



# Pharmaceutical Patents and Medical Negligence: Exploring Challenges on the Right to Health

Chitra Shukla and Kaveri Shukla

*Advocate, Tirupati District Court, Andhra Pradesh, India.*

Email: [shukla.chitra10997@gmail.com](mailto:shukla.chitra10997@gmail.com)

**ABSTRACT:** *In India, there are millions who can't afford medicines. Right to health is a recognized human right, and access to medicines is a way by which the right to health and ultimately the right to life can be secured. Most of the medicines are costly due to pharmaceutical patents, and various expired medicines are sold, due to which many people lost their lives. In the name of clinical trials for getting pharmaceutical patents without prior consent, various unethical means are used. This has become another major threat to the right to life. Every life matters; it just remains in words when it comes to the poor and vulnerable section of society. In this situation, it is very important to study the challenges faced by people in securing the right to health. This paper mainly aims to study the challenges faced in the implementation of the right to health for all. In this research, a mixed method is used to assess the impact of pharmaceutical patents and medical negligence on the right to health. It concludes with suggesting ways such as proper monitoring of clinical trials and medicines sold in chemist's shops, strict punishments for medical frauds so that the international right to health can be secured.*

**KEYWORDS:** *Pharmaceutical Patents, Right to Health, Medical Negligence, Affordable Medicines, Right to Life.*

## INTRODUCTION

*"Of all forms of inequality, injustice in health care is the most shocking and inhumane."*

—Martin Luther King

The Above statement of Martin Luther King mentions the importance of the right to health in our lives.<sup>1</sup> The right to health is a universally recognized human right. In India, nearly 649 million people lack regular access to essential medicines due to their high prices, as reported by WHO. Globally, more than two billion people in developing countries cannot afford life-saving medicines. The right to health faces numerous challenges in the present society. The main reasons include a lack of food safety measures taken by industries and when we consume these products, we suffer from various diseases, apart from this increase in environmental pollution has also caused various chronic diseases. Several public interest litigations have been

<sup>1</sup> Luther King M, Jr. Presenting at the Second National Convention of the Medical Committee for Human Rights, Chicago, 25 March 1966.

filed to safeguard the right to health in India. Numerous things affect the right to health, but only pharmaceutical patents and medical negligence are two potential areas that have been studied to analyse their impact on the right to health in India. The main reason for choosing only these two areas is their wide growth in the present times. In this research, various cases have been studied for understanding Judicial approaches to address the challenges of pharmaceutical patents and medical negligence on the right to health of citizens.

### **OBJECTIVES OF THE RESEARCH**

This research has the following objectives:

- To assess whether patented medicines are affordable.
- To analyse the impact of medical negligence on the patient's health.
- To bring out other challenges that affect medical assistance in India.
- To explore measures through which the right to health of citizens can be strengthened.

### **RESEARCH METHODOLOGY**

This research has used mixed methods to study the importance of health in our daily lives and how medical negligence and pharmaceutical patents are affecting it. In qualitative analysis, national and international legal reports, research papers from various legal databases and books on pharmaceutical patents, right to health and medical negligence have been studied to understand the pharmaceutical patents and medical negligence on right to health. Moreover, legal statutes and precedents have been studied and analyzed to understand judicial approaches to the problems faced by people due to pharmaceutical patents that increase the cost of medicines and medical negligence, which leads to disability and death of the people.

In quantitative analysis, structured questionnaires have been administered to 800 people. Among these, 500 people have responded. Stratified random sampling has been used. The questions are framed on Likert scale to assess the impact of pharmaceutical patents and medical negligence on the right to health of people. Descriptive statistics have been used for data interpretation and analysis. Degree of agreement or disagreement with the statements based on the perceived impact of pharmaceutical patents and medical negligence on the right to health. Chi-square for goodness-of-fit test is done to assess the people's view on two different statements that have gathered people's views on the impact of pharmaceutical patents on the right to health of citizens and the impact of medical negligence on the right to health of patients.

### **CONSTITUTIONAL PROTECTION FOR THE RIGHT TO HEALTH**

The Indian Constitution includes the right to health as an important part of the right to life.<sup>2</sup> There are various precedents in which the Supreme Court stressed the right to health as a fundamental right of citizens and the State, along with medical professionals, are accountable to provide required medical aid to patients on time so that their life can be protected. The Constitution also outlines the State's duty to raise the level of nutrition and living standards of its people, and to improve public health. It specifically mentions the State's duty to prohibit the consumption of intoxicating drinks and drugs except for medical purposes.<sup>3</sup> It is both the morals enshrined by our Constitution and professional ethics to be followed by medical

---

<sup>2</sup> Indian Constitution Art. 21

<sup>3</sup> Indian Constitution Art. 47

professionals follow to ensure that they protect and improve public health in India. Here we are studying some of the landmark case law where the right to health has been prioritized by the Supreme Court.

In the case of *Parmanand Katara v Union of India*,<sup>4</sup> the Supreme Court held that it is the professional obligation of all doctors, whether government or private, to extend medical aid to the injured immediately to preserve life without waiting for legal formalities. Article 21 of the Constitution casts the obligation on the State to preserve life. No law or State action can intervene to delay the discharge of this paramount obligation of the members of the medical profession. This case highlights the obligation of medical staff to provide immediate care to the patient.

In the case of *Vincent Parikurlangara v Union of India*,<sup>5</sup> the Supreme Court held that the right to maintenance and improvement of public health is included in the right to live with human dignity enshrined in Article 21. A healthy body is the foundation of all human activities. In a welfare State, this is the obligation of the State to ensure the creation and sustaining of conditions conducive to good health. In this case, the court has stressed the State's responsibility to ensure proper health care facilities for citizens.

In *Paschim Bhag Khet Mazdoor Samiti v State of W.B.*<sup>6</sup> the Supreme Court has held that denial of medical aid by government hospitals to an injured person on the ground of non-availability of beds amounts to a violation of the right to life under Article 21 of the Constitution. Failure on the part of government hospitals to provide timely medical treatment to a person in need of such treatment results in a violation of the right to life guaranteed by the Indian Constitution. The Court directed the State to pay Rs. 25,000 to the petitioner as compensation. This case highlights the responsibility of government hospitals to provide basic infrastructure to patients.

All these judgments are significant for their recognition of the right to health as an important part of the right to life and their detailed directives for addressing public health crises and also highlighting the State's responsibility, be it Union or State Government and also public or private industries is to ensure access to health care and protect the health of all the citizens.

### **JUDICIAL APPROACHES ON PHARMACEUTICAL PATENTS: WITH SPECIAL REFERENCE TO RIGHT TO HEALTH**

Pharmaceutical patents are generally granted to newly innovated medicines. On the granting of these patents, the cost of medicines rises, due to which many poor people cannot afford the life-saving medicines. Earlier, only product patents were granted on pharmaceutical products, but after India became a signatory to the TRIPS Agreement, both product and process patents were granted. There are various cases in which the Supreme Court has raised concerns about the misuse of pharmaceutical patents, due to which many poor people cannot afford medicines.

In the case of *Novartis AG v Union of India*,<sup>7</sup> the Supreme Court had upheld the view that to grant a Patent to any Pharmaceutical company under Indian Patent Act the invention should pass the test of novelty, having inventive step in invention, industrial application of product along with a new test of therapeutic efficacy of medicine if the claim covers incremental change

---

<sup>4</sup> AIR 1989 SC 2039

<sup>5</sup> (1987) 2 SCC 165

<sup>6</sup> (1996) 4 SCC 37

<sup>7</sup> AIR 2013 SC 1311

to existing drugs. The Court further mentioned that a Patent holder cannot use a restricted interpretation of an already existing invention when assessing its novelty in relation to a salt derivative while simultaneously asserting a wide interpretation of the same Patent in infringement proceedings. Hence, the appeal by the Novartis company was dismissed by the Supreme Court of India.

In the case of *Boehringer Ingelheim Pharma GmbH & Co. v Vee Excel Drugs & Pharmaceuticals Pvt. Ltd. & Others*,<sup>8</sup> the Supreme Court held that IN301 was prior claimed in IN719 as the test of substantial structure, the diagram explained in the application and all other details of the specification of both the compounds are similar. So, the selection patent granted earlier to the plaintiff had been cancelled. This is the landmark case on pharmaceutical patents, which has raised concerns about evergreen patents, due to which many people cannot access life-saving medicines.

In the case of *Bayer Corporation & Another v Union of India*,<sup>9</sup> Bayer and Cipla came into conflict when Bayer challenged the attempt of Cipla to get approval from DCGI for a generic version of a drug patented by Bayer with the name of the drug Nexavar. This drug was used for treating liver and kidney cancer. Bayer constantly argued that if approval is given to the Cipla company, it will ruin the patent granted to it. Bayer Corporation relied on Section 48 of the Patent (Amendment) Act, 2005. Cipla, on the other hand, argued that considering Novartis' case, this is a situation that would amount to the creation of unwanted impediments for generic competition and derogate public interest and welfare. The Supreme Court rejected arguments made by Bayer Corporation for patent linkage, holding that "linking the regulatory and patent regime would undermine TRIPS agreement provisions, which on the one hand encourage innovation and also stress safeguarding the public health of the citizens. It noted that grant marketing approval for development of a drug does not amount to a violation of the patent holder's right to make, use, exercise, sell, or distribute his invention in India. The Patent holder must formally prove such an infringement before the court.

In *Merck Sharp and Dohme Corporation and Another v Glenmark Pharmaceuticals Ltd.*,<sup>10</sup> the patent was granted on the Sitagliptin drug to Merck Company. Merck had licensed the drug for retailing in India to Sun Pharmaceuticals Pvt. Ltd. However, an application was filed by the Merck company for a patent on the Phosphate salt of the Sitagliptin drug, but as the application was unable to fulfill the criteria for patentability, the Patent Office rejected the application. The Glenmark company also applied for a patent on the Phosphate salt of the Sitagliptin drug with the names of 'Zita' and 'Zita Met'. They wanted a 'safe harbor' for the use of their drug in the name of Januvia. The Merck company, along with the Sun Pharma company, opposed the patent application of the Glenmark company and filed an infringement petition against them and demanded for permanent injunction on manufacturing, selling, using, or distributing the drug. The Delhi High Court had passed a permanent injunction order against the Glenmark company and stopped it from further using, selling, manufacturing, or distributing the drug. This decision of the Delhi Court had also been upheld by the Supreme Court.

In *Hoffman-La Roche Ltd. Vs Cipla Ltd.*,<sup>11</sup> A Patent application was filed by Roche and Pfizer company for a patent on the drug named Tarceva. This drug was useful in the treatment of

---

<sup>8</sup> 2021 SCC OnLine Del. 3746

<sup>9</sup> 162 (2009) DLT 371

<sup>10</sup> (2015) 63 PTC 257

<sup>11</sup> 148 (2008) DLT 598

cancer. This drug got a patent in India and was also granted recognition by the Indian authorities. In the meantime, Cipla Ltd. The company announced the manufacture of the same drug with the name Erlecip. Plaintiff filed a suit of infringement and claimed a permanent injunction order. Cipla company argued that their action is in favor of public interest, as the drug in question was a life-saving drug. The Delhi High Court's Division Bench adopted the "Marksman Test" to determine whether infringement took place or not. The test involves determining the meaning and scope of patent claims and then comparing them with the alleged infringing item. The Division Bench therefore held that Defendant's product had infringed the Plaintiff's patent and awarded Roche company a compensation of the sum of Rupees 5,00,000. The court deliberated upon the newly added "anti-ever greening" provision of the Patents Act. They further set standards for measuring infringement in patent infringement suits. It was one of the first patent infringement cases to be tried in court after the 2005 amendment of the Patents Act.

From various judgments we have seen that the Court has taken strict action against the infringement of pharmaceutical patents so that innovations can be protected as well as promoted in our country. But the Court has also ensured that pharmaceutical companies do not misuse these patents and by their judgements, they could control the pharmaceutical patents so that the right to access lifesaving medicines, when they are they, play a significant role in protecting the right to health as well as the right to life of citizens.

### **JUDICIAL APPROACHES TO MEDICAL NEGLIGENCE**

Apart from pharmaceutical patents, negligence of medical professionals also impacts the right to health, which is the most important part of the right to life guaranteed in the Constitution.<sup>12</sup> Medical negligence can cause injury, disability, or even death. Every medical staff member has a duty to care while doing their work, be it pharmacists who have a duty to use the proper amount of chemicals in medicines, nurses who help doctors and ultimately doctors who should properly see medicines before giving to patients. Any negligence by medical staff can have severe consequences for a patient's life.

Two legal remedies have been provided to the victims of medical negligence; either they can file a civil suit for compensation or a criminal case against the responsible health care professionals, generally in death cases. Both the Indian Penal Code<sup>13</sup> and the Bharatiya Nyaya Sanhita<sup>14</sup> impose criminal liability on medical professionals. The criminal liability requires gross negligence in an acceptable standard of care, a medical opinion that proves that medical negligence has caused death, and prima facie evidence should be produced of a competent Doctor and the standard of care that a doctor has to follow while treating a patient.

Medical negligence impacts in various ways, such as affecting public health, causing psychological trauma and distrust in the health care system, financial losses, disability etc. The Judiciary has taken significant steps against medical negligence. Doctors can be prosecuted for criminal activities such as organ transplant without the consent of the person whose organ has been transplanted, or negligent behaviour of doctors while treating patients, due in he has death.

---

<sup>12</sup> Indian Constitution Art. 21

<sup>13</sup> Indian Penal Code 1860, s 304A

<sup>14</sup> Bharatiya Nyaya Sanhita 2023, s 106



In *Dr. N. Ummar v K.A. Hameed*,<sup>15</sup> A biopsy was conducted by a pathologist and the illness was wrongly diagnosed as Tuberculosis, while the patient actually suffered from cancer. As a result of a wrong diagnosis by a pathologist, the patient died. The Kerala High Court held the pathologist liable for his medical negligence. In *Ashish Kumar Mazumdar v Aishi Ram Batra Charitable Hospital Trust*,<sup>16</sup> the plaintiff, an in-door patient in the hospital fell out of the window of the hospital room. Applying the principle of *res ipsa loquitur*, the Supreme Court held that hospitals have a duty of care towards patients so they are liable for their medical negligence.

In *Sishir Rajan Saha v The State of Tripura*,<sup>17</sup> the petitioner's son met with an accident. The Senior Specialist of G.B. Hospital, Agartala Dr. P. Roy was unavailable in the hospital as he was busy attending to private patients. Due to which his son died. Dr. P. Roy was held liable to pay Rs. 1,25,000 as compensation for the death of the deceased. In *R.P. Sharma v State of Rajasthan*,<sup>18</sup> the petitioner's wife was admitted to S.M.S. Hospital, for operation of removal of gallstones. She was 'O' positive and the blood transfusion given to her was 'B' positive, due to which first she lost her eyesight and then died. The State which ran that hospital was held vicariously liable for the death caused due to negligence of hospital staff.

There are plenty of cases of medical negligence. The Court has secured some of the rights of doctors as criminal liability cannot be enforced on them for all the deaths. But the Court has also considered civil suits of medical negligence in which medical practitioner's negligence has caused disability and deaths of patients. These judgments have played a crucial role in ensuring the right to health of citizens.

### **IMPACT OF PHARMACEUTICAL PATENTS AND MEDICAL NEGLIGENCE ON RIGHT TO HEALTH: AN EMPIRICAL RESEARCH**

To understand the views of people and analyze the impact of pharmaceutical patents and medical negligence on people a survey is conducted. A structured questionnaire has been used. Stratified random sampling has been used in this research. First demography related questions are asked. This includes name, age, gender, occupation and residence. First five questions assess the impact of pharmaceutical patents on access to medicines. The next five questions explore the impact of medical negligence on the health of patients. The next four questions aim to understand other challenges associated with the medical sector and proper reforms people think can improve the situation. The last question is an open ended in which suggestions of respondents have been asked with regard to strengthening protection for the right to health in India. The questions are based on Likert Scale. Responses have been gathered with options strongly disagree code 1, disagree code 2, neutral code 3, agree code 4 and strongly agree code 5. Descriptive statistics have been used for data interpretation and analysis.

#### *Data Interpretation and Analysis*

As data is collected to gather the people's views on the impact of pharmaceutical patents and medical negligence on the right to health. The questionnaire has been framed by the researchers and proper care has been taken to include sufficient questions so that not just impact of pharmaceutical patents and medical negligence on right to health but also to explore the

---

<sup>15</sup> AIR 2014 (NOC) 49 (Ker.)

<sup>16</sup> AIR 2014 SC 2061

<sup>17</sup> AIR 2002 Guwahati 102

<sup>18</sup> AIR 2002 Raj. 104

reforms by which existing situations can be improved. For this number of suggestions have been gathered from respondents and they are included in the recommendation section.

Here data analysis is done to assess if there is a relationship between respondent's level of agreement or disagreement on right to health which is a dependent variable on pharmaceutical patents and medical negligence that are independent variables of this research. In this section descriptive statistics has been used for data interpretation and analysis. Below table represents level of agreement or disagreement of people in percentages. In the below table 'S.D.' represents strongly disagree, 'D' represents disagree, 'N' represents neutral, 'A' represents the agree and 'S.A.' represents strongly agree.

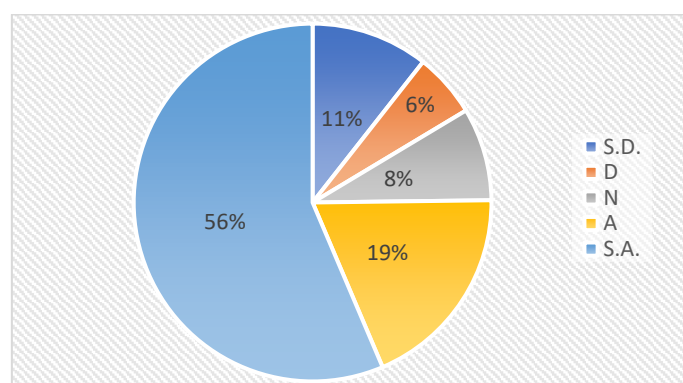
For the research such people have been selected who have suffered from medical negligence and have knowledge about pharmaceutical patents. The questionnaire has been sent to 800 people. Among which only 500 have responded. There were 52.2% male respondents in which 43% were rural residents and 57% were urban residents. Apart from male 47.8% are female respondents in which 52.7% are from rural and 47.3% are from urban background. All the people have to choose their age between the provided interval that had a margin of 12 years. All the people selected belong from 18 to 78 years. 12 years' margin have been included in each interval. Among all the respondents 23.8% belonged to 18 - 30 age group, 23.4% belonged to the 30-42 age group, 22.4% belonged to the 42-60 age group and 30.4% were from the 60-78 years' age group.

**Table 1: Descriptive statistics of data.**

Statements	S.D. (%)	D (%)	N (%)	A (%)	S.A. (%)
Pharmaceutical patents increase the price of life-saving drugs.	10.6	5.8	8.4	18.8	56.4
Patent protection hinders further innovations in developing new medicines.	12	7.6	14	21.6	44.8
Compulsory licensing has been effectively used in India to ensure access of medicines to the poor.	10.8	8	8.6	20.6	52
There are delays in getting generic versions of patented medicines.	10.2	9.2	14.4	27.2	39
Pharmaceutical patents have an impact on the health of citizens.	8	10.8	12.4	24.6	44.2
Medical negligence causes permanent impairment or disability.	7.4	8	10.6	23.2	50.8
Delay in treatment is also a part of medical negligence.	7.6	10.8	5.2	24.2	52.2
Lack of accurate information about the treatment and medicines given to patients increases the scope of medical negligence.	14	12	10	28	36
Medical negligence impacts the right to health of patients.	8.6	7.6	7	18.8	58

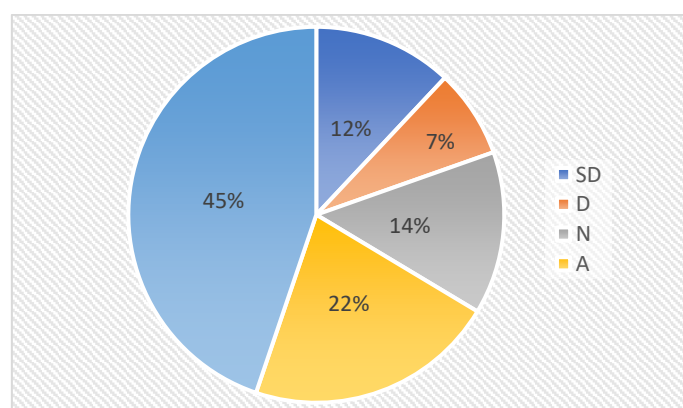
Implementation of strict laws are highly needed to control medical negligence.	8.4	12.8	10.8	18.6	49.4
Inadequate health infrastructure also impacts the health of people specifically in rural areas.	13.6	10.6	11.2	25.8	38.8
The non-availability of medical staff and hospitals in remote areas has affected access of health care in India.	7.8	7.6	13	23.8	47.8
Proper monitoring should be done for pharmaceutical patents so that these patents cannot be misused.	10.2	5.8	9	24.8	50.2
Medical staff involved in medical negligence should be strictly punished.	14.4	4.2	10.8	27	43.6

In the above table we can see the exact percentage of people who have shown their level of agreement on the Likert scale. For the first section of statements which were based on the impact of pharmaceutical patents on access to medicines and right to health approximately 56% strongly agree, 19% agree, 8% are neutral, 6% disagree and 11% respondents strongly disagree with the first statement that pharmaceutical patents increase the price of life-saving drugs.



**Figure 1: Shows the increase the price of life-saving drugs due to pharmaceutical patents.**

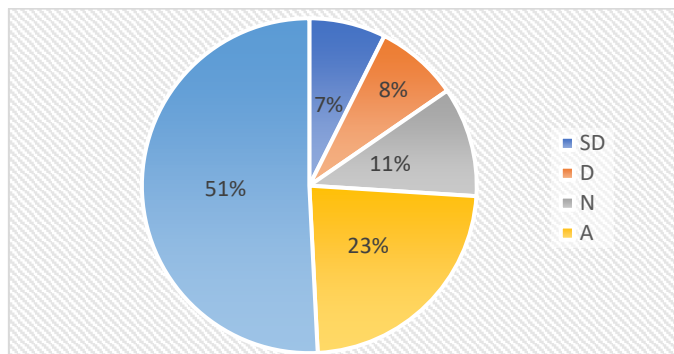
Approximately, 45% people have strongly agreed, 22% agreed, 14% were neutral, 7% disagreed whereas, 12% strongly disagreed with the statement that patent protection hinders further innovations in developing new medicines.





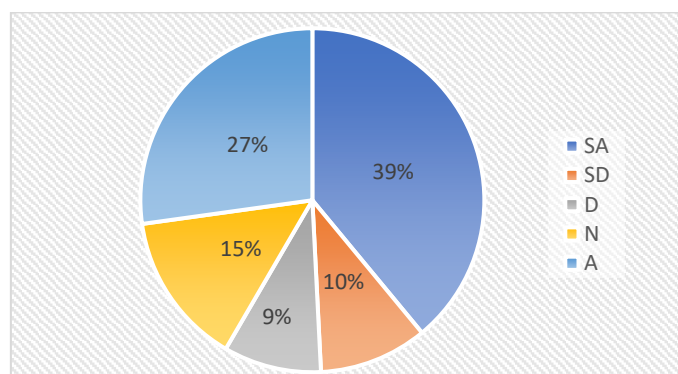
**Figure 2: Shows how Patent protection hinders further innovations in developing new medicines.**

Approximately, 51% strongly agree, 23% agree, 11% were neutral, 8% disagree and 7% strongly disagree with the statement that compulsory licensing has been effectively used in India to ensure access of medicines to the poor.



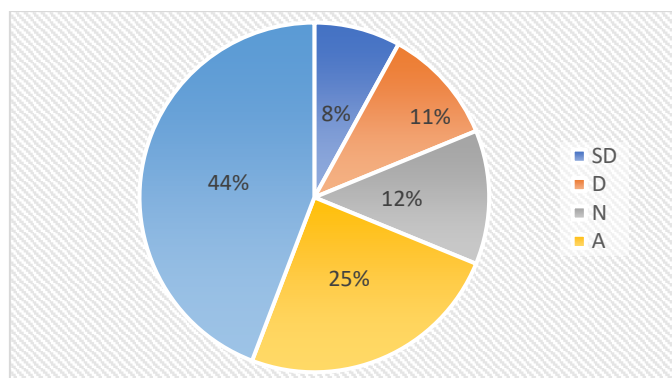
**Figure 3: Shows how compulsory licensing has been effectively used in India to ensure access of medicines to poor.**

Approximately, 39% of people strongly agree, 27% agree, 15% neutral, 9% disagree and 10% strongly disagree with the statement that there are delays in getting generic version of patented medicines.



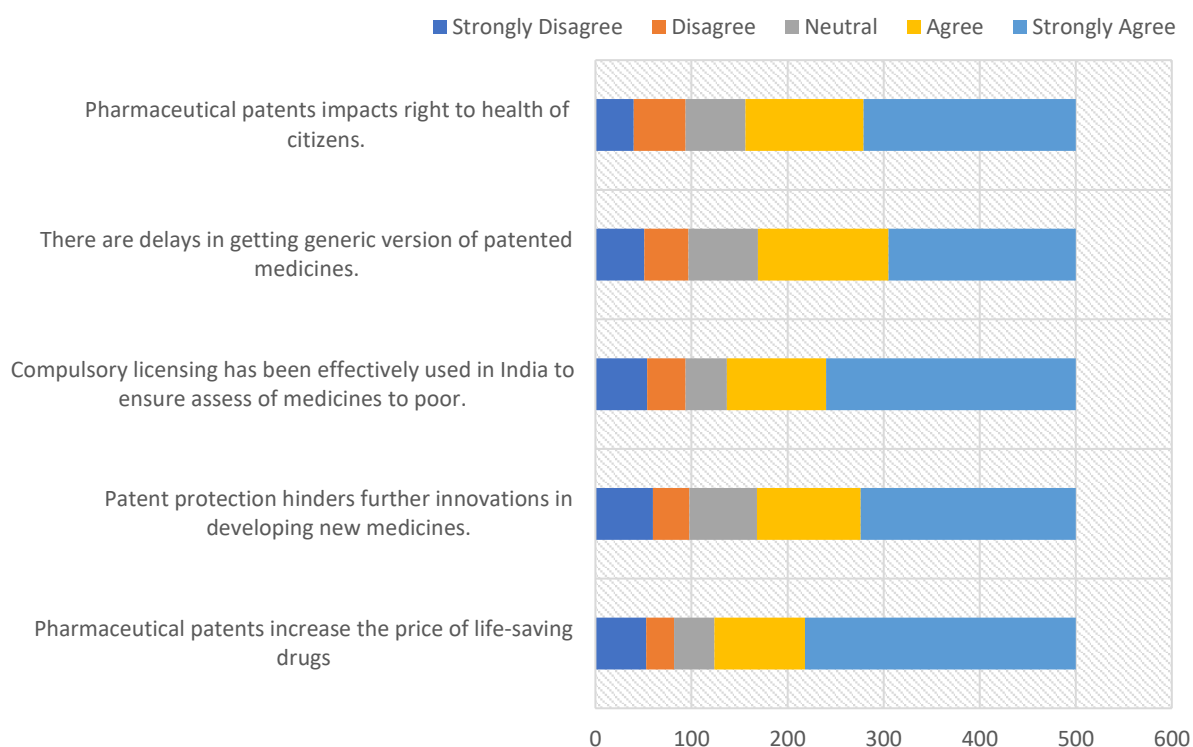
**Figure 4: Shows response of people on the delays in getting generic versions of patented medicines.**

Approximately, 44% of people strongly agree, 25% agree, 12% are neutral, 11% disagree and 8% strongly disagree with the statement that pharmaceutical patents have an impact on the health of citizens.



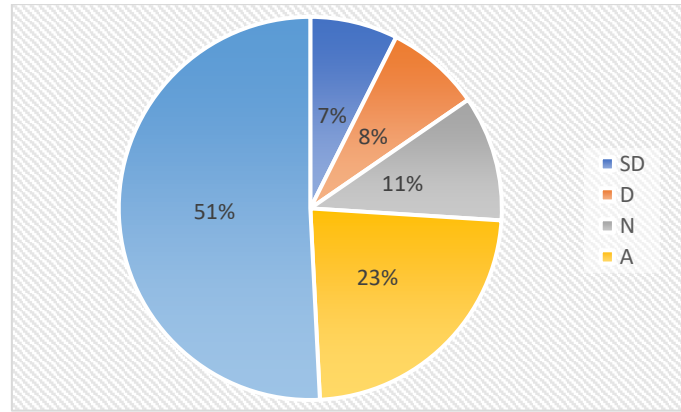
**Figure 5: Shows impact of pharmaceutical patents on the health of citizens.**

For the first five statements which were basically related to analyse people's views on pharmaceutical patents impact on the right to health of citizens. Majority of people have strongly agreed that pharmaceutical patents impact the health of people. Pharmaceutical patents have increased the prices of life-saving drugs, hindered the further innovations and also delayed in getting generic versions of patented medicine. Compulsory licensing which is a very important policy associated with pharmaceutical patents in India has to some extent helped poor in assessing patented medicine.



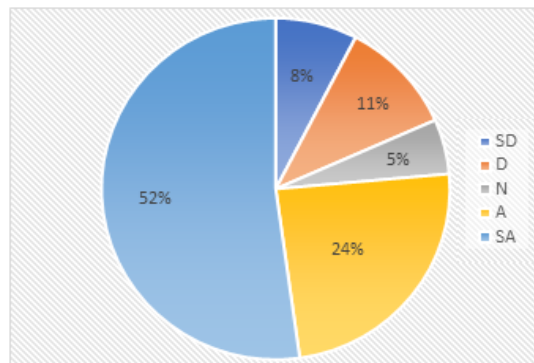
**Figure 6: Plot shows the overall analysis of people response on the impact of pharmaceutical patents on right to health.**

In the second section for the statement mentioning that medical negligence causes permanent impairment or disability approximately, 51% of people have strongly agreed, 23% agree, 11% were neutral, 8% disagreed and 7% strongly disagreed.



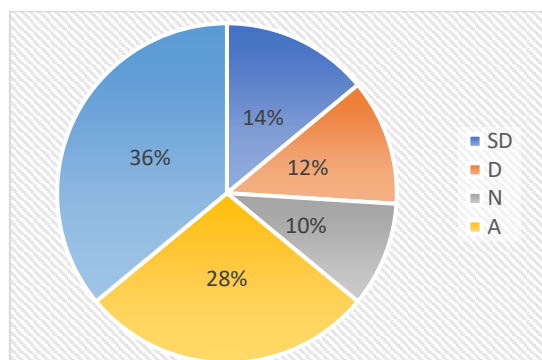
**Figure 7: Shows details of medical negligence causes permanent impairment or disability.**

Approximately, 52% have strongly agreed, 24% agreed, 5% were neutral, 11% disagreed and 8% strongly disagreed with the next statement that delay in treatment of patients is also a part of medical negligence.



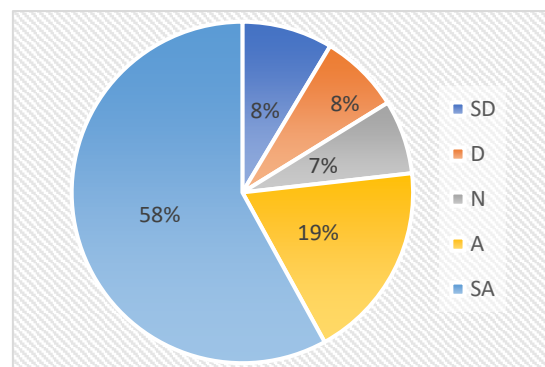
**Figure 8: Shows responses on the delay in treatment is also a part of medical negligence.**

Approximately, 36% of respondents strongly agreed, 28% agreed, 10% were neutral, 12% disagreed and 14% strongly disagreed with the statement that lack of accurate information about the treatment and medicines given to patients increases the scope of medical negligence.



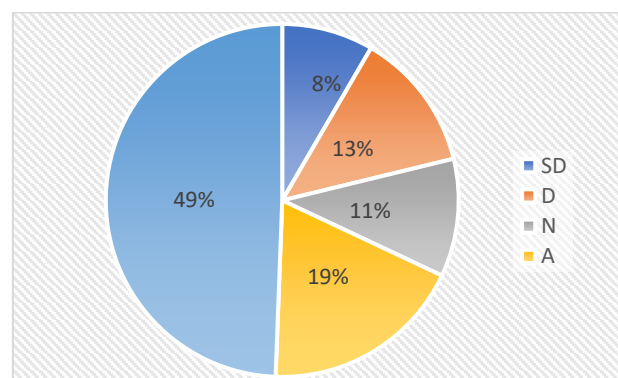
**Figure 9: Shows lack of accurate information about the treatment and medicines given to patients increases the scope of medical negligence.**

Approximately, 58% people have strongly agreed, 19% have agreed, 7% were neutral, 8% disagreed and the remaining 8% have strongly disagreed with the statement that medical negligence impacts right to health of patients.



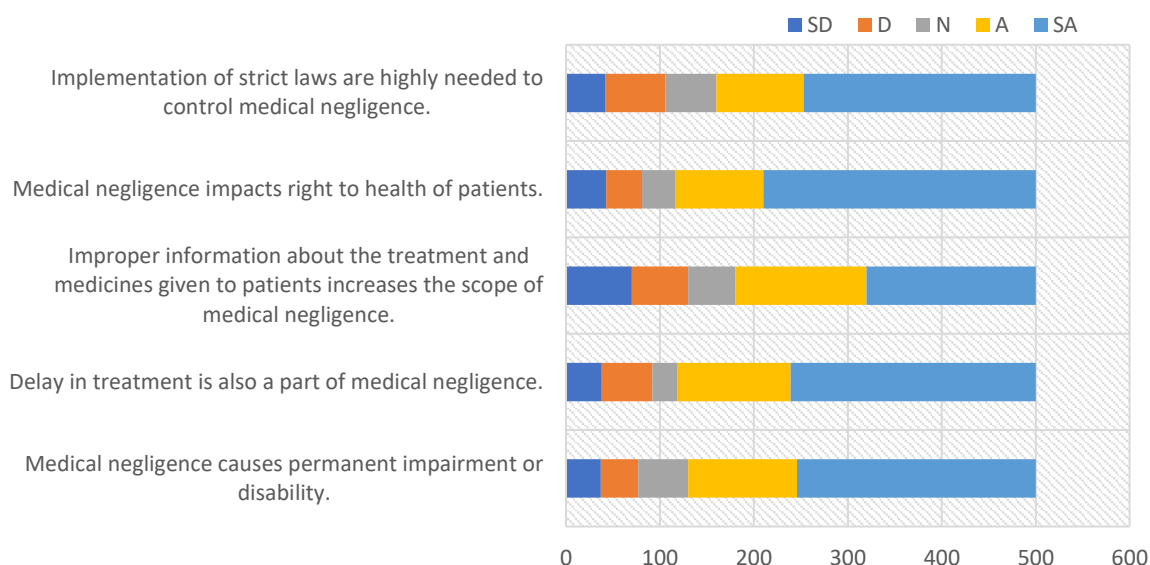
**Figure 10: Shows medical negligence impacts right to health of patients.**

Approximately, 49% people have strongly agreed, 19% agreed, 11% were neutral, 13% disagreed and 8% have strongly disagreed with the statement that implementation of strict laws are highly needed to control medical negligence.



**Figure 11: Shows implementation of strict laws are highly needed to control medical negligence.**

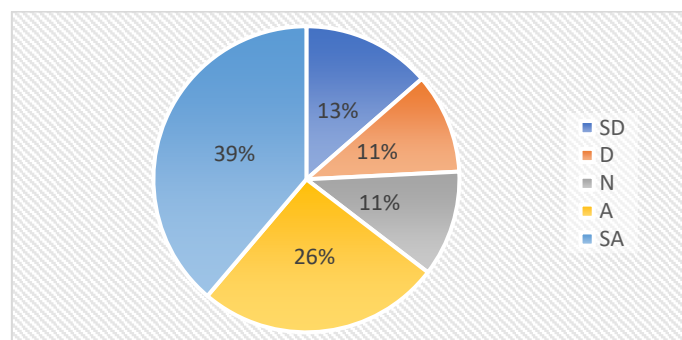
In overall analysis of responses that have been gathered for the statements associated with the impact of the right to health of citizens it has been found that the majority of people have strongly agreed that medical negligence causes permanent impairment or disability. The delays in treatment is also a part of medical negligence. Lack of accurate information on treatment and medicines given to patients further increases the scope of medical negligence. Whereas majority of people have strongly agreed that Implementation of strict laws are highly needed to control medical negligence.



**Figure 12: Overall analysis of responses on the impacts of medical negligence on right to health.**

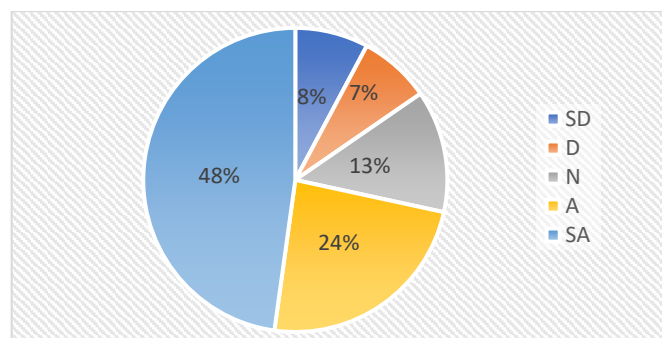
The third section of statements were based on other challenges associated with medical sectors and reforms that can be brought for strengthening the right to health in India. There were four statements on which responses had been gathered on Likert scale whereas the last question was an open-ended question in which people were asked to suggest some reforms through which the medical sector can be strengthened. Their suggestions have been included in the recommendation section of this research paper.

Approximately, 39% people have strongly agreed, 26% agreed, 11% were neutral, another 11% respondents have disagreed and 13% respondents have strongly disagreed with the statement that inadequate health infrastructure also impacts health of people specifically in rural areas.



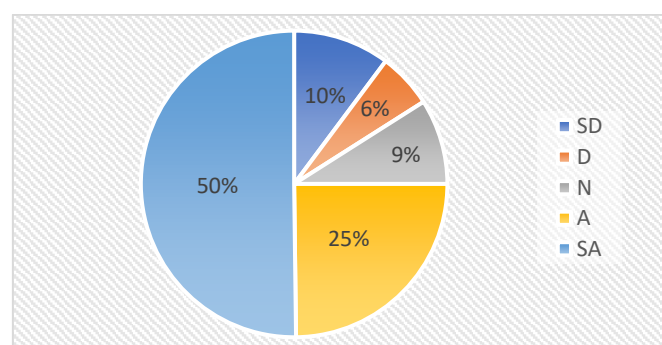
**Figure 13: Shows details of inadequate health infrastructure also impacts health of people specifically in rural area.**

Approximately, 48% people strongly agreed, 24% agreed, 13% were neutral, 7% disagreed and 8% strongly disagreed with the statement that non-availability of medical staff and hospitals in remote areas has affected access of health care in India.



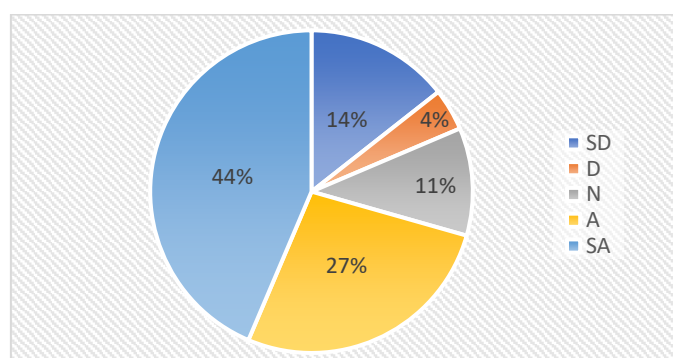
**Figure 14: Shows the non-availability of medical staff and hospitals in remote areas has affected assess of health care in India.**

Approximately, 50% people strongly agreed, 25% agreed, 9% were neutral, 6% disagreed and 10% strongly disagreed with the statement that proper monitoring should be done for pharmaceutical patents so that these patents cannot be misused.



**Figure 15: Shows that proper monitoring should be done for pharmaceutical patent so that these patents cannot be misused.**

Approximately, 44% people strongly agreed, 27% agreed, 11% were neutral, 4% disagreed and 14% strongly disagreed with the statement that medical staff involved in medical negligence should be strictly punished.



**Figure 16: Shows that medical staff involved in medical negligence should be strictly punished.**

## RESULT AND DISCUSSIONS

For this data there were two main statements on which responses had been gathered. The fifth statement was asked to know the patient's level of agreement on the statement that



‘Pharmaceutical patents impact the right to health of citizens’ and the ninth statement ‘Medical Negligence impacts the right to health of patients. Chi-square test for goodness-of-fit test has been done on both the statements. In both the statements we have assumed that an equal number of respondents have chosen each level of agreement. Hence expected frequency was calculated as 100. For the fifth statement ‘Pharmaceutical patents impact on the health of citizens’ Chi-square ( $X^2$ ) calculated is 223.3 and for degree of freedom 4 with significance of 0.05 the  $X^2$  critical value is 9.488. The calculated value of chi-square ( $X^2$ ) is more than the critical value of ( $X^2$ ), which means that the p-value is very less than 0.05 and hence it is established that pharmaceutical patents impact right to health of citizens. For the ninth statement ‘Medical negligence impacts the right to health of patients’ calculated value of chi-square ( $X^2$ ) is 474.54. Here also the degree of freedom is 4 and for the same significance of 0.05, chi-square ( $X^2$ ) critical is 9.488. The calculated value of chi-square  $X^2$  is more than the critical value so the p-value is also very less than 0.05. Hence, it can be concluded that medical negligence impacts the right to health of patients.

The entire data analysis establishes the fact that pharmaceutical patents and medical negligence impact the right to health of citizens. For the last open-ended question in which they have to suggest reforms for improving the current situation. People have suggested bringing specific regulatory authorities to monitor the use of pharmaceutical patents and ensure that the price of life-saving drugs can be reached to all. Many suggested bringing specific laws for properly controlling misuse of patented medicine and appointment of proper authorities to see that correct medicines are sold in the chemist shops as major expired medicines are also sold in shops. For controlling medical negligence, they recommended making it mandatory for medical staff to provide accurate information about procedures involved in treatment and medicines given to patients. Staff involved in medical negligence should be punished and proper compensation should be provided to patients who are suffering due to medical negligence. They have also suggested improving health infrastructure in remote areas. Some of their suggestions had also been included in the next section.

## CONCLUSION

From this research we can conclude that millions of people die due to costly health care facilities which they cannot afford on time. Right to health is a universal safeguard provided to all the citizens. Economic inequalities have affected citizens as they cannot afford medicines. When we go to hospitals for treatment, doctors suggest we conduct a number of tests. These tests already charge a huge amount of money. Then for performing major surgeries lakhs of money is required. Without depositing money even in serious accidents hospitals refuse to admit the patients and start treatment only after the amount is deposited. So people who cannot afford these costly treatments ultimately lose their life. Further there are a wide range of wrong medicines sold in the chemist’s shops. Consuming these expired medicines also causes numerous side effects to people.

Inadequate health infrastructure in India specifically in rural areas is a major challenge in safeguarding the right to health. Only the few villages in India have proper primary health care centers with all facilities including doctors and nurses. Due to this, villagers have to go to other villages or cities to get treatment. Sometimes they could not reach hospital on time or get any medical aid immediately which causes major deaths in India. There is a lack of medical facilities in comparison with the population in India. This situation has already been suffered by us during the spread of Coronavirus. Where there has been shortage of medical equipment,

protection kits, injections, oxygen cylinders and essential medicines. This actually happens due to insufficient expenditure in the health sector in normal times. These loopholes become a discussion point only during the pandemic situation.

The next challenge is posed by pharmaceutical patents. We all know that if any medicine has to be given pharmaceutical patents, before that they have to perform clinical trials. Many times, no informed consent has been asked before doing these clinical trials. This raises major ethical issues especially in developing countries like India where these fraudulent practices are very common as we have very limited resources to identify it. Ultimately the people suffer due to side effects of such medicines. There are a number of movies which have highlighted this concern but still such clinical trials are going on in an uncontrolled manner. The medical negligence in the treatment process causes disability, side-effects and death in some cases. As a result, medical negligence is also a major challenge to right to life and also right to health of citizens in India. These challenges have to be resolved so that universal human right to health can be protected. As health is the major wealth of any person, proper steps have to be taken so that the right to health can be protected. Apart from socio-economic inequalities that have majorly affected the health of citizens, pharmaceutical patents and medical negligence is also a major challenge in safeguarding the right to health.

Following reforms can be brought so that right to health can be safeguarded:

- Pharmaceutical patents should be properly monitored so that they cannot be misused by the pharmaceutical industry.
- Before granting pharmaceutical patents to the international pharmaceutical industry, it should be seen what the impact of these medicines was in other countries. So that medicines can be properly ensured to everyone.
- Ensuring timely and effective implementation for compulsory licensing provisions. This can address public health crises specifically during pandemic times.
- Judges should be provided specialised training on pharmaceutical patents and medical negligence. This will enable them in deciding complex cases.
- Implementing a system of independent and qualified medical experts to provide unbiased testimony in medical negligence cases to ensure accuracy in assessment of professional standards.
- Medical negligence should be strictly punished so that this negligence will not affect other people.
- Strict rules should be framed so that illegal organ transplant can be controlled as it is also a major crime done in India which affects the health of people.
- Stringent laws should be properly implemented and monitoring has to be done on which medicines are sold in chemist's shops whether it is branded or generic medicines. As many people die by consuming expired medicines.
- Public awareness should be made about the wrong medicines which are sold in the market so that people can identify the medicines and not purchase them. The awareness should also be done on how people can lead healthy lives.
- There should be removal of such medical staff and closure of those pharmaceutical industries that are actively involved in the medical negligence of giving medicines,

manufacturing of medicines, giving wrong medical treatment or any other serious medical crime. This will help in the development of professional ethics in all people who have the responsibility of protecting the lives of people.

- More conferences and seminars can be organized along with the development of researchers to identify all the challenges that may affect the right to health of citizens and can help in protecting the right to life at global level.
- The hospitals which are not maintaining international standards of clean and hygienic conditions should be first given notice and if they do not follow the international standards such hospitals should be closed. This is very important as lack of cleanliness and hygiene also causes multiple diseases specifically at hospitals where multiple patients are living certain cleanliness should be maintained. This will help in protecting the health of citizens.

If all the above measures are adopted properly, then the right to health of citizens can be protected and everyone can get better treatment. Right to health is not just a fundamental right, rather it is a goal by which the right to life can be secured for all the citizens. Having a proper healthy environment is our moral responsibility for which all of us should bind together. Only then the right to health and the right to life can be secured. There is a need for collective efforts where not just its government but all of us should see that proper health infrastructure can be available in various rural and remote areas. The access to accurate medicine and effective punishments to culprits involved in pharma industries whether it is from top companies or medical professionals.

## REFERENCES

- [1] Florian Aerts, *Pharmaceutical Patents: Issues and Considerations*, (Nova Science Publishers, 2013) 69-87.
- [2] Tanusree Debnath, *Compulsory Licensing of Pharmaceutical Patents and Access to Medicines*, (Satyam Law International, 1st Edition 2022) 66-84.
- [3] Tapas Kumar Koley, *Medical Negligence and the Law in India: Duties, Responsibilities, Rights*, (OUP India, 1st Edition 2010) 88-96.
- [4] Dr. Siddhartha Goswami, *Introduction to Medical Negligence Law in India*, (BFC Publications, 2021) 63-79.
- [5] Ram Shelkar, *Medical Negligence and Compensation*, (Kamal Publishers 2024) 94-114.
- [6] Yagesh V. Nayyar, *Medical Negligence and Medical Evidence: The Five Elements of Negligence (Medical Negligence-Defenses-Remedies) (Presumptions & Medical Evidence*, (Lexman (PPH); 1st Edition 2024) 79-96.



This is an open access article distributed under the terms of the Creative Commons NC-SA 4.0 License Attribution—unrestricted use, sharing, adaptation, distribution and reproduction in any medium or format, for any purpose non-commercially. This allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms. For any query contact: [research@ciir.in](mailto:research@ciir.in)