform the medical practices?

In contrast, **Bahraini legislation** emphasizes that the medical centers are obligated to ensure the fulfillment of certain conditions before carrying out practices. Law No. 26 of 2018 regarding the use of assisted reproductive techniques and artificial insemination states in Article 6 that health institutions using these techniques must ensure the presence of all legal conditions and regulations before resorting to any practices related to human embryos.<sup>25</sup>

**Tunisian legislation** assigns the responsibility of verifying the conditions and regulations to the relevant doctor and requires them to submit a request from the spouses to the coordinator of the reproductive medicine unit.<sup>26</sup>

Based on the Algerian Health Law, Article 441 stipulates the punishment for a legal entity that commits violations listed in the eighth section of this law. The legal entity could be subject to the following penalties:

- A fine that cannot be less than five times the maximum fine imposed on a natural person.

- One or more of the following additional penalties:

\*Seizure of the tools and equipment used in committing the violation.

\* Prohibition of practicing healthcare activities for a period not exceeding five years.

\* Closure of the institution or one of its branches for a period not exceeding five years.

\* Dissolution of the legal entity.

From this article, it can be inferred that the legislator holds the legal entity criminally responsible for certain violations, including those related to medical assistance for reproduction and clinical studies involving human embryos and fetuses. These violations include:

**1. Operating without obtaining the necessary license for medical assistance in reproduction.** In this case, if a center or institution carries out these practices without having obtained the required license from the relevant authorities, it may be fined 5,000,000 Algerian dinars and be subjected to one of the aforementioned additional penalties.

**2. Violating the provisions of Article 371 concerning the conditions for resorting to medical assistance for reproduction.** If a method of medical assistance for reproduction is applied without the center or institution adhering to these conditions, it becomes subject to criminal responsibility and may receive one

of the penalties previously mentioned, including a fine not less than 5,000,000 Algerian dinars or one of the specified additional penalties under Article 441.

**3. Criminal responsibility for centers and institutions where processes such as egg and sperm donation, surrogate motherhood,** cloning of genetically identical living organisms, sex selection, and clinical studies are conducted is outlined in Algerian law. The prescribed penalties are as follows:

- Centers and institutions involved in processes of egg and sperm donation, surrogate motherhood, and allowing the use of surrogate mothers may be subject to a fine not less than 10,000,000 Algerian dinars, along with one or more additional penalties.

- Centers and institutions engaged in cloning genetically identical living organisms and sex selection may face a fine not less than 10,000,000 Algerian dinars, coupled with one or more additional penalties.

- Centers and institutions conducting clinical studies without the required authorization from the competent authority may be penalized with a fine not less than 50,000,000 Algerian dinars, in addition to one or more additional penalties.

Based on the above, it can be inferred that under Algerian law, criminal responsibility for legal entities involved in medical assistance for reproduction and clinical studies related to human embryos and fetuses arises under the following circumstances:

- Violation of licensing requirements.
- Violation of conditions and regulations related to these practices.
- Engagement in unauthorized and illegal practices as defined by the law.

### **CONCLUSION:**

In conclusion of this study, we have found that legislation must keep up with the developments occurring in the field of reproductive medicine, given the significant threats it poses to reproductive health, kinship relations, and even the fetus. The latter could potentially become a subject of research and experimentation. This legislative alignment wouldn't be effective if we merely establish criminal responsibility for violations by natural persons. It is equally crucial to extend this responsibility to legal persons, particularly in the context of fertility centers.

However, examining the legislative stance on this matter reveals that these centers are held responsible only if violations are committed by their members or representatives.

As a result, it becomes impossible to hold these centers criminally liable for medical intervention violations in reproduction since such violations are

committed by specialized doctors who are neither members nor representatives under the law.

Hence, the legislator is obligated to revisit this issue and establish clear criminal liability for fertility centers. This aspect is currently lacking, especially when we refer to the provisions specifying the conditions for establishing responsibility, which necessitate the involvement of a member or a representative.

---

<sup>1</sup> :Defined as an entity composed of individuals and assets recognized by the law as having separate legal personality and identity, Ahmed Mohamed Lotfi Ahmed, *Artificial Insemination: Between Physicians' Statements and Jurists' Opinions*, 1st Edition, Dar Al-Fikr Al-Jami'i, Egypt, 2006. , p 375.

<sup>2</sup> : Taheri Hussein, *Administrative Law and Administrative Institutions*, Dar Al-Khaldounia, Algeria, 2007, p 31.

<sup>3</sup> : Bin Ouda Sanusi, *Human Medical Experiments in the Context of Criminal Liability*, PhD Thesis, University of Tlemcen, Algeria, 2017/2018, p374.

<sup>4</sup> : The phrase "practices associated with and resulting from one of the methods of assisted reproduction" was written because, as we have seen in Chapter Two of this thesis, in most cases, therapeutic or non-therapeutic experiments are applied to embryos or human vaccines after resorting to one of the methods of assisted reproduction. For example, the previous diagnosis for transplantation may come after in vitro fertilization. The same applies to genetic modification. And, for instance, the process of gender selection of the fetus is also within the framework of implementing one of the methods of assisted reproduction. Scientific research, in most cases, is conducted on surplus fertilized eggs from assisted reproductive procedures"

<sup>5</sup> : "... A physician practicing in a multidisciplinary prenatal diagnosis center as defined by Article L. 2131-1..." - It can only be carried out under certain conditions, in a facility specifically authorized for this purpose by the Biomedicine Agency established by Article L. 1418-1...", Article L2131-4 of the French Public Health Code.

<sup>6</sup> : Article 4 of the Law on the Use of Assisted Medical Reproductive Technologies and Artificial Fertilization in Bahrain stipulates:

"...1- No natural or legal person shall establish, manage, or operate a healthcare institution unless they obtain a license issued by the Authority in accordance with the conditions and regulations provided in this Law and relevant laws, as well as the executive regulations of this Law

. 2- The activity shall not be practiced except after providing the administrative and specialized medical staff according to the requirements issued by the Authority."

<sup>7</sup> : Article 19 of the Saudi Law on Reproduction Units, Embryos, and Infertility Treatment states: "It is not permissible to establish a reproduction and embryo unit or an infertility treatment unit, nor operate them, except after obtaining a license from the Ministry, based on a recommendation from the supervisory committee."

<sup>8</sup> : Chapter 16 states: "A National Committee for Reproductive Medicine is established, responsible for expressing its opinion on the matters provided for in this Law. This Committee shall determine its composition and procedures by order."

<sup>9</sup> : Article 3 of the Lebanese Law on Licensing Reproductive Centers states: "The Supervision and Control Committee for Reproductive Centers is responsible for the following:

-1 Supervising the application of the conditions and criteria for licensing reproductive centers in accordance with the law. Recommending the granting of licenses for reproductive, embryo, and infertility treatment units, determining their level of activity after ensuring compliance with the licensing conditions outlined in the executive regulations...

2- No license shall be granted to any center within the country except after verifying the technical conditions, specifications, availability of equipment, medical and technical staff determined by the executive regulations of this law. -3 For the initiation of any assisted reproductive technology activity within any healthcare facility, obtaining a license according to the regulations and conditions specified in the law and the executive regulations for center licenses is required, regardless of the healthcare facility's license in which this activity is conducted...

-4 Establishing a technical committee to ensure compliance with licensing conditions, studying reports and complaints referred to it by the Minister or the Committee Chairman, and making recommendations regarding them, and conducting oversight on reproductive centers and any subject the supervisory committee deems necessary, and determining the remuneration of these technical committees by the Minister of Health and the Committee Chairman.

-5 Updating the conditions, criteria, and regulations for licensing centers and adopting them by the Minister, considering them a part of this law."

<sup>10</sup> : No natural or legal person shall establish, operate, or manage any center within the country except after obtaining a license from the Ministry in accordance with the conditions and regulations provided in this law and its executive regulations and decisions issued for its implementation.

<sup>11</sup> : According to Article 384, paragraphs 2 and 3 of the Health Law: "The practitioner is a natural or legal person who undertakes clinical study. They can also be a pharmaceutical laboratory or a service provider accredited by the Ministry responsible for health or a treatment institution, scientific association, research body, or a natural person possessing the required qualifications and competencies."

<sup>12</sup> : Article 8 of the ministerial decision dated July 31, 2006, regarding the regulatory role of administrative bodies in clinical trials states that the owner of the scientific project or the promoter must submit a prior authorization request to the Ministry of Health and Population and Hospital Reform, including several details about the trial. Also, Article 37 of this decision mentions the possibility for

**Criminal Liability of fertility institutions and centers -comparative study-**

---

administrative authorities to request additional information about the trial from the owner of the scientific project, and they have the right to prevent or halt the trial at any stage.

<sup>13</sup> : Committee of Medical Ethics, according to Article 382, is: "The Committee of Medical Ethics for Clinical Studies at the level of external health entities." The tasks, composition, organization, and operation of the committee are determined through regulation.

<sup>14</sup> : Committee of Medical Ethics, according to Article 382, is: "The Committee of Medical Ethics for Clinical Studies at the level of external health entities." The tasks, composition, organization, and operation of the committee are determined through regulation.

<sup>15</sup> : The legislator emphasized the supervisory role of these committees in the Health Protection and Promotion Law, Article 168, which explicitly states that the National Council for the Ethics of Medical Sciences is responsible for guiding and monitoring various medical activities, including medical trials.

<sup>16</sup> : Article 20 of the Tunisian Reproductive Medicine Law states that every practicing physician engaged in reproductive medicine must maintain an individual record of their work, and the pages of this record must be numbered consecutively and indexed by the competent territorial judge.

<sup>17</sup> : Article 18 of the Reproductive Units, Embryos, and Infertility Treatment System stipulates that: "The supervisory committee is responsible for the following:

...4: Forming technical committees ...to carry out supervision on these units..."

<sup>18</sup> : Article 3 states that: "The supervisory and oversight committee on fertility centers has the following responsibilities..."

3- Forming a technical committee ...to carry out supervision on fertility centers...

6- Evaluating the quality of work in fertility centers in the republic, with the evaluation process taking place annually or, if necessary, twice a year.

<sup>19</sup> : "Legal entities, excluding the State, are criminally responsible according to the distinctions of articles 121-4 to 121-7 in cases provided by the law..."

<sup>20</sup> : Executive Decree 07-321, dated October 22, 2007, regulating private hospital institutions and their operation, published in Official Gazette No. 67, which repealed Executive Decree 88-204 dated October 18, 1988, defining the conditions for establishing and operating private clinics.

<sup>21</sup> : Karim Karima, Criminal Liability of Private Hospital Institutions Organized as Single-Person Limited Liability Entities, Critical Journal of Law and Political Science, Faculty of Law, University of Mouloud Mammeri, Special Issue, Part I, 2008, p. 331.

<sup>22</sup> : Amr Ibrahim Al-Wakad, Criminal Liability of Legal Persons in the Field of Genetic Engineering, Genetic Engineering Conference: Between Sharia and Law, College of Sharia and Law, United Arab Emirates University, 2002, p. 1208.

<sup>23</sup> : Ben Ouda Snoussi, as cited earlier, p404.

<sup>24</sup> : Abdelrahman Khalafi, Criminal Liability of Legal Persons for Money Laundering Crimes, Academic Journal of Legal Research, Issue 2, Faculty of Law and Political Science, Abdelrahman Mira University, 2001, p. 28.

<sup>25</sup> : Article 6 states: "Health institutions commit to using medical techniques that assist in artificial insemination and fertilization with the following duties:

A) Ensuring the existence of a duly registered marriage contract with the competent authorities before and during treatment until embryo implantation, and attaching a copy identical to the original in the medical file. In the event of knowledge of the death of one of the spouses or the termination of the marital relationship for any reason, it is necessary to refrain from performing artificial insemination, fertilization, microinjection, and all freezing programs related to their embryos and dispose of them in the scientifically accepted manner.

B) Informing the spouses about the expected success rates, the possibility of multiple attempts, and the effects and risks on the health of the mother and fetus



C) Obtaining written consent from the spouses to perform any of the medical techniques that assist in artificial insemination and fertilization, according to the model prepared by the authority.

D) Obtaining written consent from the spouses to implant embryos resulting from zygote fertilization, according to the model prepared by the authority..."

<sup>26</sup> : Article 22 of the Tunisian Reproductive Medicine Law states that: **"Before starting actual practice in reproductive medicine, the practitioner concerned must ensure compliance with the conditions specified in Articles 3, 4, and 5 of this law."**

#### **BIBLIOGRAPHY LIST SETTING:**

##### **-First: legal texts**

1. Executive Decree No. 92-276 dated July 6, 1992, containing the Code of Ethics for the medical profession, published in Official Gazette No. 52.- a-
2. Tunisian Law No. 93 dated 08/07/2001, concerning reproductive medicine, published in Official Gazette No. 63.
3. Preliminary draft of the Algerian Public Health Law on the website: [www.Santemaghreb.com](http://www.Santemaghreb.com), published on October 22, 2020.
4. Executive Decree 07-321, dated October 22, 2007, regulating private hospital institutions and their operation, published in Official Gazette No. 67, which repealed Executive Decree 88-204 dated October 18, 1988, specifying the conditions for establishing and operating private clinics.
5. Saudi Arabian Law regarding the system of fertilization units, embryos, and infertility treatment, No. 86, issued on 23/9/1424 AH.
6. Lebanese draft law regarding the licensing of fertility centers, "In Vitro Fertilization Units."
7. Bahraini Law No. 62 of 2017 regarding the use of medical techniques to assist artificial insemination and fertility, published in Official Gazette No. 3325 on August 3, 2017.
8. Algerian Law No. 18-11 dated July 2, 2018, related to health, published in Official Gazette No. 46 dated July 29, 2018.
9. Law No. 94-654 of July 29, 1994, concerning the donation and use of elements and products of the human body for medical assistance in reproduction and prenatal diagnosis, published in J.O. July 30, 1994, JCP No. 39, September 28, 1994, texts 66974.
10. Law No. 88-1138 of December 20, 1988, concerning the protection of individuals participating in biomedical research, published in J.O. December 22, 1988; J.C.P. No. 2, January 11, 1989.
11. Human Fertilization and Embryology Act 1990.
12. Law No. 94-654 of July 29, 1994, concerning the donation and use of elements and products of the human body for medical assistance in reproduction and prenatal diagnosis, J.O. July 30, 1994, JCP No. 39, September 28, 1994, texts 66974.
13. Criminal Code, amended by Ordinance No. 2000-916 of September 19, 2000 - art. 3 (V) JORF September 22, 2000, effective as of January 1, 2002.
14. Law No. 2013-715 of August 7, 2013, amends Law No. 2011-814 of July 7, 2011, regarding bioethics by authorizing, under certain conditions, research on embryos and embryonic stem cells. JORF No. 182 of August 7, 2013.
15. French Public Health Code, Ordinance 2000-548 of June 15, 2000, Law 2002-303 of March 4, 2002, art. 92, published in JORF on March 5, 2002. Amended by Ordinance No. 2018-4 of January 3, 2018.

##### **-Second: books**

1. Ahmed Mohamed Lotfi Ahmed, Artificial Insemination: Between Physicians' Statements and Jurists' Opinions, 1st Edition, Dar Al-Fikr Al-Jami'i, Egypt, 2006.
2. Taheri Hussein, Administrative Law and Administrative Institutions, Dar Al-Khaldounia, Algeria, 2007.

**-Third: memory**

1. Bin Ouda Sanusi, Human Medical Experiments in the Context of Criminal Liability, PhD Thesis, University of Tlemcen, Algeria, 2017/2018.

**-Fourth: Articles**

1. Abdelrahman Khalafi, Criminal Liability of Legal Persons for Money Laundering Crimes, Academic Journal of Legal Research, Issue 2, Faculty of Law and Political Science, Abdelrahman Mira University, 2001.
2. Amr Ibrahim Al-Wakad, Criminal Liability of Legal Persons in the Field of Genetic Engineering, Genetic Engineering Conference: Between Sharia and Law, College of Sharia and Law, United Arab Emirates University, 2002.,
3. Karim Karima, Criminal Liability of Private Hospital Institutions Organized as Single-Person Limited Liability Entities, Critical Journal of Law and Political Science, Faculty of Law, University of Mouloud Mammeri, Special Issue, Part I, 2008.