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CRIMINAL LIABILITY ARISING FROM DRUG TRIALS (COMPARATIVE STUDY)

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Abstract
The study of criminal liability related to pharmaceutical experiments had been conducted with a focus on Jordanian law and in comparison, with the legal regimes of France and Egypt. These changes of the drug trial system have been of utter vital importance in the advancement of medicine. But yet, the ever-present legislations and ethical gaps sometimes freeze aging efforts of having wrongdoers punished, especially in cases where such trials ended in the harm or outright violation of the rights of the participants. With the descriptive-analytical methodological approach grounded on doctrinal and comparative legal analyses, the research scrutinized major national laws such as Jordan's Drug and Pharmacists Law No. 12 of 2013, Pharmaceutical Studies Conducting Law No. 67 of 2001, and Medical and Health Liability Law No. 25 of 2018, alongside international conventions like the Declaration of Helsinki, and the UN Convention on the Rights of the Child. The findings pointed towards an inconsistency of laws in Egypt, a stronger requirement of institutional liability in France, whereas Jordan reveals substantive gaps in regard to definition and enforcement. In particular, penal sanctions in Jordanian law can go as far as five years imprisonment, and fines can reach 20,000 dinars; however, institutional responsibility specifically in relation to non-therapeutic trialsand institutional responsibility. The study recommends harmonizing national legislation with international ethical standards to ensure effective accountability, protect vulnerable populations, and balance pharmaceutical innovation with fundamental human rights.

Keywords: Criminal Liability, Drug Trials, Pharmaceutical Regulation, Jordanian Drug Law, Legal Accountability.

1. Introduction

In parallel with the promotion of the advanced status of human societies and the resultant increasing exposure to various communicable and non-communicable diseases, there exists an ever-growing demand for treatment based on scientific evidence and pharmaceutical innovation. As a result of these needs, modern healthcare systems must, in fact, place great weight on pharmaceutical development. When finally ready to be marketed, the drug undergoes an entire gamut of clinical testing phases, many involving the participation of human subjects. In essence, while these clinical trials may never be deemed trivial in medicine, they do engender a very complicated web of ethical, legal, and humanitarian concerns-especially in those cases when these clinical trials serve to injure, violate participant rights, or are conducted without adequate oversight.

Drug experimentation has its own place in therapeutic development, while it also puts the very physical safety and well-being of the participant at risk as well as his dignity. The fundamental problem arises when one has to negotiate the delicate line between scientific imperative and individual rights. Within this context, criminal impregnation appears to act not merely as an ex post facto penal sanction but as a deterrence against breach and negligence during clinical trials. It puts individuals and institutions before justice and instills the moral imperative upon them to undertake research both within the letter of the law and ethical standards. The study thus explores whether the existing legislative framework-in particular in the Hashemite Kingdom of Jordan-provides an adequate definition of, regulates, and penalizes misconduct in pharmaceutical experimentation or whether a major legal reform should urgently fill the normative and procedural gaps and dovetail with internationally acknowledged ethical frameworks.

In addressing the issue at hand, the present inquiry undertakes a comparative study of the legal and regulatory provisions concerning drug experimentation in Jordan, France, and Egypt. Whereas Jordan exemplifies a research case with emerging regulatory frameworks trying to align itself with the existing parameters set on the international stage, France stands as an example of statutory control defined by the Code de la Santé Publique, with stringent oversight mechanisms and well-defined criminal liabilities. Contrarily, Egypt exemplifies a scenario where guidelines in ethical terms are laid down, and below these, it is an unstructured inconsistency of law enforcement application. This comparison provides a window into understanding how these jurisdictions view the criminal responsibility, procedural safeguards, and institutional accountability pertinent to drug trials.

The study attempts to look at how these four legal systems charge criminal responsibility for pharmaceutical experimentation, particularly with regard to actions of negligence, breaches of informed consent procedures, and perhaps the role of institutions such as pharmaceutical companies or medical and pharmaceutical research centers. In particular, it is investigated whether the prevailing consent regimes protect adequately the vulnerable groups such as children, the elderly, and afflicted persons in giving an autonomous consent. In addition, the paper further looks into whether punishments imposed for corporate offenders and institutions are deterrent enough, proportional, and truly applied.

The descriptive-analytical, doctrinal method was applied in this study. Sources include statutory texts, judicial interpretations, and regulatory instruments, with a major focus on Jordanian laws, namely, the Drug and Pharmacists Law No. 12 of 2013, Pharmaceutical Studies Conducting Law No. 67 of 2001, and the Medical and Health Liability Law No. 25 of 2018. For purposes of comparison, the pertaining French and Egyptian legal frameworks are equally canvassed. International instruments, including the Declaration of Helsinki, UN Convention on the Rights of the Child, and UNESCO Universal Declaration on Bioethics and Human Rights, will be used for evaluating the conformity and sufficiency of national legal systems in regulating pharmaceutical experimentation.

In seeking to offer multidimensional comparisons and analyses to the legal systems in question, the study strives to contribute to academic discourse as well as public policy debates. Eventually, it aims to provide targeted recommendations to strengthen criminal accountability, participant protections, and ethical integrity in pharmaceutical research amongst various jurisdictions.

2. Literature Review

2.1 Defining “Medicine” Across Legal Systems

In pharmaceutical regulations and clinical trials, the concept of drugs lies at their core. How these are defined will carry heavy implications in determining legal requirements, eligibility for phases of trial, and liability when harm is occasioned. Although it is an elementary concept, the very definition of "medicine" will be different in different jurisdictions, pointing to divergent legal interests.

According to Article 1 of the Jordanian Drug and Pharmacists Law No. 12 of 2013, a drug is any substance included in a pharmaceutical constitution prepared by the Minister or any pharmaceutical form containing active ingredients used in diagnosis, treatment, or prevention of disease in humans. This definition is comprehensive and functionally anchored, addressing both pharmacological intent and compositional structure. Furthermore, Article 3 mandates that

medicines be approved only after clinical testing confirms their safety, effectiveness, and quality (Jordanian Drug and Pharmacists Law No. 12, 2013, arts. 1 & 3).

Article 511 of the French Public Health Code defines medicine as any substance with therapeutic or preventive properties or one that alters physiological functions for medical purposes. This includes diagnostic aids and non-nutritional therapeutic substances such as slimming products. French jurisprudence has extended this definition, such as in the Paris Court ruling of 24 September 1980, where hydrogen peroxide and alcohol-based solutions were legally categorized as medicines based on concentration and purpose (Al-Daraji, 2020, p. 120).

The U.S. Food and Drug Administration defines a drug as any article intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease (Altibbi, n.d., para. 3). Burst (2012, p. 36) adds that a drug may be of plant, animal, or chemical origin and may be administered orally, topically, or via injection. This broad formulation emphasizes therapeutic function over form and reflects the operational flexibility in American regulatory law.

The Egyptian Pharmacy Practice Law No. 127 of 1955 does not provide a single, unified definition of what constitutes a "medicine." Instead, it classifies substances into categories such as “special pharmaceutical preparations” and “pharmacopoeial drugs,” resulting in a fragmented legal framework. Articles 58 and 62 indicate that any substance purporting therapeutic efficacy, whether or not its components are transparently disclosed, is subject to regulatory oversight (Egyptian Pharmacy Practice Law No. 127, 1955, arts. 58 & 62). This suggests an intent to cast a wide regulatory net but without clear definitional precision.

From a comparative standpoint, this lack of terminological cohesion stands in contrast to Jordan’s more comprehensive and modern legislative model, which defines pharmaceutical substances through a dual lens of objective function and procedural authorization. Egypt’s approach, by contrast, generates interpretive ambiguity that may complicate enforcement and judicial consistency. Meanwhile, France and the United States demonstrate robust regulatory control through public health codes and administrative regulation, respectively, though their definitional frameworks vary in detail and institutional anchoring. In this regard, Jordanian legislation stands out for its clarity, integration, and legislative coherence.

2.2 Objective and Procedural Conditions in Drug Classification

In pharmaceutical regulation, a substance is legally classified as a “drug” only when it meets both objective and procedural conditions. The objective criteria pertain to the substance’s therapeutic intent and pharmacological activity. A valid drug must exhibit curative or preventive functions and be capable of producing measurable biological effects. For example, cosmetic products such as hair dyes or nail polishes, while chemically active, do not qualify as drugs due to the absence of medical purpose (Mahmoud, 2002, p. 95 ff.; Al-Hussaini & Abdul Wahab, 2016, p. 14).

Equally important are procedural conditions, which involve state oversight mechanisms such as licensing, safety assessments, and manufacturing standards. In Jordan, the Drug and Pharmacists Law No. 12 of 2013 prohibits the circulation of unregistered substances and mandates prior authorization for pricing (arts. 3(A)(1), 7). This is reinforced by the Jordanian Pharmacy Practice Law No. 12 of 1972, which regulates the licensing of pharmaceutical factories and the importation of medicines through ministerial approval (art. 132(B)). Egypt’s Pharmacy Practice Law No. 127 of 1955 outlines similar procedural controls, including licensing requirements for drug production and qualifications for factory managers (arts. 10/11).

These legal mechanisms are designed to ensure pharmacological safety and regulatory compliance. However, the integration of ethical safeguards, particularly during the pre-authorization and trial phases, remains limited, especially in jurisdictions where procedural standards are not supported by robust enforcement or bioethical review.

2.3 The Concept and Classification of Drug Trials

Drug experimentation is the cornerstone of pharmaceutical progress, but it also introduces substantial legal risk, particularly regarding informed consent, harm, and the role of institutional actors.

Drug experiments are defined as scientific procedures undertaken to evaluate the safety, efficacy, and pharmacokinetics of pharmaceutical substances. These experiments are distinct from routine therapeutic interventions in that their primary aim is not necessarily to benefit the individual patient, but rather to advance scientific or humanitarian objectives. As noted by Maabara (n.d., p. 2), Aliwi (n.d., p. 79), and Al-Arabi (2012, p. 24), three essential characteristics define drug experimentation: its inherently technical and medical nature, its role in advancing medical knowledge, and the participation of either patients or healthy volunteers as research subjects.

Aliwi (n.d., p. 79) emphasizes that drug experimentation often departs from conventional medical practice, as it is not necessarily driven by therapeutic necessity. Instead, its rationale frequently lies in contributing to broader scientific understanding or future public health benefits. This distinction is critical, as it separates drug trials from therapeutic interventions whose primary concern is the immediate well-being of the patient. As Psychology Today (n.d., para. 2) observes, such differentiation has important implications for both ethical oversight and legal accountability.

The World Medical Association's Declaration of Helsinki (2013) provides an internationally recognized typology for categorizing drug trials. One primary category includes therapeutic drug trials, which are conducted on patients in situations where existing treatment methods are ineffective. These trials seek to discover new medical interventions that offer better clinical outcomes, as emphasized in paragraph 34 of the declaration. Clinical trials involving the extremes of experimental treatment are seen to represent exploratory or scientific trials, since they have a more theoretical basis and endanger the welfare of the patient to a higher degree in the absence of any medical benefit to the patient himself. The said paragraph 37 states that such studies are more inclined to test a hypothesis or study a new mechanism of action. Particularly, some investigations are carried out on healthy volunteers to learn about pharmacodynamics or toxicity levels and other physiological reactions of medicinal substances.

Within the Jordanian legal system, the Pharmaceutical Studies Act No. 18 of 2011 gives a structural classification of pharmaceutical trials in Article 3. Therapeutic drug studies are supposed to take place with either sick or healthy volunteers whereas the non-therapeutic studies concentrate on the assessment of drug efficacy, bioavailability, and bioequivalence. This typology aligns for the most part with international typologies, especially those put forth by the World Medical Association, but it falls short on more critical ethical issues. For instance, the Jordanian legislation fails to consider important safeguard mechanisms for vulnerable populations and does not consider any other mechanisms that would ensure access to beneficial treatment for participants once the treatments have proven to be beneficial after the trials.

From the ethical standpoint, these classifications touch on fundamental bioethical principles, including respect for autonomy, beneficence, and non-maleficence of the maximization of benefits. These values derive not only from the Belmont Report (1979) but also from UNESCO's

Universal Declaration on Bioethics and Human Rights (2005), which constitute normative anchors for rendering judgments concerning the ethical soundness of national pharmaceutical research regulations.

2.4 Legal and Ethical Convergence: Towards Criminal Liability

Due to the various definitions pertaining to drug trials and the enforcement of ethical safeguards, differing degrees of criminal accountability exist. In Jordan, although precise trial types exist with legal classification, explicit and direct and criminal provisions in relation to drug research remain vague. Egypt has no unified classification system, and enforcement is undertaken by way of general codes of law. France, however, classifies drug research more explicitly, thereby adopting typologies alongside ethical supervision and institutional liability.

Table 1. Legal and Ethical Frameworks Governing Drug Trials: A Comparative Analysis

Jurisdiction	Trial Typology	Ethical Oversight	Criminal Liability
Jordan	Therapeutic / Non-therapeutic	Implicit	Ambiguous; lacks explicit trial-specific criminal clauses
France	Therapeutic / Exploratory	Embedded in Public Health Code	Stronger, includes institutional liability
Egypt	Undefined	Weak	Poorly codified

These disparities highlight the need for clearer statutory alignment between ethical principles and criminal responsibility in drug research.

2.5 Synthesis and Implications

Historically, it appears that the Jordanian laws provide a good definition and some procedural guarantees. However, there is an apparent lack of detailed criminal provisions applying within the context of experimental drug violations. A comparative perspective thus shows a need for an integrated reform to adequately reconcile the legal definitions and trial types with bioethical considerations for the protection of scientific advancement and human rights.

3. Methodology

This study adopts a descriptive-analytical legal methodology backed by a doctrinal and comparative analysis, focused on criminal liability emerging from drug experimentation. The study analyzes the various ways through which the legal systems view and regulate pharmaceutical trials, particularly with regard to the protections extended to human subjects, informed consent, institutional accountability, and criminal sanctions.

3.1 Doctrinal and Comparative Design

This study follows a doctrinal legal methodology focusing on the systematic interpretation of statutory provisions, judicial rulings, and regulatory instruments governing pharmaceutical experimentation. The analysis proceeds beginning with a close examination of the principal legislative texts under the Jordanian rubric. Drug and Pharmacists Law No. 12 of 2013 is the lead statute, enunciating definitions for medicinal substances and procedural modalities pertaining to their relationship in registration, circulation, and use. A secondary but complementary statute is the Pharmaceutical Studies Conducting Law No. 67 of 2001, which outlines the procedural requirements for drug clinical trials, including the distinction between therapeutic and non-therapeutic investigations. Further, the Medical and Health Liability Law No. 25 of 2018 stays in

the backdrop to criminalize the liability for medical negligence or illegal interference, thereby situated the idea of legal responsibility in drug-related research within the ambit of health law.

In providing a broader analytical thrust, the study adopts a comparative legal approach, thus confronting two contrasting jurisdictions: France and Egypt. The reason France was selected is that regulations are well established there, especially with respect to the stringent enforcement of informed consent procedures and the clear legal codification of pharmaceutical trial regulation in the Code de la Santé Publique. Egypt, on the other hand, is exemplified as one based on ethical-medical practice, wherein the legal control system combines formal statutory provisions such as the Pharmacy Practice Law No. 127 of 1955 and soft-law provisions, i.e., professional ethical codes. Such contrasting systems allow a most critical look at how differing legal cultures view accountability, risk reduction, and procedure safeguards in drug experimentation.

Doctrinal and comparative analysis is further grounded in some international legal instruments and internationally accepted ethical norms. In particular, the study relies heavily upon the United Nations Convention on the Rights of the Child, which stresses the improvement of legal safeguards for vulnerable groups, such as minors, in all phases of medical and experimental treatments. The Declaration of Helsinki of the World Medical Association can never be undermined while considering ethical principles for medical research with human subjects. These instruments stand as interpretative tools and normative standards for assessing domestic regulatory regimes.

This study blends positivist jurisprudence with moral reasoning for conducting a rigorous and context-sensitive inquiry into the issue of criminal liability arising from pharmaceutical trials across Jordan and selected comparative jurisdictions.

3.2 Analytical Framework

The thematic comparative approach, used to analyze legal texts, makes it possible to discern the features of the jurisdictions under study. The framework focused upon four highest core dimensions depicting the structural and normative framework with regard to criminal liability attached to pharmaceutical experimentation.

The first of these dimensions analyzed informed consent requirements, particularly with regard to the national laws' articulation of voluntariness, capacity of a subject, and safeguards in the procedure. This would involve statutory provisions as well as judicial interpretation rendering the thresholds for valid consent in both therapeutic and non-therapeutic trials.

Secondly, lay criminal sanctions have been analyzed with respect to their range and severity with regard to punishments applicable to individuals and institutional actors who within certain circumstances violate or contravene clinical trial regulations. The question whether the systems actually made a differentiation between deliberate infringements and negligent breaches of procedure was also discussed within this sphere.

Third, the research looked into the different victim protection measures, particularly those involving post-trial remedies, such as civil liability, compensation through insurance, and access to restitution. It examined which systems are most efficacious in backing the rights of wrongfully treated victims through their avenues of redress.

Lastly, the study went into regulatory oversight structures and charted the institutional frameworks responsible for licensing, monitoring, and ensuring compliance of pharmaceutical research. It looked at that regulatory bodies were independent; how much sanctioning power they wielded; and how transparent their enforcement actions were.

Taken together, these identifiers allowed a layered understanding of how legal systems operationalize ethical norms and assign criminal responsibility within the context of drug experimentation. This framework, therefore, allowed a critique from a normative standpoint as well as a standpoint of enforcing capacity in varying national and international contexts.

3.3 Case Law Interpretation

The research also consists of the consideration of a few selected cases from the Jordanian judiciary where unauthorized acts in the field of medicine and negligence regarding pharmaceuticals were deemed punishable. These cases shed some light on how the judiciary interprets statutory provisions and highlight the practical use or lack of use of legal remedies in cases of clinical experimentation. French and Egyptian case law has been consulted in-depth when available, but the analysis is hinged on Jordanian case materials for purposes of jurisdictional relevance.

3.4 Limitations

Some limitations must, therefore, be weighed when going through the learnings derived. The first and perhaps most evident is language barrier, barring the study from reaching more elaborate Egyptian court case law style material. Much of this jurisprudence remains either wholly or partially untranslated or unavailable to researchers outside the national legal system itself, seriously limiting comparative depth. Besides, systemic opacity within pharmaceutical oversight agencies in the analyzed jurisdictions also very often stood in the way of obtaining enforcement data, especially, data on imposed sanctions or compliance mechanisms set in place.

Another limitation is the study's high preference for formal legal instruments and doctrinal analysis. While this allows for stringent textual and normative criticism, this made an unfortunate omission in that it could not capitalize on empirical data gleaned through interviews with practitioners of medicine, lawyers, or regulatory officials. Such qualitative accounts would provide greater insight into the real-world working of legal frameworks and expose enforcement issues or ethical tensions that cannot be captured purely through statutory text.

In spite of the limitations, the method adopted sets a sound ground for the legal examination in so far as it identifies inconsistencies at a legislative level, enforcement gaps, and a desperate need for the reform of ethical and criminal regulation concerned with drug experimentation, especially in Jordan and similar legal systems.

4. Results

Here are the major findings of the doctrinal and comparative analyses. The results are grouped under five key legal dimensions: (1) legal definitions and procedural safeguards; (2) recognition and regulation of drug trials; (3) liability and compensation mechanism; (4) consent protocols; and (5) the primacy of human welfare in experimentation.

4.1 Legal Definitions and Procedural Safeguards for Medicine

Medicines are defined with varying degrees of precision across the jurisdictions studied, ranging from very general to very specific. The common elements required for a medicine are that it must have an active pharmacological substance and perform a therapeutic or preventive function. The procedural safeguards, however, carry significant weight as well. These safeguards require the pre-market registration and licensing of all drugs and attend to strict regulatory control of pharmaceutical manufacture standards and factory specifications. Simultaneously, the Jordanian Drug and Pharmacists Law No. 12 of 2013 embodies the principle of a dual-criteria regime by requiring both empirical clinical trial data and regulatory registration before the legal distribution

of any pharmaceutical product, as said in Articles 1 and 3 of the law. However, Egyptian legislation reveals a deafening silence and gap, split into increasingly slight fragments in its definitions of medicine and, above all, in the procedural enforcement mechanisms governing imported drugs and herbal products. This regulatory uncertainty ultimately threatens pharmacovigilance and the law's ability to persecute.

4.2 Recognition and Regulation of Drug Trials

It is apparent from the jurisdictions studied that most legal systems do not offer any clear definitions of "drug trials" under either their criminal or medical laws. In countries such as Egypt, protections concerning personal integrity and bodily autonomy are often considered within the realm of a broader constitutional or civil structure, rather than within specific statutory wording aimed at regulating pharmaceutical experimentation. Hence, procedural and ethical regulation of drug trials ceases to exist in the legal arena. Meanwhile, Jordan plans to fill this breach with the Pharmaceutical Studies Law No. 18 of 2011, which explicitly bounds therapeutic and non-therapeutic studies and thus prescribes procedural methods of institutional approval, supervising, and scientific justification into a new paradigm of accountability. The law clearly identifies bioequivalence studies and underscores the need for a scientifically valid protocol before undertaking drug trials.

Similar has the path in France, where national oversight is ensured through regulatory bodies exercising trial validation and compliance. Jordan, therefore, through these legislative advancements, particularly through its 2011 law, occupies a foreground in relation to jurisdictions that continue legislating through assorted provisions in health codes or privacy legislation.

4.3 Liability and Compensation Mechanisms

A dual-layered system of accountability comes as one of the glory strengths of the Jordanian legal system. Both civil and criminal liabilities are invoked for damages arising out of drug experiments. Specifically, Article 5 of the Pharmaceutical Studies Law No. 18 of 2011 required compensation for otherwise harmed in clinical experiments through compulsory insurance, thus institutionalizing victim protection. Complementing it, Article 17(1) of the same law provided for criminal sanctions for breaches, showing the desire of the legislator for deterrence and justice. In France also great police work is done by the civil and criminal liabilities as courts measure the gravity of circumstances, and ethics boards themselves exert the power of sanctions. Under French penal law, custodial sentences are possible where breaches of consent procedures occur. In Egypt, on the other hand, we find a more undefined situation. Civil liability arises in general from tort law, whilst criminal sanctions emanate from other general provisions related to bodily harm or medical malpractice, but there are no statutes providing for drug experimentation. Table 2 below summarizes how each jurisdiction handles civil and criminal liability related to drug experimentation:

Table 2.Civil and Criminal Liability in Drug Trials Across Jurisdictions

Jurisdiction	Civil Liability	Criminal Penalty
Jordan	Article 5 of Law No. 18 of 2011 mandates compulsory insurance-based compensation	Article 17/1 prescribes criminal penalties for violations
France	Civil and criminal liability based on harm severity; includes ethics board sanctions	Penal Code imposes custodial penalties for non-consensual trials
Egypt	Limited statutory clarity; depends on general tort law	No trial-specific criminal statute; relies on broader assault or malpractice codes

Though an important lacuna abides in Jordanian law. Whereby, penalizing or demanding compensation from individuals seems possible, no institutional sanctioning can thus be recorded whereby pharmaceutical companies or research hospitals become the object of systemic or repeated violations. This focus on the individual may render the law incapable of dissuading such unlawful conduct on the part of organizations and ensuring a collective level of accountability in drug research.

4.4 Consent Protocols and Ethical Authorizations

The analysis showed a relevant departure existing between legal systems in regulating consent requirements for drug experimentation. In Jordan, an explicit consent of the participant or his legal representative in writing must be obtained before the commencement of any clinical trial. Such requirement is set forth within the Pharmaceutical Studies Law itself and in accordance with international ethical standards for research involving human beings. France does not stop there and implements a multi-tiered oversight system. As per Article L.1121-1 of the French Public Health Code, Drug trials must obtain the participants duly documented informed consent and also receive prior approval from one or more national ethics committees. These committees ascertain that the protocol of experimental research is scientifically valid and that the welfare of the participants is protected, hence reinforcing the ethical oversight on both procedural and institutional levels.

By contrast, Egypt's regulatory environment looks less rigorous. Upon acknowledgement of autonomy and non-maleficence principles in medical practice, the legal framework to ascertain consent requirements appeared deficient. More commonly applied rules of thumb revolve around verbal consent with occasion for concern on the issue of the participants' protection and trial legitimacy in the absence of clearly charted procedures, safeguards, and oversight avenues.

Over and above anything else, the study confirms that stronger protection against coercion, miscommunication, and abuse is offered by jurisdictions demanding a pre-trial written consent plus an independent third-party ethical review, such as the French model, as opposed to those relying on verbal assurances or informal protocols. While greater strides towards this cause are being made under the present Jordanian system, it might well benefit from further refinement and institutional oversight.

4.5 The Principle of Human Primacy Over Scientific Interest

One of the essential foundations of all laws reviewed is the recognition that the welfare and dignity of the human subject must stand ruled over any interest in scientific or pharmaceutical advancement. This ethical imperative, enshrined as the doctrine of "human primacy," becomes an ethical and legal boundary within which drug experimentation must be performed. According to the Pharmaceutical Studies Law of Jordan, Article 4, no clinical trials shall be conducted in situations where a very high probability of serious harm to the participants exists. This provision is a legislative safeguard underscoring the significance of risk reduction and individual protection within the regulatory framework of Jordan. On an international scale, the Declaration of Helsinki (2013), especially paragraph 8, further strengthens this duty by stating that "the rights, safety, and well-being of the subject shall become paramount in relation to interests of science and society." This declaration still serves as ethical guidelines throughout the globe integrated into national law and codes of conduct of professionals.

French legal codes gave further institutionalization to the primacy of humans by requiring thorough risk assessment and pointed justifications concerning instances of harm or benefit

before the authorization of trials. These procedural guarantees make sure not to let the scientific objectives eclipse participants' safety and ethical accountability.

Thus, the mainstream still differentiates the application of this principle from one jurisdiction to another, but the underlying consensus is clear: no potential for scientific benefit can justify the intentional endangerment of human life or dignity. In this way, it fulfills the function of a non-negotiable ethical anchor upon which are grounded regulations for human-subject biomedical research.

4.6 Jurisdictional Contrasts in Drug Trial Regulation

Across those three jurisdictions of Jordan, France, and Egypt, there is a starkly diverging set of legal approaches regulating drug trials. The jurisdictions display varying degrees of legislative accuracy, ethical supervision, and institutional accountability. Jordan shows more of a marked structure than the other two with their own legislation, such as Law No. 18 of 2011, detailing drug trials, mandating informed consent in writing, and marking both criminal and civil liability for compensation. France also has specific and detailed statutory provisions concerning drug trials, mainly reflected in the Public Health Code, with ethics committee review procedures and institutional sanctions at a national level. Contrarily, Egypt is mostly fragmented and relies upon broad legal principles and ethical considerations without there being a specific procedural or enforcement mechanism concerning drug experimentation.

Table 3 below summarizes the key differences across these domains:

Table 3. Diverging Legal Structures for Drug Trials: A Comparative Analysis of Jordan, France, and Egypt

Legal Domain	Jordan	France	Egypt
Drug Definition	Comprehensive, dual conditions	Functional/physiological focus	Fragmented, inconsistent
Drug Trial Recognition	Explicit (Law No. 18 of 2011)	Integrated in Public Health Code	Implicit via general codes
Written Consent	Mandatory	Mandatory + Ethics Review	Often verbal or implied
Criminal Liability	Defined for individuals	Defined for individuals + institutions	General criminal code only
Civil Compensation	Insurance-based (Article 5)	Judicial or administrative remedy	Tort-based, no trial-specific mechanism

This contrast underscores the need for harmonized legal safeguards that simultaneously uphold individual rights, foster medical innovation, and ensure ethical accountability across national and institutional boundaries.

5. Discussion

5.1 Therapeutic Drug Studies

The legal and ethical framework concerned with the conduct of therapeutic drug studies in Jordan has seen great developments but also left some crucial areas unregulated. Article 5 of Jordanian Drug Studies Law No. 2 of 2011 sets forth such basic protections as voluntary informed consent and medical screening prior to study, in line with international ethical standards. But unlike the approaches taken with other laws, inconsistencies arise here. For instance, the Medical Liability Law of 2018 sets relatively low sanctions for medical offences

when compared to the Pharmaceutical Studies Law No. 67 of 2001, thus creating some doubts as to their enforceability. These dissimilarities could prevent the creation of a coherent accountability framework, especially when an infringement straddles more than one jurisdiction of law.

Moreover, therapeutic studies involving vulnerable populations such as children or individuals with impaired legal capacity pose heightened ethical and procedural challenges. While Article 43 of the French Medical Profession Regulation Law mandates parental or guardian consent and encourages seeking the patient's opinion where possible, Jordanian law lacks a similarly explicit mechanism. To address this, a possible legislative enhancement would be the appointment of independent pediatric advocates or legal proxies in drug trials involving minors, mirroring models seen in France and supported by international ethical frameworks (World Medical Association, 2013, paras. 26–27). Such a step would ensure both medical beneficence and respect for autonomy, especially where family structures may be absent or coercive, such as in the case of institutionalized or orphaned minors.

The Amman Criminal Court of First Instance's ruling in Case No. 1836/2016 clarified that the trial participants, university students, had indeed provided informed consent, and the study was approved by the Jordan Food and Drug Administration. Yet, this judgment exposes a broader ethical vulnerability: the voluntariness of consent when economic or institutional power dynamics are at play. Even if consent appears formally valid, it may be compromised by subtle coercion or misrepresentation, issues not robustly scrutinized in Jordanian courts. A more rigorous legislative approach should be developed to define and sanction deceptive consent acquisition in therapeutic contexts, with special protections for socioeconomically marginalized groups.

5.2 Non-Therapeutic Drug Studies

Non-therapeutic drug studies, done without the intent of benefiting the subject, are often carried out for the advancement of science and, as such, present deeper ethical and legal dilemmas. While Article 5 of the Jordanian Drug Studies Law provides for fundamental protection such as informed consent and insurance coverage, it still leaves open questions about acceptable risk levels healthy volunteers might be exposed to. Meanwhile, the Public Health Code (Art. 209) of France forbids any non-therapeutic trial that could subject participants to "any potential or serious risk" with no direct benefit, thereby setting a clear threshold of proportionality between risk and anticipated scientific gain.

This legal asymmetry becomes critical when looking at Jordan's rather timid reliance on general legal statutes like Article 93(K) of the Jordanian Drug and Pharmacists Law No. 12 of 2013, which criminalizes unauthorized drug studies while failing to either specify risk thresholds or codify them in ethical terms as limits on volunteer exploitation. For instance, institutions are required to obtain licenses and structural safety approval. These requirements, however, do not prevent systemic abuse, especially in privately funded or academic trials.

Interestingly, a certain angle missing within Jordanian legislation is the regulation of financial incentives for volunteers. The Declaration of Helsinki of the World Medical Association (2013, paras. 26–27) cautions that the use of payment to compromise the voluntary nature of participation should be against ethics. In contrast, Jordanian law does not proscribe or restrict financial reward for participation in non-therapeutic trials, thus laying the legal foundation upon which ethical inducement could take place. This lacuna is far more dangerous when dealing with populations living in socioeconomic torment where money can become a way out regardless of

the safety norms purportedly in place. An outright ban on payments in non-therapeutic trials, or at minimum, stringent regulation thereof, would ensure the integration of Jordanian law with emerging international ethical standards and managing above the risk of price-tagging the human body.

From an institutional governance perspective, the Jordan Food and Drug Administration (JFDA) has made notable strides. The establishment of specialized pharmaceutical research centers demonstrates a move toward operational specialization and procedural oversight. Yet, while the JFDA enforces licensing and infrastructure requirements, its supervisory capacity lacks clarity in terms of auditing for coercion, verifying consent authenticity, and sanctioning ethical violations.

The Jordanian legal enforcement framework, particularly Articles 17(b–e) of the Pharmaceutical Studies Law, outlines fines and prison sentences for procedural breaches. Still, penalties largely target individual professionals or institutions while neglecting legal personhood sanctions, such as administrative closure or reputational blacklisting. Moreover, the Jordanian Penal Code No. 16 of 1960 (art. 72) enforces the harshest penalty when multiple violations are committed, as seen in a case involving unregistered drug sales. However, the law does not extend proportional accountability to institutional actors in drug trials, especially when legal entities collude with researchers or exploit volunteer vulnerability.

Further jurisprudence, such as North Amman Criminal Court of First Instance Case No. 69/2006, affirmed penalties for multiple violations of pharmaceutical and public health laws. However, even here, the court's emphasis remained on statutory violations rather than the broader ethical breach of exploiting research subjects. There remains no provision in Jordanian law criminalizing a volunteer's acceptance of payment or a researcher's offering of inducements, despite the principle that the human body is not a tradable commodity. Codifying this in criminal law would represent a substantive step toward aligning Jordanian pharmaceutical ethics with international jurisprudence.

6. Conclusion

This study has examined the criminal liability associated with pharmaceutical experiments in Jordan, alongside comparative analyses drawn from French and Egyptian legal frameworks. It has explored the concept of new drug experiments, the principles of pharmacovigilance, and the penal consequences for violating established legal and ethical norms. Through this legal analysis, several findings and insights have emerged that contribute both practically and theoretically to the existing body of knowledge on pharmaceutical law and bioethics in the Arab region.

Among the core contributions of this research is its emphasis on the normative character of the Jordanian legislation, as opposed to the French. While Jordanian law seems to emphasize compensatory and punitive consequences after the fact, France leans toward preventive ethics, institutional control, and ex-ante regulatory review. This distinction brings about a very valuable comparative insight that places the Jordanian framework in a wider international setting and exposes the urgency for legal reforms proactive in nature and grounded in preventive ethics.

Moreover, this research has made an innovative contribution by advocating the expansion of criminal liability to include legal persons such as hospitals, colleges, and private research centers when wrongdoing occurs in the course of pharmaceutical experimentation. Such a proposal is in line with international counterparts in OECD and EU jurisdictions and could be seen as a leap forward in Arab legal thought, in which institutional accountability is often lacking or underdeveloped in penal codes. The recommended escalation of sanctions from mere warnings

to outright closure brings forth the rarely formalized notion of regulatory escalation in Jordanian pharmaceutical law, yet it is indispensable from the standpoint of securing its future compliance.
The study also makes a case for adding financial coercion to the list of criminal offenses for therapeutic and non-therapeutic experiments. Typically, it is an ethical matter with no enforceable legal counterpart in Jordan. Proposing both the party conducting the experiment and the participant may be held liable in instances of financial inducement, the paper seeks to bridge the gap between ethical imperatives and statute enforcement. This intersection of bioethics and criminal law is one that has largely been overlooked in the region's legal systems.
Another contribution is doctrinal in nature. The study proposes codifying a scientifically-based and legally sound definition of "drug" that characterized treatment as well as prevention, diagnosis, and physiological regulation so as to not only make legislative clarity but also bring Jordanian law in line with pharmacological and regulatory standards internationally.
The research opines that several legal reforms deserve prioritization based on these findings. First, the Jordanian legislator should criminalize financial coercion in human drug trials, making sure consent is informed and voluntary. Second, penalties under pharmaceutical and medical liability laws should be harmonized to remove contradictions and remain certain. They should also provide legal accountability to institutions through a graduated sanctioning scheme, beginning with the least severe sanctions and increasing after repeated violations. Third, death or permanent harm caused by counterfeit medicines should be subject to harsh punishment, including the confiscation of parties and long closure of the entities behind it. Fourth, long-term study should be launched that looks at the effectiveness of these penalties over time, while future research should explore how emerging technologies, notably artificial Intelligence, can assist in pharmacovigilance, monitoring, and implementation of the law.
Through its comparative lens, regulatory recommendations, and doctrinal innovations, this study offers an original academic contribution to the discourse on pharmaceutical liability and ethical experimentation, helping to advance both scholarly debate and practical policymaking in Jordan and the broader Middle East.

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