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# Dose of Indemnity for the COVID-19 Vaccine Manufacturers and it's Effectiveness in India

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## ABSTRACT

*Amid the deadly chaos caused due to the Coronavirus, vaccines emerged as a boon for humanity. These vaccines have been produced at lightning speed. The leading vaccine manufacturers have been leading the vaccine industry, such as United States biotechnology company Moderna and German pharmaceutical company Pfizer. Further, the vaccines produced by these companies have been proven to be 95% effective in reducing the mortality rate due to Coronavirus.<sup>2</sup> As the vaccines produced by these companies are in high demand, developed nations like the United States of America and the United Kingdom have granted indemnity to these companies from civil liability. In India, there are no such legal arrangements for vaccine manufacturers to escape criminal or civil liability. Thus, the purpose of this paper is to examine the viability of indemnity contracts with the vaccine manufacturers in India, considering that a similar demand for indemnity clause has been made by the Serum Institute of India, which has been producing vaccines for Coronavirus on a large scale in India.*

## I. INDEMNITY IN INDIAN CONTRACT ACT

Term indemnity originates from the Latin word *indemni(s)*, which means 'without loss' or 'uninjured'.<sup>3</sup> In contracts, indemnity implies that a party to the contract may agree to incur losses for the other, which is also the party to the contract. In general parlance, the most common example of an indemnity contract can be insurance. Here the insurance companies agree to compensate the insured if the insured party incurs any losses covered under the clauses of the agreement. However, indemnity contracts are not just limited to insurance but have a much broader scope. Indemnity clauses are common in contracts between tenants and landlords. Residents agree to indemnify the property owners for any injuries sustained on the property, while the property owners are responsible for any hazards or concerns. The property

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<sup>1</sup> Author is a student in India.

<sup>2</sup> JAMES GALLAGHER, MODERNA: COVID VACCINE SHOWS NEARLY 95% PROTECTION, BBC. COM (OCT 16, 2021), [HTTPS://WWW.BBC.COM/NEWS/HEALTH-54902908](https://www.bbc.com/news/health-54902908)

<sup>3</sup> Origin of term 'indemnity,' Online Etymology Dictionary, <https://www.etymonline.com/word/indemnity>

owner is protected from damages if an accident occurs on the property.<sup>4</sup>

In the Indian Contract Act, the indemnity provision is dealt with under Section 124, which defines a contract of indemnity as a contract by which one party promises to save the other from loss caused to him by the conduct of the promiser himself or by the conduct of any other person. While Section 124 defines the indemnity contracts, the following section specifies the rights of the person indemnified or the indemnity holder.<sup>5</sup> Under Section 125, the indemnity holder, when sued, has the right to be indemnified from all the damages, including the legal expenses that he might incur during the course of his suit, to the extent of the promise of the indemnifier to indemnify the indemnity holder.<sup>6</sup> The whole purpose of having these provisions or the contract of indemnity is to make good certain losses experienced by the contracting party. Depending upon the facts and circumstances of a contract, the right of indemnity may arise from express terms of the contract or can be implied. The provisions for implied indemnity can be found in sections 69, 145, and 222 of the Indian Contract Act.

## II. INDEMNITY OF VACCINE MANUFACTURERS IN THE REST OF THE WORLD

Over time, Indian courts have dealt with multiple cases involving contracts of indemnity and thereby, from time to time, have elaborated on the concerned provisions. However, the issue of providing protection from liability to the vaccine manufacturers and compensating for any negative medical repercussions that may result from their vaccines is unique to India. While indemnifying the vaccine manufacturers may be a unique concept in India, it is pretty common in many developed nations.

Such protection has been in place in the USA since the 1970s, with the legislature passing numerous laws. The National Childhood Vaccine Injury Act enacted in 1986 is one of the government's major vaccine compensation programs. It compensates those injured by the childhood vaccines used to prevent diseases like diphtheria, tetanus, measles, and rubella. The people who claim injury under this scheme must first fully adjudicate their claims through the program before filing any civil suit.<sup>7</sup> Thus, it provides two alternatives to the injured party the party can either avoid the trial or, if dissatisfied by the compensation, can opt for a civil action.

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<sup>4</sup> Anubhav Pandey, Law of Indemnity in India, Blog.leadere.in (May 22, 2017) <https://blog.ipleaders.in/laws-indemnity/>

<sup>5</sup> Indian Contract Act, 1872, No.09, Acts of Parliament, <https://www.indiacode.nic.in/>

<sup>6</sup> *Id.*

<sup>7</sup> Thomas Allen Heller, *VACCINES IMMUNIZE PEOPLE; LEGISLATION IMMUNIZES VACCINE MANUFACTURERS. LEGISLATION IN THE UNITED STATES REGULATING LIABILITY FOR THE MANUFACTURE, DISTRIBUTION AND ADMINISTRATION OF VACCINES*, *Medicine, Law and Society* (April 24, 2021) Vaccines Immunize People; Legislation Immunizes Vaccine Manufacturers. Legislation in the United States Regulating Liability for the Manufacture, Distribution and Administration of Vaccines | *Medicine, Law & Society* (um.si)

The injured party has the onus of proving the injury caused and must prove three things in this civil action: first, a biological theory of harm; second, a logical sequence of events linking the vaccine to the injury; and third, an appropriate time frame in which the injury occurred. If the injured party sues, the vaccine manufacturer is not the defendant but the US Department of Health and Human Services secretary and US Department of Justice attorneys.<sup>8</sup> Therefore the vaccine manufacturers are entirely immune from the liability they would in the ordinary course of nature bear. Through this Act, the government aimed to reduce the shortage of vaccines in the market due to civil suits filed demanding compensation for injuries caused by vaccine side effects and protect vaccine manufacturers from liability arising from unavoidable adverse vaccine effects. More than seventy percent of the injured people have availed relaxation under this legislation, signifying the efficacy of this scheme.<sup>9</sup>

However, NCVIA could only exempt vaccine manufacturers who produce vaccines for diseases like diphtheria and measles. Thus, in 2005, the Public Readiness and Emergency Preparedness Act was enacted to protect the population from viral diseases by encouraging vaccine producers to develop vaccines faster and thus preventing people from getting sick from infectious diseases. This Act exempts vaccine manufacturers from contractual or tort liability related to vaccine production, development, testing, or administration if the vaccines or countermeasures are used to prevent terrorism, epidemics, and pandemics. The only exception to the producers' liability is if the vaccine caused severe injury or death to the plaintiff due to 'willful misconduct.'<sup>10</sup> The Act removes any financial risk barriers for newly produced vaccines to deal with medical emergencies like COVID-19. In addition to this, considering the severity of the Coronavirus, even the devices or any drug used to prevent the transmission other than vaccines has also been included under the scope of the act. Under this amendment, any person can also claim losses resulting from the equipment or drug used to prevent the virus. The Countermeasures Injury Compensation Program (CICP) compensates claimants under PREP.<sup>11</sup> Both the NCVIA and PREP Act, as is evident, tend to indemnify the vaccine manufacturers by excluding them from the liability arising in any contractual or civil action filed by the appellants and paying the compensation through the compensation programs. These Acts have benefited both vaccine producers and claimants, as they allow claimants also to avoid lengthy and costly lawsuits, which the poor claimants would otherwise bear. Other than the USA, the European governments also have similar provisions for compensation. These

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<sup>8</sup> *Id.* at 11.

<sup>9</sup> *Id.* at 20

<sup>10</sup> *Id.* at 31

<sup>11</sup> *Id.* at 32

governments agreed to pay claimants above the agreed-upon compensation threshold against vaccine producers like AstraZeneca for potential side effects during the pandemic.<sup>12</sup>

### III. VIABILITY OF INDEMNIFYING VACCINE MANUFACTURERS IN INDIA

As these developed nations and even the developing nations such as Nepal and Vietnam provide protection to the vaccine manufacturers from liability, similar demands for the indemnity clause were raised in India by the foreign companies and even by the domestic vaccine manufacturers such as Serum Institute of India.<sup>13</sup> Although the Indian government was successful in providing the vaccines to the population without accepting this demand, this debate still did posit a vital question that whether the current legal position in India where the vaccine manufacturers incur the sole liability in the suits related to the injury caused due to the adverse impact of their vaccines, is viable?

The Serum Institute of India was recently served with a legal notice where the claimant who had allegedly suffered from severe neurological side effects of the Covishield vaccine developed by the company was claiming a whopping compensation of five crores.<sup>14</sup> The major problem here is that during the ongoing pandemic, the vaccines are being produced at a fast rate to control the virus from spreading, and hence many side effects are not revealed in the trial phase only. Furthermore, the vaccines are approved by governmental authorities before getting administered to the population, but the government authorities enjoy sovereign immunity. Hence, even if the vaccine's certain side effects are not discovered in the trial phase and have been authorized when later those side effects are diagnosed in an individual, the vaccine manufacturer would have to bear the sole burden of compensation since it does not enjoy any immunity. However, in the present case, the Serum Institute of India didn't compensate the person and called the earlier stated allegations malicious.<sup>15</sup>

Furthermore, even from the perspective of the claimant, the current legal position in India concerning this issue is not promising. In India, no compensation programs or legislations like NCVIA or PREP Act are present. The compensation programs give the claimant an assurance to get compensated without going through the painful process of litigation. In a country like India, the need for such a compensation program is even more urgent as most of the population

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<sup>12</sup> Priyanshi Bhageria & Khushboo Sharma, *Liability or Indemnity: The New Debate in India's Vaccination Program*, Bar and Bench.com (June 1, 2021) <https://www.barandbench.com/apprentice-lawyer/liability-clause-or-indemnity-clause-the-new-debate-in-the-vaccination-program>

<sup>13</sup> Murali Neelakantan and Ashish Kulkarni, *When a Vaccine Maker Asks for Indemnity, Does the Government Debate Pennies?*, The Wire.in (June 1, 2021), <https://thewire.in/health/pfizer-vaccine-price-indemnity-insurance>

<sup>14</sup> Bhageria, *supra* note 10

<sup>15</sup> Bhageria, *supra* note 10

already do not have access to basic necessities such as food. In the Global Health Index released by the Food and Agriculture Organization, India's rank has drastically fallen from 94 to 101, reflecting the grave issue of food insecurity.<sup>16</sup> Here, when the poor are not even able to quench their hunger, then how can it be expected that when they suffer an injury on account of the adverse effects of the vaccines, they would be able to also incur the cumbersome legal expenses in a suit against the big pocketed vaccine companies.

Moreover, the clause of indemnity is necessary for the encouragement of the vaccine producers. The false claims of compensation can lead to the discouragement of vaccine manufacturers, which could hinder the supply of vaccines, as was the case when a virus known as Zika had spread in many parts of Africa.<sup>17</sup> The vaccine supply to prevent it was interrupted as a vaccine production company due to the fear of liability arising from false claims delayed the vaccine's administration.

Also, in India, the government's stance that the vaccine manufacturers should only be liable if due to their vaccines' adverse effects people suffer is itself fallacious as it runs in contradiction to the provisions the Indian Constitution stipulates. According to Article 294 (4) of the Constitution, the government's liability may arise 'out of any contract or otherwise. So, the Union government can be held liable even in a contract with the vaccine manufacturers but unfortunately in all the contracts between the Union government and vaccine producers, the producers have to account for any medical injury that their vaccines might cause.<sup>18</sup>

#### IV. CONCLUSION

In sum, absolving the liability of the vaccine manufacturers even in India can go a long way in both encouraging the vaccine producers to produce vaccines in the medical emergency such as COVID -19 pandemic and facilitating the process of compensation for the appellants, which is presently highly exhaustive to the claimants as they in the process of litigation tend to lose much more time and high legal fees than what the amount of compensation would be able to compensate for the deteriorated health conditions due to the vaccine that they took in the belief that it would save from the deadly diseases. India should take inspiration from the US legislations such as NCVIA and PREP Act that provide an alternative recourse to the plaintiffs for compensation and also ensure that that the producers are not worried about how many civil

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<sup>16</sup> India Today.in( October 15, 2021) *Dip in India's rank in Global Hunger Index 'shocking', methodology used is 'unscientific': Centre*, <https://www.indiatoday.in/india/story/dip-india-rank-global-hunger-index-shocking-methodology-unscientific-centre-1865295-2021-10-15>

<sup>17</sup> Bhageria, *supra* note 10

<sup>18</sup> Bhageria, *supra* note 10

or contractual suits they would have to go through due to the adverse impact of their vaccines but are more focused on the medical research needed for the development of vaccines and speedy production of the vaccines to curb the spread of highly contagious diseases that pose a danger to the humanity.

Now, other than the developed nations, the developing nations such as Nepal, Vietnam, and Thailand are also realizing the importance of such programs of compensation. As of now, 25 nation members of the World Health Organization have implemented compensation programs for injuries resulting from the vaccines. In this list of 25 nations, six nations are from the Asia continent. In 2010, however, the number of countries offering such indemnity to the vaccine producers and compensation was as low as 18 nations. Astonishingly, there has been a significant increase in this number, and in 2020 the number recorded was 25 jurisdictions.<sup>19</sup> Therefore, it's high time for India to realize the effectiveness of these programs and thereby reduce the burden on courts, producers, and claimants.

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<sup>19</sup> RANDY G. MUNGWIRA, ET.AL, *GLOBAL LANDSCAPE ANALYSIS OF NO-FAULT COMPENSATION PROGRAMMES FOR VACCINE INJURIES: A REVIEW AND SURVEY OF IMPLEMENTING COUNTRIES*, PLOS.ORG (MAY 21, 2020)[HTTPS://DOI.ORG/10.1371/JOURNAL.PONE.0233334](https://doi.org/10.1371/journal.pone.0233334)

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