

Supreme Court, Division Bench
Honorable Justice Bishwambhar Prasad Shrestha
Honorable Justice Dr. Anand Mohan Bhattarai

Date of Order: 2075/03/14 (corresponding to 28 June, 2018)

Case No.: 069-WO-0202

Subject: Certiorari /Mandamus

Petitioner: Advocate Dhal Bahadur Dhami and others, resident of Bajhang District Maulali V.D.C. Ward No. 4 Rakail, currently living in Kathmandu District, Kathmandu Metropolitan City Ward No. 11 Babbar Mahal

Vs.

Respondent: Nepal Government Prime Minister and Secretariat of Council of Ministers, Singh Durbar, Kathmandu and others

- The right to health falls within the ambit of economic, social, and cultural rights. In order to realize these rights, the State is required to progressively utilize the maximum available resources and adopt necessary measures for their gradual fulfillment. However, rights that are linked to the basic necessities of human life such as food, housing, basic education, and health constitute the State's *core minimum obligations*. Accordingly, in respect of these rights, factors such as the country's economic condition or the availability of resources are not relevant, and the State is required to take immediate steps to ensure their effective implementation.

(Para No. 9)

- It is not sufficient for the State merely to make available medicines, vaccines, or other health services, and such provision alone cannot be considered as guaranteeing the citizens' right to health. Equally important is the question of the quality of the services provided by the State, and whether such services are capable of addressing the health-related problems of the targeted population. If receiving quality health services is a right of the citizens, then ensuring the availability of such quality services constitutes a duty of the State.
- The act of providing vaccines and medical treatment to a patient falls within the definition of "service" for the purposes of the Consumer Protection Act. Accordingly, the State bears the obligation to ensure that the goods and services provided to consumers meet the required standards of quality.
- The State must treat health services which are directly linked to the right to life of humans with due sensitivity and exercise adequate care in their provision. Similarly, medical practitioners involved in treatment must exercise due diligence when distributing medicines and vaccines or employing other methods of treatment. Effective treatment requires that the correct medicine be administered in the correct dosage, by the correct method, within the correct time frame, and at the correct cost.

(Para No. 11)

- The provision of vaccines and medicines by the State is not a mere formality. It constitutes a fundamental obligation of the State to address the health-related problems of its citizens and to guarantee their right to health. Accordingly, the State must undertake adequate preparatory measures to assess the quality and safety of medicines and vaccines, ensuring that they do not cause any adverse effects to the citizens. Moreover, the State must remain vigilant and prepared to take necessary remedial measures in the event of any harm or negative impact resulting from such provision.

(Para No. 12)

- The State cannot absolve itself from liability by attributing the death of children to human error or environmental contamination that led to the vaccine being tainted. The mere assertion that a vaccine was contaminated due to some reason does not exempt the State from responsibility for the adverse effects caused by the vaccine it has distributed.

(Para No. 15)

On behalf of the Petitioner:

On behalf of the Respondent: Learned Joint Government Attorney Mr. Shyam Kumar Bhattarai

Precedents Cited:

Relevant Laws:

Order

Justice Bishwambhar Prasad Shrestha: The summary of the facts and the order submitted pursuant to Article 32 and 17 (2) of the Interim Constitution of Nepal, 2063 is as follows:

Content of the Writ Petition

We, the petitioners, are practicing legal professionals and also human rights activists working in the field of human rights. According to reports, during the measles vaccination campaign conducted by the respondent, the Government of Nepal, in Doti District, including Kathmandu V.D.C., four children died and several others fell ill while receiving the measles vaccine. Preliminary investigations indicated that the deaths were caused by the measles vaccine. A team of pediatric specialists from the Ministry of Health was assigned to study the incident on site and prepare an accurate report; however, no such report has yet been made public. However, despite such a serious incident in which four children lost their lives unnecessarily, the respondents instead of halting the program continued the vaccination program thereby resulting in the death of a child in Ganeshpur-7, Dadeldhura. Even in the face of repeated deaths and illnesses among children, the respondents persisted with the vaccination program. Given the imminent risk of further loss of innocent lives, the petitioners under Article 32 and 107 (2) of the Interim Constitution of Nepal, 2063, have appeared before this honorable Supreme Court seeking issuance of a writ of certiorari including mandamus and any other appropriate orders. The petitioners also request that a high-level investigation be formed to examine the incident, that compensation be provided to the affected families, and that strict procedures be established for testing vaccines and medicines before administration, ensuring the protection of human life and the right to life of citizens.

Under the Interim Constitution of Nepal, 2063, Article 12 guarantees every individual the right to live with dignity as a fundamental right. Similarly, Article 16 guarantees the right to a healthy environment and health, and Article 22 guarantees the rights of children. Nepal has also ratified numerous international human rights instruments, including the International Covenant on Economic, Social and Cultural Rights, 1966; the Convention on the Elimination of All Forms of Discrimination against Women, 1979; and the Convention on the Rights of the Child, 1989. Article 6 of the Convention on the Rights of the Child, 1989 recognizes the inherent right of every child to life, while Article 14 guarantees the right to health. The preamble of the Children Act, 2048, emphasizes the protection of the rights and interests of children and the promotion of their physical, mental, and intellectual development, and Section 4 guarantees the right to health. Once international treaties are ratified, corresponding national laws must be enacted and implemented in conformity therewith. Section 9 of the Nepal Treaty Act, 2047 provides that, after ratification of international conventions or treaties, they are to be applied as if they were national laws.

Reports have repeatedly emerged indicating that the respondents, the Government of Nepal and the Ministry of Health and Population, have conducted various drug trials that jeopardize public health. The health status of children in Nepal is already precarious, and it is even worse in the Far-Western region. While the administration of the measles vaccine is not inherently objectionable, it was initiated without any prior study of its positive or negative effects, and without a pre-arranged plan to manage any adverse outcomes. This has directly threatened the right to life of children. District Health Office officials have publicly stated that some children died as a result of the vaccine, and doctors at Doti District Hospital have also indicated that the deaths may have been caused by the same vaccine. Despite these warnings, the respondents publicly indicated that the vaccination program would continue. Consequently, the death of a child in Ganeshpur, Dadeldhura, is attributable to the respondents' actions. Furthermore, no concrete data exists regarding how many children remain at risk, and reports indicate that several children in Doti are still hospitalized and receiving treatment.

Accordingly, any vaccination program should not be conducted on the basis of mere assumptions. Vaccination must only be carried out after thorough study of the vaccine and detailed prior preparation to prevent any potential adverse effects. The program must be implemented in a manner that fully safeguards the right to life and health of all citizens, with particular attention to children, who are especially vulnerable. Furthermore, a writ of certiorari including a writ of mandamus is sought against the respondents to ensure that all parents of deceased children receive appropriate compensation, that the surviving affected children receive free treatment, and that they are provided additional compensation for the hardships they have endured.

Although the present writ petition may take time to be finally adjudicated, the respondents have continued the measles vaccination program in local villages, forcibly administering the vaccine even when local residents refuse, and claiming through local health workers that the vaccine has no adverse effects. Given the resulting risk to a large number of children, the petitioners seek an interim order directing the respondents to suspend the vaccination program until the final disposal of the case. Furthermore, considering the highly sensitive nature of the matter involving children's lives and health, and the possibility of greater harm if delayed, the petitioners request that the matter pursuant to Rule 63 (3) of the Supreme Court Regulation, 2048, be accorded priority and that the case is heard on a priority basis.

Show Cause Notice

A show cause notice had been issued by this court on 2069/5/18 (corresponding to 3 September, 212) which reads as follows: What has transpired in this matter? Why should an order as sought by the petitioners' not be issued? It is hereby ordered to provide a copy of the petitioner and notify the respondents to submit their rejoinder with 15 days excluding the period of travel through the Office of the Attorney General and to provide a copy of the same to the Office of the Attorney General and to submit the case file upon receipt of the rejoinder or upon the expiry of the limitation period.

Given that the petitioners have also sought for an interim order, the court finds it appropriate to issue an order upon hearing both the parties. Accordingly, a hearing has been scheduled for 2069/05/27 (corresponding to 12 September, 2012) and it is hereby ordered to issue a notice to the respondents to participate in the discussions. Furthermore, since the petition directly concerns public health, the court pursuant to Rule 63 (3) (f5) of the Supreme Court Regulation, 2049, has accorded priority to the case.

Rejoinder Submitted by District Health Office, Doti

The rejoinder submitted by Ramswarth Yadav, Acting Officer-in-Charge of District Health Office, Doti is as follows: Allegations that children died due to the measles vaccine administered in Doti District, Kathmandu V.D.C., are entirely unfounded. The first phase of the vaccination program in Doti District, including Kathmandu V.D.C., falls under the Sanagaun Health Post area. In this phase, vaccination was conducted simultaneously in Kathmandu V.D.V. including ten V.D.Cs and the entire municipality. On 2069/05/03 (corresponding to 19 August, 2012), a total of 19 children were vaccinated in Kathmandu V.D.C. Among them, six children received the measles vaccine, and reports received by the District Health Office, Doti, on the evening of 2069/05/04 (corresponding to 20 August, 2012) indicated that four children had allegedly died. On 2069/05/05 (corresponding to 21 August, 2012), a team led by Dr. Sandip Shrestha, comprising the vaccination section chief of the District Health Office, the head of Sanagaun Health Post, and a journalist, visited the site for on-the-spot observation and study. Based on the team's findings, *Milan Nepali*, a 12-month-old child residing in Ward No. 6, Dhanukada, Kathmandu V.D.C., received the vaccine at 11:00 AM on 2069/05/03. The child developed high-grade fever with rigors in the evening and was reported deceased at 5:00 AM on 2069/05/04. Sujata Nepali, an 8-month-old child residing in Ward No. 7, Thapagaun, vaccinated at 9:30 AM on 2069/05/03, developed high-grade fever with rigors in the evening and was reported deceased at 5:00 AM on 2069/05/04. Gauri Chiral, a 19-month-old child residing in Ward No. 7, Thapagaun, vaccinated at 10:00 AM on 2069/05/03, developed vomiting, loose stool, and fever with rigors in the evening and was reported deceased at 3:30 AM on 2069/05/04. Anju B.K., a 9-month-old child from Ward No. 9, Pokhari V.D.C., residing at her uncle's place Kathmandu V.D.C., vaccinated at 11:00 AM on 2069/05/03, developed vomiting, loose stool, and fever with rigors in the evening and was reported deceased at 5:00 AM on 2069/05/04. It was noted that the relatives of these four deceased children performed the cremation without informing any health institution. Other vaccinated children showed adverse reactions but survived. Ratan Dhanuk, a 11-month-old child from Ward No. 5, Dhanukada, Kathmandu V.D.C., vaccinated at 12:00 PM on 2069/05/03, developed fever with rigors, vomiting (2 episodes), and loose watery stool overnight. He was brought to a local clinic on 2069/05/04 at 2:00 PM and referred to Doti District Hospital, where he received treatment on 2069/05/05 at 7:30 PM. His condition improved and is currently normal. Bhajan Dhanuk, a 7-month-old child vaccinated on the same day, developed mild fever but recovered, and his condition is now normal. Accordingly, following vaccination, the four children who developed high fever, diarrhea, and vomiting did not receive immediate treatment, which contributed to their deaths, whereas children

who exhibited milder symptoms and received timely treatment survived. Therefore, as the District Health Office, Doti, has been performing its duties and responsibilities as mandated by the Government of Nepal, the justification for the present writ petition is deemed to be and the writ petition should be dismissed.

Rejoinder Submitted by District Health Office, Dadeldhura

The rejoinder submitted by Dr. Durga Dhungana, Acting Office Chief of District Health Office, Dadeldhura is as follows: Vaccination plays a crucial role in safeguarding public health. Immunization programs are conducted in other countries as well. Smallpox has been eradicated globally, and efforts are ongoing to eliminate polio. In Nepal, the Government, through the Ministry of Health and Population, implements nationwide vaccination programs. Currently, vaccination has contributed to a reduction in the incidence of eight diseases as well as a decrease in child mortality. The child mortality rate declined from 64 per 1,000 in 2001 to 54 per 1,000 in 2011. Children have a fundamental right to receive vaccines, and access to such services provided by the State constitutes a birthright. Halting vaccination would increase child mortality due to preventable diseases. Since investigations have not revealed any defect in the vaccines, the vaccination program should not be suspended. Specifically, the measles vaccine in Dadeldhura District has not caused the death of any child. Although media reports suggested that deaths were caused by the B.C.G. vaccine, these reports did not include any conclusions from health experts regarding the quality or efficacy of the vaccines used. Subsequent investigations have confirmed that these claims were unfounded and therefore, the writ petition in relation to Dadeldhura is entirely baseless and without merit, and should be dismissed.

Rejoinder Submitted by the Prime Minister and Office of the Council of Ministers

The rejoinder submitted by Nepal Government, Prime Minister and Office of the Council of Ministers is as follows: The Government of Nepal is committed to protecting and promoting the fundamental and legal rights of its citizens, as well as ensuring consumer safety. In this context, the Government has undertaken the measles vaccination program with the noble objective of safeguarding children from measles and fostering the development of healthy and resilient citizens. There is no dispute that the vaccination program was implemented. It is also acknowledged that during the course of the measles vaccination program, reports were received claiming that some children had died in certain districts, as claimed by the petitioners. In this regard, the Government of Nepal, through the Ministry of Health and Population, formed a team including pediatric specialists to study the matter and submit an accurate report. The respondents themselves have stated in their petition that no report has yet been submitted by this team. In such circumstances, it would not be appropriate to conclude that any child's death was caused by the measles vaccination program implemented by the Government of Nepal. As for the other claims made by the respondents, these will be clarified through the rejoinder to be submitted from the relevant authorities. Accordingly, for the foregoing reasons, the respondents claim that the writ petition should be dismissed.

Rejoinder Submitted by Department of Health Service

The rejoinder submitted by Dr. Mingmar Gelzen Sherpa, Acting Director General of Department of Health, Nepal Government, Ministry of Health and Population is as follows: According to the findings and recommendations of the independent committee tasked with monitoring and investigating the incident (AEFI Committee), the children developed Toxic Shock Syndrome, which could have arisen due to a locally contaminated vaccine vial. The vials in question had already been destroyed following standard procedures. The contamination could also have occurred due to human error during service delivery, local environmental contamination, or lapses in sanitation. The committee has communicated to all concerned that the children's deaths were not caused by the vaccine. Furthermore, to prevent recurrence, the AEFI Committee's recommendations have been strictly implemented, and the Ministry has directed its subordinate agencies accordingly. In light of these findings, the deaths were not attributable to the vaccine, and therefore, the present writ petition should be dismissed.

Rejoinder Submitted by Ministry of Health and Population

Rejoinder submitted by Dr. Tirtha Raj Burlakoti, Acting Secretary of Nepal Government Ministry of Health and Population, Ram Shah Path, Kathmandu is as follows: According to the findings and recommendations of the independent committee responsible for monitoring and investigating the incident (AEFI Committee), the children who died suffered from Toxic Shock Syndrome. The vaccine vials in question had been locally contaminated but were destroyed in accordance with standard procedures after use. The contamination could have occurred due to human error during service delivery, local environmental contamination, or lapses in sanitation, despite the vigilance of health workers. Therefore, the deaths of these children were not caused by the vaccine. Furthermore, to prevent recurrence, the Ministry has already directed its subordinate agencies to strictly implement the recommendations provided by the independent monitoring and investigation committee and therefore, the writ is liable to be quashed and the respondent requests that the writ petition be dismissed.

Rejoinder Submitted by Regional Health Directorate

The contents of the rejoinder submitted by Dr. Bikash Lamichhane, Acting Regional Director of Far-Western Regional Health Directorate, Deepayal, Doti is as follows: On 2069/05/06, it was reported that a 21-day-old child in Ward No. 7, Ganeshpur V.D.C., Dadeldhura District, died allegedly due to the BCG vaccine. The District Public Health Office received this information on the evening of 2069/05/09 at 4:00 PM. An investigative team conducted a study on 2069/05/11 and found that on 2069/05/06 at 11:30 AM, four children had received the vaccine from the same vial. No adverse effects were observed in the other children. After receiving the vaccine, the 21-day-old child was taken home by the mother, fed milk, and later fell asleep. The child was found deceased at 7:00 PM with a bluish tint and abdominal distension. Investigation Form Paragraph "C" concluded that the death was likely due to a respiratory illness, not the BCG vaccine. This conclusion was further confirmed by the decision of the expert panel of the Department of Health Services. Therefore, the petitioner's claim that the death was caused by the vaccine is baseless.

Arguments Provided by the Legal Practitioners

Pursuant to the prescribed procedure, the matter was listed in the cause-list for hearing and submitted before this bench for adjudication; however, no one appeared on behalf of the petitioner for arguments. On behalf of the respondents, learned Joint Government Attorney Mr. Shyam Kumar Bhattarai submitted that the government is committed to safeguarding citizens' rights to health and their right to life. He further contended that the administration of vaccines is a globally recognized practice. Vaccines have been developed in a phased manner. Only after the vaccine manufacturer produces the vaccine and it is certified by the World Health Organization (WHO) as safe does it become available in the market. Prior to administration, vaccines undergo testing at every stage, and they are administered only after being deemed safe. During the provision of services, child deaths may occur due to human error or local environmental contamination; however, such deaths are not attributable to the measles vaccine. The Ministry of Health has issued instructions to its subordinate bodies to strictly implement the recommendations of the independent committee assigned to monitor and investigate the incident. As the incident was not caused by the vaccine, the present writ petition ought to be dismissed.

Decision of the Court

Upon perusal of the writ petition, the rejoinder, the written arguments, and upon hearing the submissions of the learned Joint Government Attorney, it is for this Bench to decide and resolve the following questions:

1. What is the nature of the right to health, and what obligations do the State bear to guarantee this right to its citizens?
 2. What measures and precautions must the State adopt when conducting any vaccination program or distributing medicines, and whether such precautions were observed in the vaccine distribution program carried out by the State in the Far-Western region.?
 3. Whether an order as prayed by the petitioner should be issued?
2. Upon consideration of the matter, it appears that the respondents conducted a vaccination program against measles in the Far-Western region. The petitioner contends that as a result of this vaccine, children lost their lives, and therefore, the petitioner seeks an order of certiorari including mandamus directing that - the said vaccination program be immediately halted; any future vaccination programs be conducted only after thorough study of the vaccines and careful preparation to prevent any potential adverse consequences; all citizens' right to life be ensured, with particular regard to the rights of children to life and health; and adequate compensation be provided to the parents or guardians of the deceased children, as well as free treatment and appropriate compensation for any inconvenience suffered by other affected children.
 3. The petitioner contends that although the administration of the measles vaccine is not inherently objectionable, the respondents failed to study the potential positive and negative effects of the vaccine prior to its administration, and did not make any prior arrangements for managing possible adverse outcomes. As a result, the petitioner alleges that children lost their lives due to the vaccine. Furthermore, the petitioner has stated in the petition that, in the past, the respondents, the Government of Nepal and the Ministry of Health and Population have been reported to have conducted trials of various medicines in a manner that compromised public health. Thus, the present writ petition raises a serious question as to whether the State, by distributing medicines and vaccines without proper prior planning and preparation for testing, has caused the death of citizens, thereby infringing upon their right to life and right to health.

4. With regard to the first question, what is the nature of the right to health and what obligations does the State have to guarantee this right to its citizens? It is well settled that the right to health is a fundamental human right. In the context of Nepal, the Constitution recognizes the right to health as a fundamental right. At the time the present writ petition was filed, Article 16 (2) of the Interim Constitution of Nepal, 2063, provided that every citizen shall have the right to receive basic health services free of cost as provided by law. Under the current Constitution of Nepal, this provision has been further elaborated wherein Article 35 provides the following:
 35. Right relating to health: (1) Every citizen shall have the right to free basic health services from the State, and no one shall be deprived of emergency health services.
 - (2) Every person shall have the right to get information about his or her medical treatment.
 - (3) Every citizen shall have equal access to health services.
 - (4) Every citizen shall have the right of access to clean drinking water and sanitation.
5. The right to health has been recognized as a fundamental human right in various international instruments. Although the Universal Declaration of Human Rights, 1948, does not specifically provide a separate provision on the right to health, Article 25 (1) guarantees that every person has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, medical care, and necessary social services. Similarly, the International Covenant on Economic, Social and Cultural Rights, 1966, provides more detailed provisions regarding this right. Article 12 (1) of the Covenant recognizes that the States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Further, the Convention on the Rights of the Child, 1989, in Article 24, specifically addresses the right to health of children. It obligates the States Parties to recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. The Convention further mandates that States Parties shall strive to ensure that no child is deprived of right of access to such health care.
6. Thus, the right to health of citizens is recognized as a fundamental human right under various international instruments, as well as under the Constitution of Nepal, including the Interim Constitution of Nepal, 2063, which was in force at the time the present writ petition was filed.
7. With regard to the types of rights encompassed within the right to health, it is necessary to understand both health-related freedoms and health-related entitlements. In this context, the United Nations Committee on Economic, Social and Cultural Rights, in its General Comment No. 14, has explained that the right to health encompasses both health-related freedom and health-related entitlements. Health-related freedom includes, inter alia, sexual and reproductive freedom, freedom from medical testing or treatment without consent, and the right to control one's own body and health. Health-related entitlements, on the other hand, refer to the availability of a health protection system that provides all individuals equally with the opportunity to enjoy the highest attainable standard of health. In sum, the right to health guarantees citizens an environment in which they can achieve the highest possible level of health, and it is the obligation of the State to

ensure the realization of this right. While the Constitution and various international instruments recognize the right to health as a human right, the State bears the obligation to implement this right and ensure its realization for citizens. With respect to health-related freedoms, the State's duty of non-interference may suffice. However, health-related entitlements are positive rights, which require the State to take specific actions. In other words, the effective realization of such health-related rights necessitates affirmative measures by the State.

8. The provision of the right to health to citizens entails a corresponding duty on the part of the State to ensure its realization. The State must take all appropriate measures to progressively implement this right, making the maximum use of available resources to provide quality health services. In its General Comment No. 14, the United Nations Committee on Economic, Social and Cultural Rights, while interpreting the right to health under Article 12, has identified four essential dimensions for the effective enjoyment of this right, similar to the enjoyment of other rights. These are firstly functioning public health and healthcare facilities, goods, services, and programs must be available in sufficient quantity; secondly health facilities, goods, and services must be accessible to all without discrimination; thirdly health facilities, goods, and services must be respectful of medical ethics and culturally appropriate; and fourthly health facilities, goods, and services must be scientifically and medically appropriate and of good quality.
9. In examining the obligations of the State to implement the right to health, it is apparent that the steps the State must take to ensure this right cannot be exhaustively enumerated in a limited manner. The measures required may vary depending on the country's social, economic, and cultural conditions, as well as the awareness and needs of its citizens. Nevertheless, the State bears certain core obligations, which include: ensuring that health services and facilities are made available to citizens; guaranteeing equal access to such services and facilities without any form of discrimination; and ensuring that the services and facilities provided are culturally acceptable, medically appropriate, and of good quality. The State is duty-bound to take measures in accordance with these obligations. The right to health falls within the ambit of economic, social, and cultural rights. In order to realize these rights, the State is required to progressively utilize the maximum available resources and adopt necessary measures for their gradual fulfillment. However, rights that are linked to the basic necessities of human life such as food, housing, basic education, and health constitute the State's *core minimum obligations*. Accordingly, in respect of these rights, factors such as the country's economic condition or the availability of resources are not relevant, and the State is required to take immediate steps to ensure their effective implementation.
10. In the present writ petition, the primary issue raised by the petitioner pertains to the allegation that the State, while conducting the measles vaccination program in the Far-Western region, distributed medicines and vaccines without proper testing and due care, resulting in the death of children. Accordingly, the second question for consideration is: what measures and precautions must the State adopt when conducting any vaccination program or distributing medicines, and whether such precautions were observed in the vaccine distribution program carried out by the State in the Far-Western region.
11. As noted in the foregoing paragraphs, it is not sufficient for the State merely to make available medicines, vaccines, or other health services, and such provision alone cannot be considered as guaranteeing the citizens' right to health. Equally important is the question of the quality of the services provided by the State, and whether such services are capable of addressing the health-

related problems of the targeted population. If receiving quality health services is a right of the citizens, then ensuring the availability of such quality services constitutes a duty of the State. In this context, it is pertinent to note that Section 6 (1) (a) of the Consumer Protection Act, 2054, provides that, for the purpose of safeguarding the rights and interests of consumers, every consumer shall have the right to be protected from the sale or distribution of goods and services that may cause harm to life, health, or property. Furthermore, Section 8 (2) of the same Act obliges the Government of Nepal to make necessary arrangements for the effective implementation of measures relating to the protection of consumer rights and interests, regulation of supply, and control of the price and quality of goods and services. The act of providing vaccines and medical treatment to a patient falls within the definition of “service” for the purposes of the Consumer Protection Act. Accordingly, the State bears the obligation to ensure that the goods and services provided to consumers meet the required standards of quality. The State must treat health services which are directly linked to the right to life of humans with due sensitivity and exercise adequate care in their provision. Similarly, medical practitioners involved in treatment must exercise due diligence when distributing medicines and vaccines or employing other methods of treatment. Effective treatment requires that the correct medicine be administered in the correct dosage, by the correct method, within the correct time frame, and at the correct cost.

12. Traditionally, the relationship between a patient and a medical practitioner was governed by the principle of the Professional Standard of Care. Since the 1960s, however, this relationship has increasingly been guided by the Informed Consent Theory. Under this principle, a medical practitioner is required to provide the patient with information regarding the nature of the illness, available treatment options, and the risks associated with undergoing or foregoing treatment, and may proceed with treatment only after obtaining the patient’s informed consent. According to this modern understanding, the medical practitioner bears greater responsibility toward the patient and must provide treatment with full care, diligence, and prudence. Failure to do so, resulting in harm to the patient, entails liability on the part of the treating practitioner and other healthcare personnel involved. The use of substandard or expired medicines, vaccines, and other medical materials can lead to serious health complications. Therefore, the State bears the responsibility to ensure that such materials are of proper quality, scientifically appropriate, and to take measures to minimize accidents or risks when distributing them. The provision of vaccines and medicines by the State is not a mere formality. It constitutes a fundamental obligation of the State to address the health-related problems of its citizens and to guarantee their right to health. Accordingly, the State must undertake adequate preparatory measures to assess the quality and safety of medicines and vaccines, ensuring that they do not cause any adverse effects to the citizens. Moreover, the State must remain vigilant and prepared to take necessary remedial measures in the event of any harm or negative impact resulting from such provision. In a developing country like ours, where a large portion of the population is uneducated and lacks even basic knowledge regarding the types of medicines and vaccines being used, the State’s obligation to test and ensure the quality of the health services it provides is correspondingly greater. In this regard, while interpreting the right to health in its General Comment No. 14, the United Nations Committee on Economic, Social and Cultural Rights has emphasized the importance of the quality of health facilities, and in Paragraph 12 underlines the following: 12(d) Quality- As well as being culturally accepted, health facilities, goods and services must be scientifically and medically appropriate and of good quality. This

requires inter alia skilled personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

13. Thus, the Committee has emphasized that the services and facilities provided by the State must be scientifically and medically appropriate and of good quality. To achieve this, it is necessary to have skilled personnel, scientifically validated medicines and equipment that have not expired, and adequate sanitation and hygiene.
14. Thus, it is evident that the State bears the obligation to ensure that the health services and facilities provided to citizens are appropriate and of proper quality. In considering whether such precautions were observed in the vaccine distribution program conducted in the Far-Western region, the present writ petition reflects the petitioner's allegation that the State, while conducting the vaccination program, did not undertake a thorough study of the vaccine or take any measures to prevent potential adverse effects, which allegedly resulted in the death of children. Upon perusal of the rejoinder submitted by the respondents, it appears that, to ensure that no one was left out, five vaccination centers were established in each V.D.C. to conduct the vaccination program. The deceased children, however, were reportedly from the Sanagaun area under the Kadamandu V.D.C. Health Post. On 2069/5/3, the Health Post administered vaccines to a total of 19 children in Kadamandu V.D.C., of whom six received the measles vaccine resulting in the death of four children. The deceased include: Milan Nepali, aged 12, residing in Ward No. 6 of Kadamandu V.D.C., who was vaccinated on 2069/5/3 and died on 2069/5/4; Sujata Nepali, an 8-month-old girl residing in Ward No. 7 of the same V.D.C. vaccinated on 2069/5/3 and died on 2069/5/4; Gauri Chiral, a 19-month-old girl residing in Ward No. 7 of the same V.D.C. vaccinated on 2069/5/3 and died on 2069/5/4; and Anju B.K., a 9-month-old girl originally from Pokhari V.D.C. Ward No. 9, residing at Kathmandu V.D.C. at her uncle's house was vaccinated on 2069/5/3 and died on 2069/5/4.
15. Although the petitioner in the writ petition has alleged that a child had died due to vaccination in Ganeshpur V.D.C. of Dadeldhura District, the details of the deceased child have not been disclosed. The respondents, in their written statement submitted by the District Public Health Office, Dadeldhura, have asserted that no death in the district was caused by the vaccine. Thus, while four children reportedly died in Kadamandu V.D.C. of Doti District following vaccination, an independent committee was constituted to monitor and investigate the incident. According to the report submitted by the committee, the deaths of the children were not attributable to the vaccine but were caused by Toxic Shock Syndrome, which may have resulted locally from **contamination of the vaccine vial**. It has further been stated that the contamination of the vial could have occurred due to human error during the course of service delivery, despite the health workers exercising caution, or as a result of local environmental contamination or deficiencies in sanitation. However, as the vial had already been used and subsequently destroyed, it could not be subjected to further laboratory examination. Thus, from the rejoinder submitted by the respondents, it appears that, according to the report of the independent commission constituted by the Government to monitor and investigate the incident, the Government has acknowledged that errors occurred in the course of vaccine distribution. Although it has been contended that the deaths of the children were not caused by the vaccine itself but resulted from local contamination of the vaccine vial, it is evident that such contamination occurred due to the failure to observe the

necessary precautions required when reusing the remaining medicine after administering vaccines to children. Furthermore, the respondents' rejoinder does not disclose what measures were adopted to ensure the safe and quality preservation of the vaccine, including whether skilled personnel and trained experts were deployed, or what technologies were used to maintain vaccine safety during distribution. Thus, it appears that the Government failed to adopt the necessary scientific measures required to safely preserve vaccines and medicines through the deployment of skilled human resources. It is further evident that the deaths of the children occurred the very next day following the use of such contaminated vials. The loss of four innocent children due to the State's failure to exercise the required level of caution in the distribution of vaccines is deeply tragic, and this court has taken the incident with utmost seriousness. Although the respondents have stated that the contamination of the vaccine vial may have resulted from human error or local environmental contamination, regardless of the cause of such contamination, the responsibility therefor rests with the State. The State must not only ensure that the vaccines, medicines, and related materials it distributes are correct and of proper quality, but must also maintain their safety throughout the entire distribution process. Likewise, the responsibility to arrange trained personnel and scientific equipment for the distribution of such vaccines rests with the State itself. The State cannot absolve itself from liability by attributing the death of children to human error or environmental contamination that led to the vaccine being tainted. The mere assertion that a vaccine was contaminated due to some reason does not exempt the State from responsibility for the adverse effects caused by the vaccine it has distributed.

16. Upon examination of the records annexed to the present writ petition, it appears that the parents and guardians of the deceased children, Shanta Bahadur Nepali, Gagan Nepali, Jundevi B.K., and Raghunath Chiral submitted an application on 2069/05/19 to the District Administration Office, Doti, seeking compensation. The said office forwarded the application to the District Health Office, Doti, for necessary action. Thereafter, the District Health Office, Doti, noting that it was appropriate to provide compensation to the families of the deceased, forwarded the file with a recommendation regarding compensation to the Far-Western Regional Health Directorate on 2069/05/24 for further necessary action. From the contents of the said correspondence, it is evident that the State has itself acknowledged its obligation to provide compensation to the families of the deceased. However, the records do not disclose whether the families of the deceased have received any compensation to date, nor have the respondents stated in their rejoinder that compensation has already been paid. In such circumstances, where official correspondence from a State authority has already recognized that compensation ought to be provided, the failure to initiate or advance any compensation process to date cannot be regarded as justifiable.

17. Now, with regard to the third question as to whether or not an order as prayed for by the petitioner should be issued? Upon consideration of the reasons and grounds discussed above, it is found that the State failed to conduct a thorough study of the vaccines it distributed or to adopt measures to prevent possible adverse consequences. As a result, the deaths of children occurred, thereby constituting a violation of the rights guaranteed under Articles 12, 16, and 22 of the Interim Constitution of Nepal, 2063. From the rejoinder of the District Public Health Office, it is evident that due to negligent administration of vaccines, minors Milan Nepali, Sujata Nepali, Gauri Chiral, and Anju B.K. of Doti District fell ill within a few hours of vaccination and died the following day. Thus, it is established that the loss of innocent children's lives resulted from the negligence and irresponsible conduct of State authorities, amounting to an infringement of constitutionally guaranteed rights. Therefore, an order of mandamus is hereby issued in the names of the

respondents wherein it is ordered that compensation in the amount of Nepalese Rupees Ten Lakh (one million rupees) each be provided to the parents or guardians of the deceased children through the District Administration Office, Doti within three months. It is further ordered that other children who fell ill as a result of the use of the contaminated vial be provided with free medical treatment and appropriate compensation for the suffering and hardship endured by them. Further, in order to prevent recurrence of such incidents, directive orders are also issued in the name of the respondents, requiring that future distribution and administration of vaccines and medicines be carried out in accordance with the directions set forth below.

- Prior to the distribution of vaccines and medicines relating to public health, ensure that testing is conducted at every stage, from procurement to distribution and that such vaccines and medicines are distributed only after being verified as correct and of proper quality in accordance with international standards. The distribution process shall proceed only after making appropriate arrangements for necessary equipment and qualified human resources to ensure safe handling and delivery;
- While conducting vaccination programs, undertake comprehensive prior preparations to prevent any potential adverse effects arising from the use of vaccines. Vaccines and medicines shall be administered and distributed only after providing adequate information to the intended recipients and obtaining their informed consent for such use;
- Establish an effective monitoring mechanism to ensure that vaccine and medicine distribution programs are being conducted in a proper manner and that no form of contamination has occurred. In the event that any harm is caused to citizens as a result of the use of vaccines or medicines, make immediate arrangements for free medical treatment and ensure the provision of appropriate compensation in accordance with law.

18. For the purpose of monitoring the implementation of this order, a copy of this judgment shall be forwarded to the Judgment Execution Directorate. The respondents shall be duly notified of this order, and is it hereby ordered to remove the writ petition from the case registry and accordingly submit the case file to the Record Section.

Consenting with the above Opinion

Justice Dr. Anand Mohan Bhattarai

Bench Officer: Sandesh Shrestha, Durga Prasad Bhattarai

Dated: Year 2075 of the Month of Asadh Date 14 Day 5

(Corresponding to Year 2018 of the Month of June Date 28 Day 5)