Legal Controls for the Legitimacy of Biomedical Experiments on Man in Accordance with the Algerian Health Law N^0 18-11.

الضوابط القانونية لمشروعية تجارب الطب الحيوي على الانسان وفقا لقانون الصحة الجزائري رقم 18-11.

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Received: 09/04/2020 *Accepted: 19/07/2020* *Published:09/11/2020*

Abstract:

There is no doubt that scientific progress has a positive and negative side that may lead to a violation of ethics and law, hence; the need for human protection has increased. Therefore, the legislator decided to criminally protect the human right to the safety of his body, and biomedical research is at the forefront of the developments that have caused widespread controversy for the Algerian legislator to intervene and organize these researches under Law No. 18-11 on health, with a view to placing it within its legal framework.

Key words: Medical experiments; clinical researches; cloning; genetic engineering; human body.

ملخص:

لا شك أن للتقدم العلمي جانبا إيجابيا وآخر سلبيا قد يؤدي في أحيان كثيرة إلى مخالفة الأخلاق والقانون، نتيجة لذلك ازدادت الحاجة لحماية الإنسان، لذا فقد قرر المشرع حماية جنائية لحق الأنسان في سلامة جسده، وتأتي أبحاث الطب الحيوي على رأس التطورات التي

أثارت جدلا واسعا، ليتدخل المشرع الجزائري وينظم هذه الأبحاث بموجب القانون رقم 18-11 المتعلق بالصحة، بغية وضع موضوع الأبحاث الحيوية على جسم الإنسان في إطارها القانوني.

كلمات مفتاحية: التجارب الطبية، الدراسات العيادية، الإستنساخ، الهندسة الوراثية، الجسم البشري.

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Introduction

Medical experiments are any research or test on the human being in the light of the development of biological or medical data(1). They are of two types: therapeutic medical experiments, intended to achieve the patient's healing; and scientific experiments directed to acquire new knowledge without having any direct interest (2).

Scientific experiments and biotechnology are indispensable to mankind. Nevertheless, this research of a scientific nature outside the scope of treatment with its various forms related to the human embryo, stem cells, the human genome, genetic engineering, gene therapy, human cloning, and DNA research, are the most dangerous to the human entity in the scope of scientific and technological progress, has, generally, caused much controversy as they are, most often, not with guaranteed success, which results in prejudice and damage to health, which is the basis to the life of humanity, furthermore, some of these experiments are being carried out in secret, and this leads to serious abuses of flagrant violation of human rights in an attempt to discover a new drug or

modern treatment technique or to try to clone a human being, in addition to the use of embryos in stem cell research. Therefore, it has become a must when the volunteer or patient undergoes an experiment, to be assured that the law guarantees their protection against any attack on their bodies [3]. This is what has prompted the Algerian legislator to enact Law No. 18-11, including the Health Code. Henceforth, to what extent has the national legislator succeeded in organizing the conduct of biomedical experiments on humans?

1- The Legal Basis for Biomedical Research on Persons in the Health Act No. 18-11

Because scientific experiments aim at scientific progress, they must have special conditions in order to protect the subject- since if practiced freely without limitations or limits they would certainly harm the individual and society together.

1.1- The Scope of Human Biomedical Research

Scientific experimentation is the basis of any scientific development in the field of experimental sciences, including medical sciences, even if it is practiced on the human body. This authorizes the individual, within the the limits of the law, maintain the level of health that they live and be freed from physical and psychological pain [4]. As a result, significant efforts were devoted by some international organizations to establish common standards hence, marking the beginning of an international biomedical law[5] under which, and within those limits, biomedical researchers are allowed to try their research on persons. This is the same endeavor of the Algerian legislator, who attempted to

address this issue on the occasion of the enactment of Law No. 18-1[(6)], which repealed the Protection and Promotion of health Law issued in 1985 in an effort to remedy the shortcomings of the latter, which did not specify the legal concept of medical experiments and their essential characteristics that distinguish them from other medical work, and only specified some of its conditions, such as the need for free and informed consent, and the necessity to treat the person under control or develop medical sciences, in addition to respecting the ethical and scientific principles governing medical practice while conducting human trials, without mentioning the possibility of criminal accountability for criminal behaviors that may be committed on the occasion of conducting medical experiments, which forces one to refer to the general rules in this regard.

The Algerian legislator remedied this through the promulgation of Law No. 18-11 of July 2nd ,2018 on health, which established the basic provisions and principles relating to research in the field of biomedicine in section IV of chapter IV, in which the Algerian legislator was defined according to Article 377 of the same law. The Algerian legislator in this law called such studies "clinical studies".

In the next paragraph of the same article among the fields of these clinical studies, which varied according to their intent to three types: therapeutic, diagnostic and preventive studies; studies of bioequivalence and bioavailability; epidemiological studies and pharmaceutical epidemiology, one finds that the definition of the

Algerian legislator for clinical studies, could be considered as a successful definition that is commensurate with the definition of medical experiments in general, while its identification of areas of clinical studies, one may argue, was not correct, as it was limited to medical experiments aimed at treatment or prevention and pharmaceutical experiments, yet did not refer to scientific experiments that have become practiced in many countries, even in Arab countries, especially that bio-pharmaceutical experiments, have been broached twice, because bioequivalence and bioavailability studies are terms used in pharmacy to evaluate two formulations of the drug within the human body (7).

Therefore, medical research may focus on the study of a disease, which makes patients suffering from this disease a good sample to help the researcher to progress in his research. This has prompted the legislator to intervene through the text of Article 386 of the same law to protect the category of patients undergoing clinical studies from any coercion or pressure that may affect their freedom.

It is also the same texts governing this type of research. It is discovered that healthy people can volunteer to undergo this type of research and study in order to develop medical and biomedical knowledge and expand scientific and vital data that benefit the community with no interest or individual benefit to the volunteer. Thus, the legislator tried to strengthen the legal protection of this group by granting them additional guarantees under Articles 391 and 392 of the same law.

1.2- Conditions for Permitting Biomedical Research for Subjects

Because scientific experiments are aimed at scientific advancement, they must have special conditions in order to protect the subject. These conditions are

a. Satisfaction

The legal practice of any scientific research or medical experimentation is legally subject to the free[8], explicit and informed consent of the person[9].This is based on his constitutional right to physical and mental integrity and respect for his human dignity, which is known in the legal sciences as the right to self-determination. It is required that the consent be true, free, enlightened and issued by a qualified person, as most legislations require that this consent be void in written form[10].

Article 386 of the Health Act No. 18-11 contains the special conditions for those who are undergoing clinical studies informed by the researching physician or their representative, in particular about:

- The objective, methodology, duration, benefits, difficulties, expected risks and potential medical alternatives;
- The right to refuse to participate in a research or withdraw their consent at any time without taking any responsibility and without prejudice to their treatment.

Article 387 of the same law states: "The consent of the person who is prepared to undergo a clinical study must be included in the protocol of studies."

b. Eligibility

Scientific medical experiments do not raise problems if it comes to experiments on the integrated human being, because he has the legal personality and full capacity, as it can be free and informed consent to undergo the experiment(11), whether therapeutic or scientific, because it is fully aware of the seriousness of the experience like any contractor must be free from defects of the will, as a general principle requires that the person subjected to the test to be fully qualified, the latter is to attain the legal age determined by the legislation and the enjoyment of civil forces, and therefore lack of capacity does not give people the ability to understand and distinguish the nature of experiences dissatisfied with it, and cannot defend their rights and it shall not expose the minor and the insane, they cannot be exempted from experiments, though .

A woman who carries the risk of medical and scientific experiments, which does not benefit the person in question(12).

2- The Special Conditions of the Experimenter and the Criminal Responsibility Resulting therefrom

The nature of the work carried out by physicians during human experimentation is very different from therapeutic medical work. This makes them acquire a clear specificity either in terms of controls to do these experiments or in terms of the responsibility of those responsible for the application of this research on the human being.

This will be addressed in what follows from the study. Firstly, the controls imposed by Law No. 18-11, including the Health Act, will be addressed to the person conducting the experiment.

Secondly, the penal responsibility for the promoter, as described by the law on conducting these reseaches on human beings, will be examined. The study will be limited to criminal responsibility only rather than civil and disciplinary responsibility, as this study is related to the provisions contained in Law No. 18-11.

2.1- The Conditions of the Experiment and the Experimenter

In order to remedy the legislative vacuum surrounding the abolished Health Protection and Promotion Law, which became evident in its shortcomings and its failure to keep pace with the various modern developments in the field of health in general, the Algerian legislator has, through Law No 18-11 relating to Health, introduced a set of conditions to subjugate the human being to medical researches.

With regard to the conditions that must be met for the conduct of clinical studies were as follows:

a. Observance of Ethical and Scientific Principles[(13)]According to article 378 of the Health Law No. 18-11.

b. Structural and Medical Specialization Requirement[(14),]One of the conditions imposed by the law for conducting research and clinical studies as stated in Article 379 and 380 of the Health Act.

c. The Benefits of the Experiment are Greater than the Potential Risks(15),This is the aim of the Algerian legislator, which is included in article 380 and 391of the Health Code.

d. Medical Ethics Committee Approval for Biomedical Research, Clinical studies, as provided for in Article 383 of the Health Code, are subject to the opinion of the Medical Ethics Committee (16).

e. Obtaining a License to Conduct Biomedical Research

The practice of biomedical research cannot be carried out without obtaining a license from the Minister in Charge of Health who decides on the medical and technical file submitted to them by the promoter within three months. Any amendment to the study file after obtaining the license will be subject to the approval of the Minister in Charge of Health(17).

f. Editing a Protocol on the Biomedical Research Project, As stipulated in Article 385 of the Health Code, the promoter must write a protocol regarding the clinical study to be conducted. The Protocol assures the consent of the person who is prepared to undergo the study, as provided for in article 387 of the same Code.

g. Compensation of Damages Caused by Medical Experiments

the Algerian legislator, obligated the researcher to compensate for the damages resulting from the experiment, whatever the cause of the damage, and whatever the degree of intervention of the researcher to compensate for the person under study and their rights. This has been inspired by many legislations

namely the French legislation [18], and is confirmed by article 393 of the Health Code.

h. Biomedical Research Risk Insurance, the Algerian legislator obligated, according to the Health Act No. 18-11, the experimenter, to underwrite insurance to cover their civil and professional responsibility[19] .

2.2- Penal Responsibility for Biomedical Research

In article 384 of Law 18-11, which contains the Health Code, the Algerian legislator has defined the person in charge of clinical studies and termed them "promoter". A promoter is a natural or legal person who initiates a clinical study who can be a therapeutic institution, a scientific association, a research body or a natural person with the required qualifications. Accordingly, the question of criminal responsibility for biomedical research on human beings will be addressed by dividing the study into two branches. First, the responsibility of the natural person will be broached, and in the second section, the responsibility of the legal person.

2.2.1- The Natural Penal Responsibility of a Person for Carrying out Biomedical Research on Humans

In regards, the Algerian legislator in organizing the subject of medical research through Law No. 18-11, which includes the health law, set out a set of conditions that make it respectable and which have already been discussed earlier in this study. The legislator did not set a strictly defined legal model for each outcome of the study. Like most legislation, only the need to abide

by the conditions and controls to give legitimacy to the clinical study, and that failure to adhere to it changes the description of behavior and turns it into an intentional crime.

With regard to biomedical research, the Algerian legislator punishes the person conducting a study for the purpose of trading in scientific research by donating, selling or any other form of treatment related to the human body materials, by imprisonment from ten (10) to twenty (20) years and a fine of 1.000.000 DZD to 2,000,000 DZD [(20)].

Under article 436 of the same law, anyone who violates the prohibition stipulated in article 375 of the same law on the reproduction of genetically identical organisms and the selection of sex shall be punished by imprisonment from ten (10) to twenty (20) years and a fine of 1,000,000 to 2,000. .000 DZD

The text of article 437 of the same law punishes anyone who uses the situation under observation of a person for a purpose other than their interest by imprisonment from two to five years and a fine of 100,000 dirhams to 500,000 dirhams. Nonetheless, the text is vague as the clinical studies that do not directly benefit the subject to it in many stages, including the observation, are not illegal under this law.

Under the provisions of Article 438 of the same law, the legislator punishes any person who carries out clinical studies on a human being without a license from the Minister in charge of health, by imprisonment from two to five years and a fine of between 5 million and 10 million dirhams.

The Algerian legislator also decided imprisonment from two to five years and a fine of 100,000 to 500,000 dinars each research physician starting a clinical study without the free, explicit, and informed consent of the subject subject to the research protocol.

In addition, anyone who commits one of the above offenses may be punished by one or more of the supplementary penalties provided for in the Penal Code [(21)].

2.2.2-Criminal Liability of the Legal Entity for the Application of Biomedical Research to Humans

The punishment of natural persons who commit violations and abuses when practicing clinical research and studies on human beings is not enough to combat such serious abuses. The criminal responsibility of the laboratories and centers that have such crimes must be established[(22)], especially with the increasing activities of moral persons in the medical field [(23)].

A juridical person means a group of persons or funds that unite or join together and cooperate to achieve a legitimate purpose recognized by the legal personality [(24)].

Amending its previous position not to hold legal persons accountable, the legislator, then, reaffirmed their position in this regard through Law No. 18-11 of the Health Code, promising to establish the principle of criminal responsibility for medical research on the practice of the human being.

While the legislative and judicial hesitation on the criminal liability of the legal entity is resolved by an explicit provision to

hold such persons accountable, through the text of Article 411 of the Health Code, it is understood from the text of the article that the legal persons are charged that the legislator active in the medical field has criminal responsibility, which was previously only civil liability(25) and in some cases disciplinary or administrative liability. Its criminal responsibility is based on all the violations stipulated in Chapter Eight of Law No. 18-11 which includes the Health Law, that is, the violations that have already been talked about when the responsibility of the natural person regarding medical research is dealt with. This means that the legislator did not exclude moral persons from one of the violations. The difference, however, lies in the fact that the legal nature of the moral person is punishable by the same nature as the natural person, hence(26); the Algerian legislator is keen to establish a set of penalties that can be imposed on the legal persons concerned with the application of criminal responsibility, specified in Article 411 of the 18-11 law.

It is clear that the legislator has taken into account the special nature of the legal person, which never prevents it from being punished, especially with the increasing practice of biomedical research recently. A fine of not less than five times the maximum fine provided for the natural person, together with the seizure of the means and material used to commit the offense. The legislator also decided to severely punish the legal entity's activity and reputation by preventing the health activity for a period not

exceeding five years which is considered the most severe penalties applicable to the legal person.

Conclusion

There is no doubt that the progress in the field of medicine in general, was the result of scientific research, which was often applied to Man. From this perspective, it is clearly observable how huge are the risks threatening human dignity. As a result, the Algerian legislator intervened under Law No. 18-11 on Health, which regulated the subject of experiments to which the human being could be subjected in detail.

- The compromise position of the Algerian legislator between the need of mankind to achieve further development in the level of medical techniques, and the need to protect the safety of those who have accepted to participate in those experiments. The study requires compensation, in addition to the penalties li
sted by the Algerian legislator in case they violate the terms and conditions prescribed by law, and this is a positive and commendable step calculated for the Algerian lawmaker.

In examining this issue, we have reached a set of recommendations as follows:

- The need to allocate a committee to raise awareness of the effects of the experiment and its consequences and to ensure full satisfaction of the conduct of the experiment, requiring this committee not to include any of the medical staff assigned to conduct the experiment.

- Strict and serious control of research centers in the field of biomedical experiments to ensure that doctors respect the conditions set by the law to practice the profession.

Marginalization

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2 - J.George Annas, A.Michal Grodin, The Nazi Doctors and the Nuremberg code, Human Rights in Human Experimentation, 1992, New York, p.47.

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4 - Favoreu (L.), Philip (L.), Les Grands décision du conseil constitutionnel, Dalloz 8 éd, 1995, p.215, and Rémy C Brilloc, Le corps humain, droit et libertés fondamentaux, 3eme éd, 1996, p.51.

5 - Roberto Andoro, Biomedicine and International Human Rights Law: In Search of Global Concensus, Bulletin of the World Health Organisation, 2002, p 259.

6 - Law N 18-11, on July 02nd 2018 Related to health, Official Journal 46 issued on July 29th 2018.

7 - For more details see htt//ar.wikipedia.org/wiki, consulted 20/08/2018 at 3 pm.

8 - Marshall B Kapp, Ethical and legal issues in research involving human subjects :di you want a piece of me ?, joutnal of clinical pathology v.59(4), US national library of medicine, 2006.

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13 - Dominique Nickel, Berne, ibid, p.16.

14 - Mathieu Gagné, ibid, p.1156.

15 - Dominique Nickel, Berne, ibid, p.50.

16 - See article 395from Health Law N 18-11.

17 - See article 394 and 399 from Health Law N 18-11.

18 - Irma Arnoux, les droits de l'être humains sur son corps, presse universitaires de Bordeaux, Pessac, 2003, p. 272.

19 - See article 397 from Health Law N 18-11.

20 - Article 435 of the Health Law No 18-11.

21 - See article 439 from Health Law No 18-11.

22 - Léon Michoud, La théorie de la personnalité morale et son application au droit français. Partie 2, editeur libr. Générale de droit et de jurisprudence, F.Pichon et Durand-Auzias, 1909, p.503.509.

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