

The principle of precaution and its impact on civil medical liability

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Abstract

The precautionary principle is defined as the principle that obligates not to invoke the absence of scientific certainty when it comes to the harmful effects of activities to refrain from taking the necessary precautionary measures or delay in taking them to avoid the occurrence of such damages.

By examining the precautionary principle in the medical domain, it appears at first sight that it is opposed to and opposite to the civil liability of doctors, with reason of the compensable nature of damages within the framework of this liability, which requires that the damage be direct, fixed and verified, overtly certain. All of this is inconsistent with the application of the precautionary rules, It requires that the danger is not scientifically certain on the one hand, and on the other hand, that The precautionary principle appears before the damage occurrence, while civil liability, in addition to the compensation system that it decides, engender later, so after the damage has occurred, which creates a contradiction between them.

Keywords: The precautionary principle - scientific uncertainty - medical liability - risk – damage - objective civil liability.

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Introduction :

Due to the scientific and technological developments that the world has witnessed in various fields, human life has not become without risks, and dealing with these risks of all kinds, which among them whether expected or unexpected in order to confront them, that is what is representing a prerequisite for the existence of humanity.

Perhaps the optimal solution to confront most of these risks is embodied in the application of the precautionary principle, which means preparedness and taking the necessary precautionary measures to confront any potential or assumed threat in the absence of forceful scientific evidence toward the occurrence of these threats or risks, as well as the possibility of realizing all its results and effects, which are considered as a difficult matters and requires precaution.

The precautionary principle is a principle related to the measures must be taken in order to limit or reduce the damages caused on environment and health. It does not aim to stave off risks because these latter are inherent to life and to any activity practiced by human, so the precautionary principle is limited to unknown and potential risks.

Sometimes risks arise in the health field as a result of scientific and technological progress, as previously mentioned, and they arise also largely from still unknown risks that have not been scientifically proven yet.

However, the unexpected risks resulting from modern medical practice imposed more precaution on the doctor, by embodying the precautionary principle in medical field, which expands the scope of the doctor's fault liability, then precaution is prior to taking any decision, while the doctor's civil liability is established after the occurrence of the damage. The doctor, when providing treatment to the patient, bases his decisions on two important things: diagnosing the disease and choosing the appropriate treatment, taking into account scientific attempts and experiments, as well as the uncertain risk that may occur. Thus, precaution during providing treatment is essential.

In view of the novelty of the issue related the precautionary principle generally in the environmental field as well as particularly in the medical field, and what it poses as several problematic, subsequently the problematic of this intervention revolves **around the extent of the measures effectiveness of the precautionary principle and its applied procedures in establishing the doctor's liability and its expand?**

In order to answer the problematic posed, the descriptive approach will be relied upon to introduce the various concepts containing this study, as well as the analytical approach for analyzing the legal texts used. Accordingly, the subject of the current intervention was divided into two sections. In the first section, we will discuss the concept of the precautionary principle, and in the second section, the application of the precautionary principle in the field of civil medical liability.

The First Topic: What is the Precautionary Principle

The precautionary principle is considered as one of the most important principles that came as a result of a new understanding for progress, which is based on protection from unexpected risks that are set up on suspicion and fear of them. Therefore, in this topic, we will discuss the concept of the precautionary principle (the first requirement) thereafter to determine necessary condition for its application (the second requirement).

The First Requirement: The Concept of the Precautionary Principle

To define the concept of the precautionary principle, it is necessary to define the principle through its emergence and development (section one), then we will discuss the precautionary principle in Algerian law (Section two).

Section One: Definition of the Principle of Precaution

Precaution linguistically is derived from the root of “hawata”, which is the sensory awareness of something (Samai, 2007, p. 14). Precaution or prudence are those measures taken to obviate or avoid damage and limit its several effects.

the precautionary principle appeared for the first time in Germany during the seventies of the last century through the German government's policy in the field of environmental protection from the risk of pollution, as it was called at that time by the German word Vorsorgeprinzip, which means a precautionary principle to justify strict measures devoted to deal with acid rain, global warming and North Sea pollution. Where the German legislator initiated in 1970 within the framework of a law included the political orientation towards precaution, represented in the draft law to ensure clean air, which is called Vorsorgeprinzip in relation to the Vorsorgeprinzip conference in 1974 (Milod, June 2017, p. 496)

Soon, this principle began to appear at the level of international agreements and the internal laws of countries until June 13, 1992 during the

famous Rio de Janeiro conference, known as the “Earth Summit”, where this principle was included in the provisions governing human relationship with environment, and stipulate in the principle 15 thereof that: **« In order to protect the environment ,the precautionary approach shall be widely applied by states according to their capabilities. Where There are threats of serious or irreversible damage, lack of full science certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. »**

As for the French legislation, the principle was explicitly stipulated for the first time in the Barnier Law of February 02, 1995, where it approved the precautionary principle as the most important general principle of environmental law, and it tried to define the principle of precaution, as it stipulated in Article 200/1 thereof that: **“In the absence of scientific and technical certainty, it should not delay taking effective and appropriate prior measures to avoid a grave and irreversible danger to the environment at an acceptable economic cost.”** (Khalidiyah, 2021, p. 661)

In 1998, the French Council of State applied this principle in the health field, and defined it as follows: **“It is the obligation applied in charge of the decision-maker, whether general or specific, to abstain from acting or refuse within reason of the risks resulting from this action, it is not enough to considering known and possible risks, but Also it requires to bring up the scientific evidence that confirms the absence of any possible danger”.**

What is noticed about this definition is that it radically changed Barnier's definition, where it did not speak the enormity of the risks and the specificity of economic costs resulting from measures taken to prevent damages (Faudel, 2011-2012, p. 112).

Some internal legislations have also taken care to include the precautionary principle in their texts, especially those related to the environment, this is what was stated in the European directive (CE / 18L2001) on the environment and organisms in Article 8 thereof, where it stated: **“The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.”**

As well as Article 5 of the European Directive (CE/25/2001), which is reinforced through it the concept of precaution and the necessity to take preventive measures in case of an expected environmental damage, and environmental liability were established.

As for the health field, the mad cow disease incident, or what is known as the epidemic of bovine spongiform encephalitis, it was considered as a transit road of the principle from the environment field to public health field and consumer protection, not only at the European level, but also at the international level, despite the lack of conclusive evidence about a relationship between this disease and animal feed, consisting of animal flour prepared from contaminated animal dead bodies that are unfit for consumption. The British government decided to completely ban the use of this flour in feeding livestock, and therefore slaughter all cows that could transmit the disease, which is considered as an effective application of the precautionary principle in protection Consumer field and Public Health. (Amal, p. 67)

In the same context, Professor Marc Hunyadi of the University of Laval considers that: "Caution lies in the uncertain potential risks that have not yet been confirmed scientifically, but the possibility of their occurrence can be determined from experimental and scientific knowledge, such as hormonal meat ... etc." (Naima, 2013-2014, pg. 04)

Based on the foregoing, there is no collecting excluding definition that legal doctrine has settled on for the precautionary principle. Therefore, it revolves around the same concepts, namely:

The necessary measures must be taken when there are serious reasons suggesting that an activity or a product threatens gross and morally unacceptable damage to health or the environment, and then the nature of these measures is to reduce or put an end to the activity or product from circulation, even in the absence of confirmed evidence of the causal relationship between the activity or product and the negative effects that the fear is based on. (Naima, 2013-2014, p. 108)

The Second Section: The Principle of Precaution in Algerian Law

The precautionary principle is based on special conditions for its application, so it begins to work when its three conditions are met, represented in absence of scientific certainty (First), possible occurrence of risk (Second), adaptation of the potential damage (Third).

First: Absence of Scientific Certainty

It is considered one of the most important conditions for applying the precautionary principle, and according to Principle 15 of the "Rio de Janeiro" Declaration on the Environment and Sustainable Development of 1992, in case of a danger that warns of gross or irreversible damage, the absence of scientific certainty in that case and that time should not be an

obstruction to delaying taking appropriate measures to prevent the deterioration of environmental situation.

The principle aims to take precautions in front of dangers that are still unknown or not well known, and science has not proven with certainty their possible occurrence, so their occurrence, although it seems likely, is not achieved. (Martin-Bidou, p. 646)

The content of this condition is that when sufficient scientific evidence is not available based on current scientific knowledge, which its availability would provide sufficient data about the risk and the extent of potential damage, it is necessary to resort to the principle of precaution, as it is considered one of the non-traditional solutions that constitute an exception to the rule of subordination of law to science. Where it arose to remedy the absence of scientific certainty or scientific evidence regarding the effects of dangers. (Siham A., page 76)

The absence of scientific certainty is explained by lack of scientific evidence with reason of a causal relationship between the gross damage and potential risk, therefore the inability to provide a conclusive scientific explanation for potential risk impact on health, environment and biodiversity... so the absence of scientific certainty in itself is considered as suspected risk that is not certain, its criterion is damage that may be caused to environment. (Omar, March 2015, p.16)

Since the state of scientific uncertainty means the absence of full scientific knowledge of all or some aspects related to the potential risk in environment, or that concerning product, or service, due to the fact that the scientific data is not available in a sufficient way to verify it, and therefore, it is an established risk among some scientists and experts due to the scientific data, which they have, so whether it is a total absence of sufficient knowledge or the inadequacy of this knowledge, we are in a state of scientific uncertainty. (Naima, 2013-2014, p. 150)

It should be noted that the case of uncertainty is not a permanent and stable case, but rather it is subject to disappearance and reduction through scientific research progress, so the risk' effects on the environment or on consumer's safety and security do not appear directly, but require more research and analysis to know its potential effects, and therefore it must be activate the precautionary principle trough taken all measures to prevent the possible occurrence of environmental or health risks in the future.

And since scientific certainty has become an inevitable reality, it has emerged two positions that can be adopted: (Martin-Bidou, p. 646)

The first opinion is permitting the establishment of the activity or product presentation, while tighten that it would better to deepen and continue scientific research and not precipitate to put enact laws in such way that prevent obstruction of industrial and medical development in particular.

This opinion has been criticized on the basis of ignoring environmental and health dimensions when authorizing the establishment of projects, and the gross and not repairable or recoverable damages that could be, or it could be possible but at a very high economic cost, as well as advantages that could be achieved. (Naima, 2013-2014, p. 153)

As for the second opinion, on the contrary, it prefers and supports resorting to immediate organization of measures taken from a legal point of view, whereby the necessary environmental and health conditions are set for permitting their establishment, in order to avoid any dangerous and irreparable damage in absence of appropriate measures. According to this opinion, by applying the precautionary principle, the absence of an absolute scientific uncertainty do not became an obstacle to any action aimed to protect environment and health. (Faudel, 2011-2012, p. 115)

Accordingly, we conclude from what precede that precaution has been purified to try to fill the void due to the absence of scientific safety, and that this principle is always in a state of continuous development, thus its content will change according to scientific developments, and therefore its existence is temporary and threatened with disappearance as soon as absolute scientific certainty subrogate uncertainty. (Faudel, 2011-2012, p. 116)

Second: The Possibility of Risk Occurrence

A risk is every incidence, whatever the reality of its causes, that would turn something from benefit to harm, and to define the risk concept that justifies precautionary principle application represent a considerable importance with reason that the risk varies according to possibility degree of its occurrence, and because there are risks that are likely to fall in a potential occurrence, then they are suspicious, so which of these dangers applies the precautionary principle?

1- The risk that is certain to occur is the obvious danger which their causes and damages result are reconized and known to scientists, experts and political decision-makers, so there is scientific certainty in them, and therefore state takes the necessary procedures and measures to prevent the occurrence of damages in accordance with the principle of interdiction, prohibition or prevention.

So, this risk is not submitted in any way to the precautionary principle, because it is a certain risk as long as it can be expected to occur, but the risk

is distinct by surprise characteristic, so its occurrence is always not fixed, however the causal relationship between possible accident and expected damage is confirmed, and thus the risk becomes certain with reason of the causal relationship between these medical activities and between ecological phenomena, then these well-known risks are submit to the preventive measures application, and therefore they cannot be included within the precautionary principle' risks.

Accordingly, the confirmed risk is that clear one, which is scientifically certain, and being certain, so that it is a real risk and with regard for the threat, it poses, it does not depend on hypotheses, but is based on definitive scientific evidence.

In this framework, there is another type of risk that does not subsist within precautionary principle application, which is what is known as secondary risk, which is about those guessed risks that are based on evaluative considerations without any scientific reason. Assumption, guess and intuition cannot justify separately the principle application. (Faudel, 2011-2012, p. 119)

2- Suspicious risk: It is the one that entails the precautionary principle application, as it is a hypothetical risk that is uncertain, representing damages that are expected to occur. Lack of full knowledge of the activity, product or service raises doubts about its safety on the environment or on the health and consumer's security.

Accordingly, scientific uncertainty should not be understood as the complete absence of risk, but rather it means the existence of risks without the possibility to provide a definitive scientific evidence. (Calais-auloy J. and f. Steinmetz, 2000,)

In this framework, the Paris Agreement on the Northeast Atlantic Ocean of 1992 has declared **“reasonable causes for inquietude.”** As soon as there are **“serious reasons,”** the precautionary principle can be applied without waiting for conclusive evidence. In this case, this principle can be applied to all medical risks whenever a causal relationship between action and its effects has not been clearly established.

So, the suspicious fault is an uncertain and potential risk.

Third: Conditioning Potential Damage

The damage must be characterized by a certain degree of riskiness in order for a precautionary measures to be taken, which is what most doctrinal jurists went to, and according to their opinion in what concerns the precautionary principle, it relates to the risks lead to considerable and massive damages.

Determining the damage is a great importance, because the expansion of damage's concept and its extent is often given it a general concept, as many treaties mention damage caused on environment or on human health without specifying its type or degree of severity, while there are some treaties such as those related to combating marine pollution that their texts were more accurate, as it mentioned the infringements on various sea resources in an extensive sense.

Accordingly, defining a certain degree of damage (risk) has become necessary to avoid the extension and expansion of the precautionary principle application on many cases that may not fall within its application, as the majority of jurists consider that the precautionary principle application is related to the risks that lead to important and massive damages. (Faudel, 2011-2012, p.120)

However, the problem subsist in the fact of this condition which is personal, and some give it a different concept according to concerned people, place and time in which it occurs, for example, if the doctor commit a mistake by removing the womb' woman, then he condemn her to be barren in the future, then it is considered a gross harm for this woman, but if this happens with a woman whose tests showed that she has infertility not treatable, so the harm is not considered massive for her.

Also, the degree and importance of the risk effects is difficult to estimate, especially if it encounters other dangers that can multiply or recur, or having a sudden accident that can take another unexpected extent. Therefore, the precautionary principle takes into account the impotent risks because in the case of its accumulation and collecting, it can lead to serious threats. (Faudel, 2011-2012, p. 121)

The damage must also be irreparable, it means that it is not possible to return to starting point or comeback the situation to what it was before the damage occurred, and this leads to the precautionary principle application on several risks according to its specialization and its application domain, but the criterion of damage' irreversibility does not always provides a satisfactory solution, and therefore most definitions accommodate the seriousness criterion and the damage irreversibility. (Takarli, 2005, p. 102)

The Second Topic: The Precautionary Principle Application in The Medical Civil Liability Domain

In this topic, we will discuss the current expansion of the fault liability domain based on the precautionary principle (the first requirement), then the objective medical liability based on the precautionary principle (the second requirement).

The First Requirement: Expanding The Scope of Fault Liability based On the Precautionary Principle

According to the principle, fault liability cannot be established except based on previous knowledge, and this means that a person cannot be responsible for something he does not know, then the precautionary principle came to expand the concept of liability based on the classic fault, and this one was taken for its existence even in the scientific uncertainty case.

However, this shift does not mean a regression in objective liability, but rather aims to improve the people's protection against risks, by tightening the duties and obligations imposed on the doctor and health services.

In this requirement, we will discuss the concept of fault in the precautionary principle (the first section), and the expansion of the assumption of fault proven under the precautionary principle (second section), and this is based on French law and judiciary due to the absence of a text related to it in Algerian legislation.

The First Section: The Concept of Fault

In Article 1382 of the French Civil Code, the French legislator did not define fault, but doctrine was concerned with that. One of the most important definitions of fault was the definition given by Professor PLANIOL as: "breach of a previous obligation." However, the professor did not differentiate in his definition between fault in contractual liability and tort liability, and that the implementation of this definition requires defining duties and obligations of the person in order to make it easier for the judge to determine the extent to which the behavior of the violator deviates from this duty. This is what Professor PLANIOL tried to remedy by presenting four types of obligations that lead to fault, which are: abstention from using force towards things and people, abstention from cheating, abstention from every action that requires an ability or skill that a person does not possess sufficiently, adequate control for what a person possesses of dangerous things and people who are under his control. (Leaders, 2005, p.153)

Doctrine and jurisprudence have established that the doctor is responsible for his fault, whether it is a professional or ordinary mistake, gross or minor, positive or negative, this is due to the special nature of the doctor's profession, because he deals with the human body, which is the most precious thing we own, and the harmful potential for it is major on the basis that the doctor is not obligated to achieve a result, which is the

recovery of the patient, but is limited to exerting care, and thus the patient remains the charge of proving the fault that resulted, which is often difficult as a result of the specificity of the medical fault, especially if the latter was technical (Naima, 2013-2014, p. 306)

Wherefore, and about the traditional legal rules insufficiency in protecting patients, it has become imperative to resort to the precautionary principle with the aim of emphasizing the doctor's liability.

the precautionary principle is considered a restoring factor of the fault concept, as the lack of respect for this principle in itself is considered an evaluator of fault, and on this basis every doctor who did not take preventive precautions from a known or expected risk is considered faulty, and the same applies to those who do not take the necessary precautions even in the case of doubt, and thus the precautionary principle is so far away from the obligation to exert care, which imposes caution in front of known risks. (Faudel, 2011-2012, p. 123)

According to the principle of precaution, fault arises even in the case of uncertainty and probability, and the jurisprudence dated on 1993 has indicated that the precautionary principle is an inevitable principle when the state of uncertain knowledge has a harmful effects on public health, so, if we are faced of an imminent and unknown risk, failure to act is considered as a fault (Tourneau, 2009., p. 138).

So, the fault concept evolved from a provable fault to a probabilistic fault.

The second section: Expanding the Assumption of Proven Fault under The Precautionary Principle

The rising sense of traditional legal rules insufficiency to provide protection for patients, has prompted judiciary to resort to the idea of potential fault, even if it has no legal basis, in front of contemporary scientific developments that have made a huge leap in therapeutic methods. (Ghosn, 2006, p. 317)

The judge resorts to the potential fault when there are many cases in which the proof of the fault is exaggerated, whether because it is difficult to reach the proof or there is a high probability that the fault has actually occurred, in addition to the fact that the doctor's commitment to exercise care forces the patient to prove it when the doctor fails.

The potential fault enables the judge to deduce the doctor fault possibility and not to conclude that he made a definite fault. However, there are cases in which the doctor is responsible without needing to prove the fault by

patient, the fault here, as previously mentioned, is assumed and this is the case in: medical research (first) and hospital infections (second).

First: Medical Research

Medical research has a great importance as it is indispensable in the medical domain because of benefits it can bring to the patient's interest.

Article 1121/7 of the French Health Code defines medical research as: **“attempts or experiments that are performed on humans for the purpose of developing scientific and medical knowledge.”**

French law has distinguished between two types of scientific and medical research. There is biomedical researches that achieve direct individual benefit for the person subject to it, and is called scientific research with direct individual benefit, and research that does not achieve individual and direct benefit for him, which is research practiced on people whether they are sick or not, without make certain its effectiveness and usefulness, it is called scientific research without direct individual benefit. (Amal, page 78)

With regard to scientific research that is expected to achieve direct benefit, the burden of proof is attributed to the doctor, as he proves that the resulting damage has no relation with his personal fault, or that he tries to ward off liability for himself by proving the action of others or the victim fault. (Castelletta, 2002, p. 65)

Paragraph 7 of Article 1121 of the French Health Code, also stipulates the obligation of the person who is conducting biomedical research to compensate for the damages incurred by the person submitted to it or his heirs after his death, if such research does not achieve a direct individual benefit for him, and even if there is no fault. In this case, the person conducting this research may tries to ward off liability for himself by proving the action of others or voluntary withdrawal of the person from the experience. (Amal, p. 85)

But if the biomedical research that a person undergoes achieves an individual and direct benefit for them, then the person conducting this research is obliged to compensate themselves or their heirs for the damages incurred unless the person conducting, it proves that he was not at fault but he cannot, as in the first case to ward off liability for themselves by proving the action of others or voluntary withdrawal of the person from the experience. (Amal, p. 75)

The burden of proof in this case rests on charge of the person conducting the research and not on the patient or the damaged person, that the resulting damage has no relation with their personal fault, and therefore the fault here

is assumed to be able to prove the opposite, and liability is assumed, as in the case with research that achieves individual and direct benefit for the person who accepted submission. As for the liability of the researcher in which the person subject to it does not obtain any direct individual benefit for him, it is an objective liability. (Saleh, 2006, pp. 145-146)

And we conclude, while the doctor practicing his scientific research, he must take maximum precautions in order to avoid the fault that the burden of proof turns over in such way to be attributed to the doctor, and this is what expands the scope of the doctor's fault liability. (Naima, 2013-2014, p. 319).

Second: Hospital Infections

Hospital infections are considered one of the dangerous health problems that may affect patients, and it was defined for the first time in the Ministerial Decree of the French health Ministry on October 13, 1988 as: **“Every disease that a patient develops in the hospital through microbes or bacteria, provided that symptoms of infection with these bacteria appear during The patient’s presence in the hospital”** (Beun, 2003, p. 69)

It was repealed by another decree issued by the Ministry of Labor and Solidarity on December 29, 2000, as this decree obligated the health service to prove that it is doing everything he can to combat infection that the patient might contract inside the hospital, and the French law of March 4, 2002 related to public health did not give a definition of nosocomial infection, and left that to the judiciary and its interpretation, so that nosocomial infection has several causes and forms that are difficult to include in one definition. (Faudel, 2011-2012, p. 128)

Accordingly, the French Court of Cassation adopted the idea of the potential fault, as it considered that the hospital’s risk exists once the infection is transmitted to the patient during their stay there, considering that, the patient’s contamination in this case can only be explained by a fault referred to the hospital. (Qasim, 2006, p. 67)

The causes of hospital infections may be internal or external, so they are internal if the patient develops his infection because of the disease he contracted, provided that a medical action is signed on him or because of his weak health condition, and the infection is external when the patient is exposed to an infection transmitted to him from another patient due to the hospital disrespect standards that must be taken when placing two patients in the same room, or due to the use of non-sterile tools, The doctor is

obligated to respect these standards and to use sterile tools, whether that is before or during or after the medical action. (Beun, 2003, p.68)

The French Court of Cassation enshrined the principle of assumption of fault for the first time in its famous decision issued on May 21, 1998, known as *Arrêt staphylocoques dorés*, in which it was stated that the contract of hospitalization for treatment concluded between the patient and the hospital puts on the liability of the latter, with regard to pathological infection inside the hospital while the patient is in the operating room, and it is considered as an obligation of guarantee subject to achieving a result, so it cannot ward off liability for itself; and this obligation unless it proves the foreign cause. Thus, the Court of Cassation has established assumption of fault in charge of the hospital. ((Al-Hamid, 2007 p. 137)).

Then a decree was issued by the Ministry of Labor and Solidarity on December 29, 2000, which obligated the health service to prove that it is doing everything in its power to fight the infection that the patient suffers from inside the hospitals, then came the French law of March 04, 2002 related to public health, which expanded the concept of fault liability by granting the judge full discretion to override the assumption of the doctor's fault and to take into account other considerations and reasons that are sufficient, in order to establish the liability of the doctor. (Naima, 2013-2014, p. 318)

These reasons, according to the interpretation given by the judiciary in Mme Neveux's decision, are that the patient leaves the hospital and is exposed to another infection that has no relation with the first reasons that admitted him to the hospital. (Faudel, 2011-2012, p. 129)

The Council of State considered maternity and surgery halls to be among nosocomial infections, and that the doctor's fault is assumed and there is no need to prove it, and if the patient wants to establish the doctor's liability outside the previous cases, he must prove the latter's mistake. (Chaubrot, 1999, p. 21)

The expanded interpretation of the potential fault concept is due the Court of Cassation willingness to save the victims of nosocomial infection from the necessity of fault proving, and then there is nothing left for the health service except to prove the fault absence on its part in order to avoid the establishment of its liability, therefore it has become imperative for hospitals and doctors to take all precautions in order to avoid the occurrence of nosocomial in hospitals and medical clinics. (Dolivet, 2008, p. 92)

The second requirement: objective Medical Liability Based on the Precautionary Principle

It is well known that the traditional civil liability is a legal system according to which everyone who commits a fault or an illegal act is obligated to give indemnity for whoever harms him on himself or his money. (Al-Awji, 2004, p. 09)

It is the harmful act that establishes the legal bond between the responsible and the damaged person, it is the one that imposes the obligation to give indemnity for the damages it causes to others.

Liability is based on risks, as soon as the damaged person proves the existence of a causal relationship between the damage he suffered and the activity practiced without interest for the behavior of who caused it, this is the reason why it is called the objective theory, as it does not care about the relationship between fault and damage, therefore it does not matter in the liability domain that if the risk is expected or was the result of exceptional circumstances.

Although objective liability disagrees with the precautionary principle conditions, which stipulate that the damage is probable, they intersect in both on giving consideration to the absolute risk.

Hence, it can be said that there is a radical and profound shift in the liability system, as this principle "reformulated the rules of civil liability" from the subsequent risk to the previous risk.

And with the issuance of Law No. 303/2002 related to patients' rights and the quality of the health system issued on March 4, 2002, known as Law Kouchner, the Article 98 added new articles to the Public Health Law, and among these articles Article 1142, which excluded from the scope of the doctor's liability based on fault in two cases, namely, the case of damages resulting from nosocomial infections (section one) and damages that may be caused by a defective medical product (Part 2).

Section one: Liability for Damages Resulting from Noscomial Infections.

The French Court of Cassation placed it upon the health services to assume the fault in the nosocomial infection domain that the patient may be exposed to in the surgery or accouchement room, and then seek to strengthen and double the protection of patients from damage resulting from nosocomial infection by confirming the commitment to safety achieving the result, which they cannot ward off for themselves except by proving the foreign cause, by virtue of the three decisions issued by the French Court of Cassation on June 29, 1999.(Dolivet, 2008, p. 199)

According to this obligation, it is not enough for doctors to prove that they did not make any fault to exculpate themselves from liability, but rather they must prove the existence of a foreign cause that must be external, unexpected, and not able to push aside, which is difficult to prove for the doctor, compared to proving that he did not make a fault.

Thus, the transition was made from the assuming fault system to the objective liability system based on the commitment to safety by achieving a result, by virtue of the principle of precaution that aims to protect victim from any danger, as this obligation imposes on the duty of doctor which represented in not to cause new harm to the patient, and this commitment has been confirmed by the Court of Cassation and applied by the judiciary in hospital infection domain. (Faudel, 2011-2012, p. 131)

The French legislator also considered that the existing liability in the case of nosocomial infections is an objective liability, as the French Health Code came in Article 1142/2 with two observations: the first observation is that the law explicitly provides for the liability of clinics and hospitals in the case of nosocomial infections, and that the victim is exempt from proving their fault, on the other hand, officials cannot exempt themselves from liability by proving the absence of fault on their part, except that the foreign reason is the guarantor of exempting them from it (Beun 2003, p. 77)

As for the second observation, the law defines the liability system in the face of health services, while health professionals are asked according to the provisions of fault liability.

However, the health law issued on March 4, 2002 did not aim to distinguish in the case of nosocomial infections between the liability of public services, which was an objective liability, and the responsibility of doctors, which was a fault liability, doctrine has interpreted this on the basis that the concept of nosocomial infection is not specific, but the French legislator remedied this by amending this law on December 29, 2002, where it unified the liability of doctors and facilities in the field of nosocomial infection as an objective liability without fault. (Dolivet, 2008., p. 37).

Accordingly, doctors must take all precautionary measures for the safety of patients, which is an obligation to achieve a result. Thus, medical liability in the field of nosocomial infection did not remain within the limits of judicial jurisprudence, but rather became codified and thereby moved out of the general rules scope of civil liability and has its own legal system.

Section two: Liability for Damages Resulting from a Defective Medical Product.

Medicines, drugs, medical devices, and all related tools and machines, as well as interactions that take place in laboratories and scientific research laboratories, medical samples that are taken for the purpose of testing and the active ingredients that are used in this regard are considered medical products. (Naima, 2013-2014, p. 333)

With the scientific development of medical products, the risks and potential for damages increased, so the European directive issued on July 25, 1985, which recognized producer liability for defective products with the aim of protecting consumers, this recognition was applied to doctors and all health institutions who supply health products, but these Liability cannot play its role unless the damage is actually caused by the product. (Amal, p. 81)

The question raised here is related to the issue of blood transfusion from one person to another, is this blood considered a product or not?

At first, the French Court of Cassation exempted the clinics from all liability in the event that they were provisioned with contaminated blood, as it considered that the hospital supplying this blood is responsible as it is the defective product, according to its decision issued on April 12, 1995, and wherefore, a contaminated blood, the liability of the hospital supplying this blood is established, because the patient is considered as a consumer according to the law of May 19, 1998, followed by the law of March 4, 2002, as well as the suppliers and distributors of contaminated blood are responsible. Therefore, the blood transfusion center was imposed to ensure safety, which is subject of achieving a result, considering that patients are consumers of this blood who do not know the product composition or who is the producer is. Beun, 2003, p. 89)

The judiciary supported this opinion in several of its rulings, as it considered that the doctor is obligated by a safety obligation to achieve a result with regard to medicines, medical materials, and tools used in carrying out medical task, the judiciary expanded this jurisprudence and included dental surgeons. (Faudel, 2011-2012, p. 134)

Accordingly, the liability is objective to enhance the protection of the victim from medical task risk. It is sufficient for the victim to prove the causal relationship between the harm happened to him and the medical activity, and it makes no difference whether the risk was foreseeable or resulted from exceptional circumstances.

Conclusion:

the precautionary principle arose in the context of the scientific uncertainty surrounding environmental phenomena, but it quickly found its way to the health domain, as the practical fact in this field revealed the insufficiency of objective civil liability rules in protecting patients from the risks that might get them, and perhaps the reason is referred to the developments that the medical and health world is witnessing from the use of scientific, complex products and technologies that can expose the patient not only to known risks, but also to unknown ones, whose damages may be more gross and dangerous on the patient, in comparison with known dangers.

Accordingly, the precautionary principle had an impact on the basis of medical liability when it expanded the fault liability by expanding the concept of fault and presuming it in many cases when the damage was proven, which helped the patient to prove the medical fault that could cause severe damage to their body and their life, which represent the most precious thing that owns human.

Depending on the precautionary principle, anyone who does not take the necessary precautions in case of doubt and probability without waiting for confirmation of the risk occurrence, especially in the research domain and medical experiments is considered mistaken. This principle also had its effect by establishing objective liability in cases of nosocomial infections and defective medical products.

So, the reflection of the precautionary principle on civil liability is positive, as it expanded, as previously mentioned, from compensable damages, which should not be limited to covering past damages only, but should cover future damages as well, without the need to prove the damage, then imposing precautionary measures possibility without requiring the urgency or imminent nature of the damage.

Hence, the precautionary principle is a valuable tool added to risk management strategies, however, the Algerian legislator adopted this principle in the Environmental Law and the Consumer Protection Law, but it overlooked or neglected to stipulate it in the health domain, despite the sensitive and fateful issues it carries due to its connection to human life.

Therefore, the Algerian legislator must expand the precautionary principle application, which is an urgent necessity in the health domain, which knows great abuses in Algeria, by setting up a legal system for dealing with the damage that may befall the patient after the medical treatment that he is conducting, which allows then for preparedness and taking the necessary measures to confront any potential or assumed threat in

the absence of forceful scientific evidence and the occurrence of these threats, in regardless of whether if the location of the harm to the victim is known or not, or the absence of scientific certainty.

What should be noted, that despite stipulating the precautionary principle in Algerian legislation within the Environment and Sustainable Development Law, but it is still unknown in the scientific and even legal circles, due to the lack of scientific research on the subject, therefore, care must be taken to publish research in order to obtain the attention of the concerned parties with its application.

With regard to civil liability rules based on the precautionary principle, we note that the civil law is completely devoid of any text that allows for its application or projection, despite the clear obligatory formula contained in the principle of precaution text in the Environmental Law. Subsequently, the Algerian legislator must address this new type of civil liability, an explicit text regulating its provisions.

Finally, despite the criticisms directed at the precautionary principle, it has advantages that make it a raw material for researchers in this domain that they must work on developing.

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