Problems of Corporate and State Criminal Liability in the Pharmaceutical Production Chain: The Case of Acute Kidney Injury in Children in Indonesia

Anggi Widyastuti[1], Heni Utari Setianingrum[2], Zerine Destiva Pasa Ramadhani[3], Triana Dewi Seroja[4]

[1-4]Universitas Internasional Batam, Indonesia
✉ Corresponding email: 25.02.anggi@uib.edu

History of Article
Submitted : June 30, 2026
Revised : July 22, 2026
Accepted : August 10, 2026
Published : September 22, 2026
DOI : https://doi.org/10.37253/conescintech.v6i1.12818

Copyright© 2026 by Author(s). This work is licensed under a Creative Commons Attribution-Non Commercial-Share Alike 4.0 International License. All writings published in this journal are personal views of the authors and do not represent the views of this journal and the author's affiliated institutions.

Abstract
The 2022 outbreak of Atypical Progressive Acute Kidney Injury (APAK) among children in Indonesia triggred a serious public health crisis rooted in failures of pharmaceutical oversight and the drug production supply chain contaminated with ethylene glycol (EG) and diethylene glycol (DEG). This normative legal research analyses the issues of corporate criminal liability within the pharmaceutical production chain as well as state responsilibity for deficiencies in the conceptual approaches, the study finds that although national legal instruments, such as the Consumer Protection Law, provide as basis for criminal sanctions, their implementation remains limited to end-product manufacturers and has not effectively extended to raw material suppliers outside the primary corporate structure. The theories of identification, vicarious liability, and strict liability are considered relevant however, they require further strengthening to ensure fair and comprehensive law enforcement throughout the supply chain. On the other hand, the state is deemed to have failed to fulfill its constitutional and international obligations to protect children's right to health. The findings indicate the existence of maladministration within the supervisory system of the Food and Drug Supervisory Agency (BPOM) and the Ministry of Health. Therefore, regulatory reform is needed to strengthen the principles of due diligence, supply chain liability, and pharmacovigilance systems in order to guarantee the protection of human rights an prevent similar incidents from recurring in the future.

Keywords: Corporate criminal liability; state responsilibity; acute kidney injury in children; pharmaceutical oversight; human rights.

Introduction

The case of Atypical Progressive Acute Kidney Injury (GGAPA), or acute kidney failure, became a major concern in Indonesia in 2022. Several hospitals across the country reported a significant increase in cases involving a sudden decline in kidney function among children. Symptoms that initially appeared common, such as fever, cough, runny nose, and diarrhea, were followed by a drastic reduction in urine production, with some children becoming unable to urinate at all. Severe kidney damage, loss of consciousness, and even death could develop rapidly as a result of this condition. At the early stage of the outbreak, the exact cause of the disease was unknown, making it difficult for medical personnel to determine appropriate treatment methods. The case began with a growing number of patients reported throughout mid-2022 in various regions of Indonesia (Septina, 2022).

The significant increase in acute kidney failure cases among children became a matter of national concern at the time. Indonesia's Ministry of Health received reports spanning August through October 2022. Victims reported were predominantly toddlers and children under five years of age. Government-released data showed hundreds of children in serious condition being hospitalized, followed by a sharply rising death toll within a short period. Around the same time, the World Health Organization issued a warning regarding child deaths caused by acute kidney failure in other countries, particularly Gambia, where consumption of certain syrup-type medicines was suspected to have caused the deaths of 66 children. The Indonesian Government paid close attention to these findings, as there were similarities in the pattern of symptoms and medication consumption history among the patients (Naufal & Maullana, 2022).

The Government, together with the Food and Drug Supervisory Agency and toxicology experts, began investigating possible connections between acute kidney failure cases and syrup medications consumed by children prior to falling ill. Results showed that the majority of patients were found to have a history of consuming liquid medicines or syrups to treat fever, cough, and flu. Subsequent findings from laboratory examinations discovered the presence of hazardous substances such as ethylene glycol (EG) and diethylene glycol (DEG) in several syrup medicine products. These substances are chemical compounds commonly used for industrial purposes and must not be present in excessive levels in medications, as they can be toxic to the body, particularly the kidneys. The EG and DEG content was also suspected to have originated from additional solvents namely propylene glycol, polyethylene glycol, and glycerin that were contaminated during the drug production process (Azizah, 2022).

Furthermore, as initial investigations showed strong indications of a link between syrup medications and acute kidney failure cases, Indonesia's Ministry of Health issued instructions in October 2022 to all healthcare workers and pharmacies to temporarily halt the sale and use of syrup medicines for children. This step was taken as a preventive measure to suppress the number of victims from continuing to grow. The public was also urged by the Government to refrain from giving syrup medicines to children in the meantime, before receiving certainty regarding which products already circulating in the market were safe. Shortly after, the Food and Drug Supervisory Agency announced a list

of syrup medicine products suspected of being contaminated with EG and DEG levels exceeding the safe threshold, and those products were consequently withdrawn from circulation (Hardiantoro, 2022).

Further developments in the investigation revealed issues in the production and distribution processes of pharmaceutical raw materials. Law enforcement authorities found indications that several pharmaceutical companies had used raw materials that did not meet pharmaceutical standards and had failed to conduct adequate safety testing before distributing their products to the public. As the case progressed, several companies were named as suspects by the police, including PT Afi Farma, PT Yarindo Farmatama, PT Universal Pharmaceutical Industries, and CV Samudera Chemical. These companies were responsible for manufacturing dozens of syrup-based medicines, including paracetamol syrup, cough syrup, and fever syrup. In addition, the companies were allegedly involved in the distribution of contaminated raw materials and their use in the production of children's syrup medicines. Furthermore, other allegations emerged concerning weak quality control systems and negligence in supervising the quality of raw materials within the pharmaceutical industry (Hardiantoro, 2022).

The case triggered strong criticism of drug regulatory oversight in Indonesia, particularly regarding the roles of the National Agency of Drug and Food Control (BPOM) and the Ministry of Health of the Republic of Indonesia in ensuring the safety of pharmaceutical products before they are distributed to the public. Many parties argued that oversight of laboratory testing for imported raw materials, as well as monitoring of the manufacturing process, had not been carried out effectively, allowing products containing hazardous substances to enter the market and be consumed by children. In addition, the families of the victims demanded accountability from both the government and the pharmaceutical companies for the deaths of hundreds of children resulting from the incident. Several observers also linked the case to potential human rights violations, as it concerned children's right to adequate health protection and their fundamental right to life (Ady Thea DA, 2023).

Research Method

This study employs a normative legal research method, which examines law as a set of norms or rules applicable within society (Sukmawan & Damayanti, 2025). This method was selected because the research focuses on analyzing the legal framework governing corporate criminal liability within the pharmaceutical production chain, as well as the state’s responsibility for failures in the drug regulatory system in the case of Atypical Progressive Acute Kidney Injury (GGAPA) among children in Indonesia. The study applies both a statutory approach and a conceptual approach. The statutory approach is used to examine various legal provisions regulating health protection, child protection, consumer protection, corporate liability, and state responsibility. Meanwhile, the conceptual approach is employed to analyze the concepts of corporate criminal liability, state responsibility, and unlawful acts (onrechtmatige daad) based on established legal doctrines and theories.

This study employs a normative legal research method, which examines law as a system of norms or rules applicable within society. This method was chosen because the research focuses on analyzing the legal framework governing corporate criminal liability within the pharmaceutical production chain, as well as the state's responsibility for failures in the drug supervision system in the case of Atypical Progressive Acute Kidney Injury (GGAPA) among children in Indonesia. 2The research adopts both a statutory approach and a conceptual approach. The statutory approach is utilized to examine various legal provisions governing health protection, child protection, consumer protection, corporate liability, and state responsibility. Meanwhile, the conceptual approach is employed to analyze the concepts of corporate criminal liability, state responsibility, and unlawful acts (onrechtmatige daad) based on established legal doctrines and theories.

The research utilizes secondary data, consisting of both primary legal materials and secondary legal materials. The primary legal materials include the 1945 Constitution of the Republic of Indonesia, Law Number 17 of 2023 on Health, Law Number 8 of 1999 on Consumer Protection, Law Number 35 of 2014 concerning Amendments to Law Number 23 of 2002 on Child Protection, Law Number 30 of 2014 on Government Administration, the Indonesian Civil Code, the Convention on the Rights of the Child (CRC), the International Covenant on Economic, Sosial and Cultural Rights (ICESCR), and the Draft Articles on Responsibility of States for Internationally Wrongful Acts (ARSIWA). The secondary legal materials consist of books, scholarly journals, research reports, academic articles, and expert opinions related to corporate criminal liability, state responsibility, health protection, and human rights. Data were collected through library research by identifying, examining, and reviewing various legal materials relevant to the research issues. Furthermore, the data were analyzed qualitatively using a descriptive-analytical method through processes of legal interpretation and legal reasoning in order to develop systematic legal arguments concerning issues of corporate criminal liability and state responsibility in the case of Atypical Progressive Acute Kidney Injury (GGAPA) among children in Indonesia.

Results and Discussions

The Concept of Corporate Criminal Liability in Indonesian Law is Sufficient to Hold All Parties Accountable within the Production Chain in the Case of Acute Kidney Injury in childrenn, Including Pharmaceutical Raw Material Suppliers Operating Outside the Main Structure of Pharmaceutical Companies

The incident involving Atypical Progressive Acute Kidney Injury (GGAPA), which resulted in the deaths of hundreds of children in Indonesia in 2022, was not merely a public health issue but also gave rise to serious legal concerns. The case highlighted the extent to which the Indonesian legal system has been able to implement criminal liability comprehensively against all actors involved in the pharmaceutical industry chain.

The case came to public attention after the discovery of contamination by ethylene glycol (EG) and diethylene glycol (DEG) at levels exceeding safe limits in children's syrup medicines. These substances originated from contaminated solvent ingredients, including propylene glycol, polyethylene glycol, and glycerin. As the investigation progressed, attention shifted to the question of whether the concept of corporate criminal liability under Indonesian law is sufficiently robust to support law enforcement efforts not only against pharmaceutical manufacturing companies but also against raw material suppliers who operate outside the formal corporate structure of pharmaceutical companies yet remain integral parts of the chain of events that contributed to the occurrence of the tragedy.

In line with historical legal developments, the Indonesian criminal justice system has traditionally regarded human beings as the primary subjects who may be held criminally liable. This perspective is reflected in the structure of the Indonesian Criminal Code (KUHP), which for a long time was founded on the assumption that the subject of criminal liability is an individual person (*natuurlijk person*) (Aryaputra & Triwati, 2023). However, in line with the growing complexity of corporate activities and the increasing prevalence of crimes involving business entities, Indonesian law has gradually recognized corporations as subjects of criminal liability through various provisions contained in sector-specific legislation. This development reflects a shift from the traditional view that only natural persons can be held criminally responsible, toward a broader legal framework that allows corporations to be prosecuted and sanctioned for criminal acts committed in the course of their business activities (Selvi, Januardy & Sangalang, 2026). One such regulation can be found in Law Number 8 of 1999 on Consumer Protection, which prohibits business actors from producing or trading goods that do not comply with consumer safety and security standards, as stipulated in Article 8 paragraph (1). This provision serves as an important legal basis for holding business entities accountable when products distributed to consumers fail to meet the required standards and consequently cause harm to public health or safety (Putra & Priyanti, 2021). Under these provisions, a corporation that commits a violation may be subjected to criminal prosecution pursuant to Article 62, while criminal liability may also be imposed on the corporation’s management or responsible officers as provided under Article 61. These provisions reflect the principle that accountability for unlawful corporate conduct may extend not only to the corporate entity itself but also to the individuals who direct, manage, or authorize the activities that give rise to the violation (Prayuti et al., 2025). This legal framework is particularly relevant to the case of acute kidney injury among children, as the syrup medicines involved were found to contain ethylene glycol (EG) and diethylene glycol (DEG) at concentrations exceeding the permitted safety limits. This directly demonstrates a violation of consumers’ rights to use safe products, as guaranteed under Article 4 of Law Number 8 of 1999 on Consumer Protection. The presence of hazardous contaminants in pharmaceutical products intended for children constitutes a failure to ensure product safety and quality, thereby giving rise to potential legal liability for the parties involved in their production and distribution.

When examined through the lens of corporate criminal liability theories, several approaches may be used to analyze this case. Under the Identification Theory, corporate fault is attributed to the actions or decisions of individuals who serve as the corporation's "directing mind and will" (Dwinanda, 2022). In the case of acute kidney injury among children, this theory may be applied to hold pharmaceutical company management accountable when they knew, or reasonably should have known, that the raw materials used did not meet the required safety standards. However, the application of the Identification Theory becomes limited when the contaminated raw materials are supplied by entities operating outside the formal organizational structure of the pharmaceutical company. For this reason, the doctrines of vicarious liability and strict liability are often considered more relevant approaches. Under the principle of vicarious liability, a corporation may be held responsible for the actions of other parties acting for the benefit of the company within the production chain, including distributors and raw material suppliers. This approach recognizes that corporate activities frequently involve a network of external actors whose conduct contributes directly to the production and distribution of goods. Therefore, liability may extend beyond the immediate actions of corporate management to encompass wrongful acts committed by parties whose activities support the corporation's business operations (Kurniawan & Hapsari, 2022). Meanwhile, the concepts of strict liability and absolute liability allow a corporation to be held legally responsible without the need to prove the existence of fault or intent on its part, provided that the product it manufactures or distributes is proven to have caused harm to the public. Under these doctrines, liability arises primarily from the occurrence of damage resulting from the corporation's activities or products, rather than from evidence of negligence or deliberate misconduct. In the context of the acute kidney injury case, the presence of hazardous contaminants in children's syrup medicines that resulted in serious injury and death may serve as a sufficient basis for imposing liability on the corporations involved, regardless of whether direct fault can be established (Herliana et al., 2026). In the context of hazardous syrup medicines, the strict liability approach plays a particularly significant role due to the severe impact of the products on the safety and lives of children, who constitute a highly vulnerable group.

From another perspective, various international legal instruments have also demonstrated that corporate responsibility should not be imposed solely on the final manufacturer. The Convention on the Rights of the Child (CRC), in Article 6 and Article 24, affirms children's rights to life and to obtain adequate health protection, thereby requiring the state to ensure that the entire healthcare system and drug distribution network are safe for children (Nono & Dollu, 2025). Article 12 of the ICESCR also encourages an active role for the state in supervising pharmaceutical production and preventing health risks to the public. At the same time, WHO standards on drug safety emphasize the importance of quality control and the supervision of pharmaceutical raw materials before products are distributed to the public. Therefore, if raw material suppliers are proven to have known about or negligently ignored the presence of EG and DEG contamination, then in principle they should also be held legally accountable because they formed part of the production chain that caused harm to public health.

The United Nations Guiding Principles on Business and Human Rights (UNGPs) also strengthen this argument. The UNGPs emphasize corporate commitment to respecting human rights, requiring companies to ensure that their business activities do not pose risks to public health (Luthfan & Hastarini, 2022). In the case of acute kidney injury among children, pharmaceutical companies and raw material suppliers should have applied the principle of due diligence with respect to the quality of raw materials and the safety of the products produced (Sunanto et al., 2026). The failure to conduct quality control demonstrates weaknesses in corporate governance that are not based on ESG principles and corporate sustainability. Therefore, corporate criminal liability should not be imposed solely on pharmaceutical manufacturing companies, but also on all parties who benefited from and played a role in the production chain of the hazardous medicines.

Thus, it can be understood that the concept of corporate criminal liability in Indonesian law has, in practice, not yet been fully capable of reaching all parties within the production chain in cases of acute kidney injury among children. Although various national legal instruments provide a basis for prosecuting pharmaceutical companies, the regulations concerning the liability of raw material suppliers, inter-corporate distribution, and supply chain oversight remain insufficiently strong and not comprehensively integrated. As a result, law enforcement tends to focus only on the final manufacturers, while other parties, such as raw material suppliers who also contributed to the contamination, are often difficult to hold criminally liable. On this basis, broader and more comprehensive reforms to corporate criminal liability regulations are necessary, particularly through strengthening the principles of strict liability, corporate due diligence, and supply chain accountability, so that all parties involved in the production of hazardous medicines can be held accountable in a fair, effective, and comprehensive manner.

The Concept of State Responsibility for the Failure of the Drug Regulatory System in the Case of Acute Kidney Injury Among Children in Indonesia

State responsibility is structured through several layers of norms that support one another. At the international level, Article 12 of the ICESCR requires the State to take measures to ensure the right to health, including the regulation of medicines and medical equipment. This obligation consists of three components: to respect, to protect, and to fulfill. In the case of acute kidney injury, it demonstrates the State's failure to carry out the theory of State Responsibility. This failure is most closely related to the aspect of protection, whereby it is the duty of the State to prevent producers from violating the right to health.

In its capacity as the state's independent oversight institution, the Ombudsman of the Republic of Indonesia also carries out its supervisory function over the Ministry of Health and BPOM (Indonesian Food and Drug Authority) regarding the handling of the GGAPA (Atypical Progressive Acute Kidney Injury) case. In the aspect of pharmacovigilance, which is the entire series of activities including early identification,

evaluation, deep understanding, as well as mitigation steps against potential adverse effects from the use of a medicinal product, the Ombudsman issued a critical assessment that BPOM's performance was far from the standard it should be. This was officially stated in the Ombudsman's press release highlighting the existence of maladministration practices in the supervisory system run by the institution. Furthermore, the Ombudsman's findings did not stop at BPOM alone. The Ministry of Health was also identified as having committed similar negligence in carrying out its supervisory function. Based on the results of the Ombudsman's examination, the Ministry of Health is considered to have failed in carrying out its health supervision obligations hierarchically, starting from the national level down to the provincial and district/city regional units, as mandated in the Minister of Health Regulation Number 110 of 2018 which regulates the supervisory mechanism in the health sector (Fahreza & Kongres, 2023).

The main issue in this case lies in the structure of pharmaceutical supervision by several Government agencies. First, BPOM has the duty to conduct checks before products enter the market and also to supervise medicines that are already in circulation. BPOM must routinely schedule inspections and monitoring regarding the distribution of food, beverages, and medicines to the public (Santusti & Ramadhani, 2024). Second, the Ministry of Health holds the duty to regulate drug policies and also the system to monitor drug effects after use. Third, Local Governments issue business licenses for pharmaceutical factories, supervise places that sell medicines, and oversee the distribution of medicines in their respective regions.

The state's failure in handling the GGAPA case clearly does not align with Indonesia's commitment to the SDGs. This issue has already occurred in 326 children across 27 provinces in Indonesia, where BPOM is suspected of failing to carry out proper supervision, allowing medicine containing hazardous ingredients to enter and be used, which resulted in children aged 1 to 5 years suffering from severe kidney failure (Fahreza & Kongres, 2023). The Ombudsman of the Republic of Indonesia also found problems in the way the state handled this case, with allegations that procedures were not followed properly and that the Minister of Health and the Head of BPOM did not perform their duties well. The Minister of Health is considered to have lacked caution for not declaring GGAPA as an Extraordinary Event (KLB), which resulted in the government being slow to respond (Indonesia, 2022). The goal of SDG 3.2, which aims to end preventable child deaths, is to reduce the neonatal mortality rate to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births by 2030 (Nations, n.d.) is not achieved due to the drug supervision problem in this country. WHO also notes that the number of child deaths has not experienced a significant decrease since 2015. There are 60 countries predicted not to achieve the SDG target for under-5 mortality and 65 countries unable to achieve the target for neonatal mortality ((WHO), n.d.).

In a more comprehensive Corporate Sustainability view, the GGAPA incident should be the starting point for major changes in the domestic pharmaceutical world. A holistic approach that integrates environmental, social, and governance elements into pharmaceutical regulations such as the obligation to disclose raw material supply chains, strict internal audits, and clear compensation mechanisms becomes the primary factor for

building a truly sustainable and responsible pharmaceutical industry. Good governance in pharmaceutical ESG includes clear decision-making processes, honest supply chain management, compliance with applicable regulations, and performing ESG reporting, which will increase the trust and credibility of the Company (Almanac, 2024). Pharmaceutical companies that successfully integrate ESG into their core business strategies use ESG principles to drive new ideas in sustainable manufacturing, improve access to medicines, and build transparent governance structures (Rubio, 2025), where this must be supported and guaranteed by the state through appropriate and consistent regulations.

If examined from a civil law perspective, the actions or omissions committed by BPOM in this case can be analyzed using the concept of *onrechtmatige overheidsdaad* (Anggito, 2023). The application of this doctrine requires the cumulative fulfillment of a number of elements, namely: the existence of an actual action or omission, the action conflicts with applicable legal norms, the presence of an element of fault on the part of the authority, the occurrence of a provable loss, as well as the existence of a clear causal relationship between the action of the authority and the loss suffered by the other party (Halim & Indrianto, 2022). These elements can be found in BPOM's behavior. First, there was an omission in the form of a delay in linking epidemiological data with pharmaceutical product investigations. The available data shows that the increase in cases of acute kidney injury in children first spiked in January 2022. However, product recalls and warnings to the public were only issued in October 2022. Second, this negligence conflicts with BPOM's legal obligations as stipulated in the Presidential Regulation regarding the establishment of BPOM and the Health Law. Third, there is tangible loss in the form of death and illness of children that could have been prevented if action had been taken faster.

The normative basis for the government's actions, which are deemed to have deviated from the legal corridor, can be found in the provisions contained in Article 1365 of the Indonesian Civil Code, which explicitly obligates any party who, through their fault, causes loss to another person, to provide compensation for the loss they have caused (Edyanti, 2022). The form of BPOM's civil liability in the case of children with kidney failure in Indonesia is by providing restitution for the victims who were harmed due to the negligence committed. This has been regulated in Articles 1365, 1366, and 1371 of the Indonesian Civil Code. This compensation can be in the form of money given fairly, it can also be in the form of compensation equal to the victim's loss, and then there is also compensation or punishment given to the perpetrator if the fault is evident and severe. With this, victims and families can obtain their rights and feel valued. All these forms of compensation aim to ensure that victims can regain their rights, and the guilty party is still held responsible in accordance with existing regulations (Santusti & Ramadhani, 2024).

Conclusion

The concept of corporate criminal liability in Indonesian law basically provides a legal basis to prosecute corporations involved in the production and distribution of hazardous medicines through various approaches, such as identification theory, vicarious liability, and strict liability. In the case of Atypical Progressive Acute Kidney Injury (GGAPA), these theories allow pharmaceutical companies and their management to be held accountable for the distribution of syrup medicines containing ethylene glycol (EG) and diethylene glycol (DEG) contamination above safe limits. However, this study shows that the existing legal regulations are still not fully capable of reaching all actors in the pharmaceutical production chain, particularly raw material suppliers who are outside the main structure of the pharmaceutical company. As a result, law enforcement tends to focus on final producers, while other parties who also contribute to the contamination of raw materials are often difficult to hold criminally liable. Therefore, it is necessary to strengthen regulations regarding supply chain liability, implement due diligence principles, and expand the concept of strict liability so that all parties who benefit from and have a role in the drug production process can be held accountable effectively and fairly.

On the other hand, the state also bears legal and moral responsibility for the failure of the drug supervision system that contributed to the occurrence of the GGAPA case. Based on the theory of State Responsibility, the state's obligation is not only limited to drafting regulations but also ensuring the implementation of effective supervision over drug safety to protect children's right to health and right to life. Findings regarding maladministration and weak supervisory coordination between BPOM, the Ministry of Health, and local governments indicate negligence in carrying out these obligations. From a human rights perspective, this failure of supervision can be viewed as a form of violation of children's right to health as guaranteed in the 1945 Constitution, the Convention on the Rights of the Child (CRC), and the ICESCR. Therefore, state responsibility must be manifested through improving the pharmacovigilance system, strengthening drug supervision mechanisms, increasing pharmaceutical supply chain transparency, providing proper remedies for victims, as well as policy reforms capable of preventing the recurrence of similar events in the future. In this way, public health protection, especially for children as a vulnerable group, can be guaranteed more optimally.

References

(WHO), W. H. O. (n.d.). *SDG Target 3.2: End Preventable Deaths of Newborns and Children Under 5 Years of Age*. Retrieved May 23, 2026, from https://www.who.int/data/gho/data/themes/topics/sdg-target-3_2-newborn-and-child-mortality

Ady Thea DA. (2023). *Ada Dugaan Pelanggaran Prinsip Bisnis dan HAM dalam Kasus Gagal Ginjal Anak*. https://www.hukumonline.com

Almanac, P. (2024). *How Can Pharmaceutical and Biopharmaceutical Companies Demonstrate Their Commitment to ESG Principles in Manufacturing?*

https://www.pharmasalmanac.com/articles/how-can-pharmaceutical-and-biopharmaceutical-companies-demonstrate-their-commitment-to-esg-principles-in-manufacturing

Anggito, D. B. (2023). Pertanggungjawaban Negara dan Pelaku Usaha Farmasi dalam Kasus Gagal Ginjal Akut Indonesia. *UNES Law Review*, *6*(1), 2464–2479. https://doi.org/10.31933/UNESREV.V6I1.1032

Aryaputra, M. I., & Triwati, A. (2023). Arah Kebijakan Sistem Pemidanaan Bagi Korporasi Dalam KUHP Nasional. *Jurnal Masalah-Masalah Hukum*, *52*(2), 208–216. https://doi.org/https://doi.org/10.14710/mmh.52.2.2023.208-216

Azizah, K. N. (2022). *Menkes Ungkap Penyebab Gagal Ginjal Akut Pada Anak Dipicu Cemaran EG dan DEG*.

Dwinanda, I. A. (2022). Pertanggungjawaban Pidana Terhadap Perusahaan Ekspedisi Yang Melakukan Pengiriman Narkotika Dihubungkan Dengan Identification Theory. *Jurnal Mah*, *1*(2), 137–152.

Edyanti, Y. (2022). Perbuatan Melawan Hukum Oleh Penguasa (Onrechtmatige Overheidsdaad) (Suatu Tinjauan Analisis Administrasi Pemerintahan). *"Dharmasisya" Jurnal Program Magister Hukum FHUI*, *2*(2), 14.

Fahreza, A. R., & Kongres, E. (2023). Pengawasan Kementerian Kesehatan Dan BPOM Atas Peredaran Obat Sirup Anak Yang Menyebabkan Gagal Ginjal Akut. *Jurnal Hukum Magnum Opus*, *6*(2), 102–110. https://doi.org/10.30996/jhmo.v6i2.8763

Halim, C., & Indrianto, A. (2022). PERBUATAN MELAWAN HUKUM YANG DILAKUKAN OLEH PENGUASA (ONRECHTMATIGE OVERHEIDSDAAD) DALAM PUTUSAN PENGADILAN: SEBUAH STUDI KASUS. *Justitia et Pax*, *38*(1). https://doi.org/10.24002/JEP.V38I1.5515

Hardiantoro, A. (2022). *BPOM Larang 2 Zat dalam Produk Obat Sirup Imbas Penyakit Gagal Ginjal Akut Misterius*.

Herliana, N. P. M. H., Sukadana, D. A. P., Sudharma, K. J. A., & Nandari, N. P. S. (2026). Disharmonisasi Norma Tanggung Jawab Pelaku Usaha Berbasis Strict Liability dalam Sengketa Konsumen. *Jurnal Mahasiswa Humanis*, *6*(2), 752–762. https://doi.org/https://doi.org/10.37481/jmh.v6i2.2028

Indonesia, O. R. (2022). *Kasus Gagal Ginjal Akut pada Anak, Ombudsman Sampaikan Temuan dan Tindakan Korektif Kepada Menkes dan Kepala BPOM - Ombudsman RI*. https://ombudsman.go.id/news/r/kasus-gagal-ginjal-akut-pada-anak-ombudsman-sampaikan-temuan-dan-tindakan-korektif-kepada-menkes-dan-kepala-bpom

Kurniawan, K. dwi, & Hapsari, D. R. I. (2022). Pertanggungjawaban Pidana Korporasi Menurut Vicarious Liability Theory. *Jurnal Hukum Ius Quia Iustum*, *29*(2), 324–346. https://doi.org/10.20885/iustum.vol29.iss2.art5

Luthfan, G. F. F., & Hastarini, A. (2022). Kerangka UN Guiding principles on Business and Human Rights Bagi Pengaturan Kegiatan Bisnis di Indonesia. *Jurnal Riset Dan Kajian Hukum Hak Asasi Manusia*, *1*(1). https://doi.org/https://doi.org/10.37631/jrkhm.v1i1.7

Nations, U. (n.d.). *Goal 3: Ensure Healthy Lives and Promote Well-Being for All at All Ages*. Retrieved May 23, 2026, from https://www.un.org/sustainabledevelopment/health/

Naufal, M., & Maullana, I. (2022). *71 Anak di Jakarta Terserang Gangguan Ginjal Akut, 40 di Antaranya Meninggal*.

Nono, J. D. B. S., & Dollu, D. Y. (2025). Komitmen dan Realitas: Menjawab Defisit Perlindungan terhadap Anak Pengungsi Tanpa Pendamping di Indonesia. *Kajian Ilmiah Hukum Dan Kenegaraan*, *3*(2), 69–78. https://doi.org/10.35912/kihan.v3i2.5020

Prayuti, Y., Lany, A., Yusmana, F. V., Reza, M., Sehafudin, S., & Zaelani, M. R. (2025). Analisis Tanggung Jawab Pelaku Usaha Atas Barang Tidak Sesuai Komposisi: Perspektif Pasal 62 Undang-Undang Perlindungan Konsumen No.8 Tahun 1999. *Jurnal Hukum Internasional Dan Perdagangan*, *9*(2), 56–75.

Putra, K. S., & Priyanti, G. A. P. N. (2021). Aspek Perlindungan Hukum Peredaran Obat Tanpa Izin Edar Lembaga Berwenang Menurut Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Studi Kasus: Putusan PN Singaraja Nomor 80/Pid.sus/2017/PN SGR). *Jurnal Media Komunikasipendidikan Pancasila Dan Kewarganegaraan*, *3*(2), 77–90. https://doi.org/https://doi.org/10.23887/jmpppkn.v3i2.434

Rubio, L. (2025). *ESG Compliance vs Leadership: Research from 300 Pharma Companies*. https://www.laboratoriosrubio.com/en/esg-pharma/

Santusti, E. G., & Ramadhani, D. A. (2024). Pertanggungjawaban Perdata Badan Pengawas Obat dan Makanan dalam Kasus Gagal Ginjal Akut pada Anak Di Indonesia. *DIVERSI : Jurnal Hukum*, *9*(2), 442–471. https://doi.org/10.32503/DIVERSI.V9I2.4968

Selvi, Januardy, I., & Sangalang, R. S. (2026). Pertanggungjawaban Pidana Korporasi dalam Tindak Pidana Korupsi di Indonesia : Analisis Yuridis dan Kriminologis Berdasarkan KUHP. *Jurnal Ilmu Sosial & Hukum*, *4*, 3938–3955. https://doi.org/https://doi.org/10.61104/alz.v4i1.3697

Septina, D. (2022). *Gangguan Gagal Ginjal Akut Misterius Serang Ratusan Anak Dugaan Awal Keracunan Obat*.

Sukmawan, Y. A., & Damayanti, D. (2025). Metode Penelitian Hukum Normatif dan Empiris Sebagai Strategi Penguatan Perspektif Kajian Ilmu Hukum. *Notary Law Journal*, *4*(1). https://doi.org/https://doi.org/10.32801/nolaj.v4i3.116

Sunanto, Diatmika, I. P., Istiharoh, U., & Utami, R. S. (2026). Tanggung Jawab Hukum Produsen Farmasi Terhadap Konsumen Atas Peredaran Sirup Terkontaminasi Yang Menyebabkan Gagal Ginjal Akut. *Jurnal Ilmu Sosial & Hukum*, *4*(2), 401–414. https://doi.org/https://doi.org/10.61104/alz.v4i2.4292

Acknowledgments

The authors would like to express their sincere gratitude to all individuals who contributed to the completion of this research. This study was collaboratively conducted by Anggi Widyastuti, Heni Utari Setianingrum, and Zerine Destiva Pasa Ramadhani, all

of whom made significant contributions to planning, reseach, analysis, writing, and completion of this study. The authors also extend their deepest appreciation Triana Dewi Seroja for her valuable guidance, constructive feedback, and continuous support throughout the research process. her insightful suggestions and carefull revisions greatly enhanced quality and clarity of this study. The authors are grateful to everyone who, directly or indirectly, provided support and encouragement during the completion of this research. This research did not receive any specific grant from funding agencies in the public, commercial, or not for profit sectors.

Competing Interest

The authors state that there is no conflict of interest in the publication of this article.

Generative AI Statement

During the preparation of this manuscript, the authors used ChatGPT (OpenAI) solely as a supportive writing tool to assist with translating portions of the manuscript from Indonesian into English and improving language clarity and readability. The AI was not used to generate the research ideas, research design, methodology, data collection, data analysis, interpretation of findings, or scientific conclusions. All AI generated outputs were carefully reviewed, revised, and validated by the authors to ensure their accurancy, consistency, and compliance with academic and scientific standards. The authors take full responsibility for the content of this manuscript, including its originality, accurancy, and scientific integrity. ChatGPT served only as a language assistance tool and is not credited with authorship.