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Criminal Liability for the Failure to Obtain Informed Consent in Pharmaceutical Malpractices

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ABSTRACT

This study aims to analyze criminal liability for failure to implement informed consent in a case of alleged malpractice related to drug administration, and to examine the application of Article 440 of Law Number 17 of 2023 concerning Health to medical personnel negligence resulting in serious patient injury. The study focuses on Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps, which concerns the administration of a drug injection to a patient with a history of drug allergies and subsequent severe allergic reaction. This study uses a normative juridical method with a statute approach, a case approach, and a conceptual approach. The legal material is analyzed descriptively and qualitatively through a review of laws and regulations, court decisions, and the doctrines of culpa lata, res ipsa loquitur, and ultimum remedium. The results of the study indicate that failure to obtain adequate informed consent, administering medication that is not in accordance with the patient's allergy history, and non-compliance with professional standards and medical record management are important elements in assessing the elements of medical personnel negligence. In the case analyzed, this negligence was associated with the occurrence of serious injuries, thus fulfilling the basis for criminal liability as stipulated in Article 440 paragraph (1) of Law Number 17 of 2023 concerning Health. This study also shows that the application of criminal law in medical disputes needs to be placed as the ultimum remedium, while still considering dispute resolution mechanisms through mediation, restorative justice, and professional disciplinary mechanisms. Thus, criminal liability in cases of medical negligence needs to be placed in a balanced manner between the protection of patient rights and legal protection for medical personnel.

Keywords: Informed Consent, Medical Malpractice, Culpa Lata, Ultimum Remedium, Restorative Justice.

I. Introduction

In the world of healthcare, significant changes have occurred with the enactment of Law Number 17 of 2023 concerning Health through the Omnibus Law mechanism in the medical legal landscape in Indonesia (Bernal-Camargo & Gómez-Córdoba, 2026). One crucial provision governing the criminal aspects of medical personnel and healthcare workers is Article 440 of Law Number 17 of 2023 concerning Health, which regulates criminal penalties for negligence (culpa) that results in serious injury or death to a patient. Enforcement of this provision often conflicts with the doctrine of medical risk inherent in medical practice (Viranda & Zulfiko,

2026). The provisions of Article 440 of Law Number 17 of 2023 concerning Health constitute a material offense that emphasizes the consequences of an act. Textually, this article is divided into two main paragraphs: Paragraph (1): Regulating negligence resulting in serious injury to a patient, and Paragraph (2): Regulating negligence resulting in death. In criminal law doctrine, negligence (*culpa*) in medical practice is classified as gross negligence (*culpa lata*), where a medical professional violates fundamental professional standards (Marrone et al., 2023). In the case of administering contraindicated medication due to a patient's history of allergies, the element of negligence is assessed based on the disregard for the principle of *primum non nocere* (the main thing is not to cause harm) (Pallocci et al., 2023). In this case, determining whether or not there is negligence in Article 440 of Law Number 17 of 2023 concerning Health cannot be separated from three main instruments, namely: the Criminal Law instrument which, based on Article 440 of Law Number 17 of 2023 concerning Health, is the basis for the implementation of criminal sanctions for violations that endanger public safety, in the case of unlicensed health professional practice, illegal drug distribution, or violations of health service standards, to provide a deterrent effect and protect the public from serious threats to health (Lawongsa, 2025).

In this case, there is actually a dimension of administrative legal instruments, as Law Number 17 of 2023 concerning Health also regulates administrative sanctions such as license revocation, administrative fines, or suspension of activities (Marrone et al., 2023). These instruments serve as preventative measures to prevent violations from escalating into criminal acts, including the revocation of the practice licenses of doctors or pharmacies that violate regulations (Nacu et al., 2025). Furthermore, they provide a platform for the public to seek compensation for losses resulting from health violations (Isailă & Hostiu, 2022). Patients harmed by malpractice can sue for compensation, and the restoration of the rights of the injured individual can be pursued through civil law instruments (Miziara & Miziara, 2022). These three principles form a comprehensive health law system, so Article 440 of Law Number 17 of 2023 concerning Health does not stand alone but rather serves as a connecting link between criminal provisions and other legal instruments, as well as a parameter for determining whether medical personnel have acted with due care (duty of care) and as a manifestation of the patient's right to autonomy (La Micela et al., 2026). Failure to disclose the risks of specific drugs can be categorized as a form of administrative negligence with criminal implications (Taufik Muhlisani Ihsan et al., 2024). Based on the provisions of Article 296 of Law Number 17 of 2023 concerning Health, medical records are primary evidence. Data inconsistencies or modifications to medical records without proper procedures can strengthen the case for negligence in the evidentiary process in court (Tronconi et al., 2025).

Although Article 440 of Law Number 17 of 2023 concerning Health stipulates criminal penalties, it provides room for dispute resolution outside of court. As stipulated in Article 443 of Law Number 17 of 2023 concerning Health, disputes arising from medical personnel negligence must be resolved through out-of-court dispute resolution first, including through mediation or restorative justice (Maila et al., 2025). This aims to ensure that imprisonment remains the last resort (*ultimum remedium*) in medical disputes. Although Article 440 of Law Number 17 of 2023 concerning Health regulates the criminal liability of medical personnel or healthcare workers for negligence resulting in serious injury or death to a patient, legal issues remain regarding the limits and parameters for linking failure to inform consent to criminal liability for medical negligence. The provisions regarding negligence do not automatically make every failure to inform consent a criminal offense, as criminal liability still requires proof of a breach of professional obligation, a causal relationship between the act or omission and the patient's outcome, and the fulfillment of the qualifications for consequences as referred to in Article 440. Therefore, the legal issue is not simply whether informed consent was given, but rather how the failure to inform consent is positioned within the framework of proving criminal negligence.

This gap becomes even more significant in Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps. In this case, the patient had previously reported allergies to ibuprofen and aspirin, was subsequently given a drug injection and experienced a severe allergic reaction. The facts of the case also indicate that the informed consent was not accompanied by an adequate explanation of the medications administered. The court further considered the administration of Antrain, the patient's allergy history, the

predictability of the risk, the consequences of a severe allergic reaction, and the issue of medical record documentation in assessing the defendant's negligence. However, a doctrinal analysis is still needed regarding the position of the failure of informed consent within the overall construction of criminal liability. Failure of informed consent can be related to a violation of the patient's right to autonomy and the obligation to provide information, while Article 440 focuses on negligence resulting in serious injury or death. Therefore, it is necessary to distinguish whether the failure of informed consent is an element that directly constitutes a criminal offense, an indicator of a violation of professional standards that strengthens the proof of culpa, or an independent circumstance with distinct legal consequences (Putra et al., 2026). This issue is important because this article discusses not only the existence or absence of procedural violations but also the limits of medical personnel's criminal liability in cases that intersect medical risk, professional negligence, and violations of patient rights.

Furthermore, there are doctrinal issues regarding the application of the principle of ultimum remedium. The text indicates that the Health Law also provides space for dispute resolution through out-of-court mechanisms, including mediation and restorative justice, while the case under review has resulted in criminal liability under Article 440 paragraph (1). Therefore, it remains necessary to analyze how to determine the appropriate boundary between cases that are sufficiently resolved through professional disciplinary mechanisms or other dispute resolution mechanisms and those that are appropriate for criminal prosecution, particularly when there is an allegation of gross negligence resulting in serious injury (Afandy et al., 2026). Based on this gap, this study aims not only to apply Article 440 of Law Number 17 of 2023 to the facts of the case, but also to analyze the legal construction linking failure to inform consent to criminal liability for medical negligence. This study aims to answer two main legal questions: (1) What is the status and relevance of failure to inform consent in proving the element of negligence as referred to in Article 440 paragraph (1) of Law Number 17 of 2023 concerning Health? and (2) what are the limits of criminal liability for medical personnel in this case, considering culpa lata, professional standards.

With this formulation, this research is expected to contribute to the development of health law doctrine by clarifying the relationship between the patient's right to informed consent and the criminal liability of medical personnel. The analysis also aims to demonstrate that not every failure to provide informed consent is a criminal offense in itself, but its relevance to criminal liability must be assessed in conjunction with the violation of professional standards, the form of negligence, the causal relationship, and the resulting consequences for the patient. The medical profession is closely associated with risk (medical risk), but the boundary between acceptable risk and medical negligence is often debated in court. The case involving Dr. Shillea at the Denpasar District Court stemmed from the administration of medication contrary to the patient's allergy history. Under health law, a doctor is obligated to act in accordance with Professional Standards (SP), Service Standards (SPEL), and Standard Operating Procedures (SOP). The issue arises when a doctor is suspected of prescribing an NSAID (Antrain) to a patient who has expressed an allergy to ibuprofen and aspirin. This raises legal questions regarding the fulfillment of the elements of negligence as stipulated in Article 440 of Law No. 17 of 2023 concerning Health.

II. Literature Review and Hypothesis Development

2.1 Informed Consent as a Form of Protection of Patient Autonomy

Indonesian health law literature positions informed consent not merely as an administrative formality prior to medical procedures, but as an instrument to protect the patient's right to determine their own actions. Komalawati explains that informed consent is an essential part of the therapeutic relationship because medical procedures fundamentally concern the patient's personal interests and bodily integrity. This view aligns with the provisions of Law Number 17 of 2023 concerning Health, which explicitly requires that every individual healthcare procedure obtain consent after the patient has received adequate explanation (Tronconi et al., 2025). Regulatory developments demonstrate the strengthening of the substance of this consent. Article 293 of Law Number 17 of 2023 requires that consent be given after the patient has received an explanation of

at least the diagnosis, indications, the procedure and its objectives, risks and complications, alternative procedures and their risks, risks if the procedure is not performed, and the prognosis. Consent can be given in writing or verbally. Thus, the measure of informed consent is not solely determined by the presence of a signature on the form, but also by the availability of substantial information that allows the patient to make an informed decision (Lawongsa, 2025).

In this context, two approaches need to be distinguished. The first approach views informed consent primarily as a form of fulfilling the patient's right to autonomy. The second approach simultaneously positions it as part of the medical professional's obligation to provide safe care. This distinction is important because failure to obtain adequate consent does not necessarily equate to malpractice or criminal conduct. Rather, such failure can be an indicator of a breach of professional obligation if there is a link between the information not provided, the action taken, and the harm the patient subsequently experiences (Amelink et al., 2026). This issue is directly relevant to the case under review. In Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps, the research document states that the patient had disclosed a history of allergies, but the consent regarding the medication administered was not accompanied by an adequate explanation. Therefore, the issue of informed consent in this study does not stop at whether the patient or family signed the document, but rather whether the obligation to provide information relevant to the risks of the medication was fulfilled and whether this failure is relevant to proving negligence (Griffiths, 2026).

2.2 Medical Negligence, Professional Standards, and Culpa Lata

The literature on medical personnel liability distinguishes between the medical risks inherent in healthcare services and professional negligence. Hanafiah and Amir position professional standards and the principle of due care as important parameters for determining whether a medical action falls within the acceptable risk range or deviates from professional obligations. Arief, from a medical criminal law perspective, positions this issue within the framework of criminal wrongdoing, so the relationship between the medical personnel's actions, professional standards, the error, and the consequences must be carefully proven (Amelink et al., 2026). The problem is that the use of the term culpa lata should not automatically equate every error in healthcare. In criminal law, negligence must be analyzed based on the obligations that should have been fulfilled, the degree of deviation from those obligations, the perpetrator's ability to foresee the consequences, and the causal relationship between the negligence and the consequences. Thus, the doctrine of culpa lata is more appropriately used as a framework for testing the degree of deviation from the standard of care rather than as a label that directly proves criminal culpability (Plaiasu et al., 2022).

The development of Indonesian legal research following the enactment of Law No. 17 of 2023 has shown increasing attention to Article 440. Pabidang et al. examined the criminal liability of medical personnel or healthcare workers under Article 440 and linked it to the issue of negligence and the responsibility of healthcare workers and healthcare facilities. Other research on patient protection under Law No. 17 of 2023 also identified medical personnel obligations, breach of duty, causal relationships, and patient harm as important elements in the analysis of medical malpractice (Tronconi et al., 2025). However, these studies generally position Article 440 as the basis for liability for medical negligence in general. There is still room to clarify how failure to obtain informed consent functions in proving culpa, particularly when such failure occurs concurrently with alleged irregularities in the selection or administration of medication. This is where This study uses the Denpasar case as a case study to examine the relationship between the obligation to provide information, the duty of care in administering medication, professional standards, and the consequences of serious injury (Nacu et al., 2025).

2.3 Article 440 of Law No. 17 of 2023 and the Construction of Criminal Liability

Article 440 of Law No. 17 of 2023 provides a specific basis for the criminal liability of medical personnel or health workers for negligence resulting in serious injury or death of a patient. Systematically, this provision

demonstrates that criminal liability is not simply based on medical actions that fail to produce the desired outcome. There must be negligence and consequences that meet the qualifications specified by law. In the case studied, the indictment was based on Article 440 paragraph (1), and the Denpasar District Court found the defendant guilty of negligence resulting in serious injury to the patient (Viranda & Zulfiko, 2026). The literature discussing Article 440 tends to emphasize the elements of negligence, consequences, and the responsibility of medical personnel. Research by Pabidang et al. specifically discusses Article 440 as the basis for criminal liability for medical or healthcare personnel. Research on patient legal protection under Law No. 17 of 2023 also places professional obligations, breach of duty, causal relationships, and losses as important components of the construction of liability (Marrone et al., 2023).

However, there are issues that remain unclear if the analysis focuses solely on the elements of Article 440. Informed consent has a different legal character from the element of serious injury. Consent relates to the patient's rights and obligation to inform, while Article 440 emphasizes negligence that results in specific consequences. Therefore, the doctrinal question that needs to be answered is whether failure to provide informed consent is a direct element of the crime under Article 440, an indicator of a breach of professional standards that helps prove culpa, or a violation of health law with its own consequences. In the case studied, this issue becomes more complex because the court considered not only consent but also the patient's allergy history, the administration of Antrain, the appropriateness of the medication, the predictability of the risk, the results of the medical examination, and irregularities in medical documentation. Thus, this study views Article 440 as a norm that must be read systematically alongside the obligation to provide health care and informed consent, not as a stand-alone provision (Mostafa et al., 2025).

2.4 Medical Malpractice, Patient Safety, and Professional Accountability

Health law literature demonstrates a tension between two interests that both need to be protected: the patient's right to safe care and the accountability of medical personnel, on the one hand, and the protection of medical personnel from criminalization for reasonable medical risks, on the other. The distinction between medical risk and malpractice is important because the outcome of health care services cannot always be guaranteed even if medical personnel act according to standards (Bolino et al., 2023). Within the framework of patient safety, medical personnel's obligations relate not only to the success of the procedure but also to the prevention of identifiable and controllable risks. Therefore, the patient's allergy history, medication selection, provision of information regarding risks, and medical documentation have interrelated functions. In the case studied, the patient had disclosed allergies to Ibuprofen and Aspirin prior to the procedure, and then experienced facial swelling and respiratory distress after administering the medications. A professional accountability perspective helps explain why these issues cannot be analyzed solely through medical cause-and-effect relationships. Accountability requires research to examine whether medical personnel have met professional standards, service standards, operational procedures, and communication obligations with patients. Law No. 17 of 2023 itself places health services within the framework of improving the quality and safety of services, while Government Regulation No. 28 of 2024 provides further implementing regulations regarding the implementation of health efforts, medical and health personnel, health care facilities, and pharmacy (Maila et al., 2025). With this perspective, informed consent is not treated as a separate issue from patient safety. Failure to provide relevant information about drug risks may indicate a failure to fulfill professional obligations, but its relevance to the error and its consequences must still be proven. This perspective allows research to distinguish between three situations: acceptable medical risks, violations of professional standards without grounds for criminal liability, and negligence that meets the elements of criminal liability under.

2.5 Proportional Criminalization and Ultimum Remedium in Medical Disputes

Medical criminal law literature positions the criminalization of medical personnel as an issue that must be analyzed proportionally. The application of criminal law is legitimate when there is an error that meets the elements of a criminal act and the consequences stipulated by law, but the use of criminal law should not eliminate the function of professional, administrative, or civil disciplinary mechanisms (Mostafa et al., 2025). The ultimum remedium perspective is relevant because Law No. 17 of 2023 provides more than just criminal instruments. This research paper also places out-of-court dispute resolution mechanisms and restorative justice as part of the medical dispute resolution framework. Contemporary literature on Law No. 17 of 2023 also shows that the new regime seeks to balance patient protection and the protection of medical personnel through various accountability mechanisms (Maila et al., 2025).

The Supreme Court, in its study of the development of medical malpractice law, also emphasized the importance of informed consent and the patient's right to understand the consequences of medical procedures. At the same time, the Supreme Court established Article 440 as the basis for criminal prosecution for negligence that causes serious injury or death. This perspective demonstrates that patient protection and professional protection do not have to be positioned as mutually exclusive interests. Both can be reconciled by establishing clear boundaries regarding when professional misconduct is sufficiently addressed through disciplinary or dispute resolution mechanisms and when such misconduct meets the basis for criminal liability (Isailă & Hostiuć, 2022). Based on this literature synthesis, this research does not develop empirical hypotheses. As a normative legal study, the theoretical framework is directed at the analytical proposition that: ****Failure to obtain informed consent does not in itself constitute a criminal offense under Article 440, but may be relevant to proving negligence if the failure demonstrates a breach of professional obligation and has a relevant relationship to the patient's outcomes. Criminal liability must then be tested through professional standards, the form of negligence, the causal relationship, the qualifications for serious injury, and the principle of proportional criminalization (Mostafa et al., 2025).**

III. Research Method

Qualitative research, such as case studies, utilizes normative legal research methods (doctrinal research), which position law as a system of norms comprising principles, values, statutory regulations, and court decisions. (Indonesia, 2023). The primary focus of this research is the legal synchronization between field practice and new norms during the transitional period of criminal law. The approach used in this study includes a statutory approach (statute approach), conducted by examining Law No. 1 of 2023 (National Criminal Code) and Law No. 17 of 2023 concerning Health to determine the consistency of regulations regarding medical liability. Meanwhile, the case approach analyzes the details of legal events that occurred in the Badung jurisdiction as a basis for legal material to determine the boundary between medical risk and negligence. The conceptual approach departs from legal views and doctrines developing in health law, particularly regarding the doctrines of *Res Ipsa Loquitur* and *Culpa Lata*. (Ibrahim, 2006). This research uses legal materials consisting of primary legal materials in the form of statutory regulations, in this case Law Number 1 of 2023 (New Criminal Code), as well as judges' decisions from courts in the Badung region.

The legal materials were collected through library research. The collected legal materials were then analyzed descriptively and qualitatively using the deductive method, which draws conclusions from general matters (national legal norms) to specific matters (cases in Badung). This research employs qualitative case studies and normative legal research methods (doctrinal research), which position law as a system of norms comprising principles, values, statutory regulations, and court decisions. The primary focus of this research is the legal synchronization between field practice and new norms during the transitional period of criminal law. The approaches employed in this study include a statutory approach (Statute Approach), conducted by examining Law No. 1 of 2023 (National Criminal Code) and Law No. 17 of 2023 concerning Health to determine the consistency of regulations regarding medical liability. The case approach, meanwhile, analyzes the details

of legal events occurring in the Badung jurisdiction as a basis for legal material to determine the boundary between medical risk and negligence. The Conceptual Approach departs from legal perspectives and doctrines developing in health law, particularly regarding the doctrines of *Res Ipsa Loquitur* and *Culpa Lata*.

This research utilizes legal materials consisting of primary legal materials in the form of statutory regulations, in this case Law Number 1 of 2023 (the New Criminal Code), as well as judges' decisions from courts in the Badung region. The legal materials were collected through library research. The collected legal materials were then analyzed descriptively and qualitatively using the deductive method, drawing conclusions from general matters (national legal norms) to specific matters (cases in Badung). The legal materials are classified into primary legal materials, secondary legal materials, and supporting legal materials. First, primary legal materials are legally binding and serve as the primary basis for analysis. The primary legal materials in this research include: (a) the 1945 Constitution of the Republic of Indonesia; (b) Law Number 17 of 2023 concerning Health, particularly provisions regarding consent to health care services, medical records, negligence of medical personnel or health workers, and dispute resolution; (c) Law Number 1 of 2023 concerning the Criminal Code; (d) implementing regulations relevant to health services and professional standards; and (e) Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps dated March 25, 2025 as the main decision that is the object of the case approach. The Denpasar District Court Decision is treated as primary legal material because it contains legal facts, the construction of the indictment, evidence, the judge's considerations, the application of Article 440 paragraph (1) of the Health Law, and the decision that is directly related to the research problem. In this study, the decision is not only used to determine the chronology of the case, but is analyzed to identify how the court constructs the relationship between professional obligations, the patient's allergy history, drug administration, informed consent, consequences in the form of serious injuries, and the element of negligence. Second, secondary legal materials are used to explain, criticize, and develop primary legal materials. Secondary legal materials include law books, scientific journals, research results, legal articles, theses or dissertations, and expert opinions regarding informed consent, therapeutic relationships, medical negligence, medical malpractice, culpa, culpa lata, criminal liability of medical personnel, patient safety, ultimum remedium, and restorative justice. Third, supporting legal materials are used to assist in the verification and retrieval of primary and secondary legal materials. Supporting materials include official legal databases, scientific publication indexes, and academic search engines. The primary legal databases used are the Legal Documentation and Information Network (JDIH) of the Audit Board of the Republic of Indonesia (BPK) and the Directory of Decisions of the Supreme Court of the Republic of Indonesia.

Legal materials were selected based on inclusion and exclusion criteria. The inclusion criteria for primary legal materials include: (a) laws and regulations directly regulating healthcare services, informed consent, medical records, service standards, medical personnel negligence, or criminal liability; (b) court decisions directly related to medical negligence, informed consent, medical malpractice, or the application of Article 440 of Law Number 17 of 2023; and (c) Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps as the primary case object. The inclusion criteria for secondary legal materials include: (a) scholarly works discussing health law, informed consent, medical negligence, medical malpractice, criminal liability of medical personnel, patient safety, or criminalization in healthcare; (b) publications with verifiable bibliographic identity; and (c) sources directly relevant to the case. Legal materials were excluded if they only discussed clinical or pharmacological aspects without relevance to the legal problem, lacked verifiable source identification, were popular opinions without adequate legal argumentation, or lacked a substantive relationship to informed consent, medical negligence, criminal liability, or the legal issues that were the focus of the research.

The research employed four complementary approaches: the legislative approach, the case approach, the conceptual approach, and the historical-transitional approach. The legislative approach was used to identify norms governing the obligation to obtain consent for healthcare services, the professional obligations of medical personnel, medical records, negligence, serious injury, and criminal liability. Article 293 of Law Number 17 of 2023, for example, requires consent after the patient has received adequate information, including regarding the diagnosis, indications, procedures and their objectives, risks and complications,

alternatives, risks if the procedure is not performed, and the prognosis. Consent can be given in writing or verbally. A case-based approach was used, using Denpasar District Court Decision No. 962/Pid.Sus/2024/PN.Dps as the primary case. The decision was analyzed through four layers: (a) identification of proven legal facts; (b) identification of the norms used by the judge; (c) identification of the relationship between the proven facts and elements of the crime; and (d) evaluation of the coherence of the judge's reasoning with relevant legal norms, principles, and doctrines.

A conceptual approach was used to analyze the concepts of informed consent, duty of care, medical negligence, culpa, culpa lata, medical risk, patient safety, criminal liability, ultimum remedium, and restorative justice. These concepts were not used as standalone definitions but were combined to determine the boundaries between failure to fulfill professional obligations, acceptable medical risks, disciplinary violations, and negligence that meet the elements of criminal liability. A historical-transitional approach was used to a limited extent to explain changes in Indonesia's criminal law regime. This approach is important because the incident at issue occurred on February 14, 2024, when Law No. 17 of 2023 concerning Health was already in effect, while Law No. 1 of 2023 concerning the Criminal Code had not yet come into effect. Law No. 1 of 2023 was enacted on January 2, 2023, and under Article 624, it came into effect three years later, on January 2, 2026.

IV. Result and Discussion

4.1 Chronology and Legal Evidence in the Case

Based on Denpasar District Court Decision Number 962/Pid.Sus/2024/PN.Dps dated March 25, 2025, the case involved Shillea Olimpia Melyta as a general practitioner at Hydro Medical and Jamie Irena Rayer-Keet as a patient. The incident occurred on February 14, 2024, when the patient complained of back pain and fever and sought medical services. Before administering the medication, the defendant asked about her drug allergy history and the patient stated that she had an allergy to Ibuprofen and Aspirin, which are referred to in the case as Nonsteroidal Anti-inflammatory Drugs (NSAIDs). After that, several medications were administered via intravenous injection. Approximately 30 minutes after administering the medication, the patient experienced swelling of the face and eyes and tightness in the chest that caused difficulty breathing. The case also uncovered issues regarding informed consent. According to the verdict, the defendant did not obtain verbal or written consent from the patient for the administration of medication, as documented in the medical record. Consent was granted solely through a document signed by the patient's husband, without further explanation of the medication administered. This fact is relevant because it highlights a distinct issue regarding the fulfillment of informed consent obligations in the medical care process.

Another piece of evidence that formed the basis of the case was the administration of Antrain injections. The case considered the administration of Antrain inappropriate due to the patient's history of allergies to ibuprofen and aspirin. Following administration, the patient experienced swelling of both eyelids and respiratory distress. Visum et Repertum No. 445/2237/RSDM/2024, dated February 26, 2024, stated that swelling of both eyelids was found, consistent with an immediate allergic reaction, and that such an allergic reaction could have caused death. Furthermore, expert testimony regarding medical records indicated issues with the documentation of clinical information. The case explained that if errors were made in recording clinical information, corrections should be made without deleting the previous record. These irregularities in documentation were then considered a factor that reinforced the issue of fulfilling professional obligations in identifying and documenting patient conditions.

4.2. Relationship of Evidence with Elements of Article 440 Paragraph (1) of Law Number 17 of 2023

Article 440 paragraph (1) of Law Number 17 of 2023 concerning Health in this case is applied to the actions of medical personnel or health workers who commit negligence resulting in serious injury to a patient. Therefore, an analysis of the evidence is not sufficient to simply show that the patient experienced an allergic

reaction after receiving medical services. A relationship must be established between the perpetrator's status as a medical worker, the actions or negligence committed, the form of negligence, and the resulting serious injury. Based on this construction, the evidence in the case can be analyzed into three sets of elements, namely (1) the subject as a medical professional; (2) the existence of negligence; and (3) the existence of consequences in the form of serious injuries. These three elements must be seen as a series that has a factual and normative relationship.

First, the subject element as a medical professional. In the case, Shillea Olimpia Melyta is a general practitioner who works at Hydro Medical and administers medication to patients. Thus, her position as a medical professional is the starting point for the application of Article 440 paragraph (1). This fact also shows that the actions that are the object of the case were carried out in a professional capacity, so that the standard of care and professional obligations of medical professionals are relevant in assessing whether or not there was negligence. Second, the element of negligence. This element is analyzed through a series of evidence showing that the defendant had obtained information regarding the patient's allergy history before administering the medication. The patient had disclosed a history of allergies to Ibuprofen and Aspirin, but after this information was known, the medication was still administered, including Antrain. In considering the verdict, the administration of Antrain was associated with the same drug group as the drug to which the patient had previously been allergic. The Panel of Judges then considered the violation of the standard of care and the aspect of *foreseeability*, namely the ability of medical personnel to predict the possibility of an allergic reaction as a result of the action. Thus, evidence regarding a history of allergies serves not only as medical evidence but also as a legal criterion for assessing whether the defendant has fulfilled the duty of care inherent in his profession. Information about allergies known before the act is important in assessing whether the subsequent risk is an unavoidable medical risk or the result of an act that could have been avoided with reasonable care.

The element of negligence is also supported by evidence regarding medical records and documentation. Medical records demonstrate the existence of information regarding the medication administered, while expert testimony explains the obligation to correct recording errors without replacing or removing previous records. In the context of proof, documentation issues do not in themselves prove a crime, but they can serve as supporting evidence to assess whether professional obligations regarding record-keeping, risk identification, and service delivery have been properly implemented (Viranda & Zulfiko, 2026). Third, the element of consequence is serious injury. The relationship between the act and the consequence is supported by evidence regarding the patient's condition after the administration of the drug and the results of the forensic examination. Approximately 30 minutes after the injection, the patient experienced swelling of the face and eyes and shortness of breath. The Visum et Repertum then identified this condition as an immediate allergic reaction and stated that such an allergic reaction could cause death. The Panel of Judges used this evidence to link the patient's medical condition to the qualification of serious injury in the application of Article 440 paragraph (1). Thus, medical evidence does not stand alone as proof of negligence. It serves to prove the consequences required by Article 440, while allergy history, medication administration, precautionary standards, and expert testimony are used to establish a link between the defendant's actions and the patient's consequences.

4.3. The Position of Informed Consent in Proving Negligence

The issue of informed consent in this case is related to professional obligations, but it needs to be distinguished from the element of consequence in Article 440. The fact that consent was not given adequately indicates a problem regarding the fulfillment of the patient's right to obtain information and give consent to medical procedures. In this case, the consent document was signed by the patient's husband, but there was no further explanation regarding the medications given to the patient. Analytically, failure to provide informed consent does not in itself prove that all elements of Article 440 have been met. Its position must be viewed in relation to professional obligations and the medical action performed. In this case, the failure to

provide information regarding the medication becomes even more relevant due to the fact that the patient had previously disclosed his history of allergies. Therefore, the issue of informed consent and the issue of caution in administering medication have a mutually reinforcing relationship in the analysis of professional obligations, even though they are distinct legal issues (Amelink et al., 2026). In other words, informed consent primarily serves to assess the fulfillment of a patient's right to autonomy and obligation to provide information, while Article 440 focuses on the negligence of medical personnel and the resulting consequences. The relationship between the two in this case lies in the possibility that failure to provide information and obtain consent reflects a suboptimal fulfillment of professional obligations, but criminal liability still requires proof of negligence and the consequences as stipulated in Article 440.

4.4. Causal Relationship between Negligence and Serious Injury

The evidence in the case demonstrates a chronological link between the administration of the medication and the allergic reaction. The patient had reported a history of allergies prior to the procedure, then received the injection, and approximately 30 minutes after administration, experienced facial and eye swelling and shortness of breath. Subsequent post-mortem examination results supported a potentially fatal, immediate-type allergic reaction. From a criminal law perspective, this relationship is crucial because Article 440 is a provision that requires consequences. Therefore, the analysis does not stop at the question of whether the medical action deviated from the standard of care, but also whether that deviation is related to the consequences that constitute the basis for criminal liability. In this case, the Panel of Judges linked the administration of Antrain to the patient's history of allergies, considered the possibility of an allergic reaction as a predictable consequence, and then linked this to medical evidence regarding the patient's condition. With this construction, the chain of evidence regarding the history of allergies, the administration of the medication, the appearance of symptoms, the results of the forensic examination, and expert testimony formed a chain of evidence regarding negligence resulting in serious injury.

4.5. Court Decisions and Fulfillment of the Elements of Article 440

Based on all the evidence and considerations, the Denpasar District Court through Decision Number 962/Pid.Sus/2024/PN.Dps dated March 25, 2025 stated that Shillea Olimpia Melyta was legally and convincingly proven to have committed a crime as per Article 440 paragraph (1) of Law Number 17 of 2023 concerning Health. The court imposed a fine of IDR 40,000,000.00 with the provision that if the fine is not paid it will be replaced with imprisonment for two months. Analytically, the decision shows that compliance with Article 440 is not based solely on the presence of an allergic reaction following a medical procedure. The evidentiary framework consists of several layers, namely the defendant's status as a medical professional, the defendant's knowledge of the patient's allergy history, the administration of the medication, consideration of the inappropriateness of the medication given to the patient's condition, the predictability of the risk of an allergic reaction, the appearance of the reaction following the administration of the medication, and medical evidence supporting the qualification of the result as a serious injury. Consideration of medical records and expert testimony further serves as supporting evidence in assessing compliance with professional obligations. Thus, the research results show that the relationship between case evidence and Article 440 can be constructed through the pattern of professional obligation → deviation or negligence → causal relationship → serious injury. Informed consent falls within the realm of the obligation to provide information and respect patient autonomy, but its relevance to Article 440 arises when the failure is analyzed together with medical actions, standards of care, and the resulting consequences. This construction shows that the failure of informed consent should not be treated as sole evidence of criminal liability, but rather as part of a whole series of facts that must be linked to the elements of negligence and consequences as required by Article 440.

In this case, SHILLEA OLIMPIA MELYTA as a Medical Personnel or Health Worker who committed negligence which resulted in the Patient being seriously injured when Witness JAMIE IRENA RAYER-KEET felt pain in the back and had a fever, so that ALAIN DAVID DICK-KEET, the husband of the victim witness, contacted the HYDRO MEDICAL clinic asking officers and doctors to come to his residence on Jalan Pantai Berawa, Gang Madu, Tibubeneng Village, North Kuta District, Badung Regency, Bali Province, to check the health condition of Witness JAMIE IRENA RAYER-KEET, then the Defendant along with a nurse and the Defendant worked as a General Practitioner at HYDRO MEDICAL Your IV & Dental Solution and before giving the medicine, the Defendant asked whether Witness JAMIE IRENA RAYER-KEET had a drug allergy and Witness JAMIE IRENA RAYER-KEET answered that he had an allergy to Ibuprofen and Aspirin which contained Nonsteroidal Anti-inflammatory Drugs (NSAID), after that The defendant injected several drugs in an intermittent IV drip to Witness JAMIE IRENA RAYER-KEET, but after receiving the injection of drugs for approximately 30 (thirty) minutes, Witness JAMIE IRENA RAYER-KEET felt swelling in the face and eyes, and a feeling of tightness in the chest which caused difficulty breathing, because it turned out that the medical records stated that the drugs were given as a treatment for the illness experienced by Witness JAMIE IRENA RAYER-KEET and the defendant did not ask for permission or ask for verbal or written approval from the patient Witness JAMIE IRENA RAYER-KEET or her family to provide drugs in accordance with the medical records, instead the defendant only provided a letter of consent for the action to be signed by Witness ALAIN DAVID DICK-KEET without explaining further about what drugs were given to Witness JAMIE IRENA RAYER-KEET;

In administering Antrain injection to Witness JAMIE IRENA RAYER-KEET it is not appropriate considering that Antrain comes from the same group as the drugs that cause allergies to Witness JAMIE IRENA RAYER-KEET, namely ibuprofen and aspirin which contain Nonsteroidal Anti-inflammatory Drugs (NSAID), so that the complaint experienced by Witness JAMIE IRENA RAYER-KEET is swelling on both upper eyelids which from the description is in accordance with the fast type allergy, and based on the Visum Et Repertum Number: 445/2237/RSDM/2024 signed by doctor Ida Bagus Putu Alit SpFM(K), DFM, Forensic and Medicolegal Consultant doctor at Mangusada Regional Hospital dated February 26, 2024, after an examination it can be concluded that swelling was found on both upper eyelids, which from the description is in accordance with the fast type allergic reaction and the allergy experienced by Witness JAMIE IRENA RAYER-KEET can cause death and based on the testimony of Expert Dr. YUDY, Sp.F.M, in handling a patient, may not have more than one medical record, so that in the event of an error in recording or documentation in writing clinical information, the Health worker providing Health services can be corrected and may not be replaced, the Defendant's actions as regulated and threatened with criminal penalties in Article 440 paragraph (1) of the Republic of Indonesia Law Number 17 of 2023 concerning Health, after the examination was completed, the Public Prosecutor demanded that the Defendant SHILLEA OLIMPIA MELYTA, be proven legally and convincingly guilty of committing the crime of "Every Medical Personnel or Health Personnel who commits negligence resulting in serious injury to the Patient" as regulated and threatened with criminal penalties in Article 440 paragraph (1) of the Republic of Indonesia Law Number 17 of 2023 concerning Health as the sole indictment of the Public Prosecutor so that the Court imposes a fine of Rp. 50,000,000,- (fifty million rupiah) subsidiary 3 (three) months in prison;

The Denpasar District Court in decision number 962/Pid.Sus/2024/PN.Dps dated March 25, 2025, stated that the Defendant SHILLEA OLIMPIA MELYTA mentioned above has been legally and convincingly proven guilty of committing the crime of "Every Medical Personnel who commits negligence resulting in serious injury to the Patient" as the sole indictment of the Public Prosecutor and sentenced the Defendant therefore with a fine of IDR 40,000,000.00 (forty million Rupiah) with the provision that if the fine is not paid, it will be replaced with imprisonment for: 2 (two) months; According to the indictment, the incident that occurred on February 14, 2024, in Badung, Bali, indicated a violation of standard procedures. The defendant, a general practitioner, administered an intravenous injection to witness Jamie Irena Rayer-Keet, who had previously reported a history of allergies to nonsteroidal anti-inflammatory drugs (NSAIDs).

The patient's post-procedure clinical condition, which included facial swelling and shortness of breath, was a manifestation of an anaphylactic reaction. From a criminal law perspective, this raises the

question of whether the incident constituted a personal fault or a medical failure that falls within the realm of professional disputes (Laurijssen et al., 2022). In its ruling, the Panel of Judges considered that the essence of Article 440 paragraph (1) of Law No. 17 of 2023 concerns the negligence of medical personnel or health workers resulting in serious injury. In this case, the Panel of Judges considered the following:

- a. Violation of Professional Standards: The Defendant, as a medical professional, administered an Antrain injection to Witness Jamie Irena Rayer-Keet. However, based on medical records and anamnesis, the witness was known to have a history of allergies to Ibuprofen and Aspirin.
- b. Drug Class Appropriateness: Antrain (Metamizole/Antalgin), Ibuprofen, and Aspirin are all drugs in the same family, namely Nonsteroidal Anti-inflammatory Drugs (NSAIDs). Medically, administering drugs from the same class to a patient with a history of drug allergies constitutes a clear lack of caution (negligence).
- c. Foreseeability: As a professional, the Defendant should have been able to predict (guess) that administering an NSAID injection to a patient allergic to NSAIDs would trigger a severe allergic reaction (anaphylaxis/immediate-type reaction).

The Panel of Judges also considered that the Defendant's negligence resulted in a medical condition in Witness Jamie Irena Rayer-Keet, as evidenced by:

- a. Visual Facts: Swelling was found on both upper eyelids, which is characteristic of an immediate allergic reaction.
- b. Documentary Evidence: Based on the Visum Et Repertum Number: 445/2237/RSDM/2024 signed by Dr. Ida Bagus Putu Alit SpFM(K), DFM, it was concluded that the allergic reaction was classified as dangerous and could cause death.
- c. Injury Qualification: Given that the reaction was life-threatening (potentially fatal), the condition meets the qualifications for "serious injury" as referred to in Article 440 paragraph (1) of the Health Law.

Based on the expert testimony of Dr. Yudy, Sp.F.M., the following facts were found regarding the Defendant's irregularities in documenting clinical information:

- a. Medical records are legal documents that cannot be replaced; they can only be corrected if there are errors in recording them without deleting the previous record.
- b. The Defendant's failure to manage these medical records reinforces the element of negligence in identifying the patient's allergy history prior to the injection.

In this case, the Panel of Judges applied the principle of *ultimum remedium*, which mandates that criminal law should be used as a last resort if other legal means (such as administrative or civil law) are ineffective. In the medical context, the goal of punishment has shifted away from retaliation against the perpetrator. Judges examining this case are required to not only apply the law textually (legal-formalistic) but also consider whether mediation mechanisms or professional disciplinary hearings were fully implemented before the case proceeded to criminal court (Tronconi et al., 2025). If the judge issues a decision that emphasizes imprisonment, it is considered to remain trapped in the old paradigm (retributive justice) (Mostafa et al., 2025). Conversely, a progressive decision would consider that excessive criminalization of doctors could trigger defensive medicine, where medical personnel are afraid to take emergency action due to the risk of criminalization. In this regard, harmonization of Health Law No. 17 of 2023 has occurred. This latest law provides greater protection for medical personnel.

Thus, the application of criminal penalties should only be reserved for cases containing elements of gross negligence accompanied by malicious intent or aversion (Mostafa et al., 2025). In a therapeutic

relationship, a doctor provides health services in the form of medical procedures to a patient in order to seek the patient's recovery (Plaiaasu et al., 2022). In carrying out their duties, doctors must perform medical procedures in accordance with norms, professional standards, service standards, standard operating procedures, and the patient's needs (Amelink et al., 2026). If a doctor, in performing a medical procedure, fails to meet these standards and causes harm to the patient, this is classified as medical malpractice (Mfutso Bengo et al., 2022). Under Indonesian law, if the doctor results in serious injury or death of the patient, the doctor can be punished. Linked to the National Criminal Code's sentencing regime, this study aims to analyze imprisonment as the ultimum remedium in medical malpractice cases (Bolino et al., 2023). This research is a normative-empirical legal study using both statutory and conceptual approaches (Gharaibeh, 2022). The results of this study indicate that imprisonment is perceived by judges as the ultimum remedium in medical malpractice cases, particularly in the form of negligence onbewuste culpa (Griffiths, 2026).

V. Conclusion

This study concludes that the handling of the case of Defendant Shillea Olimpia Melyta should serve as an opportunity for law enforcement officials to implement a moderate criminal law paradigm. Judges need to ensure that every decision they make reflects a balance between protecting patient rights and protecting the medical profession, in accordance with the spirit of ultimum remedium. This research demonstrates that failure to provide informed consent in medical practice has legal relevance in assessing the fulfillment of professional obligations, but does not in itself constitute criminal liability. In the context of Article 440 of Law Number 17 of 2023 concerning Health, criminal liability must be based on negligence, a violation of professional standards, a causal relationship, and the occurrence of serious injury or death. Therefore, the primary legal contribution of this research is to emphasize the need to distinguish failure to provide informed consent as a breach of professional obligations from a criminal offense, and to prioritize criminal penalties as a last resort (ultimum remedium) while still respecting patient rights and protecting the medical profession. This research has limitations because the analysis relies primarily on a single case from the Denpasar District Court. Therefore, the results cannot comprehensively describe the application of Article 440 to various medical malpractice cases in Indonesia. Further research is needed through comparative judicial analysis of several decisions and examination of other medical malpractice cases under Law Number 17 of 2023 concerning Health.

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