LIABILITY OF MANUFACTURER OF COVID VACCINE UNDER TORTS LAW IN INDIA: A STUDY IN LIGHT OF RISING HEART ATTACKS POST-PANDEMIC

Dr Richa Srivastava, Assistant Professor, (Sr Grade) at VSLLS, Vivekananda Institute of Professional Studies, Delhi

Dr Amita, Assistant Professor, (Sr Grade) at VSLLS, Vivekananda Institute of Professional Studies, Delhi

ABSTRACT

In the aftermath of the COVID-19 pandemic, India has reported a significant increase in incidents of cardiac arrests, with a noticeable prevalence among younger individuals who typically fall outside traditional high-risk categories. This unsettling trend has sparked intense public discourse and speculation about a possible connection between COVID-19 vaccines and cardiovascular complications such as myocarditis, arrhythmia, and sudden cardiac death. While current scientific findings do not conclusively establish a causal relationship, the recurring nature of such adverse events has led to heightened scrutiny of vaccine safety and its long-term health implications.

In light of these developments, this paper undertakes a critical examination of the legal liability of COVID-19 vaccine manufacturers under the framework of Indian tort law. It investigates whether individuals who suffer post-vaccination health complications particularly those involving cardiac issues can seek redress through claims based on negligence, product liability, or strict liability. The analysis also highlights a crucial gap in India's public health infrastructure: the absence of a dedicated no-fault vaccine injury compensation scheme. By evaluating the sufficiency of existing legal remedies and redressal mechanisms, the paper aims to assess whether the current legal regime adequately protects individuals adversely affected by vaccination and whether it strikes a fair balance between public health imperatives and individual rights.

Keywords: Liability, Torts Law, Manufacturers, Negligence, Public health.

1. Introduction

The COVID-19 pandemic prompted concerted efforts across various sectors of society to mitigate its devastating impact. Central to these efforts was the rapid development of vaccines, which emerged as the most effective tool in curbing the spread of the virus. Several pharmaceutical companies undertook vaccine development on an accelerated timeline, necessitated by the urgent global demand for immunization. However, this expedited process often did not allow for the comprehensive testing and evaluation typically required to assess potential side effects or long-term consequences for human health. Given the unprecedented nature of the crisis, governments including that of India granted emergency use authorizations to enable the swift deployment of vaccines. This, however, gave rise to a critical issue concerning accountability: in instances where vaccine recipients experienced adverse effects, the question emerged as to who would bear the liability the pharmaceutical companies or the state. This concern is particularly salient in the Indian context, where a significant portion of the population falls within low-income brackets and may lack access to adequate healthcare or legal recourse.

With production and distribution of vaccines underway, the country faced a new challenge: the financial and health implications of post-vaccination adverse events, including the possibility of exorbitant medical expenses. In such a scenario, where the socio-economic vulnerability of the population is considerable, it becomes imperative to establish clear lines of liability. Prima facie, this responsibility appears to lie either with the vaccine manufacturers or the government.

Historically, liability shields have been provided to pharmaceutical firms to facilitate the rapid development of treatments during public health emergencies, thereby protecting them from legal repercussions. However, such arrangements pose significant risks, especially when governments assume full responsibility for novel medical products, particularly on the scale required for universal immunization.

Typically, vaccine development spans several years and involves rigorous multi-phase clinical trials. The COVID-19 vaccine, by contrast, was produced within a significantly shorter timeframe. Additionally, the heterogeneity of India's healthcare system adds further complexity. Variations in dosage intervals or administration protocols often adjusted in response to emerging virus mutations may complicate efforts to assign responsibility in cases

of adverse outcomes.

In this context, the reluctance of insurance providers to underwrite such risks leaves limited options for compensation mechanisms. Ultimately, the financial and legal burden of addressing adverse effects is likely to fall either on the government or the vaccine manufacturers.

2. Product liability under Torts Law[1]

Product liability, as governed by the law of torts, arises when a product is found to be defective or harmful, thereby engaging the rights of consumers and assigning responsibility for any resulting injury. It determines who may be held liable for the defect whether the manufacturer, supplier, or retailer depending on the nature and source of the fault.

Such liability cases are considered a subset of personal injury law and involve legal claims concerning the design, production, marketing, and distribution of goods or services. Multiple parties may be implicated, including manufacturers, marketers, and retail sellers. When a defect occurs during the manufacturing process, the manufacturer is generally held accountable. However, if the product has already reached consumers through a retailer, the latter may also bear responsibility for distributing a defective item.

In tort law, the onus of proof lies with the claimant, who must establish that the injury suffered was caused by a defective product attributable to the manufacturer or supplier. The claimant must also demonstrate negligence on the part of the defendant, showing that a duty of care existed and that this duty was breached. Such negligence can occur at various stages, including the design and manufacture of the product, failure to provide adequate warnings or instructions, flaws in the distribution process, or the use of substandard raw materials and ingredients.

After the amendment in Consumer Protection Act, The Amendment Act of 2019[2], provides a legal framework for holding manufacturers accountable under product liability for harm caused by defective goods. Such liability may arise due to flaws in the design or manufacturing process, or due to the failure to provide sufficient warnings or instructions regarding potential risks associated with the product's use. In cases where individuals experience cardiac events as

[1] http://www.legalservicesindia.com/article/954/Product-Liability:-Who-is-liable?.html (last visited on 18/03/2021)
[2] Consumer Protection Act, 2019, Section 85–94 (Product Liability).

adverse effects following vaccination, these incidents would need to be classified either as known risks that were not adequately disclosed or as defects in the vaccine's formulation.

However, pursuing such claims is complicated by the context in which many vaccines were released under emergency use authorizations[3]. These authorizations involve expedited approval processes and rely on ongoing data collection even after the product is introduced to the market. Manufacturers are required to update safety labels and warnings as new information becomes available. This evolving nature of regulatory compliance makes it difficult to establish a fixed point of failure or liability[4].

Additionally, a critical component of product liability is the foreseeability of harm whether the manufacturer could reasonably have predicted the adverse effect. Proving this element requires strong and credible medical evidence linking the product to the specific harm claimed. In the case of cardiac events post-vaccination, current scientific data remains limited and inconclusive. Without sufficient medical evidence to demonstrate that such outcomes were foreseeable, it becomes highly challenging for a plaintiff to succeed in a product liability claim under the provisions of the Consumer Protection Act.

2.1 Strict Liability in product liability:

"Strict liability is the legal process in which the claim filed by the plaintiff is focused not on the manufacturer's conduct, but rather the quality of the manufactured product. The California Supreme Court adopted the doctrine of strict liability in the Greenmun v Yuba Power Products, Inc[5] case. The basis of the claim is the accusation that the product itself is either defective, of poor quality, poorly constructed, or somehow dangerous or hazardous to the user" The main motive to introduce the strict liability principle in product liability, is that it mainly imposes when any matter related with the defect in the goods and it results into the dangerous for use. The doctrine of strict liability also applies where there is no contractual relationship between the plaintiff and the manufacturer.

The plaintiff's injury must have been caused by a "defect" in the product. Thus, the manufacturer is not deemed responsible when injury results from an unforeseeable use of its

[3] Ibid.
[4] Supra note 4
[5] Greenmun v Yuba Power Products, Inc *59 Cal.2d 57*

product. [6]In the case of Abouzaid v mother care (U.K) ltd[7] The court has laid down that:

"The exercise of all proper care will not necessarily protect the producer from strict liability if a consumer is injured by a defect in the product[8]. A manufacturer or supplier may be liable under strict liability even if the risk could not have been recognized at the time of supply· The development risks defense will be available only where there has been some scientific or technical advance since the time of supply, which enabled the defect to be identified".

2.2 Concept of Strict Liability[9]

Strict liability under *M.C. Mehta v. Union of India*[10] might seem appealing for claimants. But Indian courts have narrowed its scope in public health matters, especially where the activity was government-supervised and served a larger social good. In the case of vaccines, the defence of "statutory authority" or "public interest immunity" is likely to prevail.

"Strict liability is the legal process in which the claim filed by the plaintiff is focused not on the manufacturer's conduct, but rather the quality of the manufactured product. The doctrine of strict liability also applies where there is no contractual relationship between the plaintiff and the manufacturer. The exercise of all proper care will not necessarily protect the producer from strict liability if a consumer is injured by a defect in the product. A manufacturer or supplier may be liable under strict liability even if the risk could not have been recognized at the time of supply. The case law which can be referred to understand strict liability is *Rylands* fletcher.[11]

"In the landmark case of Rylands v Fletcher (1868), the House of Lords established the principle of strict liability for landowners who engage in non-natural use of their property, leading to the escape of hazardous substances that cause damage to others. The case arose when John Rylands employed contractors to build a reservoir on his land to supply water to his mill. During construction, the contractors discovered old coal shafts and passages beneath the site, which they failed to properly seal. Upon filling the reservoir, water escaped through

[6] *http://www.west.net/~smith/strict.htm*(last visited on 20/02/2025)
7 Abouzaid v mother care (U.K) ltd *[2000] All ER (D) 2436*
[8] *http://www.tradeangles.fsbusiness.co.uk/articles/product liability.htm*(last visited on 20/02/2025)
[9] Rogers, W.V.H., *Winfield and Jolowicz on Tort* (1998), p. 472.
[10] *M.C. Mehta v. Union of India* (Oleum Gas Leak), AIR 1987 SC 1086.
[11] (1868) L.R. 3 H.L. 330

these shafts, flooding Thomas Fletcher's adjacent coal mine, the Red House Colliery, and causing significant damage. Fletcher sued Rylands, and the case ultimately reached the House of Lords. The court held that a person who, for their own purposes, brings onto their land anything likely to cause harm if it escapes, is strictly liable for any resulting damage, regardless of the level of care taken to prevent the escape. This ruling marked a significant shift in English tort law, emphasizing the responsibility of landowners to prevent harm from hazardous activities conducted on their property[12]*"*

In the realm of tort law, potential claims for compensation may arise when individuals suffer harm after receiving a vaccine. The nature and amount of compensation in such cases would depend on the extent of the injury experienced. However, in the Indian legal context, the adjudication of such claims remains uncertain, given the overwhelming number of cases, the accelerated development and deployment of COVID-19 vaccines, and the limited availability of comprehensive data on their side effects and long-term impacts.

Historically, the after-effects of vaccines during pandemics have varied, and similar variability is expected in the case of COVID-19. Under tort law, affected individuals have the right to seek compensation, and liability may rest with the manufacturers, particularly as the Indian government has declined to provide them with indemnity. Although pharmaceutical companies made significant efforts to develop vaccines under highly dynamic and urgent conditions, the possibility of unforeseen adverse reactions cannot be ruled out.

The principle of strict liability in tort law holds that even if a manufacturer exercised due diligence and followed all safety protocols, liability may still be established unless a legal exemption applies. However, in the context of COVID-19, where vaccines were rolled out under Emergency Use Authorization (EUA) issued by the Drug Controller General of India, manufacturers may have some degree of legal protection. This applies to vaccines such as Covishield (Serum Institute of India), Covaxin (Bharat Biotech), Sputnik V, Moderna, and Zydus Cadila's formulation.

Given the government's central role in initiating the mass vaccination programme, it is arguable that sole liability should not rest with the manufacturers. In light of this, several policy think tanks have suggested the establishment of a national compensation fund to support individuals

[12] Supra note11.

who suffer serious adverse effects. However, implementing such a mechanism poses practical difficulties in a country like India, where the large population and limited public health resources present significant financial and administrative challenges.

Experiences from earlier pandemics, including smallpox, the Spanish flu, and other influenza outbreaks, have shown that unresolved liability issues can impede the progress of vaccine development and distribution. Therefore, in the absence of state-backed indemnity or compensation mechanisms, manufacturers may need to explore insurance options to mitigate their financial exposure in the event of claims arising from serious vaccine-related side effects.

3. Post-COVID Surge in Heart Attacks: A Medical-Legal Context

Health studies conducted by both Indian and international agencies have documented a significant rise in cardiovascular disorders following the COVID-19 pandemic. Conditions such as myocarditis, pericarditis, and sudden cardiac arrest have emerged more frequently during the post-pandemic period[13]. While these complications are known to occur as a consequence of COVID-19 infection itself, concerns have been raised about the potential for certain vaccines particularly those developed using mRNA and viral vector technologies to contribute to rare but serious adverse cardiac events. In India, however, the challenge lies in the lack of extensive epidemiological studies capable of establishing a clear and direct association between COVID-19 vaccination and such cardiac issues. This evidentiary gap creates substantial obstacles for individuals seeking to pursue tort claims, as the burden of proving causation a critical component in establishing liability remains unmet in most cases. Without robust scientific data linking the vaccine to the alleged harm, claims brought before courts or consumer forums tend to be speculative and legally fragile, thereby limiting the scope of redress for affected individuals[14]**.**

4. Applicability of Tort Law Doctrines: Negligence and Causation

In the framework of Indian tort law, a negligence claim requires the plaintiff to satisfy four fundamental elements: (1) the existence of a duty of care owed by the defendant; (2) a breach of that duty; (3) a direct and proximate causal relationship between the breach and the injury

[13] Indian Council of Medical Research (ICMR), "Annual Report 2022–23", Chapter on Non-Communicable Diseases.
[14] World Health Organization, "Global Surveillance of COVID-19 Vaccine Safety," WHO Bulletin, 2021.

sustained; and (4) actual harm or damage suffered as a result. Each of these components must be clearly established for a negligence claim to succeed in a court of law[15].

When applied to situations where individuals experience heart attacks following vaccination, these legal requirements become particularly complex and difficult to prove. The most significant challenge lies in establishing causation demonstrating that the vaccine was the direct and proximate cause of the heart attack. Since heart attacks can result from a wide range of pre-existing medical conditions, lifestyle factors, or genetic predispositions, isolating the vaccine as the singular or primary cause requires strong scientific and medical evidence. Courts demand a high standard of proof, especially in cases involving pharmaceutical products, where the link between the alleged harm and the product is not immediately obvious or universally accepted[16].

Vaccine manufacturers, in such scenarios, are likely to defend themselves by highlighting several compliance measures. First, they can argue that the vaccine underwent rigorous testing and met all regulatory requirements set by national and international health authorities. This includes pre-clinical trials, phased human trials, and approval from agencies like the Drugs Controller General of India (DCGI). Second, they may point to the fact [17]that potential side effects, including rare but serious adverse events, were disclosed in the informed consent forms signed by vaccine recipients prior to administration. This process of informed consent is a critical safeguard in medical law, which not only serves to educate recipients but also reduces the legal liability of manufacturers. Third, manufacturers may demonstrate that they conducted post-market surveillance, an ongoing process of monitoring the vaccine's performance and safety after it has been introduced to the public. If any new risks emerged, responsible companies would have communicated those findings to regulatory authorities and the public in a timely manner.

Given these defences, a plaintiff would face an uphill legal battle unless they can provide compelling evidence that the manufacturer acted with gross negligence or intentional misconduct. For instance, if it can be proven that the manufacturer was aware of critical safety data indicating a heightened risk of heart attacks but chose to suppress this information or failed

[15] Avtar Singh, *Law of Torts*, 11th ed., (LexisNexis, 2020), p. 203.
[16] Ibid.
[17]Ibid.

to update safety warnings and risk disclosures accordingly, then a claim of negligence may be sustained. However, in the absence of such evidence, it is unlikely that a court would hold the manufacturer liable[18].

Indian courts are generally cautious in imposing liability in cases involving complex medical and scientific issues, particularly when the product in question has received regulatory approval and has been widely administered for public health purposes. Assigning liability without concrete evidence could have adverse consequences, including discouraging innovation in the pharmaceutical industry and undermining public trust in essential vaccination programs. Therefore, while tort law provides a legal pathway for addressing grievances, the threshold for proving negligence in vaccine-related injury cases remains notably high.

5. Government Role and Legal Shielding

In India, while there is no formal or statutory blanket immunity granted to vaccine manufacturers unlike in the United States, where the Public Readiness and Emergency Preparedness (PREP) Act provides comprehensive legal protection there exists a form of indirect or practical indemnity. This is largely embedded in the nature of government procurement contracts and the centralized management of vaccination programs during public health emergencies such as the COVID-19 pandemic. In many cases, vaccines were procured directly by the government and administered through public health initiatives, thereby limiting the manufacturer's direct interface with individual consumers[19].

These contractual arrangements often include clauses that either explicitly or implicitly protect manufacturers from liability arising out of adverse events. Essentially, the government assumes responsibility for overseeing distribution, monitoring safety, and managing public communication, which, in turn, shields manufacturers from being held solely accountable in legal claims. This indirect legal shielding creates a situation where manufacturers may not face the full extent of liability typically associated with commercial products in the open market.

Consequently, individuals who suffer adverse effects, such as cardiac events post-vaccination, face significant legal challenges if they seek compensation. They may be required not only to file a lawsuit against the manufacturer but also to include the government as a party, especially

[18] Supra note 17.
[19] Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d.

if the alleged harm occurred through a government-administered program. This adds a layer of complexity due to the principle of sovereign immunity, which protects the state and its agencies from many types of legal action unless specific statutory provisions allow such claims[20].

Suing the government, therefore, is a highly burdensome and procedurally complex task. It involves overcoming legal doctrines that limit the government's accountability and navigating a legal system that demands substantial evidence, particularly in scientifically and medically intricate cases. For ordinary citizens, the combination of legal, financial, and evidentiary obstacles can make the pursuit of justice in vaccine injury claims extremely difficult, even when legitimate concerns exist.

6. Absence of a Vaccine Injury Compensation Scheme

India currently lacks a dedicated no-fault compensation system to address injuries caused by vaccines. In contrast, more than 25 countries including the United States, United Kingdom, and Japan have established such mechanisms. These systems allow individuals who suffer from rare but serious side effects, such as myocarditis or blood clots, to receive state-funded compensation quickly and without needing to prove legal fault. The process is designed to be simple, efficient, and non-confrontational, helping victims avoid lengthy and costly court battles[21].

In India, the approach is quite different. Individuals who suffer adverse reactions must go through the formal legal system and prove that the vaccine manufacturer or healthcare provider was negligent. This process is not only complex and time-consuming but also expensive. Many people are unaware of their legal rights or the options available to them, making it even harder to seek justice. Moreover, India does not have a specialized or independent body to assess whether the vaccine actually caused the injury an essential step in complicated cases, such as those involving cardiac issues that can stem from various factors[22].

The lack of a structured compensation framework leaves a significant gap in India's legal and public health systems. People who genuinely suffer from rare vaccine-related complications often find themselves without support or compensation. The burden of proving fault, limited

[20] Supra note 20.
[21] World Health Organization, "No-Fault Compensation Programs for Vaccine Injury," WHO Policy Brief, 2021
[22] Supra note 22.

awareness of legal remedies, and the absence of impartial medical evaluation make it extremely difficult for most victims to get justice. This gap is especially concerning in cases involving complex health conditions like heart disease, where the cause of harm may not be immediately clear. Ultimately, the system places an unfair and often overwhelming burden on the individual.

7. Policy and Ethical Considerations

Policymakers must carefully balance two critical goals: protecting public health through widespread vaccination during pandemics, and ensuring fairness and accountability for individuals who may suffer adverse effects. While mass vaccination is essential to control outbreaks and save lives, it is equally important not to ignore the rare but serious health impacts that may follow.

Overlooking post-vaccination health patterns such as a potential increase in heart-related issues can have far-reaching consequences. It may weaken public trust in vaccination programs, making people hesitant to participate in future health initiatives. Affected individuals and families may be left without compensation, recognition, or closure. More importantly, it raises ethical concerns about whether people were truly informed about the risks and whether the state is fulfilling its duty to protect all citizens, including those unintentionally harmed.

An ethically sound and effective vaccination policy must not only prioritize collective safety but also uphold the rights and dignity of individuals. This includes acknowledging adverse outcomes, providing transparent information, and creating mechanisms to support those affected.

8. Conclusion and Suggestions

The growing number of reports of sudden heart attacks across India, while not definitively proven to be caused by COVID-19 vaccines, raises significant public health and legal concerns that call for a thoughtful and proactive policy response. Even in the absence of conclusive scientific evidence directly linking these cardiac events to vaccination, the pattern of such incidents cannot be dismissed lightly particularly when public trust in health systems and vaccination campaigns is at stake. Under the current framework of tort law in India, individuals seeking legal redress for vaccine-related injuries face major obstacles. Tort claims typically require the plaintiff to prove negligence and establish a clear causal link between the

defendant's actions and the injury suffered. In cases involving complex medical conditions like heart attacks, where multiple risk factors may be involved, establishing such causation is extremely challenging especially when scientific data remains inconclusive or evolving.

As a result, the existing legal system offers limited practical relief to individuals who believe they have suffered harm following vaccination. Without adequate legal or institutional support, many affected individuals and families are left without compensation, accountability, or even official acknowledgment of their experience. Given this gap between potential harm and available remedies, there is an urgent need for policymakers to consider alternative mechanisms, such as a no-fault vaccine injury compensation scheme or a specialized tribunal to assess claims based on medical probability rather than strict legal standards. This would ensure that those who suffer rare but serious adverse effects are not left without recourse, while also preserving public confidence in national vaccination programs.

Recommendations:

1. **Establish a Vaccine Injury Compensation Program (VICP):** India should create a no-fault compensation system, similar to those in other countries, where medical experts evaluate claims of vaccine-related injuries and provide appropriate compensation. This approach ensures that individuals who experience adverse effects receive timely support without the need for lengthy legal battles[23].

2. **Ensure Transparent Reporting of Adverse Events:** Implement mandatory and clear reporting systems for adverse events following immunization, including comprehensive post-market surveillance data. Such transparency allows for continuous monitoring of vaccine safety and maintains public trust in vaccination programs[24].

3. **Enhance Informed Consent Procedures:** Strengthen the informed consent process, especially for individuals with existing heart conditions. Providing detailed information about potential risks and benefits enables individuals to make well-informed decisions regarding vaccination[25].

[23] https://pmc.ncbi.nlm.nih.gov/articles/PMC8733825/ (last visited on 13/03/2025)
[24] https://www.sciencedirect.com/science/article/pii/S0264410X16309744(last visited on 13/03/2025)
[25] https://pmc.ncbi.nlm.nih.gov/articles/PMC5543760/ (last visited on 13/03/2025)

4. **Promote Independent Research on Long-Term Vaccine Effects:** Encourage and fund independent studies to investigate the long-term effects of COVID-19 vaccines. This research is crucial for developing evidence-based policies and ensuring that any potential risks are identified and addressed promptly.

By implementing these recommendations, India can uphold the integrity of its public health initiatives, ensuring that they are both effective and ethically sound. It is essential to provide fair treatment and support to those who experience rare adverse effects, thereby maintaining public confidence in vaccination efforts.