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Analysis of the Legal Liability of Hospitals and Medical Device Vendors for Medical Device Failures that Result in Rejection of Health Insurance Claims to Patients

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Abstract: Advances in healthcare technology have significantly improved the quality of medical services through the increasing use of sophisticated medical devices. However, medical device failures may cause substantial harm to patients, including the rejection of health insurance claims, thereby creating complex legal issues regarding the allocation of liability among hospitals, medical device vendors, and health insurance companies. This study aims to analyze the legal responsibilities of hospitals and medical device vendors for medical device failures that result in patient losses and the rejection of health insurance claims under the Indonesian health law framework. It also seeks to formulate an ideal legal framework for the allocation of responsibilities among the relevant parties to ensure fair legal protection for patients. This research employs a normative legal research method using statutory, conceptual, and analytical approaches. Legal materials were collected through library research, including legislation, legal literature, and scholarly journals, and were analyzed qualitatively using a descriptive-analytical method. The findings indicate that hospitals bear legal responsibility under the doctrine of corporate liability to ensure the safety, quality, and proper management of medical devices used in healthcare services. Medical device vendors are liable under the principle of product liability for product defects, technical failures, and negligence in maintenance and after-sales services. Meanwhile, health insurance companies are obligated to process and settle claims in accordance with the principle of utmost good faith and may not reject claims arbitrarily without conducting an objective investigation into the cause of the loss. This study concludes that Indonesia requires a more comprehensive legal framework governing the allocation of responsibilities through an integrated investigation mechanism that promotes legal certainty, justice, accountability, and effective legal protection for patients as the most vulnerable parties in healthcare services.

Keywords: Legal Liability, Hospitals, Medical Device Vendors, Product Liability, Corporate Liability, Health Insurance.

INTRODUCTION

A hospital is a healthcare institution that provides comprehensive medical services through the support of healthcare personnel, facilities, infrastructure, and medical equipment.

Advances in medical technology have driven the use of increasingly sophisticated medical devices in diagnosis, medical procedures, therapy, rehabilitation, and patient monitoring. The availability of medical devices has become an integral part of modern healthcare, as their proper function significantly determines the quality of care, patient safety, and the success of medical procedures. The use of high-tech medical devices also increases legal risks if the device malfunctions. Damage to medical devices can occur due to manufacturing defects, design errors, installation failures, negligent maintenance, delayed calibration, software glitches, or the use of substandard components.

These malfunctions have the potential to lead to misdiagnosis, delayed medical treatment, failed therapy, patient injury, and even death. These risks not only impact the medical aspects but also have legal consequences for all parties involved in the provision of healthcare servicesLaw Number 17 of 2023 concerning Health requires every healthcare facility to guarantee the quality, safety, and security of healthcare services by meeting service standards, facility standards, and the use of medical devices that meet requirements. This obligation demonstrates that hospitals have a legal responsibility to ensure that all medical devices are in functional condition before being used on patients. The implementation of this obligation is inseparable from the legal relationship between the hospital and the medical device vendor, as the party that supplies, installs, maintains, calibrates, and repairs medical devices under a cooperation agreement.

The legal relationship between hospitals and vendors often becomes problematic when medical devices malfunction during use in medical services. Hospitals generally believe that equipment failure is the vendor's responsibility because it relates to product quality or maintenance services. Vendors may argue that the damage occurred due to improper use of the equipment or the hospital's negligence in daily operation and maintenance. This difference makes determining who is responsible challenging, particularly when the malfunctioning medical device has resulted in harm to the patient.

The problem becomes more complex when health insurance companies refuse to pay for medical services related to the use of malfunctioning medical devices. Claim denials can be based on policy provisions, medical audit results, or investigations that indicate the service does not meet coverage requirements. This situation has financial consequences for patients, as healthcare costs that should be covered by the insurance company are ultimately passed on to them. Patients are at the greatest disadvantage, even though they have no control over the procurement, maintenance, or operation of the medical devices used by the hospital.

Indonesian laws and regulations govern hospital responsibilities, consumer protection, civil relations, healthcare service delivery, and insurance business activities. These regulations are still sector-specific and therefore do not clearly define the division of responsibility between hospitals, medical device vendors, and health insurance companies if a medical device malfunction results in harm to a patient. This situation has the potential to create legal uncertainty in dispute resolution, as each party can disclaim responsibility based on arguments based on different contractual relationships.

This issue highlights the need to examine the limits of each party's legal liability based on the principles of hospital liability, product liability, contract law, consumer protection, and insurance law. This study is crucial for providing legal certainty regarding which party is obligated to cover patient losses resulting from medical device failure and for formulating a division of responsibility that reflects fairness, legal certainty, and utility in the provision of healthcare services.

METHODS

This study employs a normative legal research method to examine the legal framework governing the responsibilities of hospitals, medical device vendors, and health insurance companies for medical device failures that result in patient losses and the rejection

of health insurance claims. Normative legal research was selected because the study focuses on analyzing legal norms, principles, doctrines, and statutory regulations relevant to healthcare services and legal liability.

The research adopts three approaches. The statutory approach is used to examine relevant Indonesian legislation, including the 1945 Constitution of the Republic of Indonesia, Law Number 17 of 2023 concerning Health, Law Number 8 of 1999 concerning Consumer Protection, the Indonesian Civil Code, and Government Regulation Number 28 of 2024 concerning the Implementing Regulation of Law Number 17 of 2023 on Health. The conceptual approach is applied to analyze legal doctrines and theories, including the theories of legal liability, legal protection, product liability, corporate liability, and the principle of utmost good faith in insurance law. Furthermore, the analytical approach is employed to evaluate the application of these legal principles in determining the allocation of liability among hospitals, medical device vendors, and health insurance companies.

The legal materials consist of primary legal materials, including statutory regulations; secondary legal materials, comprising books, scholarly journals, legal commentaries, and previous studies; and tertiary legal materials, such as legal dictionaries and encyclopedias. These legal materials were collected through library research and analyzed qualitatively using a descriptive-analytical method. The analysis involved identifying, interpreting, and systematically evaluating legal norms and doctrines to formulate legal arguments regarding the allocation of responsibilities among the relevant parties and to propose an ideal legal framework that ensures legal certainty, justice, accountability, and effective legal protection for patients.

RESULTS AND DISCUSSION

Legal Responsibility of Hospitals and Medical Device Vendors for Medical Device Failure that Result in Losses to Patients and Refusal of Payment of Service Fees by Health Insurance Companies Based on Health Law in Indonesia

Hospitals are healthcare providers responsible for providing safe, high-quality, effective, and patient-safety-oriented services. This obligation is realized not only through the availability of competent healthcare personnel, but also through the provision of facilities, infrastructure, and medical equipment that meet safety, quality, and functional standards. The use of medical devices has become an integral part of modern healthcare because almost all diagnostic, therapeutic, rehabilitative, and invasive procedures depend on the proper functioning of medical devices. Medical device malfunction has the potential to cause physical, economic, and psychological harm to patients, thus giving rise to legal consequences for all parties involved in the provision of healthcare.

Law Number 17 of 2023 concerning Health requires every healthcare facility to meet quality, safety, and security standards in the provision of healthcare services. This obligation includes providing medical devices that meet technical requirements, have a distribution permit, undergo regular calibration, are maintained according to manufacturer standards, and are operated by competent personnel. Hospitals cannot abdicate their responsibility on the grounds that medical devices are vendor-owned products because the legal relationship between hospitals and patients is a healthcare relationship, placing the hospital as the party responsible for ensuring the quality of care.

A civil law perspective shows that the relationship between a hospital and a patient arises from an obligation stemming from a healthcare service agreement. Patients come with the expectation of receiving services that meet professional, service, and safety standards. Hospitals are obligated to provide services in accordance with these provisions. Failure of a medical device that results in patient harm can be classified as a form of breach of contract if the hospital fails to fulfill its contractual obligations. This situation can also be categorized as an unlawful act as regulated in Article 1365 of the Civil Code if there are elements of an

unlawful act, error, loss, and a causal relationship between the failure of the medical device and the harm experienced by the patient.

Hospital responsibility is developed through the doctrine of corporate liability, which places hospitals as legal entities responsible for the overall provision of healthcare services. This doctrine requires hospitals to oversee the entire service system, including procurement, use, maintenance, calibration, periodic inspections, and replacement of medical equipment that has passed its useful life. Negligence in fulfilling these obligations constitutes corporate negligence, which can result in legal liability even if the medical procedures are performed by healthcare professionals who meet professional standards.

The principle of patient safety also strengthens hospital accountability. Patient safety is influenced not only by the competence of healthcare workers but also by the quality of the service system the hospital has established. A hospital risk management system must be able to identify potential medical device failures through preventative maintenance, routine inspections, periodic calibration, incident reporting, and evaluation of the equipment's economic lifespan. Failure to establish such a system indicates a management failure, which forms the basis for hospital accountability.

The legal relationship between hospitals and medical device vendors is established through procurement agreements and after-sales service agreements. Vendors are obligated to deliver medical devices that meet technical specifications, possess distribution permits, meet safety standards, and provide installation, user training, maintenance, calibration, spare parts, and repair services during and after the warranty period, as stipulated in the contract. These obligations do not cease upon delivery of the medical device to the hospital, as the characteristics of medical devices require ongoing monitoring to ensure they maintain safety standards.

Failure of medical devices resulting from manufacturing defects, design defects, software system failures, the use of substandard materials, or installation errors constitutes vendor liability based on the principle of product liability. This principle was developed to protect product users against risks posed by marketed goods. Vendors, as business actors, are obliged to ensure that the medical devices they produce or market are safe for their intended use. Violation of this obligation can result in civil liability in the form of an obligation to compensate for losses suffered by patients and hospitals.

Law Number 8 of 1999 concerning Consumer Protection provides the legal basis for holding business actors responsible for losses arising from the goods they produce or trade. Medical device vendors, as business actors, are required to provide compensation, restitution, or replacement if the medical devices they market do not meet quality standards or contain defects that cause harm to consumers. This provision broadens the scope of legal protection because patients are not always bound by a direct contractual relationship with the vendor but can still obtain protection under the consumer protection regime.

Determining the responsible party cannot be done simply because the causes of medical device failure are very diverse. Damage arising from hospital negligence in maintenance, late calibration, use of equipment that has passed its useful life, or operation that does not meet standards is the responsibility of the hospital. Damage originating from manufacturing defects, design defects, installation errors, or system failures that are the responsibility of the vendor must be charged to the vendor. Certain circumstances allow for shared liability if patient losses occur due to a combination of hospital and vendor errors. The division of responsibility must be based on proof of the causal relationship, the level of fault of each party, the contents of the cooperation contract, and the results of a technical inspection of the medical device.

Legal issues arise when health insurance companies refuse to pay for medical services due to medical device failure. This refusal may be based on policy provisions that exclude losses resulting from negligence by healthcare providers, the use of substandard equipment, or improper care. Claim denials often result in patients being required to pay for healthcare

services that actually arose from the failure of the hospital's service system. This situation creates an imbalance in legal protection, as patients are left to bear the consequences of events beyond their control.

The legal relationship between insurance companies and participants is based on the principles of utmost good faith, indemnity, and fair claim settlement. Claim rejections must be based on objective, demonstrable reasons, and in accordance with policy provisions. Rejections made without a clear legal basis have the potential to violate the principle of good faith in the implementation of the agreement. Hospitals also cannot immediately charge patients all costs if the primary cause of additional costs stems from the failure of medical equipment for which the hospital or vendor is responsible. A fairer settlement places the patient as the party who must be protected first, while the settlement regarding the distribution of financial responsibility is carried out between the hospital, vendor, and insurance company based on the results of the evidence.

A health law perspective places patient protection as the primary objective of healthcare delivery. Hospitals, medical device vendors, and insurance companies have distinct but interrelated legal obligations to ensure safe healthcare. A clear division of responsibilities will provide legal certainty, increase healthcare provider accountability, encourage vendor compliance with medical device quality standards, and strengthen public trust in the national healthcare system. A collaborative, risk-management-based liability model is more appropriate than unilaterally assigning responsibility to patients, as patients are the weakest party in the legal relationship and have no control over the quality of the medical device or the contractual relationship between hospitals, vendors, and insurance companies.

Hospital accountability is measured not only by fulfilling administrative obligations such as operating permits or accreditation, but also by the hospital's ability to implement medical device governance that meets patient safety principles. This governance includes planning medical device needs, a transparent procurement process, verification of suitability before use, preventative maintenance, periodic calibration, documentation of repair history, and monitoring of the medical device's lifespan. Failure to establish such a system indicates a weakness in risk management that could form the basis for hospital liability if damaged medical devices result in harm to patients. This responsibility is a consequence of the hospital's position as a healthcare provider that is obligated to guarantee comprehensive service quality.

Medical device vendors also have a legal obligation to implement a quality assurance system and post -market surveillance for every medical device they market. This obligation does not stop the delivery of goods to hospitals but includes monitoring the performance of medical devices during use, providing information regarding potential risks of use, implementing corrective actions if product defects are found, and product recalls if there are indications that the medical device may endanger patient safety. Neglect of these obligations indicates a violation of the principle of caution (duty of care), which is an important basis for determining the vendor's legal liability.

Health insurance companies have a distinct legal standing because their legal relationship arises from an insurance agreement with the insured or a partnership with a hospital. The implementation of the rights and obligations of the parties must be based on the principles of good faith, transparency, and balance. Claim denials based on medical device failure require careful analysis to ensure that the reasons for denial are fully in line with the policy provisions and do not violate the insured's rights as a consumer of financial services. Investigations into the cause of the loss must be conducted objectively through technical and medical audits so that claim denial decisions are not based solely on the insurance company's financial interests.

Legal protection for patients must be a priority in resolving disputes arising from medical device failure. Patients have no contractual relationship with medical device vendors and do not have the authority to determine the type of medical device used in medical services. This position places patients as the most vulnerable party to bear the consequences of healthcare

system failures. Charging patients for services without first resolving the issue of responsibility between hospitals, vendors, and insurance companies contradicts the principles of justice, legal certainty, and the goal of healthcare delivery, which is to protect patient rights.

Proportional sharing of responsibility requires a proof mechanism capable of identifying the root cause of medical device failure. Reviewing maintenance history, calibration results, device technical specifications, incident investigation reports, the contents of the agreement between the hospital and the vendor, and the terms of the insurance policy are important instruments in determining the responsible party. This approach reflects the principles of accountability and fairness, as each party bears responsibility commensurate with the degree of fault and legal obligations. This model of sharing responsibility provides more effective protection for patients while simultaneously promoting improved healthcare governance in Indonesia.

Ideal Arrangement Regarding the Division of Responsibilities between Hospitals, Medical Device Vendors, and Health Insurance Companies in Providing Fair Legal Protection for Patients Due to Medical Device Failure

Advances in healthcare technology have transformed the delivery of healthcare services into a system that relies heavily on the reliability of medical devices. Legal relationships in healthcare delivery no longer involve only hospitals and patients, but also medical device vendors, distributors, manufacturers, maintenance companies, and health insurance companies. The involvement of these various legal entities creates a complex legal relationship, making it impossible to resolve disputes resulting from medical device failure through a single-responsibility approach. Proportional division of responsibility is essential to ensure legal certainty, patient protection, and the accountability of each party in accordance with their respective authorities and obligations.

Indonesian legal regulations still regulate the responsibilities of each party separately through various laws and regulations. Law No. 17 of 2023 concerning Health regulates the provision of health services and the obligations of health care facilities. Law No. 8 of 1999 concerning Consumer Protection regulates the responsibilities of business actors for marketed products. The Civil Code regulates contractual relationships and torts. Provisions regarding insurance companies are regulated within the insurance legal regime. These sectoral regulations do not yet provide a mechanism specifically governing the division of responsibility if the failure of a medical device results in harm to the patient and gives rise to disputes regarding payment of health care costs.

This situation creates legal uncertainty because each party tends to base its defense on different legal relationships. Hospitals may argue that losses occurred due to product defects for which the vendor is responsible. Vendors may claim that equipment damage resulted from use that did not comply with operational standards or negligence in maintenance by the hospital. Insurance companies may refuse to pay claims on the grounds that the service did not meet policy requirements or fell within coverage exclusions. Patients ultimately find themselves at a disadvantage, facing a complex process of proof involving multiple parties, even though they have no control over the procurement, maintenance, or operation of medical devices.

Equitable legal protection must place patients as the primary subject in the healthcare system. Patients' positions differ from those of hospitals, vendors, and insurance companies because they are in a vulnerable position when it comes to obtaining information, controlling the quality of medical devices, and determining cooperation mechanisms between healthcare providers. The principle of protecting vulnerable parties is part of the legal objective of achieving substantive justice. Losses suffered by patients due to medical device failure should not be borne by the patient until the party is determined based on the results of technical and legal investigations.

An ideal arrangement should be based on the principle of dividing responsibility based on the source of the loss. Hospitals are responsible for all aspects of healthcare governance, including the procurement of medical devices, periodic maintenance, calibration, technical inspections, training of healthcare workers, and oversight of the use of medical devices in accordance with standard operating procedures. Failure to fulfill these obligations constitutes institutional negligence (corporate negligence), which makes the hospital liable to compensate the patient.

Medical device vendors are responsible for the quality, safety, and suitability of the products they market. This responsibility includes manufacturing defects, design defects, installation errors, software failures, the use of substandard components, and failure to provide contracted maintenance services. The principle of product liability requires the vendor to bear responsibility for any losses arising from unsafe products, even if the contractual relationship is directly with the hospital. This arrangement provides more effective protection for patients because the burden of proof regarding product defects does not fall entirely on the patient as the end user.

Health insurance companies are obligated to pay claims in accordance with the policy's terms and conditions, based on the principles of good faith, transparency, and fairness. Refusal of claim payment cannot be based solely on the failure of a medical device without conducting an investigation into the cause of the damage and the responsible party. Insurance companies must demonstrate that the reason for the refusal complies with the policy's provisions and does not conflict with the principles of consumer protection in financial services. Unilateral refusals have the potential to create injustice for insurers who have fulfilled their obligation to pay premiums regularly.

The division of responsibility also needs to be supported by an independent investigative mechanism. Every incident of medical device failure must be examined through technical, medical, and legal audits to determine the root cause of the loss. The results of the investigation serve as the basis for determining the proportion of responsibility for each party. This mechanism will reduce the practice of shifting responsibility between hospitals, vendors, and insurance companies and provide legal certainty for patients.

Contractual aspects between hospitals and vendors need to be strengthened through clauses regarding quality assurance, after-sales service guarantees, preventive maintenance obligations, response time to damage, provision of replacement equipment during repairs, and compensation mechanisms if damage to medical equipment results in harm to patients. Cooperation agreements should not only regulate business relationships but should also reflect responsibility for patient safety as the primary goal of healthcare.

Regulations regarding health insurance companies also require updates. Insurance policies must contain clear provisions regarding claims handling related to medical device failure. These provisions should outline investigation procedures, claim settlement deadlines, participants' rights to information, and dispute resolution mechanisms in the event of disagreements regarding the cause of losses. This certainly will enhance legal protection for participants and encourage more accountable insurance business practices.

An ideal legal approach also requires the establishment of a national reporting system for incidents of medical device failure. Such a system would enable the government to monitor medical devices in circulation, identify patterns of failure, evaluate vendor performance, and implement administrative actions, including warnings, suspension of distribution, and even revocation of marketing authorizations if a medical device is found to endanger patient safety. Integrated oversight would improve the quality of healthcare services while strengthening public protection.

Legal reforms must ultimately lead to the creation of regulations that specifically address the division of responsibility between hospitals, medical device vendors, and health insurance companies in any disputes arising from medical device failure. These regulations should

establish indicators for determining responsibility, investigative mechanisms, forms of civil, administrative, and criminal liability, and dispute resolution procedures that prioritize the restoration of patient rights. The presence of comprehensive regulations will reduce the normative vacuum that has led to legal uncertainty and differing interpretations among healthcare providers.

The perspective of justice requires that patients should not be the first to bear the consequences of healthcare system failures. Hospitals, medical device vendors, and insurance companies are legal entities that benefit economically from healthcare delivery, and therefore, all three must bear responsibility according to the source of the error and their legal obligations. Proportional distribution of responsibility not only reflects the principle of justice but also strengthens legal certainty, increases the accountability of healthcare providers, and encourages the creation of a safer, higher-quality healthcare system that is oriented toward protecting patient rights.

CONCLUSIONS

Conclusion

Technological advances in healthcare have improved the quality of medical services while simultaneously creating complex legal relationships between hospitals, medical device vendors, health insurance companies, and patients. Medical device malfunction is no longer viewed as a purely technical issue but has become a legal issue with consequences for patient rights protection, healthcare provider responsibilities, contractual relationships, and healthcare financing systems. This situation demands legal certainty regarding who is responsible for losses arising from medical device malfunctions. A hospital's legal responsibility is based on its obligation as a healthcare provider to ensure safe, high-quality, and patient-safety-oriented services, as stipulated in Law Number 17 of 2023 concerning Health. These obligations include the provision of medical devices that meet standards, regular maintenance and calibration, supervision of medical device use, and the implementation of an effective risk management system. Failure to fulfill these obligations can result in civil, administrative, and even criminal liability if it results in harm to patients. The doctrine of corporate liability positions hospitals as legal entities responsible for the entire healthcare system they provide, including the failure of medical devices resulting from weak internal governance. Medical device vendors have legal responsibilities based on product liability principles and contract law. These responsibilities include providing medical devices that meet quality and safety standards, installing them according to technical specifications, providing maintenance services, calibration, providing spare parts, and guaranteeing the quality of marketed products. Losses arising from manufacturing defects, design defects, software failures, installation errors, or negligence in after-sales service are the responsibility of the vendor in accordance with consumer protection principles and civil law provisions. Determination of vendor liability must be based on proof of a causal relationship between the medical device defect and the harm experienced by the patient. Health insurance companies are obligated to pay claims based on the policy's terms, the principle of good faith, and the protection of insured people. Refusal of payment for healthcare services due to medical device failure must be based on objective and legally justifiable reasons. Refusals made without a clear basis have the potential to reduce legal protection for patients as insured people. Patients should not be the first to bear the brunt of losses due to medical device failure, as they do not have the authority to procure, maintain, or operate medical devices used in medical services. Indonesian legal regulations do not yet provide a comprehensive mechanism for allocating responsibility between hospitals, medical device vendors, and health insurance companies in the event of a medical device failure. The scattered provisions in various laws and regulations create legal uncertainty, the potential for mutual disclaimers, and prolong the dispute resolution process. This situation demonstrates the need for a more integrated regulatory framework that integrates the principles of corporate

liability, product liability, consumer protection, insurance law, and patient safety. A proportional distribution of responsibility based on the source of the error and the level of contribution of each party will provide legal certainty, increase the accountability of healthcare providers, and ensure equitable legal protection for patients.

Suggestion

The government needs to develop regulations that specifically address the division of legal responsibility between hospitals, medical device vendors, and health insurance companies in cases of medical device failure. These regulations should include criteria for determining responsibility, technical and legal investigation mechanisms, dispute resolution procedures, and the forms of accountability that can be imposed on each party. Comprehensive regulations will reduce regulatory gaps and provide legal certainty in resolving disputes in the healthcare sector. The Ministry of Health needs to strengthen its medical device oversight system by improving calibration standards, conducting regular technical audits, ensuring maintenance certification, reporting medical device incidents, and monitoring vendors providing medical devices in Indonesia. An integrated oversight system will improve the quality of medical devices used in medical services and minimize the risk of medical device malfunction. Hospitals need to implement risk-based medical device governance by ensuring that each device undergoes preventive maintenance, regular calibration, service life evaluation, and documentation of usage and repair history. Hospitals also need to strengthen cooperation clauses with vendors by establishing regulations regarding quality assurance, liability for medical device damage, repair response times, provision of replacement devices, and compensation mechanisms if device damage results in patient harm. Medical device vendors need to improve their quality control systems, from production and distribution to installation and after-sales service. Quality assurance and post-market surveillance must be consistently implemented to ensure medical devices continue to meet safety standards during use by healthcare facilities. Vendors must also provide a system for reporting and promptly addressing any suspected medical device malfunctions, demonstrating their professional and legal responsibility for patient safety.

Health insurance companies need to develop claims settlement policies that are more transparent, objective, and oriented toward participant protection. Claim denials must be based on legally accountable investigations and not solely focused on cost efficiency. Dispute resolution mechanisms between hospitals, vendors, and insurance companies should not diminish patients' rights to healthcare or impose losses on patients before there is certainty about who is responsible. It is hoped that future research will utilize not only a normative legal approach but also develop an empirical approach by examining dispute resolution practices resulting from medical device failure in hospitals, court decisions, health insurance claim settlement mechanisms, and practices in various countries. This approach will enrich the development of health law in Indonesia and form the basis for formulating policies that are more responsive to advances in medical technology and the need for legal protection for patients.

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