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**“RIGHT TO REFUSAL OF COMPULSORY VACCINATION AND THE
ABSENCE OF COMPENSATION POLICY LEADING TO UNACCOUNTED
INJURIES”**

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ABSTRACT

Vaccines are usually considered the ultimate and safest solution for an epidemic or a pandemic. However, there is significantly less attention given to the ill effects these vaccines have. These ill effects are specifically dangerous to certain groups of people like cancer patients, patients on immunosuppressants, and so on. These people rely on herd immunity. However, the question that arises is whether there should be a right to refuse vaccines. The answer to this is both yes and no. It implies that it must not be a fundamental right but must be a specific right for the group of people mentioned above or any other persons who tend to have severe side effects of these vaccines. For all other people, vaccines must be made mandatory. However, this does not mean that any injury faced by the common public can go unnoticed. For any negligence caused in the making of the vaccine, the injured party must have a right to sue the vaccine company or the government as the case may be. It means that there must not be a right to refuse vaccines, but the right to sue for injuries must be present.

For the right to sue to be enacted, the courts must have a good compensation policy in place so that uniform punishments are given all over the country. Currently, India does not have a compensation policy for vaccines which has given rise to many cases where patients are

a victim of negligent vaccine faults but are unable to get the adequate compensation for the same. The paper focuses on these lacunae and provides solutions for the same.

Keywords- Vaccination, Ill effects, Specific right, Negligence, Compensation policy.

There has been rapid growth in the field of science and technology over the past few decades. However, along with this progress, there has also been a growth in global pandemics and other newly discovered diseases, which have caused not only an economic loss but also a loss in social relationships. The past experiences of these outbreaks have shown the world that the spread of these deadly diseases can bring the entire world to a standstill. One of the remedies that have come up to tackle these pandemic situations is the use of vaccines. There is no doubt that vaccines have proved to be an effective measure in the fight to combat communicable diseases. With strict guidelines and rules to be followed and after proper testing, the use of these vaccines has proved to be a safe and efficient solution for these types of global crises. However, one question that arises is to what extent can the people be mandated to take these vaccines and if they would have a right to refuse them. In this context, should a person have the liberty to decide what he or she wishes to be done to his or her body and is it ultra vires for a law-making body to enforce these vaccines on them?

In the Indian context, vaccination was initiated in order to tackle the smallpox epidemic. This epidemic was reported in Goa in the year 1545 AD, where an estimated 8000 children died. Many historians have referred to smallpox as the 'Indian plague,' which suggests the possibility of a high prevalence of the disease in India at that point in time. The smallpox vaccine in India arrived in May 1802 and was first given to Anna Dusthall, a 3-year-old child from Bombay. This vaccine proved to be an effective solution to the smallpox epidemic and was spread to different parts of the country facing the epidemic. In the beginning, vaccines were given by 'trained vaccinators,' who would travel to different countries to give vaccines to the patients. Later this concept expanded, and 'paid vaccinators' began to give vaccines as salaried employees. In India, the Compulsory Vaccination Act was passed in the year 1892 in order to increase vaccine coverage in the country. This was followed by several events like the cholera outbreak (1896) and the influenza pandemic (1914), which reported around 17 million Indian deaths. Subsequently, the Government of India Act of 1919 was passed that gave the local state governments the right to provide health services and vaccines. Post-Independence, vaccines were produced not only for smallpox but also for other diseases like diphtheria,

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pertussis, and tetanus.¹ The first National Vaccine policy was passed in India in the year 2011 in order to provide guidelines for the functioning of the immunization program in the country.²

Although vaccines may have proved to be a highly efficient solution against various diseases, there are certain instances that show these vaccines are not efficient and have their drawbacks. One of these instances is the Cutter incident of 1955, where some batches of polio vaccine given to the public contained live poliovirus. These vaccines were immediately recalled when the cases of polio were detected. Another instance is the Simian virus vaccine between 1955-1963, where an estimated 10-30% of Polio vaccines were contaminated by Simian virus 40 (SV40). In 1976, an increased risk of Guillain-Barré Syndrome (GBS) (a neurological disorder) was observed with the vaccination of Swine flu. In 2013, Merck & Company, Inc. recalled one batch of Gardasil, a human papillomavirus (HPV) vaccine. The recall was a precaution following an error in the manufacturing process. The company had concerns that a small number of vials might have contained glass particles due to breakage. However, no health problems were reported.³ All these instances prove that even vaccines are not a full-proof solution to tackle diseases. Although much testing is done before a vaccine is introduced to the people, yet the fact that certain blunders have been committed because of vaccines is not a myth. Under such situations, the question arises who would be held liable in case a patient suffers injury because of a faulty vaccine. Also, in cases where the vaccine is made compulsory by the government, can they be held liable for the losses caused by it?

The answers to these questions are not direct i.e. they cannot be answered in a categorical 'yes' or 'no.' However, they can be deduced. One method of doing so is understanding the need for the vaccine and analyzing the degree of loss that can be caused in case the vaccine is not provided to the people. The most crucial point in favour of vaccines is that it contributes towards 'herd immunity.' When the majority of a population is inoculated, they, as a whole, develop a resistance to the disease. It not only helps to stop the spread of the disease but also strengthens the people's immunity against it in the future. However, if the vaccination is not made compulsory, there will be a free-riding issue that will arise. It means the people who do not take the vaccination will get an unfair advantage of herd immunity compared to the people who are immunized. It may mainly refer to the privileged social groups

¹ Chandrakant Laharia, brief history of vaccines & vaccination in India, Indian Journal of Medical Research, 2014.

² New Delhi: Ministry of Health and Family Welfare, Government of India; 2011. Government of India. *National vaccine policy*.

³ Historical Vaccine Safety Concerns, Centers for Disease Control and Prevention, <https://www.cdc.gov/>

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since they have the money and influence to say no to the vaccine. However, the lesser privileged class will have to compulsorily take the vaccination due to lack of knowledge, money, time, or confidence.⁴ As a result, the privileged would be taking advantage of their power, and the underprivileged will act as an experimental tool to protect the former. This is the main reason that immunization must be made compulsory, or else there will be exploitation of the underprivileged classes.

Another critical factor in favour of vaccination is the protection of vulnerable groups. Certain people in society do not have the ability to fight the disease with their immunity. These people depend on herd immunity. They may include older people, infants, or even other patients having low immunity. These people are more vulnerable to the disease as compared to an average person in society. Also, this group has many people and cannot be held as a negligible group. Therefore, vaccines have to be made compulsory for all the people in society to protect the interests of these groups.

Although the points mentioned above may prove that vaccination of all the people in the society is essential, however, the question that arises is, can this vaccination be imposed on the people who do not want to be vaccinated? In the above paragraphs, it has been proved that although vaccines are a practical solution towards pandemic diseases, they are not the most efficient options as many blunders have happened over a period of time which have caused damage to a large number of people. It creates a dilemma of choice between individual rights of refusal of the compulsory vaccination and group interests of protection through compulsory vaccination. Individual interests refer to the people who are not in favour of compulsory vaccination and believe that they must have the right to refuse it. This may be due to an apprehension towards any side effect or harm that can be caused to their body because of the vaccination or merely because they are not comfortable with the constituents of the vaccine being injected into their body and believe that their body's immunity is strong enough to fight the disease on its own, without any external help. This brings about a contradiction with the group interests mentioned above. The State must decide if these people must be given this right to refuse the vaccination or if the group interests should prevail.

A strong point of argument will be looking into the jurisprudential theories to this issue. The first theory is the will theory. The will theory gives the right holder a choice to either exercise their right or waive it off. It is more of a moral right. This theory emphasizes the will

⁴ Mark Navin, Resisting moral permissiveness about vaccine refusal, Vol.27, No.1, (2013).

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of the right holder to utilize his right in a situation pertaining to it. In the case of vaccines, it can be argued that this will theory be applied. It means that the people's will must be given importance, and the people must be allowed to choose if they want to get vaccinated or not. However, this free choice can be misused. If people are given the right to choose, most people would avoid the vaccines and depend on herd immunity. As a result, the proportion of people vaccinated will be very low, and it would be tough to fight the disease. Hence, the will theory cannot be applied in a country like India, where the population is high, and the risk of disease spreading is also very high. The next theory is the consent theory. This theory, elaborated by John Locke, states that every individual is a free agent. These free agents make decisions regarding entering into a consensual relationship with other free agents. By this theory, the decision-making power would be in the hands of the people to give their consent to participate in the vaccination process as they are the free agents. It means that they would have the power to accept or decline the consensual relationship with the government in the form of vaccines. It follows the same logic as the will theory. Both the above theory supports the idea that the people must have the option to refuse or accept vaccines. However, can these be applied to an epidemic or pandemic situation where rapid action is required? Is the will and consent of the people more important than public health? In a normal state, the option may be given to the people to be vaccinated or not following the above theories. However, in a state of a public health emergency, this cannot be granted. The right of a person cannot have the tendency to cause harm to another. The refusal of vaccination by a person can be the reason why another is infected.

The topic of vaccination refusal brings about a deadlock because the primary subject matter of a vaccine is the human body. A human body legally has no titles of ownership associated with it. It means that nobody owns a body: neither the person himself nor the government nor any external authority. A person can decide what is to be done to a property only if they have ownership over it. In this case, since there is no owner, that person cannot have the right to refuse vaccination. However, does that mean that the State can force the people to be vaccinated since there is no ownership of the body? The thin line drawn between individual interests and mandates of the government, in this case, is the welfare of the people or the greater good. In case an act is being done in order to promote public welfare, societal interests must prevail over individual interests. In this case, vaccination measures are being taken to protect the people in the society from pandemics. Under these circumstances, the interests of the community as a whole must be preserved over individual interests.

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However, there must be a strict liability imposed on the companies producing vaccines in case the people vaccinated face health problems. Mandating vaccines must be balanced out with this strict liability. Only when the people are given an opportunity of redressal in cases of any unpredicted loss, then they will be able to have the confidence to be vaccinated. Because vaccines are not always successful and that there is a probability of injury to occur, the people must be given a right to sue the companies, and the compensation must be proportionate to the losses. The current laws regarding vaccines have to be amended i.e., catering not only to the vaccine-producing multinational companies but to the ordinary people as well. For example, the law in the United States narrows down the scope of an injured person to sue a vaccine company in a civil court. As a result, the injured persons fail to get compensation from these companies, creating a trust deficit towards the vaccine.⁵ This must be changed. The people must be given a medium to find redressal in cases of injury. If the State demands mandatory vaccination, the interests of the people to sue must be considered. Vaccine cases, despite the unpredictability, must not be treated differently from other cases of medical negligence. If the courts provide heavy compensation for injuries faced by medical negligence, then faulty vaccines or any other negligence related to vaccines must also be compensated. Only cases where there is absolutely no human control must be treated as an exception. However, any other negligence taking place in the manufacture and distribution of vaccines, the company must be held liable and adequate compensation must be allowed by courts, whether it is a mass blunder or an isolated incident. If this negligence is caused by a Government entity, then the State must be held liable and provide compensation to the affected. Also, laws must be made for rigorous testing of the vaccines before giving them to the public, to reduce maximum possibilities of the vaccine being faulty and causing injury.

The main essence of this paper is the right to refuse vaccination. Although it has been established above that, there must not be a right to refuse vaccines, this is only for the general public. The right to refusal of vaccination must exist for certain groups of people prone to injury if they are vaccinated. There must be certain restrictions and not a total immunity for these specific groups. It means that this right is not a fundamental right but a special right granted to specific people for a specific purpose i.e. to save them from any injury that can be caused as a side-effect of the vaccine. This right must be given cautiously to only those people who are dependent on herd immunity or those people that are medically prescribed to be excluded from

⁵ 42 USC 300aa-22

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the vaccination process. The number of diseases in the world is innumerable, and it is impossible to individually grant a right to every patient who comes under this group. However, a rough policy can be made to identify those people who must possess this right. The other persons claiming to be eligible for this right must be decided on the particular case. The Centers for Disease Control and Prevention has stated that certain groups of people must avoid certain vaccines. For example, infants below 6 months and people that have previously faced an allergic reaction to the influenza vaccine must avoid the vaccine. People allergic to components like aluminium or neomycin must avoid the vaccine for hepatitis A. Pregnant women and people with current moderate to severe illness must avoid the Human papillomavirus (HPV) vaccine.⁶ Apart from these, cancer patients and patients on immunosuppressant medicines must also avoid most vaccines that tend to have severe side effects. It means that the above-mentioned group of people must have a special right to refusal of vaccination. Only these people must be allowed to refuse the vaccine that can cause injury to their health. The rest of the people in the society do not have a right to this refusal. These mentioned groups of people are dependent on herd immunity and hence must not be mandated to take part in the vaccine process. Although the number varies from disease to disease, on average, at least 75% of the population must be vaccinated to achieve herd immunity which is sufficient in this condition. These people who are given the right to refuse vaccines have the right to health before the compulsion of vaccination, and hence only they must have the special right of refusal of vaccination.

In the Indian context, The Vaccination Act, 1880, deals with the unregulated use of vaccines and provides for punishments for vaccines provided without sufficient cause. However, the drawback of the Act is that it only focuses on the vaccine and does not provide for the regulation of vaccinators, especially private vaccinators. Another act is The Epidemic Diseases Act, 1897, which provides for regulations to be followed in times of an epidemic that include segregation of affected persons, banning of public gatherings, etc. However, this act does not explain the powers of the authorities. Also, it provides guidelines after the outbreak of the disease and does not provide for preventive measures to avoid the outbreak of the pandemics in the first place.⁷ The Vaccination Act, 1880, and the Epidemic Diseases Act, 1897 are acts created during the British era. Today, the world is facing different challenges as

⁶ Amy Boulanger, Vaccines: Who should avoid them and why, Healthline, June 20, 2018, <https://www.healthline.com/>

⁷ Kushaan Dosajh, The legality of mandatory vaccination, Indian journal of medical ethics, December 9, 2019, <https://ijme.in/>

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compared to the time when these acts were made. The coronavirus outbreak in 2020 was a pandemic that had its effects globally. With pandemics like these or any other challenges that can be faced in the future, the laws must be amended and made so that there is no ambiguity among the people and the vaccine process takes place effectively and efficiently.

One of the main lacunae in the Indian law regarding vaccination is the lack of a compensation policy for vaccines. This means that India does not have an appropriate and uniform redressal method for the people who face injury due to vaccines. Because of the absence of law, many injured people are not able to claim compensation for the injury suffered. The courts also face an issue in deciding the appropriate redressal that gives rise to non-uniformity among different judicial decisions throughout the country. It was earlier established in this paper that the people who suffer injuries due to negligence in the production of vaccines must have the right to sue the company or the government as the case may be. However, a compensation policy will help smoothen this process and bring about adequate and uniform redressal among the different people of the country that face similar injuries. As there is no compensation policy, the people's confidence in the vaccine also reduces as they feel like they would not get adequate compensation if they face any injury. If the right to refuse is taken away by the government while imposing vaccines on the people, the least that can be done is to formulate an adequate compensation policy for any person that may face any injury due to the vaccine. It will give the people hope of seeking redressal and will stop their injury from going unnoticed. Overall, it will stop public health from being exploited. Although, recently, many judicial decisions have been passed in favour of the injured parties, yet there is a dire need for a uniform compensation policy that can deal with this lacuna.

In the case of *Dr.Durga Nursing Home vs. K. Dhanasekaran*,⁸ filed before the State Consumer Dispute Redressal Commission, the plaintiff's wife delivered a baby boy in the first defendant's nursing home and then took part in the sterilization process. The baby was later taken for OPV and DPT vaccine to the nursing home. The second defendant administered the vaccines. However, when the vaccine was given, the baby turned blue and became motionless. Even after great efforts to revive the baby, the baby did not survive. The petitioner filed a case in the consumer redressal commission claiming compensation of Rs.10,00,000/- with the argument that the defendants did not conduct proper testing of the vaccines, which led to the baby's death. The defendant, however, denied the allegations and claimed that they had

⁸ *Durga Nursing home v. K. Dhanasekaran*, State Consumer Dispute Redressal Commission, Chennai, (2014).

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conducted proper testing. The defendant also claimed that they had a well-equipped team of doctors and had made all efforts possible to save the baby. The death of the baby was a sudden development and was not in their hands. The district forum held that the defendants are liable as they did not have adequate life-saving medicines and did not have adequate gadgets and an ambulance for these types of emergencies. The forum directed the defendants to pay Rs. 1,00,000/- as compensation for mental agony and Rs. 5000/- as costs. The plaintiff filed an appeal in the State Consumer Dispute Redressal Commission. The State Commission held that, both the defendants are jointly and severally liable to pay the costs for the deficiency in the administration of their vaccination service and ordered compensation of Rs. 3,00,000/- for mental agony and Rs. 5000/- for other costs incurred.

Death or injury caused due to vaccines are considered as civil offenses and not a crime. However, the State Consumer Redressal Commission's judgement is a step towards promoting compensation for losses caused due to vaccines in India. The above case has helped to prove the need for a compensation policy in India. There have been many cases of vaccination where human negligence has been the cause of a patient's death or injury. However, due to a lack of laws or a compensation policy, adequate redressal has not been provided to the injured people. In the matter of vaccination, judicial decisions have a vital role to play. Judicial decisions like the one mentioned above prove that there are cases of vaccine medical negligence taking place. The people are not being provided with adequate redressal due to a lack of laws which shows the need for a uniform compensation policy that can be used by all the courts in the country. This judicial decision contributes significantly to this research. Judicial decision helps to understand what all must be taken into consideration while formulating a compensation policy for vaccine-related injury. For example, in the above case, the fact that the complainant's wife would not be able to give birth in the future due to the sterilization process was taken as a solid point to set aside the compensation of Rs.1,00,000/- granted by the District Consumer Redressal Commission and increase the compensation to Rs.3,00,000/-. Through precedents like these, vaccine-related injuries come to light and help to provide adequate redressal to those who suffer losses.

In the near future, vaccination will be the solution that most countries would follow in case of a medical emergency like the corona pandemic. This might be contended by many individuals as a violation of their right to personal liberty. However, under such situations, the Courts must give the society's interest primary importance. The courts must look into the intensity of the situation and pass a judgement that aims at the collective good. However, in

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cases where a person faces personal injury by consuming these vaccines, the right to sue must be upheld, and adequate redressal forums must be provided granting equivalent compensation for the loss suffered. Apart from all these factors, the government must also take up the duty to raise the immunity level of the people. The right of the people to a clean and healthy environment must be upheld. The people must have access to clean drinking water, and other sanitation facilities must be provided. If all these factors are implemented, the citizens would have more confidence in vaccines, and a pandemic will be tackled much more efficiently.

