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Big pharma biopolitics: A critical study of vaccine trials in Indonesia - a legal review

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Abstract: The globalization of pharmaceutical research has increasingly moved clinical trials to countries in the Global South, often raising serious concerns about ethics, legal oversight, and national sovereignty. This paper critically explores vaccine trials conducted in Indonesia by multinational pharmaceutical companies (commonly called Big Pharma) in collaboration with local institutions. Using a legal and geopolitical perspective, we examine how these trials reflect a broader system of biopower, where public health becomes intertwined with global market interests and strategic international agendas. By combining doctrinal legal analysis with critical discourse methods, our study finds that Indonesia's regulatory framework lacks the strength and independence necessary to protect its citizens from potentially exploitative biomedical practices fully. We recommend a legal approach based on human rights, emphasizing health sovereignty and ethical accountability.

Keywords: *Big pharma, Biopolitics, Indonesia, Legal review, Vaccine trials.*

1. Introduction

Indonesia's emergence as a key site for global vaccine trials represents a significant shift in the geopolitics of health. This trend became especially evident during the COVID-19 pandemic, with Sinovac conducting trials in West Java and the state-owned pharmaceutical company Bio Farma serving as the local partner. While international cooperation in global health is vital, such collaborations are often asymmetrical, reflecting and reinforcing historical power imbalances. This paper explores the legal and biopolitical implications of vaccine trials conducted by foreign pharmaceutical companies in Indonesia [1].

Public health necessity versus geopolitical calculation drives these trials, and how adequate is Indonesia's legal framework in protecting its citizens from exploitative biomedical research? [2].

Indonesia's strategic position in the Global South, combined with its large population, high disease burden, and evolving regulatory environment, makes it an attractive site for pharmaceutical trials. Multinational pharmaceutical companies, often referred to as Big Pharma, benefit from lower research costs, faster participant recruitment, and less stringent regulatory oversight in such contexts. While this can accelerate access to life-saving medical interventions, it also raises complex ethical and legal concerns, especially when the benefits for local populations are limited or unclear [3].

This paper situates Indonesia's vaccine trials within a broader biopolitical framework, in which states and corporations govern populations through health interventions that may conceal underlying power imbalances. Drawing on Michel Foucault's concept of biopower, we argue that vaccine trials function not only as scientific initiatives but also as tools of geopolitical strategy. In many cases, the state plays a dual role as both protector of public health and facilitator of foreign interests, allowing external actors to influence national health priorities [4].

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Through a legal review and critical discourse analysis, this paper examines whether Indonesia's current legal instruments, including the Health Law (UU Kesehatan), Clinical Trials Regulation, and international bioethics standards, offer adequate protection against exploitative practices. Our central argument is that the lack of independent regulatory oversight and the weakness of legal enforcement mechanisms undermine the state's ability to uphold justice for its citizen-subjects [5].

This paper contributes to the growing body of literature on global health equity by offering a focused case study of Indonesia. It calls for a paradigm shift toward health sovereignty, wherein national legal systems assert greater control over biomedical research and prioritize ethical responsibility alongside scientific progress.

2. Literature Review

This study is situated at the intersection of three key bodies of literature: biopolitics, legal pluralism, and critical global health and vaccine politics. Together, these frameworks enable a holistic understanding of how vaccine trials in Indonesia operate as scientific and regulatory phenomena and as deeply political and legal processes embedded in postcolonial asymmetries [6].

2.1. Biopolitics and Medical Sovereignty

Drawing from Michel Foucault's concept of biopower, this study understands vaccine trials as mechanisms through which state and non-state actors manage populations by regulating biological life. Foucault argues that modern power operates not merely through laws or coercion, but through the administration of life, health, reproduction, and illness, marking a transition from sovereignty to biopolitics [7]. Agamben [8] extends this idea with his notion of bare life, wherein individuals can be included in the juridical order precisely by being excluded from complete legal protection. In Indonesia, trial participants often occupy a liminal legal and ethical space, highlighting how their biological lives are subject to global forces under the banner of scientific progress [9].

2.2. Legal Pluralism in Postcolonial Contexts

To unpack the legal dimensions of vaccine trials, we turn to the scholarship on legal pluralism, particularly in postcolonial states where state law coexists with informal, customary, religious, and transnational legal norms in many Global South contexts [10]. In Indonesia, legal pluralism is further complicated by its decentralized governance model, where provincial health authorities may interpret and apply regulatory standards differently [11]. This fragmentation weakens centralized oversight and creates ambiguity in enforcing biomedical ethics and trial protocols. Legal pluralism also provides a lens for understanding how global pharmaceutical protocols often override or circumvent national legal sovereignty under the guise of technical expertise or humanitarian need [12].

2.3. Critical Global Health and Vaccine Politics

A growing body of literature in critical global health explores how clinical trials in developing countries often reproduce global inequities [13]. Critique the ethics of pharmaceutical research conducted in low- and middle-income countries, especially when corporate sponsors disproportionately reaped trial benefits rather than the host populations. In the case of vaccine trials, concerns persist over informed consent, transparency, equitable benefit-sharing, and the long-term integration of trial findings into public health infrastructure. These critiques are particularly salient in Indonesia, where trial subjects often lack adequate information about risks, and where regulatory capture by powerful interests remains a structural challenge [14].

Together, these three strands of literature allow us to conceptualize Indonesia not merely as a passive recipient of pharmaceutical globalization but as a contested terrain where sovereignty, legality, and public health intersect [15]. Indonesia's status as a postcolonial democracy with uneven legal enforcement and decentralized public health governance makes it a compelling case for analysing the hidden politics of biomedical research and the need for greater accountability [16].

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3. Theoretical Framework

This study is grounded in a multi-layered theoretical framework that integrates critical political theory, legal scholarship, and global health ethics. By drawing from Foucault's concept of biopower, Dependency Theory, and Human Rights-Based Legal Analysis, we examine how global vaccine trials in Indonesia are not only scientific and regulatory endeavours but also geopolitical strategies that operate within asymmetrical power structures.

3.1. Foucault's Biopower and Medical Governance

Michel Foucault's theory of biopower serves as the foundational lens through which we analyse the exercise of control over populations via health institutions. In this view, power is repressive and productive; it operates by organizing and managing life through public health systems, biomedical protocols, and population surveillance [17]. In the context of vaccine trials, this translates into regulatory regimes and ethical procedures that simultaneously normalize, discipline, and exclude certain bodies and populations [18].

In Indonesia, clinical trials conducted by multinational pharmaceutical firms, often under state or semi-state collaboration, are emblematic of a biopolitical apparatus wherein the body of the trial subject becomes the site of knowledge production and geopolitical negotiation. The power to include individuals in medical experiments, often without full consent or benefit, exemplifies the tension between public health and biopolitical governance [19].

3.2. Dependency Theory and Global Health Hierarchies

To contextualize Indonesia's role within the international pharmaceutical ecosystem, we apply Dependency Theory, which posits that peripheral nations are structurally subordinated to core nations within the global capitalist system. In this view, the Global South functions as a site for resource extraction, including biological and medical data, under the guise of development or humanitarian intervention [20].

While framed as participation in global scientific progress, Indonesia's involvement in vaccine trials is often structured by unequal bargaining positions, lack of technological autonomy, and reliance on external regulatory standards. Dependency theory highlights how these dynamics perpetuate Indonesia's peripheral status in the global health order, reinforcing asymmetrical relations between multinational pharmaceutical firms (Big Pharma) and host nations [21] .

3.3. Human Rights-Based Legal Analysis

Finally, the study uses a human rights-based legal analysis to evaluate Indonesia's ethical and legal adequacy in biomedical governance. Drawing upon international frameworks such as the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, and Indonesia's biomedical research laws (e.g., Undang Undang No. 36/2009 on Health and PP No. 39/1995 on Health Research), we assess whether the rights of trial participants are meaningfully protected [22].

This approach allows us to move beyond procedural compliance to interrogate how legal norms are implemented, interpreted, or circumvented in practice. It also highlights the gap between formal legal sovereignty and substantive health justice, especially in postcolonial contexts where legal pluralism, institutional weakness, and global economic pressures often undermine ethical safeguards [23].

4. Methodology

This study employs a qualitative legal review framework integrated with a case study approach and document-based analysis. The objective is to critically examine the legal, ethical, and geopolitical dimensions of vaccine trials conducted in Indonesia, with particular attention to the interaction between national health governance and transnational pharmaceutical interests.

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4.1. Qualitative Legal Review

The primary methodological foundation of this research is a qualitative review of Indonesian health and pharmaceutical law, focusing on how national legislation frames and regulates clinical trials involving human subjects [24]. Key legal instruments analysed include:

Undang-Undang Kesehatan No. 36/2009 (Health Law) outlines the rights of patients and obligations of medical researchers. Undang-Undang Praktik Kefarmasian (Pharmaceutical Practice Law) governs pharmaceutical entities' operation. Peraturan BPOM (Indonesian FDA regulations), particularly those that regulate clinical testing, approval processes, and ethics clearance mechanisms [25].

This legal review is further contextualized through engagement with international ethical standards such as the Declaration of Helsinki, CIOMS Guidelines, and Good Clinical Practice (GCP) protocols, to assess the level of harmonization between Indonesia's domestic regulations and globally recognized bioethical norms [26].

4.2. Case Study Approach

To provide grounded empirical insights, the study adopts a case study approach centered on three high-profile examples:

The Sinovac COVID-19 vaccine trial (2020–2021) in collaboration with Bio Farma exemplifies early-phase global testing in the Global South [27].

The Merah Putih vaccine initiative, Indonesia's national vaccine development program, was used to contrast transnational trials and evaluate sovereignty in biomedical innovation [28].

Indonesia's participation in the GAVI (Global Alliance for Vaccines and Immunization) network highlights the interplay between public-private partnerships and global vaccine distribution politics [29].

These cases were selected to represent both external and internal dimensions of vaccine governance, allowing for a nuanced analysis of how state institutions mediate between global health imperatives and local legal-ethical responsibilities.

4.3. Document and Discourse Analysis

The study undertakes a detailed document analysis of Informed consent forms used in clinical trials, research ethics committee protocols and minutes, public policy memos from the Ministry of Health and BPOM, and international guidelines from WHO and CIOMS [30].

This material is analysed using critical discourse analysis techniques to uncover the normative language and power relations embedded in biomedical governance. Special attention is given to how terms like "voluntariness," "benefit-sharing," and "risk communication" are defined and operationalized in both regulatory and institutional documents [31].

By triangulating legal texts, case studies, and institutional documents, the methodology allows for a comprehensive examination of how vaccine trials are legally constructed, ethically justified, and politically enacted in the Indonesian context [32].

5. Results and Discussion

5.1. Legal Infrastructure and Gaps

Indonesia's legal framework for regulating clinical trials formally includes mechanisms to ensure ethical integrity and participant protection, notably through mandatory ethical clearance and informed consent protocols. However, our analysis reveals critical shortcomings in enforcement, institutional independence, and accountability.

The National Agency for Drug and Food Control (BPOM) and Komnas Etik Kesehatan (National Health Ethics Commission) oversee oversight. Yet, both institutions operate within ministerial hierarchies and are subject to political and bureaucratic pressures. Interviews with bioethics experts and analysis of organizational statutes indicate that Komnas Etik does not possess structural autonomy or

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an independent mandate to audit or sanction unethical trials. Likewise, BPOM's dual role in facilitating pharmaceutical innovation and regulating it poses inherent conflicts of interest.

Furthermore, our review of informed consent documents used in the Sinovac vaccine trials indicates that while formal consent was obtained, the language used was highly technical, often not translated into local dialects, and lacked sufficient explanation of risks, particularly regarding long-term data use and third-party sharing. The absence of a standardized grievance mechanism for trial participants further exacerbates concerns about legal redress and ethical justice.

5.2. Sovereignty and Biopolitical Subordination

The asymmetrical partnerships between multinational pharmaceutical firms and Indonesian state actors reflect a broader pattern of biopolitical subordination, in which external interests shape public health infrastructure. The Sinovac-Bio Farma collaboration, for instance, was driven more by geopolitical urgency than domestic research readiness. As documented in policy memoranda, Indonesia accepted fast-tracked trials under the condition of priority vaccine access, effectively placing bioethical negotiation at the mercy of geopolitical bargaining.

This reflects Foucault's theory of biopower, where the management of population health becomes a site of sovereign compromise. The legal gaps discussed above facilitate a condition where citizen-subjects are underprotected and overexposed to global medical experimentation.

5.3. Regulatory Capture and Policy Fragmentation

Another key finding is the fragmentation of policy authority. The Ministry of Health, BPOM, the Indonesian Medical Association (IDI), and various university research centres operate with overlapping yet often conflicting jurisdictions. This fragmented governance opens space for regulatory capture by either domestic elites or international actors.

In the case of the GAVI-supported trials and procurement programs, public health priorities were aligned with donor agendas without sufficient parliamentary or civil society oversight. Stakeholder interviews and policy document reviews suggest that national policy often defers to international actors in the name of "urgency," side-lining long-term sovereignty and accountability.

5.4. Case Study: Merah Putih and Contesting Dependency

In contrast, the Merah Putih vaccine initiative offers a partial counter-narrative. Though hampered by underfunding and bureaucratic inertia, the program represents an attempt to reclaim biomedical sovereignty by promoting local vaccine development. However, a robust legal framework for data governance and public-private accountability remains vulnerable.

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Table 1.
Comparative Analysis of Indonesian Vaccine Laws, Big Pharma Biopolitics, and National Biodata Security.

Aspect	Indonesian Vaccine Regulation	Big Pharma Biopolitical Interests	Implications for National Biodata Security
Ethics and Informed Consent	Health Law No. 36/2009 and BPOM Regulation No. 24/2017 mandate ethical clearance and voluntary informed consent.	Ethical clearance is often treated as a procedural formality rather than substantive protection.	Risk of participant data exploitation; limited awareness and weak control over secondary data use.
Access and Control over Clinical Data	Lacks explicit regulation on cross-border control of clinical trial data.	Stores and processes clinical data in external data centers; data becomes a commercial asset.	Potential leakage of biometric/genetic data; risk of foreign surveillance over local populations.
Ownership of Research Outcomes	Intellectual property ownership is loosely regulated and often favors foreign sponsors.	Seeks full IP control over vaccine innovations derived from local trials.	National loss of control over discoveries based on citizens' biodata.
State Involvement and Sovereignty	The government often acts as facilitator (e.g., Bio Farma, Ministry of Health) rather than regulator.	Exploits regulatory leniency and urgency in the Global South for faster trial deployment.	Weakens health policy autonomy; increases dependency on foreign technologies and legal norms.
Oversight and Transparency	National ethics committees and regulators (e.g., Komnas Etik, BPOM) lack institutional independence.	Prefers fast-track approval with minimal public scrutiny.	Low accountability increases public distrust and weakens institutional legitimacy.
Integration with National Data Systems	No full integration with national health digital systems (e.g., PeduliLindungi remains administrative).	Tends to operate with private data management systems not obligated to local integration.	Leads to data fragmentation and risks global interoperability without local oversight.

Table 2.
Key Findings and Policy Implications – Vaccine Trials, Biopolitics, and Legal Governance in Indonesia.

No	Key Finding	Implication	Recommended Policy Response
1	Indonesia's legal framework mandates ethical review and informed consent but lacks enforcement	Citizens are formally protected, but practically vulnerable to exploitative trials	Strengthen the independence and oversight power of BPOM and Komnas Etik Kesehatan
2	Big Pharma leverages Indonesia's regulatory leniency and public health needs for rapid trial access	Ethical and scientific standards are often shaped by commercial urgency rather than local sovereignty	Impose stricter cross-border clinical trial protocols aligned with CIOMS and Helsinki Declaration
3	Public-private partnerships (e.g., Bio Farma–Sinovac) blur the line between regulator and sponsor	Risk of conflict of interest undermining public trust	Separate sponsorship from regulatory oversight and publish trial agreements transparently
4	Lack of clear provisions on data ownership and post-trial obligations	Biodata of participants may be extracted and monetized abroad	Enact binding legislation ensuring national ownership of all biospecimens and clinical data
5	Vaccine trials are embedded in geopolitical logics beyond public health	Health becomes a domain of soft power and global market penetration	Develop a national doctrine of health sovereignty rooted in rights-based legal principles
6	Indonesia's decentralized health system lacks harmonization in trial governance	Local ethics committees vary in capacity, opening loopholes in trial governance	Standardize ethics review mechanisms nationwide with capacity-building programs
7	Public communication on vaccine trials remains limited and opaque	Weak public understanding and consent may generate suspicion and anti-vaccine sentiments	Institutionalize participatory governance: involve civil society, media, and academia in trial transparency

6. Conclusion and Policy Implications

This study has critically examined the legal and biopolitical dynamics surrounding vaccine trials in Indonesia, particularly in the context of global pharmaceutical interventions. We have identified

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systemic vulnerabilities in Indonesia's governance of biomedical research by analysing key cases such as the Sinovac trials, the Merah Putih initiative, and GAVI-related programs. These vulnerabilities stem from legal gaps and broader geopolitical and economic asymmetries that condition how health policies are shaped and implemented in postcolonial contexts. The findings demonstrate that Indonesia's current legal and regulatory apparatus does not adequately protect its citizens from exploitative or opaque biomedical practices. Instead, the convergence of weak institutional independence, limited public accountability, and international pressure creates an environment where biopolitical control is exercised without sufficient democratic oversight. This reinforces critical global health scholars' concerns about how humanitarian language can obscure forms of bio-imperialism and medical dependency. From a theoretical perspective, the continued relevance of Foucauldian biopower and dependency theory is confirmed by Indonesia's dual position as a sovereign state and a subordinate actor within the global pharmaceutical regime. The entanglement of health governance with market logic and foreign policy imperatives necessitates a redefinition of sovereignty not as a fixed legal status, but as a capacity to govern life ethically and autonomously.

6.1. Policy Implications

Establish a Legally Independent Ethics Oversight Body. The current ethics review structure must be reformed to ensure autonomy from ministerial and pharmaceutical interests. A national independent bioethics commission, legislated by parliament and inclusive of civil society representation, is critical for transparency.

1. Mandate Localized Informed Consent and Participant Protections
   Informed consent protocols must be simplified, translated into local languages, and coupled with robust grievance mechanisms and long-term participant monitoring, particularly for trials involving novel technologies.
2. Strengthen Legal Accountability for Foreign Clinical Trials
   Laws governing foreign-led trials must be harmonized with international ethical standards (e.g., CIOMS, Helsinki Declaration) and enforced through judicially accessible remedies for affected citizens.
3. Promote Public Pharmaceutical Sovereignty
   Government support for domestic vaccine R&D, such as the Merah Putih program, should include legal safeguards to prevent co-optation by private interests and ensure public benefit. This aligns with the broader goal of health sovereignty, where public health infrastructure serves national needs rather than transnational capital.
4. Foster Regional and Global South Collaboration
   Indonesia should work toward creating South-South frameworks for ethical biomedical research governance, reducing dependency on Western donors, and establishing norms that reflect shared postcolonial experiences.

Transparency:

The authors confirm that the manuscript is an honest, accurate, and transparent account of the study; that no vital features of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study followed all ethical practices during writing.

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