Comparative Analysis of Pharmacy Practice Regulations: Lessons from Nigeria and the United States

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Abstract

Pharmacy practice regulation is central to safeguarding public health and shaping the professional responsibilities of pharmacists. This study provides a comparative analysis of the regulatory frameworks in Nigeria and the United States, examining their structures, scope of practice, and enforcement mechanisms. Using secondary evidence, it highlights how Nigeria's centralized model under the Pharmacists Council of Nigeria offers coherence but struggles with weak enforcement and the persistence of informal markets. At the same time, the U.S. demonstrates a layered, resource-intensive system marked by both accountability and variability across states. The findings reveal that Nigeria requires stronger enforcement mechanisms and professional integration, while the United States must address inconsistencies created by state-level fragmentation. Lessons for reform emphasize the importance of accountability, patient-centered care, and international alignment. Future research directions underscore the potential role of digital accountability, trauma-informed engagement, and socio-ethical legitimacy in strengthening pharmacy regulation.

Keywords:

Pharmacy regulation, Nigeria, United States, Enforcement, Professional practice

Introduction

Pharmacy regulation plays a central role in ensuring the safety, accessibility, and effectiveness of medicines, while also shaping the responsibilities and accountability of the pharmacy profession. Across the globe, the regulation of pharmacy practice has been closely tied to broader public health systems, with

different countries adopting frameworks suited to their legal, cultural, and economic contexts. Nigeria and the United States provide contrasting but instructive case studies in this regard. Nigeria represents a developing system where regulatory agencies, such as the Pharmacists Council of Nigeria (PCN), face challenges including enforcement difficulties, resource limitations, and the persistence of informal pharmaceutical markets (Usar & Bukar, 2020; Kyle, 2025). In contrast, the United States presents a more mature system, characterized by multiple oversight bodies including the Food and Drug Administration (FDA), the National Association of Boards of Pharmacy (NABP), and state-level boards, each with distinct enforcement powers and regulatory philosophies (American Economic Association, 2025).

Scholars have long argued that the regulatory framework of pharmacy practice influences not only professional identity but also the outcomes of patient care. Anderson (2005) observed that regulatory evolution in many countries follows the trajectory of shifting pharmacy from a focus on dispensing to a patient-centered model, requiring both legal and institutional transformation. Similarly, Gross (2018) emphasized that robust regulatory systems are crucial for preventing unsafe practices, particularly in markets susceptible to counterfeit medicines. The Nigerian case illustrates these concerns vividly, as Ofoegbu (2012) noted that fragmented enforcement enables the parallel operation of unregistered premises, undermining public confidence in pharmacy services. By comparison, the U.S. experience demonstrates that rigorous enforcement mechanisms, although resource-intensive, foster a culture of accountability that supports professional expansion into immunization, medication therapy management, and prescribing in some states (Klepser et al., 2016). The global perspective underscores the importance of regulation as a dynamic process shaped by social needs, economic pressures, and international standards. The World Health Organization (2010) emphasized that well-structured pharmaceutical governance frameworks directly improve access to essential medicines. Likewise, the International Pharmaceutical Federation (FIP, 2016) advocated for harmonized global standards in training, accreditation, and continuing professional development to ensure quality care regardless of geography. For Nigeria, aligning with such benchmarks has been identified as both a challenge and an opportunity, as regulatory gaps can be addressed by adopting tested models without simply transplanting resource-intensive systems unsuited to local realities (Usar & Bukar, 2020).

A comparative approach between Nigeria and the United States, therefore, provides fertile ground for drawing policy lessons. On the one hand, Nigeria highlights the struggles of low-resource settings, where enforcement capacity is limited and informal systems prevail. On the other hand, the U.S. demonstrates the benefits of layered regulatory institutions, albeit with challenges such as the complexity of federal–state divisions and inconsistencies in reimbursement for advanced pharmacy services (American Economic Association, 2025). By analyzing these systems side by side, this study aims to highlight actionable insights for strengthening pharmacy practice in Nigeria while also reflecting on areas where the U.S. can learn from the flexibility of developing systems.

Objectives

1. To analyze similarities and differences in pharmacy practice regulations between Nigeria and the U.S.

2. To examine how regulatory structures affect professional roles and public health outcomes.

3. To evaluate implementation challenges across both systems.

4. To identify policy lessons for strengthening regulatory frameworks in Nigeria.

Related Work

The comparative study of pharmacy regulation draws on a broad body of scholarship that emphasizes how legal frameworks, institutional arrangements, and professional roles evolve differently across countries. Historical accounts highlight that pharmacy regulation has often developed in tandem with broader reforms in public health and medicine. Anderson (2005) argued that regulatory reforms in pharmacy typically mark the profession's transition from being medicine sellers to health professionals with patient-centered roles. In Nigeria, this transition has been hindered by weak governance structures and inconsistent enforcement (Ofoegbu, 2012). In contrast, the United States has witnessed a steady expansion of pharmacist responsibilities as legal and institutional frameworks have matured, particularly under state-level boards that have progressively allowed pharmacists to prescribe medications and administer immunization services (Klepser et al., 2016).

Comparative health law analyses also note that while both developed and developing countries aim to protect patient safety and ensure the quality of medicine, the tools and mechanisms employed vary greatly. Gross (2018) noted that in contexts with fragile health governance, counterfeit and substandard medicines thrive due to inadequate oversight. This is a persistent challenge in Nigeria, where enforcement gaps allow unlicensed premises and informal drug sellers to operate in parallel with formal systems (Usar & Bukar, 2020; Kyle, 2025). Conversely, in the United States, rigorous enforcement by the Food and Drug Administration (FDA) and state boards of pharmacy provides a stronger shield against counterfeit products; however, it introduces complexity through overlapping jurisdictions and regulatory variations across states (American Economic Association, 2025). International organizations have attempted to harmonize regulatory standards. The World Health Organization (2010) stressed that robust pharmaceutical governance is directly linked to improved access and safe use of medicines. The International Pharmaceutical Federation (FIP, 2016) has similarly promoted Good Pharmacy Practice standards as benchmarks for national regulators. Nigeria's gradual adoption of such international frameworks demonstrates its recognition of global trends, despite resource limitations hindering full implementation (Usar & Bukar, 2020). In the U.S., adherence to international standards is filtered through federal and state structures, which creates both innovation and inconsistency (American Economic Association, 2025). Another theme in the literature concerns professional scope and the evolution of pharmacists' roles. Anderson (2011) highlighted that regulation not only restricts practice but also enables new functions when trust in the profession increases. This is evident in the United States, where regulatory reforms have

empowered pharmacists to deliver medication therapy management and preventive services, expanding their role beyond dispensing. In Nigeria, regulatory frameworks nominally permit expanded clinical roles; however, enforcement weaknesses and workforce shortages hinder the realization of these reforms (Usar & Bukar, 2020; Kyle, 2025).

To contextualize the evolution of these frameworks, Figure 1 compares the historical development of regulatory milestones in Nigeria and the United States, illustrating how differing political and institutional contexts shaped divergent trajectories. This work establishes that pharmacy regulation is context-sensitive, shaped by governance capacity, historical legacies, and global influences. The Nigerian case underscores the importance of enforcement and institutional strength, while the U.S. illustrates how layered regulation can simultaneously empower and complicate pharmacy practice. Together, these insights provide a foundation for analyzing similarities, differences, and potential lessons between the two systems.

Figure 1. Historical Development of Pharmacy Regulatory Frameworks in Nigeria vs. United States: *(Timeline comparison of milestones such as the establishment of the Pharmacists Council of Nigeria, the adoption of the WHO Good Pharmacy Practice, the creation of the FDA, and state-level expansions of pharmacist roles in the U.S.)*

Figure 1. Historical Development of Pharmacy Regulatory Frameworks

Nigeria
1992 — PCN established
2003 — NAFDAC strengthened
2010 — WHO Good Pharmacy Practice adopted
2016 — CPD framework introduced

United States
1906 — Pure Food & Drug Act (FDA origins)
1938 — Food, Drug & Cosmetic Act
1951 — Durham–Humphrey Amendment (Rx/OTC distinction)
2003 — Medicare MTM coverage begins
2010 — Pharmacist immunization expansion

METHODOLOGY

This study adopts a comparative qualitative design that synthesizes secondary evidence on pharmacy regulation in Nigeria and the United States. The purpose of this approach is to identify convergences and divergences in regulatory structures, scope of practice, and enforcement mechanisms while drawing lessons for strengthening governance in developing contexts. Rather than generating new empirical data, the methodology relies on a systematic review of peer-reviewed literature, policy documents, and scholarly

analyses cited in the two core works that form the basis of this study. The first stage of the analysis focused on selecting relevant secondary sources that examine pharmacy regulation from historical, institutional, and policy perspectives. Priority was given to comparative health law studies, regulatory policy reviews, and international frameworks such as those advanced by the World Health Organization and the International Pharmaceutical Federation. Sources that addressed broader themes of pharmaceutical governance, professional accountability, and public health outcomes were also included, since these shape the context in which pharmacy regulations operate.

The second stage employed thematic analysis to categorize findings into three domains: regulatory structures and frameworks, scope of practice and professional roles, and enforcement and implementation challenges. This thematic categorization allowed for a structured comparison between Nigeria and the United States, highlighting both shared objectives and context-specific constraints. Attention was also given to the socio-political and economic contexts in which regulations emerged, recognizing that governance capacity influences the success of regulatory enforcement. The synthesis emphasized triangulation by comparing insights across multiple secondary sources to minimize bias. Where discrepancies appeared, such as differences in reported enforcement effectiveness, the analysis considered methodological limitations and contextual differences. By combining historical, policy, and professional perspectives, this methodology provides a balanced and comprehensive framework for assessing the regulatory landscapes of Nigeria and the United States.

The Comparative Landscape of Pharmacy Regulation

Regulatory Structures and Frameworks

Pharmacy regulation in Nigeria and the United States reflects divergent historical trajectories and institutional capacities, yet both systems share a central aim of safeguarding patient safety and promoting professional accountability. In Nigeria, the Pharmacists Council of Nigeria (PCN) serves as the primary regulatory authority, empowered by the Pharmacists Council of Nigeria Act to license pharmacists, accredit schools of pharmacy, and monitor practice standards (Usar & Bukar, 2020). However, scholars such as Ofoegbu (2012) have observed that despite the legal framework, weak enforcement and limited resources constrain the PCN's ability to ensure compliance, particularly in rural areas where informal markets for medicines remain active. In contrast, the United States features a multi-layered system that combines federal oversight with state-level authority. The Food and Drug Administration (FDA) regulates the approval, manufacturing, and distribution of drugs. At the same time, the National Association of Boards of Pharmacy (NABP) provides coordination among state boards, which retain authority over licensing, scope of practice, and disciplinary procedures (American Economic Association, 2025).

The Nigerian system illustrates how fragile governance capacity influences regulatory outcomes. Ogunsheye (2015) argued that inadequate funding and limited inspectorate staff restrict the PCN's ability to conduct routine inspections. Moreover, informal practices undermine legitimacy, as observed by Adegboye (2014), who noted that patent medicine vendors often operate beyond their legal remit, filling a gap created by limited access to qualified pharmacists. By comparison, the United States system

demonstrates more vigorous enforcement through a layered institutional structure. Klepser et al. (2016) reported that state boards play a crucial role in defining pharmacists' clinical authority, such as immunization rights, while maintaining disciplinary oversight to preserve professional accountability.

International frameworks also shape national structures. The World Health Organization (2010) and the International Pharmaceutical Federation (2016) emphasize the importance of harmonized Good Pharmacy Practice standards as a foundation for regulation. Nigeria has made efforts to align with these recommendations, but implementation remains inconsistent due to systemic challenges (Usar & Bukar, 2020). In the U.S., global standards are adapted within a federal structure that permits significant variation at the state level, reflecting both innovation and fragmentation (American Economic Association, 2025). Another significant difference lies in the balance between centralization and decentralization. In Nigeria, regulation is formally centralized under the PCN; however, in practice, fragmentation emerges through informal networks that often bypass formal rules. Conversely, in the U.S., decentralization is intentional, with state boards exercising autonomy over licensing and scope of practice. This creates variability; for instance, some states grant pharmacists the right to prescribe, while others limit their role to dispensing (Gross, 2018). Although this can create inequities in access to services, it also allows for policy experimentation and innovation at the state level (Anderson, 2011). To illustrate these structural contrasts, Figure 2 presents a side-by-side comparison of the key regulatory agencies, their functions, and scope of authority in Nigeria and the United States.

Figure 2. Regulatory Structures and Oversight Agencies in Nigeria vs. the United States

Nigeria's regulatory framework is centralized but constrained by enforcement challenges, whereas the United States' system is decentralized, resource-intensive, and characterized by institutional layering. Both systems demonstrate strengths: Nigeria in creating a unified structure and the U.S. in ensuring robust

accountability. However, they also reveal weaknesses shaped by capacity and complexity. These structural dynamics set the stage for a deeper examination of the scope of practice and enforcement mechanisms.

Scope of Practice and Professional Roles

The scope of pharmacy practice defines the professional boundaries within which pharmacists operate and reflects the maturity of regulatory systems. In Nigeria, the Pharmacists Council of Nigeria (PCN) formally recognizes pharmacists as custodians of medicines, responsible for dispensing, compounding, and counseling. However, as Ofoegbu (2012) highlighted, these roles remain restricted largely to traditional dispensing functions, with limited authority to provide advanced clinical services. While the legal framework theoretically supports expanded practice, weak enforcement and insufficient workforce capacity hinder progress (Usar & Bukar, 2020; Kyle, 2025). In contrast, the United States has steadily broadened the pharmacist's role, with regulatory reforms empowering them to engage in medication therapy management, immunization, and, in certain states, prescribing authority (Klepser et al., 2016). Historical perspectives demonstrate the divergence. Anderson (2005) noted that the expansion of pharmacists' roles globally often coincides with stronger regulation and professional recognition. Nigeria has sought to align with such trends by emphasizing continuing professional development (CPD), but implementation remains inconsistent due to resource shortages and inadequate institutional capacity (Ogunsheye, 2015). Adegboye (2014) further observed that in many rural Nigerian communities, patent medicine vendors fill gaps left by the shortage of qualified pharmacists, further restricting opportunities for clinical role expansion. By contrast, in the United States, state boards of pharmacy serve as catalysts for professional advancement, gradually extending pharmacists' roles in response to public health needs (American Economic Association, 2025).

Evidence from comparative studies underscores how professional roles are shaped by regulation. Gross (2018) argued that when enforcement is weak, pharmacists' professional boundaries blur, leading to encroachment by unqualified providers. This is evident in Nigeria, where informal providers often perform dispensing functions without formal training or oversight (Usar & Bukar, 2020). Conversely, in the U.S., clear licensing and disciplinary mechanisms protect professional boundaries while enabling innovation. Anderson (2011) described this as a "dual effect" of regulation: restricting unsafe practices while enabling new functions through structured reforms. Patient-centered care has also shaped the evolution of pharmacists' roles. The World Health Organization (2010) emphasized that pharmacists should play an active role in primary health care teams. In the United States, this vision has materialized through expanded authority in immunization programs, medication therapy management, and collaborative drug therapy agreements (Tan & Stewart, 2016). In Nigeria, progress has been slower. Although pharmacists are increasingly involved in health promotion and counseling, particularly in urban areas, their role in preventive and clinical services remains underdeveloped (Usar & Bukar, 2020).

The issue of remuneration also influences professional practice. In Nigeria, the lack of structured reimbursement mechanisms discourages pharmacists from expanding services beyond dispensing, as such roles are often not financially sustainable (Ofoegbu, 2012). In the United States, reimbursement through Medicare and Medicaid for certain services has facilitated the integration of pharmacists into clinical

care pathways, although disparities exist across states and health systems (American Economic Association, 2025). While Nigeria's regulatory framework provides the foundation for the expansion of the pharmacist's role, systemic weaknesses limit its implementation, leaving practice confined mainly to dispensing. The United States demonstrates how strong regulatory structures, state-level experimentation, and reimbursement mechanisms collectively support the expansion of professional responsibilities. The contrast between these systems illustrates both the potential and the challenges of aligning regulation with evolving public health needs.

**Challenges and Enforcement Mechanisms**

Enforcement represents the most visible test of pharmacy regulation, as laws and frameworks only achieve impact when consistently applied. Nigeria faces persistent difficulties in this regard. The Pharmacists Council of Nigeria (PCN) is legally responsible for licensing, monitoring, and disciplining practitioners; however, studies show that its enforcement capacity is limited (Usar & Bukar, 2020; Kyle, 2025). Ofoegbu (2012) observed that widespread resource constraints, such as inadequate inspectorate staff and funding, prevent routine inspections of pharmacies. Ogunsheye (2015) further noted that the proliferation of unregistered premises and patent medicine vendors undermines compliance and public trust. These challenges reveal a gap between regulatory intent and practice, where informal markets thrive due to weak enforcement. By contrast, the United States demonstrates stronger enforcement capacity but also greater complexity. Federal agencies such as the Food and Drug Administration (FDA) ensure strict oversight of drug approval and manufacturing. At the same time, state boards of pharmacy enforce professional standards at the state level (American Economic Association, 2025). Klepser et al. (2016) reported that disciplinary mechanisms, including suspension and license revocation, are routinely used to ensure accountability. However, the decentralized system also generates variation: some states adopt more expansive enforcement of scope-of-practice regulations, while others remain conservative, creating unevenness across the country (Gross, 2018).

Both systems confront challenges that affect enforcement effectiveness. In Nigeria, weak governance, lack of political will, and limited financial resources restrict the ability of regulators to ensure compliance (Adegboye, 2014). In the United States, the fragmentation between federal and state jurisdictions creates duplication and inconsistencies, which can sometimes complicate enforcement actions (Anderson, 2011). Nevertheless, Nigeria's centralized but under-resourced enforcement contrasts with the U.S. model of layered but resource-intensive oversight, each with unique strengths and weaknesses. To illustrate these dynamics, Figure 3 outlines the enforcement pathways in both systems, highlighting the distinct processes of complaint reporting, investigation, disciplinary action, and appeals.

Figure 3. Enforcement Pathways in Nigeria and the United States

Enforcement is the cornerstone of effective regulation, but also the most challenging element to sustain. Nigeria's experience highlights the dangers of weak enforcement, while the U.S. system illustrates how complexity can undermine consistency. Both cases underscore the importance of establishing effective

enforcement mechanisms that strike a balance between authority, resources, and accountability, thereby safeguarding public health and upholding professional standards.

Figure 4. Enforcement Pathways in Nigeria (Left) vs. United States (Right)
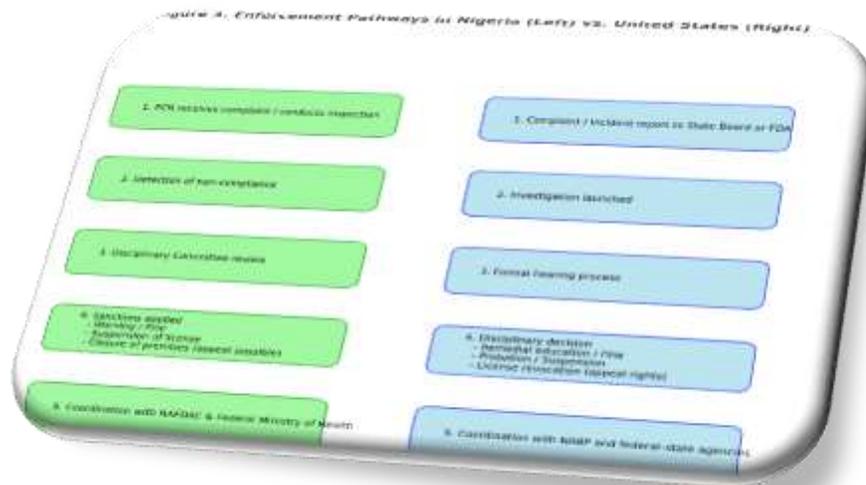
Findings and Discussion

The comparative analysis of pharmacy regulation in Nigeria and the United States reveals both convergence and divergence in how governance frameworks shape professional practice and patient outcomes. While both systems share the overarching goal of ensuring safe and effective access to medicines, their structural, functional, and enforcement approaches differ considerably.

Regulatory Structures

Findings indicate that Nigeria's centralized structure under the Pharmacists Council of Nigeria (PCN) provides a coherent legal framework but suffers from implementation weaknesses. Ofoegbu (2012) and Ogunsheye (2015) highlighted that limited inspectorate capacity and inadequate resources result in inconsistent monitoring of licensed premises. In contrast, the United States benefits from a layered framework in which federal agencies such as the Food and Drug Administration (FDA) regulate medicines. At the same time, state boards and the National Association of Boards of Pharmacy (NABP) oversee practice standards (American Economic Association, 2025). Klepser et al. (2016) demonstrated that this structure enables greater flexibility; however, variation across states also introduces inconsistency. Figure 2 made this contrast clear, showing Nigeria's centralized but under-resourced model versus the U.S.'s decentralized, resource-intensive system.

Scope of Practice

The study also finds significant differences in professional scope. Nigerian pharmacists are primarily confined to dispensing roles, with limited involvement in advanced clinical services (Usar & Bukar, 2020). Adegboye (2014) noted that informal vendors often fill gaps left by shortages of trained pharmacists, weakening professional influence. Conversely, in the United States, regulation has enabled pharmacists to expand their scope to include immunization, medication therapy management, and, in some states,

prescribing authority (Tan & Stewart, 2016). This evolution reflects what Anderson (2011) described as the dual effect of regulation: restricting unsafe practices while enabling new functions through structured reforms. Figure 1 illustrates these developments historically, showing how professional roles expanded in the U.S. while remaining stagnant in Nigeria.

Enforcement Mechanisms

Enforcement represents the most significant divergence. Nigeria's enforcement challenges, rooted in limited capacity and weak political will, create space for informal practices (Usar & Bukar, 2020). Ogunsheye (2015) emphasized that the proliferation of unregistered premises undermines the legitimacy of regulations. By contrast, U.S. enforcement is stricter, with state boards employing disciplinary measures such as license suspension and revocation (Klepser et al., 2016). However, Gross (2018) observed that variation among states can weaken uniformity. Figure 3 illustrates these pathways, contrasting Nigeria's centralized but fragile enforcement with the U.S.'s decentralized but robust system.

Comparative Lessons

Discussion of these findings suggests that both systems provide important lessons. For Nigeria, adopting elements of U.S.-style enforcement and accountability could strengthen compliance, while adapting strategies to local resource realities. For the U.S., Nigeria's example serves as a cautionary reminder of the risks associated with unchecked informal providers, underscoring the importance of accessibility and affordability for policymakers. International bodies, such as the World Health Organization (2010) and the International Pharmaceutical Federation (2016), continue to call for harmonized global standards, underscoring the need for context-sensitive and globally aligned reforms.

Contribution to Research

This study contributes to pharmacy regulatory scholarship by demonstrating the comparative value of examining both centralized and decentralized models of oversight, with Nigeria and the United States serving as representative case studies. It underscores the importance of aligning professional roles with regulatory capacity, and of ensuring that enforcement mechanisms are not only legally robust but also operationally feasible. By situating these findings within broader debates, this work advances the argument that pharmacy regulation must be adaptive, interdisciplinary, and anchored in both local realities and global standards. Future research directions extend beyond regulatory frameworks into broader intersections of technology, ethics, and social systems. Badmus, Adebayo, and Ehigie (2018) have already highlighted the critical role of structural accountability in healthcare technologies, particularly in the deployment of AI, where compliance and traceability must be engineered into systems rather than retrofitted. Integrating such perspectives into pharmacy regulation could enhance oversight of digital tools, electronic prescribing, and supply chain monitoring. Similarly, Fuseini, Boateng, Osekre, and Braimoh (2022) demonstrated how trauma-informed communication strategies reshape care delivery and improve outcomes in mental health. Applying analogous frameworks in pharmacy practice may support regulatory models that prioritize patient-centered care and trust-building within communities. Finally, Ehigie (2025) advanced a socio-ethical critique of stigma and the reimagining of health narratives, offering a lens through which regulation can be

reconceived not merely as compliance but as legitimacy-building, inclusivity, and strengthening of public confidence in health systems. Together, these strands point toward an agenda in which pharmacy regulation is conceived as part of a larger ecosystem that integrates legal, technological, and socio-cultural dimensions. By embedding accountability, patient engagement, and ethical innovation into regulatory practice, future research can ensure that pharmacy continues to evolve in ways that are both globally coherent and locally meaningful.

CONCLUSION

The comparative analysis of pharmacy practice regulation between Nigeria and the United States underscores how different governance contexts shape professional roles, enforcement capacity, and patient outcomes. Nigeria's centralized framework under the Pharmacists Council of Nigeria provides a coherent legal foundation but suffers from resource shortages, weak enforcement, and the persistence of informal markets. By contrast, the United States demonstrates a resource-intensive but fragmented model, with federal, state, and professional bodies dividing responsibilities. This structure fosters innovation, such as expanded prescribing rights and medication therapy management, but also creates inconsistencies across states. The comparison highlights that effective regulation depends not only on the presence of legal instruments but also on the robustness of enforcement and the adaptability of frameworks to evolving health needs. Moving forward, both systems offer reciprocal lessons. Nigeria can draw from the U.S. emphasis on layered accountability, standardized enforcement, and integration of pharmacists into broader care pathways. At the same time, the U.S. might reflect on Nigeria's experience in addressing inequities created by variations across states. At a broader level, the study reinforces the call by international bodies, such as the World Health Organization and the International Pharmaceutical Federation, for regulatory systems that are globally aligned yet context-sensitive. In addition, future research integrating insights from Badmus, Adebayo, and Ehigie (2018), Fuseini, Boateng, Osekre, and Braimoh (2022), and Ehigie (2025) suggests that pharmacy regulation must also evolve to incorporate digital accountability, trauma-informed patient engagement, and socio-ethical legitimacy. By embedding these principles, pharmacy regulation in both Nigeria and the United States can become more resilient, equitable, and responsive to contemporary healthcare challenges.

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