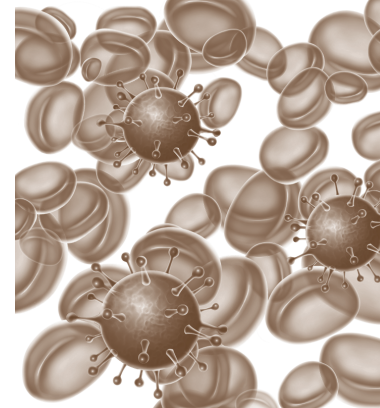


# Правовое регулирование вакцинации: сравнительное исследование



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Обязательная вакцинация – важный элемент охраны общественного здоровья. Она позволила всем странам эффективно бороться с рядом заболеваний, таких как оспа и полиомиелит. Государства, как правило, проводят политику обязательной вакцинации, чтобы предотвратить распространение болезней на основании принципа коллективного иммунитета. Однако всякий раз при возникновении какого-либо нежелательного эффекта такая практика обязательной вакцинации поднимает вопросы, касающиеся рисков, связанных с введением вакцин. В США проблема обязательной вакцинации и ее правовых основ актуальна с начала XX в., за это время сформировалась устоявшаяся система решения этих вопросов. Изучение системы обязательной вакцинации в США чрезвычайно важно, поскольку Индия, активно участвующая в программе вакцинации, не имеет эффективного механизма правовой защиты в области вакцинопрофилактики, прообразом которой может стать система, существующая в США.

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## Regulating vaccination: a comparative study

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Mandatory vaccination is seen as a landmark in public health. It has allowed all countries to effectively deal with several diseases such as small pox, polio. States usually follow a policy of mandatory vaccination in order to prevent the diseases from ever happening based on the principle of herd immunity. However, such a mandatory practice has raised issues regarding the risks associated with the administration of such vaccines, whenever any adverse effect arises. The United States of America has been grappling with the problem of mandatory vaccination and its legality since the beginning of the twentieth century and has an established system of dealing with this kind of issues. A study of the U.S system is extremely important since India which is highly involved in the vaccination program does not have an effective vaccination redressal mechanism, so the U.S. experience can be seen as a blueprint.

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The legality of mandatory vaccination has gained a lot of attention due to various outbreaks of several diseases, along with a general skepticism which has cropped up towards the efficacy of vaccines. Vaccines and their adverse effects have made the state acknowledge that an over emphasis on cost effective public health without a redressal mechanism is an extremely controversial approach; both for the general populace as well as for the manufacturers. There exists a conflict between the duty of the government to provide for proper public health in tandem with ensuring the rights of the few who suffer because of vaccine related adverse effects.

America has been coping with the issue of vaccination and has an established legal system regarding it. Therefore, it becomes imperative that an analysis of the US mandatory system, its legality, its acknowledgement of exemptions to vaccination and adverse effects due to vaccines needs to be done.

In contrast to India, the U.S. gives due emphasis to mandatory vaccination and provides for a robust mechanism for providing adequate redressal to people affected because of vaccine related adverse effects. This redressal system due to its speedy and cost-effective manner should be specifically taken into account.

The following pages focus on the U.S regarding the manner in which mandatory vaccination was legalised, the issues it faced, what exemptions are provided for, the redressal mechanism and some recent controversies.

### Mandatory vaccination and the United States

Public health and its preservation stem from the general police powers of a state. Furthermore, in relation to communicable diseases, a state is powered with taking measures such as “quarantine, isolation and the enactment of mandatory vaccination laws” [1]. This is exemplified by the state of Massachusetts which became the first state in the United States to authorize mandatory vaccination laws in 1809 against Smallpox [2]. Boston in 1827 became the first city to introduce vaccination as a prerequisite for admission into public schools, with other cities following the same [1].

### Mandatory vaccination policy concerns

The mandatory policy issues stem from the fact that the polices provide for compulsory vaccination as a prerequisite for admission into any public school [3]. Legislations state that in case of any outbreak, the school authorities have the right to prevent a non-vaccinated child from entering the school till the time the outbreak is controlled (overruling the right to educa-

tion against the need to prevent the spread of the disease) [3]. The *Jacobson* case is frequently cited as a justification, and the non-applicability of (religious) exemptions in West Virginia and Mississippi is testament to the importance given to the mandatory nature of such legislations. Even then, it is this prerequisite which is frequently cited as an instance of the draconian and coercive powers of the state. This is despite the fact that mandatory vaccination and its benefits were clearly visible when six states (in order to control Measles) enacted such laws between 1976 and 1979 and the subsequent incidence rate in these states reduced to half as compared to the other states in 1977–1978 and a tenth of what the other states had in 1978–1979 [4]. Such statistics also pointed out that the states with the lowest levels of incidence rates were the ones which had strictly enforced vaccination laws covering the entire school population and not just the newly admitted ones [4].

### Basis of mandatory vaccination

The landmark case of *Jacobson v Massachusetts* in 1905 provided legality to the mandatory nature of vaccines<sup>1</sup>. The concerned case dealt with the legality of a legislation which empowered the State to demand mandatory vaccination (smallpox) of people above the age of 21. The court while upholding the validity of the law stated that the powers of the state to introduce such laws as being important for maintaining public health and safety would come under the ambit of a state’s police powers, overruling the Fourteenth Amendment. It said, “the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety”<sup>2</sup>. The court disagreed with the petitioner’s contention of such legislations being against the ‘inherent’ right of a person to take care of his own body along with it being an assault on his person. It clarified on the conflict between public health and personal choice by stating, “The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good”<sup>3</sup>. However, the value of such a judgement as a precedent stems even more from the fact that the court acknowledged the existence of mandatory vaccination along with the limits of a state to enforce the same i.e. the reasonable test principle<sup>4</sup>.

*Zucht v. King* provided for the refusal of admission to a student who did not meet mandatory vaccination requirements with the complainants’ argument concerning violation of

<sup>1</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>2</sup> *Ibid.*

<sup>3</sup> *Ibid.*

<sup>4</sup> *The reasonable test principle allows for the courts to take cognizance if the state in dealing with an epidemic, takes steps which are arbitrary and unreasonable.*

the fourteenth amendment being set aside<sup>5</sup>. The case gained importance since it dealt with vaccination enforcement at the school level and a challenge to the constitutionality of mandatory vaccination among children probably for the first time, with the court using the Jacobson case and the corresponding arguments regarding the police powers of the state as a justification for the same.

### Exemptions to vaccination

The prevalent American vaccination laws draw sharply from the measles outbreak of the 1960s and 1970s on account of which mandatory vaccination was legalised (as mentioned above), with exemptions being given to people who raise concerns under the following:

- religious grounds;
- philosophical and moral grounds;
- health grounds.

While medical exemptions are seen as being necessary, it is primarily the religious exemptions which raise several issues. The issues arise on account of the first amendment which allows for a right to religious freedom. The First Amendment conflict raises an issue known as 'Forced care' wherein the state is allowed to provide for medical care even when the concerned raises objections based on religious grounds [5]. Such instances arise when the state believes that the patient does not have the capacity or is not able to make an informed decision concerning the requisite medical treatment and non-availability of the treatment may result in death.

Every state provides for laws requiring vaccination based on the vaccination requirements set out by the CDC, as a cost-effective method of preventive health care. All but the states of Mississippi and West Virginia have built in religious exemption clauses to vaccination programs. However, Religious exemption clauses are constantly criticised and fail against the notion of the forced care doctrine [5].

It was in the 1980s that the courts started recognising the validity of a religious exemption concerning forced care as was exemplified in the case of *Public Health Trust of Dade County v. Wons*<sup>6</sup> wherein it was stated the courts should take into account an "individual's right to make decisions vitally affecting his private life according to his own conscience"<sup>7</sup>. However, such a recognition of the deference is limited to parents and is highly contentious with respect to children.

Since mandatory vaccination programs are a conflict between the state's interest of public health against the individual's right to religious freedom, the conflict assumes a constitutional debate based on the First Amendment. Usually, there is a strong inclination of the courts to rule in favour of the state for pursuing mandatory vaccination. Such an attitude is on account of several disease outbreaks in states, with the latest one being in 2019<sup>8</sup>.

Another argument (based on religion) in favour of vaccination is that the provision of religious exemption indirectly allows for state preference towards a particular religion which goes against the First Amendment and the equal protection doctrine [5]. This is most prominent in the states of Mississippi and West Virginia which do not allow for religious exemption at all. The Supreme Court of Mississippi stated that a religious exemption provision raises the problem of discriminating against people whose religious beliefs do not conflict with the vaccination requirements, in effect stating that the clause allows for a preference being given to a specific religion [5].

The *Parens Patriae* doctrine provided for in the case of *Prince v. Massachusetts* rules in favour of mandatory vaccinations. The case refused to accept a parent's absolute authority over his/her children and allowed for state intervention if the intervention is for the welfare of the child. While the case dealt with labour law, the court stated, "Neither rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth's wellbeing, the state, as *parens patriae*, may restrict the parent's control by requiring school attendance, regulating, or prohibiting the child's labour and in many other ways. Its authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience. Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child"<sup>9</sup>.

As mentioned above, people opposing vaccination on religious grounds and consequently not getting themselves vaccinated have been seen as having a higher chance of contracting Measles (Approx. 35 times more) [5]. This showcases drawbacks of vaccination exemption as most of the vaccines deal with communicable diseases and there is a high tendency among the religious groups (such as the Amish) to live together, thereby drastically reducing herd immunity and making their community susceptible. Furthermore, the present test established by the Supreme Court in 1990 is testament to the fact that there is a strong legislative will to support mandatory vaccination; "the right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)". Such a judgement thereby reduces the scope of religious exemptions under the First Amendment against mandatory vaccinations [5].

### National Childhood Vaccine Injury Act, 1986

The issue of compensation due to vaccine related side effects had long been debated. Such side effects were even possible when vaccines had been properly manufactured and

<sup>5</sup> *Zucht v. King*, 260 U.S. 174 (1922).

<sup>6</sup> *Public Health Tr. of Dade County v. Wons*, 541 So. 2d 96 (1989).

<sup>7</sup> *Ibid.*

<sup>8</sup> *Measles Cases and Outbreaks*. URL:<https://www.cdc.gov/measles/cases-outbreaks.html>

<sup>9</sup> *Prince v. Massachusetts*, 321 U.S. 158 (1944).

administered and were therefore put in the category of “unavoidable dangerous products” whereby dangerous was seen as being socially useful, and not being too dangerous<sup>10</sup>. (Adverse effects would be a sore arm or a mild fever, which wasn't the main concern. In extremely rare cases, the vaccine would result in a long-lasting injury or death)<sup>11</sup>. In such a scenario there was, in effect no one at fault unless there was some gross negligence, thereby making a claim based on the tort of negligence not feasible. In order to deal with such a scenario and provide the claimant with some sort of relief in such a no-fault situation, the courts focused on the legal doctrines of “informed consent” and a “duty to warn”. Such a system was problematic because:

- The claimant did not find any support from the government (namely the public health authorities) regarding the issue of a vaccine related side effect and was thus forced to approach a civil court to prove the issue of “fault” for compensation, which was extremely tedious.
- Consecutive cases on the issue of side effects and the courts' willingness to provide them with due compensation while being a positive approach was seen as detrimental for the vaccine manufacturers since they were made to pay compensation. Several lawsuits in the 1970s and 1980s made the manufacturers liable. This “liability” led them to move away from the production of vaccines. This raised alarm bells for the public health officials since they feared the outbreak of a disease along with a major supply problem.
- The legal doctrines were vague and provided the people with an opportunity to refuse vaccination, which the state did not want (schools require children be vaccinated as a mandatory requirement). The “duty to warn” was a contentious topic since it targeted either the state or the manufacturer, both of whom did not want the liability to fall on them. This resulted in a very tardy and complicated system which made it difficult for the victim to claim his due (there was no proper victim compensation program).
- Lawsuits which claimed injury due to the vaccine and which were subsequently debunked were seen as primary factors in causing a massive trust deficit towards vaccines.

In order to deal with these issues, the National Childhood Vaccine Injury Act came about in 1986. The main purpose of the act was twofold:

- to provide the claimants with a fast and cost-effective mechanism;
- to limit the liability of a manufacturer, thereby ensuring that the manufacturer remains in business.

The act provides for a “Vaccine Injury Table” which provides for various injuries, illnesses and disabilities covered in case they occur due to a vaccine, along with a stipulated time period<sup>12</sup>. In case this happens, the issue of burden of proof regarding due compensation immediately shifts to the government which then has to prove otherwise (thus providing for a quick compensation if one suffers any of the concerned side effects)<sup>13</sup>. The act accepts that there do exist adverse effects following vaccination. In addition to this, it provides for a dedicated National Vaccine Program which is tasked with coordinating research, production, licensing, side effects, testing and efficacy of a vaccine among the various organisations such as the CDC, DOD, Office of biologics Research. All legal fees in case the claim is genuine are provided by a vaccine fund and if the claimant does not accept the ruling of the “Vaccine Court”<sup>14</sup>, he is allowed to move to the main court system.

For manufacturers, the main benefit is the fact that liability is not imposed on them if they duly cater to various regulations, do not withhold information from the patient (Duty to warn), have no criminal dealings.

A major issue which cropped up was the fact that the manufacturers were not held liable for any “unavoidable, adverse side effects”. This was subsequently dealt with in the case of *Bruesewitz v. Wyeth*.<sup>15</sup> The majority in the case held that any side effects based on a design defect are barred by the compensation act if there was “proper manufacture and warning”. A major problem with this judgment (as was recognized by the minority judgment) is that it de-incentivises the manufacturers from improving upon the design on the vaccine since they are automatically insulated, which can also put public health in danger [6].

## Conclusion

The main difference between the two systems is based on vaccine related side effects specifically concerning a forum for quick and speedy justice in case of any concerned side effects. The Indian system has its own National Immunisation Programme and has had moderate success in recent years. However, the system lacks a well-developed public health infrastructure, especially in terms of dealing with adverse effects. While there have been efforts, they are simply not enough. The government spends less than 3% of the GDP on this issue, when it requires much more [7]. While these institutional weaknesses have persisted for a long time, it is the legal framework where immediate attention is required.

India unlike the U.S. does not have any proper compensation legislation and program for dealing with any AEFI (Adverse effects following immunization) problems. There does not exist

<sup>10</sup> The catch is that the risk being talked of is extremely miniscule.

<sup>11</sup> For eg. The Oral Polio Vaccine carried a risk of 1 in 4 million.

<sup>12</sup> National Childhood Vaccine Injury Act 42 U.S. C. § 300aa-15, 2016. URL: <https://www.govinfo.gov/content/pkg/USCODE-2016-title42/html/USCODE-2016-title42-chap6A-subchapXIX-part2-subparta-sec300aa-14.htm>

<sup>13</sup> Vaccine Injury Table, (March 17, 2019). URL: <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>

<sup>14</sup> Also known as the U.S. Court of Federal Claims.

<sup>15</sup> *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011).

any proper legal framework dealing exclusively with vaccination and its legality, with reliance primarily on colonial era laws such as the Epidemic Diseases Act, 1897. A PIL filed in 2013 regarding the death of 7 tribal girls based on the testing of the HPV vaccine under the aegis of the PATH Foundation is still pending<sup>16</sup>. There are no laws comparable to the National Childhood Vaccine Injury Act, 1986. There do not exist any specific vaccine courts with the burden on the primary judicial system in which there is a possibility of delay. There is an extreme dearth of "proper legal database" which deals specifically with this issue, despite India being a state with high emphasis on vaccination, with involvement from various foreign agencies such as the Bill and Melinda Gates Foundation, GAVI and the WHO. PATH, another organisation involved in the vaccination system is despite its credible work, mired in controversy [8]. Mandatory vaccination without the consent of the govern-

ment in relation to the MR (Measles Rubella) vaccine has been stopped by the Delhi high Court, which has ordered that any vaccination without parental consent would not be allowed [9], something which has been dealt with by adequately in the U.S.A.<sup>17</sup>

A weak judicial and accountability system, along with illiteracy and a dearth of adequate information, results in a severe trust deficit and creates massive scepticism towards vaccination. This scepticism leads to lesser coverage and a higher probability of the outbreak of a disease, as herd immunity is not established.

Therefore, the authors conclude by saying that it is high time that the Indian legal and medical systems take account of the US system pertaining to vaccination, since the issue is bound to play a major role in the public health scenario of the country, for which the state is presently ill prepared.

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<sup>16</sup> *Sama-Resource Group For Women And Health vs. Union of India, 2013. W.P (C) No. 921 of 2013.*

<sup>17</sup> *In the U.S. Parental consent will not triumph public health, and health of the individual.*