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# المسؤولية الدولية عن الأضرار الناشئة عن مخاطر التطور العلمي (لقاحات كورونا نموذجاً)

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# International Liability for Damages Arising from the Risks of Scientific **Development (COVID-19 Vaccines as an Example)**

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# الملخص:

مع ظهور جائحة فيروس كورونا المستجد (COVID-19)، سارعت شركات الأدوية إلى تطوير وصناعة اللَّقاحات والأدوية بهدف الحد من انتشار الفيروس أو الوقاية منه. وقد أدى هذا التسابق العلمي، الذي اتسم بسر عة غير معتادة، إلى بروز العديد من الإشكاليات القانونية، خصوصًا تلك المتعلقة بالإجراءات التنظيمية للمو افقة على هذه المنتجات من قبل الهبئات الصحبة و الوكالات المختصة. إذ أصدر ت بعض الجهات تر اخيص استخدام طارئة دون استيفاء المدد الزمنية الكاملة لإجراء التجارب السريرية، مما أثار تساؤ لات حول مدى قانونية تلك المو افقات، ومدى تأثير ها على تحديد المسؤولية القانونية في حال وقوع أضرار الاحقة. ويطرح هذا الواقع القانوني مسألة أساسية تتعلق بقيام المسؤولية الدولية عن الأصرار الناجمة عن المخاطر التي ترتبت على هذه الاكتشافات العلمية، لاسيما فيما بتعلق بلقاحات فير وس كور ونا. وتير ز أهمية هذه الإشكالية في احتمال ظهور آثار صحية سلبية على المدى الطويل والتي لم تكن معروفة أو ظاهرة وقت منح الموافقات. وهو ما بثير تساؤ لات قانونية بشأن طبيعة هذه المخاطر، وما إذا كانت تشكّل سببًا للاعفاء من المسؤولية الدولية، خاصة إذا تبين أن الجهات المنتجة أو الدول المصرحة التزمت بالمعابير العلمية المتاحة

# الكلمات الدالة: المسؤولية الدولية، مخاطر التطور، اللقاحات، جائحة كورونا، التعويض.

# **Abstract:**

The COVID-19 pandemic has prompted pharmaceutical companies to rapidly develop and produce vaccines and treatments to limit or prevent the virus's spread. This unprecedented scientific race has brought about numerous legal issues, particularly concerning the regulatory processes for approving these products by health authorities and specialized agencies. Some entities issued emergency use authorizations without completing the full duration of clinical trials, raising questions about the legality of these approvals and their implications for legal liability in the event of subsequent harm.

This situation introduces a crucial question regarding international liability for damages resulting from the risks associated with these scientific developments, especially concerning COVID-19 vaccines. The significance of this issue is underscored by the potential for long-term negative health effects that were not known or apparent at the time of approval. This raises legal inquiries about the nature of these risks and whether they justify an exemption from international liability, particularly if it is determined that the producing entities or authorizing countries complied with the scientific standards that were available at that time.

**Keywor:** International liability, developmentrisks, vaccines, COVID-19 pandemic, compensation.

# **Introduction:**

The world is witnessing unprecedented events. The World Health Organization (WHO) has called for the declaration of a global pandemic due to the outbreak of the virus that causes COVID-19, a disease belonging to a family of viruses called coronaviruses. This calls for international cooperation to unify mechanisms to limit its spread. The WHO has acknowledged that, to date, there are no licensed medications to treat or prevent this disease, due to the lack of a safe and effective vaccine to prevent infection.

All countries around the world have recognized the necessity of adhering to their responsibility to protect human life, as it is the most precious thing that states, governments, societies, and institutions can preserve. On the other hand, they must balance the need to preserve human life, which constitutes an assault on the rights and freedoms of individuals, with the risks of economic damage resulting from a complete or partial lockdown of a country for an indefinite period. This could lead to the collapse of some countries' economies and the imbalance of global power centres, depending on the ability of each country's economy to survive independently, without relying on others countries.

Although it is accepted that the general rule is that liability must be based on fault, this rule has been undermined in contemporary societies as a result of scientific progress and the consequent increase in risks as legal scholarship. began to demand that liability be absolute and not restricted to fault. The judiciary moved to establish this principle, and the legislator in most countries intervened to establish the state's liability for damages without fault being committed, in line with the conclusions reached by legislation, legal doctrine, and comparative case law regarding the state's liability on the basis of risk in all areas.

This issue remains ongoing and renewed, and its importance increases each time the principles of liability and accountability emerge in the face of the risks of scientific development, especially when scientific development unleashes itself, as was clearly demonstrated during the COVID-19 pandemic. Therefore, attention must be paid to the risks of scientific development, to inform, warn, and sound the alarm. On the other hand, legislators have become aware of this scientific development and the resulting increased risks. They have sought to establish appropriate systems to protect individuals, such as preventive systems that prevent the realization of risks, punitive systems that deter and punish those who endanger the safety of individuals, and systems for redressing damages to the safety and security of individuals. Perhaps the most prominent example of these systems is European Directive No. 374 of 1985 regarding liability for defective products.

One of the most significant problems faced by European legislators while drafting the aforementioned directive is the extent to which producers are held liable for risks that could not have been discovered within the limits of scientific and technical knowledge at the time the product was put on the market. The process of legally regulating these risks poses several difficulties, particularly given that legislators must take into account two conflicting considerations when formulating legal rules related to this type of risk. The first relates to the principles of justice: It is not fair to hold producers accountable for risks that could not have been anticipated or mitigated within the limits of scientific knowledge at the time their products were put on the market.

The second consideration is: - The state's fulfilment of its responsibilities in terms of legal regulation of liability for defective products in general, which is to ensure the safety and security of individuals, and that the producer's failure to be held accountable for these risks represents a grievance to the consumer in obtaining compensation.

# Significance of the Research

The significance of this research lies in its examination of the damages resulting from the risks inherent in scientific advancement and the corresponding international responsibility. On one hand, it addresses the pressing and contemporary issue of international liability for harms arising from scientific progress—particularly in relation to vaccines and medications developed for COVID-19—an issue that has preoccupied the international community since the onset of the pandemic, whose effects continue to reverberate worldwide to this day. On the other hand, the study highlights the scope of international responsibility, whether in the form of state liability, product liability, or

the obligation to provide compensation for such damages. Therefore, an in-depth analysis of international responsibility for harms resulting from the risks of scientific progress is both timely and of paramount importance.

# **Research Objectives**

The objectives of this research are cantered on examining the grounds for establishing or exempting international responsibility—whether on the part of states or manufacturers—in relation to vaccines and medications for COVID-19, along with the corresponding obligations for compensation. Furthermore, the study seeks to clarify and highlight the role of both international and national legal frameworks that underpin or exempt such international responsibility. In addition, the research aims to elucidate the legitimacy of conducting medical experiments, the conditions governing their implementation, and whether the majority of states permit such experiments.

Research Problem

The central question of this study revolves around the harms arising from the risks associated with scientific advancement, particularly in the development of vaccines and medications for COVID-19, and the extent to which such risks necessitate the intervention of international law to determine international responsibility or grounds for exemption from it.

# From this overarching problem emerge several subsidiary questions, including:

- 1. Do the risks of scientific advancement constitute grounds for establishing or exempting liability for harms caused by COVID-19 vaccines and medications?
- 2. Does the state bear responsibility in this regard, and what is the scope of its obligations toward individuals?
- 3. What are the available mechanisms for compensating harms arising from the risks of scientific advancement?
- 4. Should compensation be borne by the state or by the manufacturer of these vaccines?

#### ResearchMethodology

This study adopts the descriptive-analytical method, as it is the most suitable approach given the primarily theoretical nature of the subject. In addition, a comparative method has been employed in most sections of the research, with the aim of drawing on the experiences and findings of previous scholars in the field.

## Research Methodology

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#### **Rationale for Selecting the Topic**

One of the most important reasons for choosing this research topic was its novelty, as our colleagues had not addressed it in their graduation projects. In addition, personal motivations played an important role, particularly the strong desire to take on a new academic challenge by engaging in a new scientific endeavor: the ability to research modern sciences and laws.

# Research Plan

In this study, we adopted a binary division into two parts. The first section addresses international responsibility and the nature of risks associated with scientific progress. The second section addresses the of the results associated with scientific progress, followed by a conclusion with the most important findings and recommendations.

# Section One: The Legal Nature of the Risks of Scientific Development

Scientific development involves the legal analysis and discussion of concepts and principles, as well as the comparison of legal experiences across different systems. Legislators must address the challenges arising from scientific changes by providing timely and appropriate responses. This depends on the nature of the legal response, its feasibility, and its ability to effectively address the risks posed by scientific development.

It is well known that COVID-19 vaccines and medications, resulting from scientific advancement, pose several risks or even harms to individuals who have received them. These harms may arise due to defects in their manufacturing, which necessitates liability for such damages. Harm is an essential element that must be present from the outset in order to establish responsibility under the rules governing liability for wrongful acts. 1

Therefore, we can divide this topic into three sections. In the first, we discuss the nature of the risks of scientific development. In the second, we discuss international responsibility for damages resulting from the risks of scientific development (contractual or tortious). In the third, we discuss damage and the causal relationship.

# The first requirement: the nature of the risks of scientific development

The risks of scientific development are relatively recent changes that have begun to spread recently, as indicated by both the European Directive and, before it, the Strasbourg Convention<sup>2</sup>, The reason for this is that this term implies a highly developed thought specific to the theory of security, which calls for the adoption of the principle of ensuring safety in the face of scientific development.<sup>3</sup>

Rather, he expressed it by clarifying its meaning, which is that scientific development reveals defects that were found in the product after it was put into circulation, and science had not reached a level that would allow for its discovery at the time of its introduction ((, so the term "risks of scientific development" does not in fact represent the risks of development, but rather, contrary to the name, it means that scientific development reveals defects that were found in vaccines and medicines when they were put into circulation at a time when the state of science and development did not allow for their discovery.<sup>4</sup>

If we consider the legal implication, we find that many national legislations have not focused on defining scientific progress from a legal standpoint, as scientific progress is an idea rather than a legal concept. It is merely an organizational concept without legal existence. However, its entry into the legal domain is due to its subjection to the rules of liability and accountability, making it the subject of numerous legal studies.<sup>5</sup>

As for the European level, despite the ongoing dispute between the European market and the United Kingdom regarding the definition of the risks of scientific progress, the European Court of Justice resolved this dispute on May

<sup>&</sup>lt;sup>1</sup> - Alaa El-Din Muhammad Abu Aqil, State Liability for Damages Arising from the Risks of Scientific Development (Coronavirus Vaccines as a Model), Journal of Jurisprudential and Legal Research, Issue 40, 2023, Al-Azhar University, p. 702.

<sup>&</sup>lt;sup>2</sup> - Fatima Zahra Boumediene, Producer Responsibility for the Risks of Scientific Development in the Field of Medicine, Journal of Law and Human Sciences, Volume 3, Issue 19, 2014, Ziane Achour University, Algeria, p. 163

 $<sup>^3</sup>$  - Hassan Abdel Basset Jami, Producer's Responsibility for Damages Caused by Defective Products, Dar Al Nahda Al Arabiya, Cairo, 2000, p. 260.

<sup>&</sup>lt;sup>4</sup> - Previous reference 262.

<sup>&</sup>lt;sup>5</sup>-Murad Mahmoud Hammad, Civil Liability Resulting from Failure to Implement Technology Transfer Contracts, PhD Thesis, Institute of Arab Research and Studies, 2006, p. 13.

29, 1997, stating: "The risks of scientific progress refer to knowledge and technology on a global scale, not limited to a specific country or a particular industrial or production sector."

Following the spread of the COVID-19 pandemic and the World Health Organization's declaration of it as a global pandemic on March 11, 2020, the organization called on governments to take urgent and more stringent measures to halt the virus's spread. Health and pharmaceutical professionals played a significant role in combating this pandemic. The World Health Organization and the international community emphasized the need to develop a vaccine to limit the spread of the virus. However, the matter extends beyond just developing the vaccine; it is also linked to the effectiveness of the vaccine in eliminating the coronavirus, and its efficacy is more closely related to the absence of any unforeseen harmful side effects.<sup>2</sup>

Coronavirus vaccines and medications have sparked controversy over side effects and long-term complications, which have been reported in some cases. The most prominent of these effects includes myocarditis, which has appeared most often among young males (12-24 years old) after the second dose of mRNA vaccines such as Pfizer and Modern.<sup>3</sup>

Rare cases of spinal cord inflammation have also been recorded in the context of vaccines such as AstraZeneca, where symptoms of muscle weakness and movement disorders appeared, necessitating close medical follow-up.

An agency called the "National Agency for Pharmaceuticals Used in Human Medicine" has been established, which includes four specialized committees, including the Drug Registration Committee. We also find the text of the amended Article 174, which states that "in order to protect or restore the health of citizens, ensure the implementation of preventive programs and campaigns, diagnose and treat patients, and protect the population from the use of unauthorized substances, medical practitioners may only prescribe or use registered medicines and approved pharmaceutical substances used in human medicine and included in their special codes, or medicines that have been subject to a temporary license for use."

Although some rare and long-term side effects have been reported with COVID-19 vaccines and medications, they remain a pivotal tool in combating the pandemic. International health authorities, including the Centers for Disease Control and Prevention (CDC), have confirmed that the benefits of vaccines in preventing serious illness and reducing mortality rates substantially outweigh the potential risks, as has the World Health Organization (WHO).<sup>5</sup>

Accordingly, the side effects resulting from coronavirus vaccines and medications are attributed to the unprecedented speed in their development and the adoption of innovative treatment methods, which made it impossible to predict their harmful consequences until after they were widely circulated and used. These treatments showed some health damages that were not visible in the early stages of their use.<sup>6</sup>

Thus, we find that some jurisprudence defines it as those risks that cannot be discovered until after the products are put into circulation<sup>7</sup>, Some define it as "the scientific discovery of defects in products after they have been released into circulation, at a time when the state of scientific and technical knowledge did not allow for their discovery before they were released into circulation."

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<sup>&</sup>lt;sup>1</sup> - Qasi Alal, Cases of Non-Product Liability, Journal of Legal and Political Research, Issue 2, 2012, Saad University, Aleppo, p. 144.

<sup>&</sup>lt;sup>2</sup> - Siham Al-Mamar, Civil Liability for Unexpected Adverse Effects of Vaccines, Journal of Research in Contracts and Business Law, Vol. 6, No. 1, 2021, Maghnia University Center, Algeria, p. 153.

<sup>&</sup>lt;sup>3</sup> - Dr. JAMA cardiol, patients with Acute myocardial it is following mrn covid19 vaccination, American, Vo10, No6, pages 1196-1201, 2021

 $<sup>^4</sup>$  -See Algerian Law No. 8 of 2008 on the National Agency for Pharmaceutical Products Used in Human Medicine, Articles (173/10) - (173/1).

<sup>&</sup>lt;sup>5</sup> - U.S. Centers for Disease Control and Prevention, 2022, <a href="http://www.cdc.gov">http://www.cdc.gov</a>, accessed February 21, 2025, time 7:30 PM

<sup>&</sup>lt;sup>6</sup> - Ayyub Falaq, Producer Liability for the Risks of Scientific Development, A Comparative Study, Electronic Journal of Legal Research, Issue 1, 2018, p. 42.

<sup>&</sup>lt;sup>7</sup> - Mahdi Alloush, The Impact of the Inability to Comprehend the Product of Scientific Progress on Civil Responsibility, Sharia and Economics Journal, Volume 7, Issue 13, p. 42.

<sup>8 -</sup> Ayyoub Falaq, Producer Responsibility for the Risks of Scientific Development, previous reference, p. 41.

When discussing the nature and extent of the risks of scientific development, we must also clarify the nature of liability for damages resulting from the risks of scientific development. This is what we will address in the next section.

# The second requirement: International liability for damages resulting from the risks of scientific development (contractual or tortious (\*)):

The World Health Organization has classified the coronavirus outbreak as a pandemic due to the rapid spread and scale of the infection, as well as the serious concern about its impact. To control the virus, efforts have been directed toward containing it and developing effective vaccines, medications, or treatments. <sup>1</sup>The Libyan Supreme Court ruled that "force majeure that exempts from liability must be something unforeseeable..." <sup>2</sup> The French Court of Appeal ruled on 3/12/2020. <sup>3</sup> The Corona pandemic is considered a force majeure, and thus the question arises as to whether the Corona pandemic can be invoked as a force majeure to obtain compensation... There is a recent ruling by the Egyptian Administrative Court in which it ruled that "a force majeure situation has swept the world, prompting the World Health Organization to consider the novel coronavirus a pandemic, and the state has taken some precautionary measures to confront it in order to preserve the health of citizens, including restricting the ban on human gatherings for any reason." <sup>4</sup>

However, these vaccines and medications may pose several risks or even harm to individuals who receive them. These harms may vary and may have multiple causes. Nevertheless, the side effects of these scientific developments have raised legal questions about liability for potential harm from COVID-19 vaccines and medications, and whether this international liability is contractual or tortious. From the above, we will clarify this requirement regarding international liability for damages through the following:

# First: Contractual liability

Contractual liability refers to the legal consequences resulting from a breach of obligations stipulated in a contract, such as non-performance or delayed performance. It arises when specific performance becomes impossible. Contractual liability has been adopted as a legal mechanism to justify the application of its provisions, establishing a framework for contractual relationships, even in the absence of a direct connection between the user and the producer. To provide legal coherence to this application, a mechanism was sought. The concept of the product first appeared in French jurisprudence, which serves as a foundation for European law. French legal thought defined the product by holding all parties involved in the production process accountable for compensating damages caused by the product. In this context, the final product is equated with any component that contributes to the overall commodity.<sup>5</sup>

Given the nature of the composition of coronavirus vaccines and medications, consumers are not legal or chemical experts capable of understanding the flaws in these formulations. Experts, such as doctors, pharmacists, researchers, and vaccine manufacturers, are more likely to comprehend these issues, as they are

<sup>&</sup>lt;sup>1</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers (A Comparative Study), Master's Thesis, Middle East University, 2022, p. 18.

<sup>&</sup>lt;sup>2</sup> - See the ruling of the Libyan Supreme Court in Administrative Appeal No. 147 of 50 Q, session of April 23, 2006, The Eastern Law System; Dr. Misbah Omar Al-Tayeb, The Theory of Emergency Circumstances and Its Impact on the Implementation of Administrative Contracts, Al-Haq Journal of Sharia and Legal Sciences, Issue 8, January 2020, p. 159.

<sup>&</sup>lt;sup>3</sup> - Judgment published in the Journal of Legal Studies, website.

 $<sup>^4</sup>$  -See the ruling of the Egyptian Administrative Court in Appeal No. 37214 of 74 Q, session of 6/28/2020 AD, Eastern Laws System.

<sup>&</sup>lt;sup>5</sup> - Badr Osama, Guarantee of Medical Products Risks (Comparative Study), Dar Al-Kotob Al-Qanuniyah, Cairo, 2008, p. 51.

specialists in the field. Many individuals have been harmed due to defects in coronavirus vaccines and medications.<sup>1</sup>

As for the companies that manufacture coronavirus vaccines and medicines, they have concluded contracts with countries (such as COVAX\*²) to supply them with vaccines. These contracts include a guarantee of vaccine quality and safety from defects. If the product turns out to be defective or does not meet the safety standards agreed upon in the contract, the manufacturer can be held responsible for unforeseen damages. However, companies always try to include clauses that exempt them from international liability.³

Contractual liability in general has three pillars: error, damage, and the causal relationship between the error and the damage. In the first pillar, error, contractual liability does not arise simply because of non-performance, due to an error, whether intentional or unintentional. Therefore, there is a deficiency in applying the general provisions of contractual liability to the relationship between producers and consumers. The French Health Code, in its Article (1/1515), prohibits the establishment of any direct contractual relationship between the producer and the consumer.<sup>4</sup>

Therefore, it can be argued that the provisions of contractual liability are not compatible with many of the damages resulting from defective vaccine products. Therefore, it is necessary to examine the provisions of tort liability to determine whether they are compatible with the damages resulting from the risks of scientific development of coronavirus vaccines and medications.

## **Second: Tort Liability**

Tort liability arises from a breach of an obligation resulting from a harmful act that violates a legal duty, i.e., a breach of any duty that is not derived from a contract. Therefore, its source is the harmful act itself.<sup>5</sup> The application of tort liability for vaccine-related harms has received strong support from both the judiciary and jurisprudence, based on legal justifications and foundations, such as those outlined in Article (1/1515) of the French Health Code, which prohibits the establishment of any direct contractual relationship between the vaccine producer and the consumer. It clearly defines that the nature of liability is tortious, not contractual<sup>6</sup>. Tort liability is based on the premise that the consumer may not be someone who has a relationship with the manufacturer or seller. Consumers can sue the manufacturer on the basis of harmful acts or negligent liability, given that the manufacturer is obligated to guarantee the safety of vaccines and medicines.<sup>7</sup>

Tort liability is fundamentally based on the presence of the elements of fault, damage, and a causal relationship between them. However, the COVID-19 pandemic has shown that the traditional system, based on fault, damage, and causality, has failed to provide adequate protection for those harmed by COVID-19 vaccine recipients. Individuals may suffer side effects despite the absence of medical error or negligence that can be proven against the

<sup>&</sup>lt;sup>1</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers (A Comparative Study), previous reference, p. 28.

<sup>&</sup>lt;sup>2</sup> - COVAX: A global initiative that aims to ensure the fair and equitable distribution of coronavirus vaccines and secure countries regardless of their income level. It is an international alliance program that includes several organizations, most notably: GAVL, WHO.

<sup>&</sup>lt;sup>3</sup>-(WHO), Covax, working forglobalen quitable accessto covid19 vaccines, 2020.

<sup>&</sup>lt;sup>4</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers, previous reference, p. 21.

<sup>&</sup>lt;sup>5</sup> - The previous reference, Al-Shoubaki, p. 30

<sup>&</sup>lt;sup>6</sup>-See Article (1515) of the French Public Health Code, which grants any direct contractual relationship between the pharmaceutical product and the consumer.

<sup>&</sup>lt;sup>7</sup> - Abdullah Al-Khalidi, Civil Liability of Companies Producing Vaccines and Medicines for the Novel Coronavirus (COVID-19), Qatar University Publishing House, Volume 10, Issue 2, 2021, p. 188

manufacturers of these vaccines and medications. This highlights the need for compensation for damages resulting from COVID-19 vaccines and medications.<sup>1</sup>

This is what the Egyptian legislator confirmed in a recent ruling by the Supreme Administrative Court, which ruled that "liability without fault, the difference between liability based on presumption of fault - within the scope of liability based on fault) is that there is a fault but it is impossible to discover it, and here comes the role of presumption in proving it, compensation is due even if the act was lawful, based on justice and equality of individuals before public costs."<sup>2</sup>

Therefore, it can be said that the Egyptian judiciary today has taken the responsibility of the state, whether it is based on error or without error, and this is what the French judiciary confirmed, that ignorance of the responsibility of the producer and the state, and this responsibility is objective and based on damage, not error, and implicitly includes the case of risks of scientific development, as the producer and seller have become responsible for ensuring the safety of the user of their products and making it a general obligation in the face of those affected.<sup>3</sup>

# The third requirement: harm and its causal relationship (\*4)

The causal relationship is of significant importance in the field of liability, as it determines the act that caused the damage among various acts surrounding the incident. It is entirely independent from fault, as liability arises if the damage occurs and its cause is a legitimate act of the injured party. However, if it is proven that an illegitimate act was committed by the injured party and had no impact on the occurrence of the damage, then the injured party will be exempt from liability.<sup>5</sup>

Therefore, damage is an essential element that must be present from the outset in order to establish responsibility for the party who caused it, according to the rules of liability for harmful acts that create such responsibility. The French State Council has held that the injured party is not required to prove fault; it is sufficient to prove the damage, as damage is relatively easy to establish in the first place. It is considered that the state is responsible for the vaccines it approves, regardless of whether vaccination is mandatory or optional. When issuing its approval for a vaccine, the decision must be well-considered and deliberate, and the state then bears the resulting responsibility before society, allowing individuals to hold it accountable. The state may then refer to the companies that produce the vaccines. Ultimately, the goal is for the injured party to receive fair and prompt compensation.<sup>6</sup>

Therefore, in order to hold the producer accountable for the harm caused by the vaccine, there must be a causal relationship between them, i.e. a relationship between a wrongful act and the harmful result that occurred to the consumer or patient, i.e. a relationship between the cause and the effect. If the vaccine producers commit an error while preparing and manufacturing the vaccine and the recipient then dies as a result of taking the vaccine, and then it is shown that death was certain, even if he did not take it, such as a heart attack for the person who took it, which has no relation to the error in the product, then the vaccine producer is not responsible. The presence of a causal relationship between the wrongful act of the source and the injury that occurred as a result of that act is a basic pillar

<sup>&</sup>lt;sup>1</sup> - Latifa Amazon, Tort Liability Provisions as a Basis for Defective Product Liability, Academic Journal of Legal Research, Mouloud Mammeri University, Algeria, 2018, p. 2, No. 64.

<sup>&</sup>lt;sup>2</sup> - Referred to: Dr. Abdel Aziz Abdel Moati, The Extent of the State's Obligation to Compensate for Damages Arising from the COVID-19 Coronavirus, A Comparative Study, Legal Journal, 2022, p. 102

<sup>&</sup>lt;sup>3</sup> - Alaa El-Din Muhammad Abu Aqil, State Responsibility for Harms Arising from the Risks of Scientific Development of Coronavirus Vaccines and Medications, op. cit., p. 724.

<sup>&</sup>lt;sup>4</sup> - Al-Sanhuri defined it as "a performance that is inflicted on a person in his body, money, honor, or emotions, and it is a duty of compensation regardless of its type, material or moral." See Al-Sanhuri, previous reference, p. 60.

<sup>&</sup>lt;sup>5</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers, previous reference, p. 50.

<sup>&</sup>lt;sup>6</sup> - Abdullah Hamad Al-Khalidi, Corporate Civil Liability for Novel Coronavirus Vaccines and Medications, previous reference, p. 192.

that is negated by the negation of responsibility, and the producer's act is legally adapted according to the result that it leads to.<sup>1</sup>

According to the above, the person harmed by the vaccine must provide evidence of the causal relationship between the harm and the defect in the vaccine in order to establish the liability of the producer. The harmed party must also demonstrate the time at which the defect manifested to prove that the production defects and their appearance were the cause of the harm. However, it appears difficult for the harmed party, especially in cases involving multiple parties in production, to provide evidence of the defect's existence and the causal relationship between the defect and the harm.<sup>2</sup>

The French legislator also placed the burden of proof on the injured party to prove the damage and the causal relationship in order to establish liability on the producer. French courts have applied producer liability in numerous judicial rulings, which opened the way for the injured party to prove the producer's failure to ensure safety.<sup>3</sup>

Despite the benefits that modern scientific discoveries in the field of vaccines bring to human health, they may also bring with them risks that threaten human safety. These risks can only be discovered some time after the vaccines are produced and put into circulation thanks to new scientific knowledge. This is what Islamic jurisprudence calls the risks of scientific development. The argument for the risks of scientific development as a reason for exemption from liability is relatively new and has sparked a jurisprudential debate between supporters and opponents, each with their own opinion:<sup>4</sup>

# (a) The view in favour of considering the risks of scientific development as a reason for exemption:

**(b)** Despite the importance of protecting humans from the harm caused by vaccines, there are circumstances in which such protection cannot be achieved, as these risks lie beyond the scope of human perception at the time of production. Among these circumstances are the risks associated with development that could affect humans.<sup>5</sup>

Therefore, those who advocate for this view believe it is necessary to consider the risks of scientific development as a reason for exemption, and they base their arguments on the following points:

- Holding the vaccine liable for the risks of scientific development is a clear violation of the principle that no one can be held accountable for the impossible.
- The state cannot anticipate the risks of scientific development and cannot mitigate them, and therefore is exempt from liability.
- Exempting the producer from liability encourages innovation and the renewal of activities without the fear of latent risks that were unknown at the time of production or the product's release, given the prevailing state of technical knowledge. <sup>6</sup>

# (b) The view that rejects considering development risks as a reason for exemption:

Contrary to the trend in favor of exemption from liability for the risks of scientific development, this trend believes that the producer and the state should be held responsible even if it is proven that the scientific and

<sup>&</sup>lt;sup>1</sup>-The previous reference, p. 55

<sup>&</sup>lt;sup>2</sup> - Siham Al-Mamar, Civil Liability for Unforeseen Adverse Effects of Vaccines, op. cit., p. 159

<sup>&</sup>lt;sup>3</sup> - The previous reference, p. 160.

<sup>&</sup>lt;sup>4</sup> - Mahmoud Ghazal and others, Responsibility for the Risks of Technological Development, Tishreen University Journal for Research, Syria, Volume 33, Issue 1, 2011, obtained from the Dar Al-Manzomah website, Egyptian Knowledge Bank, p. 242.

<sup>&</sup>lt;sup>5</sup> - Mashael Nayef, Management Responsibility Without Error in Light of the Corona Pandemic, Master's Thesis, King Abdulaziz University, Jeddah, 2022, p. 57.

<sup>&</sup>lt;sup>6</sup> - Alaa El-Din Muhammad Abu Aqil, State Responsibility for Damages..., previous reference, p. 741.

technical status at the time of the vaccine's introduction into circulation did not allow it to reveal the presence of a defect. They base their arguments on the following points:

- Exempting the producer and the state from liability for the risks of scientific development would place an unreasonable burden on consumers, as they cannot ascertain the status of defective vaccines. Furthermore, a fair distribution of risks necessitates that both the producer and the consumer share a portion of these risks.
- Establishing producer liability for development risks is not based on any fault on their part, but rather on the need to ensure compensation for damages incurred by the consumer, particularly physical harm.<sup>2</sup>
- Reporting this responsibility pushes the producing companies to conduct more research and experimentation to reach the highest possible level of safety for the products, which drives the wheel of development to continuous movement.<sup>3</sup>

In conclusion: If the goal of international responsibility is to redress the harm suffered by the injured party, its ultimate goal is to prevent harm before it occurs. From this perspective, the restrictions and limitations surrounding therapeutic materials in general, and vaccines in particular, are intended to ensure their safety and protect their users and consumers.

However, in the event of harm, the vaccine recipient has the right to file a lawsuit to claim compensation. This may be due to the manufacturer's failure to ensure the vaccine's safety, or in other cases, due to its failure to monitor unexpected side effects. If it is proven that a vaccine does not meet the safety standards required by both Sharia and law, it must be withdrawn from vaccination centers. In this context, the state, for reasons related to health security, is responsible for temporarily suspending the vaccine's registration when necessary.

Finally, if the injured party succeeds in proving the producer's liability, they have the right to seek compensation to remedy the harm they have suffered. Compensation may be provided either through the producer's direct obligation to pay, or through state intervention via insurance companies. In cases where there is no liability for serious harm and the injured party is not at fault, the state undertakes to compensate them, ensuring justice and protecting their rights.

# Section Two: Consequences of the Risks of Scientific Development (COVID-19 Vaccines and Drugs):

With the acceleration of scientific and technological progress, societies are facing new legal and ethical challenges due to the potential risks associated with this development. Despite the significant benefits achieved by COVID-19 vaccines in combating the pandemic, some of these advancements may lead to serious harm.

The field of vaccines is one of the most vulnerable areas to the risks of scientific development. After receiving a vaccine, a patient may suffer harm that is not attributable to professional error but rather to the inherent risks of protecting individuals. As such, the traditional rules of liability for error do not apply in these cases. Consequently, the role of international law in determining responsibility for these damages is underscored, whether in relation to the responsibility of states or producing companies. We cannot ignore the fact that COVID-19 vaccines have played a crucial role in combating the pandemic, limiting its spread, and safeguarding the lives

 $<sup>^{1}</sup>$  - Mohi El-Din Ibrahim, "Development Risks as a Reason for Exempting Producer Liability," Dar Al-Nahda Al-Arabiya, Cairo, 2007, p.

<sup>&</sup>lt;sup>2</sup> - Abdel Hamid Al-Desiti Abdel Hamid, "Consumer Protection in Light of the Legal Rules of Producer Liability," Dar Al-Fikr Wal-Qanun, Egypt, 2009, p. 717.

<sup>&</sup>lt;sup>3</sup> - Alaa El-Din Muhammad Abu Aqil, State Responsibility for Damages..., previous reference, p. 745.

of millions worldwide. However, some vaccines have caused health issues for some individuals, raising questions about the legal responsibility for these damages and the mechanisms for compensating the affected parties.<sup>1</sup>

Therefore, we can divide this topic into three sections. In the first, we will discuss the nature of compensation. In the second, we will discuss compensation for damages in contractual and tortious liability. In the third, we will discuss state liability and product liability.

First requirement: What is compensation for scientific development risks?

Compensation is a fundamental principle of law. It is a means of redressing harm resulting from an unlawful act or negligence. It aims to restore the injured party to their normal status as much as possible, whether through material or moral compensation. At the international level, compensation is considered a tool for ensuring justice and redressing damages resulting from acts that violate international law.

# First Requirement: The Nature of Compensation for the Risks of Scientific Development

Compensation is a fundamental principle in law, serving as a means to redress harm resulting from an unlawful act or negligence. Its purpose is to restore the injured party to their original state as much as possible, whether through material or moral compensation. At the international level, compensation is considered a tool to ensure justice and to indemnify damages caused by actions that violate international laws.<sup>2</sup>

Compensation is defined in legal dictionaries as<sup>3</sup>, a sum of money paid to a specific person in exchange for damages that have been incurred by him." Due to the nature of vaccines, the consumer is not a legal or chemical expert capable of identifying the defects that may have affected the composition. Experts such as doctors, pharmacists, researchers, and vaccine manufacturers are more equipped to understand these issues because they possess the necessary expertise in this field. Many individuals who have been harmed as a result of a defect in the pharmaceutical vaccine may be unaware of the causes of these complications. They do not attribute this defect due to their belief and absolute trust in the vaccine as a means of healing.<sup>4</sup>

The French judiciary relied on the European directive, so that it involved both the manufacturer, the seller and the professional in the responsibility, so that all of them are obligated to ensure the general safety of the consumer. The French legislator was not satisfied with the judicial consecration of this obligation - that is, the obligation to deliver a product with a safe product - but rather exceeded the opportunity with explicit texts, the beginning of which was the Consumer Law through Article (221), and within all of this it is clear that they are obligated to deliver vaccines that achieve security and safety for the consumer, and safety may not be controlled by the absence of a hidden defect, but rather the absence of a danger that may make people whisper. <sup>5</sup>

It has been demonstrated through the reality of liability arising from the risks of development how difficult or even impossible it is for the injured party to seek recourse from the doctor, due to the absence of responsibility on the doctor's part for any error, thus negating their responsibility to compensate the injured party. In response, France introduced a compensation system through Law No. (303) of 2002, which pertains to patients' rights. This law establishes the highest level of legal protection for patients at all stages of medical care, including prevention, diagnosis, treatment, and follow-up. As a result, individuals have the right to seek compensation for harm suffered, using new compensation mechanisms and establishing bodies that handle this process outside the judicial path. This

<sup>&</sup>lt;sup>1</sup> - Mona Kamel Turki, Human Rights and the State of Exceptional Emergency in Light of the COVID-19 Coronavirus Pandemic, Arab Renaissance, Egypt, First Edition, 2021, p. 138.

<sup>&</sup>lt;sup>2</sup> - Abdul Aziz Abdul Moati Aloun, The Extent of the State's Obligation to Compensate for Damages Arising from the Coronavirus COVID-19, A Comparative Study, Legal Journal (a specialized journal in legal studies and research), Volume 23, 2024, Egypt, p. 134

<sup>&</sup>lt;sup>3</sup> - Abdul Wahid Karam, Dictionary of Legal Terms, Dar Al Thaqafa Publishing House, Amman, Second Edition, 1998, p. 134.

<sup>&</sup>lt;sup>4</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers, previous reference, p. 28.

<sup>&</sup>lt;sup>5</sup> - Mona Kamal Turki, Human Rights and the State of Exceptional Emergency in Light of the COVID-19 Pandemic, op. cit., p. 229.

represents a new compensation system that ensures compensation for the injured party within the framework of national and international solidarity. Compensation depends on the nature of the harm and the causal relationship between the harm and the vaccine, and it can take the form of medical expenses or financial compensation for physical damages.<sup>1</sup>

There is no doubt that compensation is the inevitable result of the establishment of liability, as the injured party seeks, after the damage has been incurred, to demand compensation that is commensurate with the damage that has befallen him.<sup>2</sup>

The World Health Organization (WHO) has launched a global compensation program for damages caused by COVID-19 vaccines, the first of its kind at the international level, aiming to provide compensation to affected individuals in 92 low- and middle-income countries without the need to resort to courts to ensure speedy and fair procedures. (\*) The World Health Organization has not specified a second amount for compensation under the COVAX compensation program for damages, regardless of the party responsible for it. Instead, compensation is estimated based on the nature of the damage and the extent of its impact on the affected individual.<sup>3</sup>

Regarding the scope of compensation for damages arising from international liability for vaccine-related harm, there is no doubt that compensation incurred by the injured party as a result of a producer's fault includes compensation for both material and moral damages, in accordance with the established general principles of international law.

The French legislator has emphasized that the relationship between the consumer and the producer is not direct and is not based on any contractual basis. Accordingly, the consumer may not claim compensation based on the provisions of contractual liability. Rather, his claim for compensation is based on the provisions of tortious liability arising from a breach of legal obligations, as stipulated by relevant laws such as the Medical Liability Law, the Consumer Protection Law, or the Civil Code.<sup>4</sup>

Therefore, it can be said that anyone who has suffered harm as a result of the use of COVID-19 vaccines has the right to claim compensation based on the rules of international liability, given the damages resulting from the design or manufacture of these vaccines. This liability is not limited to the contractual relationship between the buyer and seller, but rather includes anyone harmed as a result of the use of defective vaccines, whether a direct consumer or a non-contracting party.<sup>5</sup>

Therefore, compensation is subject to the provisions of international law, depending on the nature of the obligation incurred by the manufacturing countries or producing companies. Compensation may arise either on the basis of the

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<sup>&</sup>lt;sup>1</sup>-Amal Al-Bakoush, Objective Liability for Medical Consequences, A Study in Comparative Algerian Law, Dar Al-Jamia Al-Jadida, Alexandria, 2017, p. 99.

<sup>&</sup>lt;sup>2</sup> - Nasser Mutab Al-Khurainj, Agreement on Exemption from Compensation in Kuwaiti Law, A Comparative Study, (Master's Thesis), Middle East University, 2020, p. 11.

<sup>&</sup>lt;sup>3</sup> - The program allows for the granting of temporary licenses for vaccines distributed by companies such as COVAX (GAVI), provided they comply with the World Health Organization's standards and procedures. The producing company does not guarantee compensation for damages caused by the vaccine, but governments may establish national compensation programs, with compensation amounts reaching up to \$225,000 for each affected individual. On June 30, 2028, the licenses for unapproved vaccines will expire, which may require governments to compensate affected individuals, as happened in France in January 2024, when the court ordered the state to pay 250,000 euros to an individual affected by vaccine complications.

<sup>(3)</sup> COVAX Compensation Program 2021, <a href="https://www.covaxclaims.com">https://www.covaxclaims.com</a> accessed March 13, 2025 at 7:45 PM.

<sup>&</sup>lt;sup>4</sup> -Majali, Ahmed, Producer Liability for Defective Products in Jordanian Law, A Comparative Legal Analysis with French Law, Ijtihad Journal of Legal Studies, 2020, Volume 9, Issue 3, p. 249.

<sup>&</sup>lt;sup>5</sup> - Muhammad Raed Mahmoud, Civil Liability of Drug Producers for Defects in Pharmaceutical Products, A Comparative Study, (Master's Thesis), Middle East University, 2011, p. 63.

international responsibility of countries in accordance with relevant international agreements, or on the basis of the tortious liability of the producing parties, in accordance with international law regarding damages resulting from COVID-19 vaccines and medications.<sup>1</sup>

Second Requirement: Compensation for Damages in Contractual and Tortious Liability Vaccines are among the most significant achievements that have contributed to improving public health and protecting individuals from infectious diseases. With their increasing use in combating the COVID-19 pandemic, the need for legal compensation mechanisms for damages resulting from their side effects has emerged. In this context, the World Health Organization has emphasized the importance of developing compensation programs for those affected by vaccine-related harm, with the aim of providing legal protection for individuals without resorting to lengthy legal proceedings.<sup>2</sup>

From the above, we will clarify this requirement by examining the mechanism for compensating damages resulting from vaccines within the framework of contractual and tortious liability.

# **First: Contractual Liability**

Contractual liability serves as the legal foundation upon which the obligations of the parties under international contracts concluded for the supply of COVID-19 vaccines are assessed. This principle stipulates that the contractual obligations agreed upon between producing companies, international organizations, and contracting states must be fulfilled. Therefore, a breach of any obligations constitutes a contractual violation that requires the breaching party to be held liable, provided that the compensation owed is proportionate to the extent of the damage resulting from that breach <sup>3</sup> If a person is harmed by a vaccine product and has a contractual relationship with them, they must provide notice before resorting to the courts to claim compensation. That is, affected countries or entities must notify international organizations such as the World Health Organization or COVAX of any breach of their obligations. <sup>4</sup> In addressing breaches of COVID-19 vaccine supply contracts, the French legislator relied on the general rules of compensation stipulated in the French Civil Code, which stipulate that "the debtor shall, where appropriate, be obligated to pay compensation either for failure to perform the obligation or for delay in performance, unless it is proven that performance was prevented due to force majeure."

Practical evidence indicates that, in some cases, the supply of COVID-19 vaccines did not meet agreed-upon technical standards, or were delivered late or negatively impacted national efforts to combat the pandemic. These vaccines have been shown to cause serious side effects, resulting in significant human and material losses in some countries<sup>6</sup> Therefore, vaccine-producing companies bear legal responsibility if they conceal potential defects or risks in a vaccine, especially if this results in serious health damage. Affected countries can resort to compensation mechanisms by demanding compensation from manufacturers and international organizations for the production of unsafe or inadequately selected vaccines.<sup>7</sup>

However, some believe that it is difficult to apply the warranty of hidden defects to the relationship between the manufacturer and the consumer, due to the lack of a direct contractual relationship. Usually, there is one or more intermediaries between them, and that the best way to compensate for a defective product is to rely on tortious liability as a basis for compensation for damage caused by vaccines. As the proponents of this opinion argue, the warranty of hidden defects is not effective for the injured party; this is because the defect that accompanies the

<sup>&</sup>lt;sup>1</sup> - The previous reference, p. 64.

<sup>&</sup>lt;sup>2</sup> - Mohamed Mansouri, Manal Bokoro, The Role of International Efforts in Combating the Novel Coronavirus, University of the Brothers Manthuri, Algeria, 2020, p. 102.

<sup>&</sup>lt;sup>3</sup> - Alaa El-Din Muhammad Abu Aqil, The State's Responsibility for the Harms Arising from the Risks of Scientific Development, previous reference, p. 792.

<sup>&</sup>lt;sup>4</sup> - Muhammad Issa Al-Shoubaki, Civil Liability of Vaccine Producers, previous reference, p. 73.

<sup>&</sup>lt;sup>5</sup> - See Article (1231)-1 of the French Civil Code, 2016.

<sup>&</sup>lt;sup>6</sup> - Mohamed Mansouri, Manal Boukrou, The Role of International Efforts in Combating the Coronavirus, previous reference, p. 110.

<sup>&</sup>lt;sup>7</sup> - Hussein Al-Tajmi'i, Product Liability Caused by Defective Products, Dar Al-Nahda Al-Arabiya, Egypt, 2000, p. 75.

vaccine after its physical defect, as it is connected to the human body, which does not constitute money, while the buyer only has the choice between returning or keeping the sale with compensation, in accordance with the general rules that require compensation for the buyer for the profit he lost and the loss he incurred as a result of the defect. <sup>1</sup>

#### **Tort Liability:**

Excuses are not recognized in tort liability, as the relationship between the producer and the consumer only arises after the actual occurrence of the damage. The absence of excuses in tort liability is an absolute rule, as the injured party is entitled to compensation as soon as the damage occurs. When a vaccine causes health damage, tort liability may arise if there is negligence or error on the part of the vaccine manufacturer or distributor, or if there are insufficient measures taken to protect individuals from harm. In such cases, the injured party can seek compensation for the damage they suffered through the courts. In this regard, the French Court of Cassation ruled that the injured party is entitled to compensation for the physical losses they suffered, any financial damages they incurred, as well as compensation for lost earnings that they were unable to obtain due to the damage.<sup>2</sup>

In France, compensation is also provided in certain cases through the National Vaccine Compensation Program (NFCP), the French Fund for Compensation for Injuries Caused by COVID-19 Vaccines. This program provides direct compensation to those affected by adverse effects, without resorting to the courts. This system is considered an exception to the general principle of liability and aims to expedite compensation for those affected and reduce the legal burden. This program reflects the balance between protecting public health on the one hand and protecting the rights of individuals harmed by vaccines on the other <sup>3</sup>

In short, according to French law, if a defect is proven as a result of receiving the COVID-19 vaccine, and there is a causal relationship between the vaccine and the damage, then tort liability is determined in accordance with Article 1240 of the French Code, which requires compensation for damages resulting from an unlawful act, thus balancing the protection of public health and the rights of affected individuals.

## Third Requirement: State Responsibility and Product Liability

Scientific developments in medicine and pharmacy are a double-edged sword. While they contribute to the advancement of effective treatments for various epidemics and diseases, they may, in some cases, lead to unexpected health risks. A legal dilemma has arisen regarding the determination of legal liability for damages resulting from coronavirus vaccines and medications, particularly given the speed with which these vaccines were approved and authorized for emergency use. This dilemma raises fundamental questions about who bears responsibility. Responsibility may lie either with the state, as the body overseeing the health sector and responsible for regulating and licensing these vaccines, or with the producing companies, based on their legal obligations to ensure the safety and security of medical products<sup>4</sup>.

From the above, we will clarify the scope of international legal liability through state responsibility and product liability.

According to the WHO Constitution, Member States are responsible for the mechanism for implementing international health standards to protect public health and ensure the safety of medical products. The Constitution obliges Member States to incorporate international recommendations into their national legislation and adopt oversight mechanisms to ensure that licensing procedures comply with these approved standards. In the event of a breach of these standards or negligence in oversight, this may be considered legal negligence, which results in the state being held responsible for the resulting damages. This responsibility is realized when medical licenses are

<sup>&</sup>lt;sup>1</sup> - Badr Osama Hamad, Medical Products Risk Assurance, New University Publishing House, Alexandria, 2005, p. 152.

<sup>&</sup>lt;sup>2</sup> - Ibrahim Ali Hammadi, Professional and Ordinary Errors in the Framework of Medical Liability, A Comparative Study, Al-Halabi Legal Publications, Beirut, 2007, p. 219.

<sup>&</sup>lt;sup>3</sup> - French Medical Accident Compensation Office, 2022, <a href="http://www.oniam.fr">http://www.oniam.fr</a>, accessed March 24, 2025, time: 3:00 PM

<sup>&</sup>lt;sup>4</sup> - United Nations (UN - Arabic version), 1995, <a href="https://www.un.org/ar/">https://www.un.org/ar/</a> Accessed on March 21, 2025, Time: 1:46 AM

granted without meeting the testing and evaluation standards, which enables those affected to claim compensation for the damages. <sup>1</sup>

Granting licenses for medicines and vaccines constitutes a legal obligation on the state to ensure their safety and effectiveness. Regulatory bodies review secret trials according to precise standards. Issuing licenses without meeting the necessary requirements constitutes a breach of legal duty, which entails the state being liable for damages, and there is no way to compensate for them except for state intervention. <sup>2</sup>

# **Second: Producer Liability for Damages**

The obligation to exercise care or to achieve a result is a fundamental element in determining a producer's liability to the consumer, particularly with regard to advertising risks to protect them from potential harm. While some jurists believe that the obligation to exercise care may be an alternative to achieving absolute liability for companies, this may open the door to exploiting legal loopholes. <sup>3</sup>

Legal associations have sought to reconsider product liability, especially in light of economic competition, which has prompted some countries to amend their laws. Despite the differences in theories of liability, the primary goal remains to achieve a balance between the rights of consumers and manufacturers, while ensuring effective protection against the risks of scientific development. <sup>4</sup>

COVID-19 vaccines and medications, which were approved under exceptional and rapid measures to address the global health emergency, are susceptible to previously undiscovered side effects. The detection of risks such as blood clots and heart inflammation has prompted a review of their formulations and updated usage protocols. Despite strict oversight, the issue of assigning responsibilities remains, particularly with some companies being granted legal exemptions in exchange for governments guaranteeing compensation.<sup>5</sup>

In this context, the case of Jamie Smith provides a significant example. He was the first to file a lawsuit against AstraZeneca after receiving the vaccine in April 2021. He suffered a blood clot and brain haemorrhage, which left him permanently injured and unable to work. This is one of 51 lawsuits currently pending before the UK High Court in London, seeking damages totalling approximately £100 million. <sup>6</sup>, Last February, the Administrative Court in Rabat ruled that the Moroccan state, represented by the Ministry of Health and Social Protection, must pay 250,000 dirhams in compensation to the plaintiff and must bear the legal costs of 250,000 dirhams. The ruling held that the state is responsible for the risks of vaccination, based on the causal relationship between the infection and the dose administered, without the need to prove direct error. Therefore, we can say that companies producing medicines and COVID-19 vaccines must take the necessary measures to protect individuals. Harmful effects on healthy individuals

<sup>&</sup>lt;sup>1</sup> - World Health Organization (WHO), 1948, <a href="https://www.who.int">https://www.who.int</a> Visited February 21, 2025 Time: 2:00 AM

<sup>&</sup>lt;sup>2</sup> - Fatima Zahra Boumediene, Development Risks as a Reason for Exemption from Liability for Defective Products, previous reference, p. 309.

<sup>&</sup>lt;sup>3</sup> - Balnwar Abdul-Zarq, "Development Risks as a Reason for Exemption from Liability for Product Actions," Al-Manar Journal of Research, Taheri University, Issue 5, 2018, p. 346.

<sup>&</sup>lt;sup>4</sup> - Balnwar Abdul-Zarq, "Development Risks as a Reason for Exemption from Liability for Product Actions," Al-Manar Journal of Research, Taheri University, Issue 5, 2018, p. 347.

<sup>&</sup>lt;sup>5</sup> - Alaa El-Din Abu Aqil, State Responsibility for Damages Arising from Development Risks. Previous reference, p. 762.

<sup>&</sup>lt;sup>6</sup> - British Broadcasting Corporation, 1997 https://www.bbc.com , Visited March 19, 2025, 3:44 PM.

resulting from vaccination are more severe than the severity of a patient's illness resulting from a worsening of their initial condition. Therefore, companies must provide fair and adequate compensation to those affected. <sup>1</sup>

#### **Conclusion:**

Based on the findings presented and analysed in this article, we have reached several important legal conclusions, along with some recommendations that we hope will be given due consideration by decision-makers in our country. These conclusions and recommendations are as follows:

#### **First: Results:**

- 1. Scientific development has occupied much of jurisprudence. Opinions on this matter have varied between those who support it as a reason for exemption and those who oppose it, and those who oppose it and the emergence of liability. The risks of scientific developments within the scope of medical practice represent a recent impetus for liability in the legal system.
- 2. It believes that the state is responsible for the vaccines it approves, regardless of whether vaccination is mandatory or optional. When the state refuses to approve a vaccine, the decision must be carefully considered and deliberate. The state then bears the resulting responsibility before society, allowing individuals to hold it accountable and subsequently bringing recourse to the pharmaceutical companies that produce the vaccine. The goal is to ensure that those harmed receive fair and prompt compensation. State intervention has become an absolute necessity to meet the demands of justice sought by protection from the risks of scientific development.
- 3. It is necessary to strike a balance between the individual's right to protect their body and humanity's right to produce vaccines, without underestimating the individual's right to protect their body, to inform of the risks of the drug, and to allow the trial to be terminated upon request. It must also be halted in the event of a life-threatening threat, while ensuring treatment and fair compensation in the event of harm.
- 4. The nature of liability arising from the risks of scientific development is objective and based on harm.
- 5. The field of vaccines is one of the fields most susceptible to the risks of scientific development.

#### **Second: Recommendations**

- 1. We recommend that the Libyan state establish mechanisms to compensate for damages resulting from the risks of scientific progress, based on the concept of social solidarity.
- 2. These mechanisms do not replace the inclusion of the risk of scientific progress within insurance coverage to cover the risks posed by scientific developments and scientific expansion.
- 3. We recommend strict accountability for vaccine damages that affect disease-free individuals. Being infected with a new disease is not the same as a worsening of a previous one. The drug-producing company should be responsible for these damages and fairly compensate those affected.
- 4. We recommend that all countries and governments work to establish an integrated medical database, using big data technology, and support international efforts to find new treatments and effective vaccines.

### References

The Holy Qur'an, Libyan Endowments House, Qaloon's Narration on the authority of Nafi', Fourteenth Edition, 2017 **First: Books:** 

#### **A- Arabic References:**

- 1. Amal Al-Bakoush, Objective Liability for Medical Consequences: A Study in Comparative Algerian Law, Dar Al-Jami'a Al-Jadida, Alexandria, 2017
- 2. Badr Osama Ahmed, Guaranteeing the Risks of Medical Products, Dar Al-Kotob Al-Qanuniya for Publishing, Cairo, 2008
- 3. Abdel Hamid Al-Dasiti Abdel Hamid, Consumer Protection in Light of the Legal Rules of Product Liability, Dar Al-Fikra Wal-Qanun, Egypt, 2009

 $<sup>^{1}</sup>$  - Abdullah Hamad Al-Khalidi, Civil Liability of Companies Producing Vaccines and Medicines for the Novel Coronavirus (COVID-19), op. cit., p. 195.

- 4. Abdel Wahid Karam, Dictionary of Legal Terms, Dar Al-Thaqafa for Publishing, Amman, Second Edition, 1998
- 5. Salem Muhammad Rad'an Al-Farady, Product Liability in Civil Laws and International Agreements, Dar Al-Thaqafa Al-Arabiya for Publishing and Distribution, First Edition, 2009
- 6. Muhammad Muhyi Al-Din Ibrahim Salim, As a Reason for Exempting the Producer from Liability, Dar Al-Nahda Al-Arabiya Cairo, 2007
- 7. Mona Kamel Turki, Human Rights and the Humanitarian Emergency in Light of the COVID-19 Pandemic, Dar Al Nahda Al Arabiya, Egypt, First Edition, 2021

# **B- Foreign References**

- 1. A. Ibtisam Hassan Salem Bin Issa. (2025). Medical Error Obligating Criminal Liability. Al-Haq Journal of Sharia and Legal Sciences, 1-12. https://doi.org/10.58916/alhaq.vi.275
- 1. with Acute Myocardial Infarction Following MRN COVID-19 Vaccination, American Journal of Clinical Psychology, Vol. 10, No. 6, pages 1196-1201, 2021
- 2. WHO, Covax, Working for Global Equitable Access to COVID-19 Vaccines, 2020

### Second: Research, Journals, and Scientific Articles

- Ibrahim Ali Hammadi, Professional Error and Ordinary Error in the Framework of Medical Liability: A Comparative Study, Al-Halabi Legal Publications, Beirut, 2007.
- 2. 3:00 ALTAEB, M. O. (2014). Administrative judiciary oversight in the field of public service. Al-haq Journal for Sharia and Legal Sciences, 196-219.
- 3. ALTAEB, M. O. (2020). The theory of emergency circumstances and its impact on the implementation of the administrative contract. Al-haq Journal for Sharia and Legal Sciences, 146-165.
- 4. Al-Rubaie, S. A. Q., & ALTAEB, M. O. (2019). The Legal Regulation of Administrative Control in Libyan Legislation and Comparative Systems. Al-haq Journal for Sharia and Legal Sciences, 20-56.
- 5. Ali, A. S. M. (2019). Provisions regulating trademarks in international agreements. Al-haq Journal for Sharia and Legal Sciences, 57-83.
- 6. Lamjali Ahmed, Producer Liability for Defective Products in Jordanian Law, A Legal Analysis Comparative to French Law, Al-Ijtihad Journal of Legal Studies, Vol. 9, No. 3, 2020.
- 7. Ayoub Fellaq, Producer Liability for the Risks of Scientific Development in Light of the Law: A Comparative Study, University Center, Algeria.
- 8. Alaa El-Din Muhammad Abu Aqil, "State Liability for Damages Arising from the Risks of Scientific Development: COVID-19 Vaccines as a Model," Journal of Jurisprudential Research, 2023, Al-Azhar University.
- 9. Abdullah Hamad Al-Khalidi, "Civil Liability of Vaccine and Drug Producing Companies Novel Coronavirus," Publishing House, Qatar University, 2021.
- 10. Abdel-Raouf Ramadan Abu Sitta. (2024). Civil Liability for Medical Damages ((A Study in Libyan Law)), Al-Haq Journal of Sharia and Legal Sciences, 473-482. <a href="https://doi.org/10.58916/alhaq.vi.270">https://doi.org/10.58916/alhaq.vi.270</a>
- 11. Abdel Aziz Abdel-Moati Aloul, "The Extent of the State's Obligation to Compensate for Damages Arising from the COVID-19 Coronavirus," Legal Journal, 2022.
- 12. Fatima Zahra Boumediene, "Product Liability for the Risks of Scientific Development in the Field of Medicine," Journal of Law and Humanities, Volume 3, Issue 9, 2014, Ziane Achour University, Algeria.
- 13. Dr. Ali Abu Bakr Al-Qadimi. (2025). Administrative Responsibility of Public Health Facilities in Libyan Legislation. Al-Haq Journal of Sharia and Legal Sciences, 152-166. <a href="https://doi.org/10.58916/alhaq.vi.285">https://doi.org/10.58916/alhaq.vi.285</a>
- 14. Fashi Alaa, "Cases of Exclusion of Product Liability," Journal of Legal and Political Research and Studies, Issue 2, 2012, Saad University.
- 15. Latifa Amazoun, "Tort Liability Provisions as a Basis for Defective Product Liability," Academic Journal of Legal Research, Issue 2, Mouloud Mammeri University, Algeria. 2018
- 16. Mahmoud Ghazal and others, Responsibility for the Risks of Technological Development, Tishreen University for Scientific Research and Studies, Syria, Volume 33, Issue 1, 2011.
- 17. Muhammad Mansouri and Manal Boukord, International Efforts to Combat the Novel Coronavirus, Mentouri Brothers University, Algeria, 2020.

- 18. The Role of Big Data and Artificial Intelligence in Confronting the Coronavirus Pandemic: Successful International Experiences, Journal of Research and Human Resources Development, Volume 6, Issue 3, 2021.
- 19. Siham Al-Mamar, Civil Liability for the Unexpected Harmful Effects of Vaccines, Journal of Research in Contracts and Business Law, Volume 6, Issue 1, 2021, Maghnia University Center, Algeria.

# Third: Theses:

- 1. Mahmoud Raed Mahmoud, Civil Liability of Drug Producers for Defects in Pharmaceutical Products, Master's Thesis, Middle East University, 2011
- 2. Mashael Nayef, Non-Fault Management Liability in Light of the COVID-19 Pandemic, Master's Thesis, King Abdulaziz University, Jeddah, 2022.
- 3. Muhammad Issa Oud Al-Shoubaki, Civil Liability of Vaccine Producers: A Comparative Study, Master's Thesis, Middle East University, 2022.

# **Fourth: Websites:**

- 1. COVAX Compensation Program 2021, https://www.covaxclaims.com, accessed March 13, 2025.
- 2. British Broadcasting Corporation, 1997, https://www.bbc.com, accessed March 19, 2025.
- 3. World Health Organization (WHO), 1948, https://www.who.int, accessed February 21, 2025.
- 4. U.S. Centers for Disease Control and Prevention, 2022, http://www.cdc.gov, accessed February 21, 2025.
- 5. French Medical Accident Compensation Office, 2022, http://www.oniam.fr, accessed March 24, 2025.
- 6. United Nations (UN Arabic version), 1995, https://www.un.org/ar/, accessed March 21, 2025