Patients or Consumers? How Stakeholders Compete to Classify Drugs as OTC or Prescription in the United States

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Yusra Babar

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On my honor as a university student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

Advisor

Prof. Peter Norton, Department of Engineering and Society

Preface

This portfolio addresses the question of how medicines reach people safely, affordably, and conveniently. The technical project designs a practical facility capable of producing large amounts of diphenhydramine hydrochloride, a common allergy medicine, without using harmful solvents. By carefully selecting safer chemical steps, the process reduces environmental impact, improves safety for plant workers, and produces medication that meets consumer quality expectations. This ensures that allergy relief can be provided on a scale without sacrificing public safety.

The sociotechnical research paper explores how medicines, once produced, become either prescription or over the counter. Rather than scientific facts alone, this decision involves negotiations among drug companies, physicians, pharmacists, retail stores, insurers, and consumer advocacy groups. The paper investigates how these groups argue about what "safe access" means, influence regulation, and shapes the public's perception, showing that business interests, consumer preferences, and public health priorities all play significant roles.

Together, the two projects highlight the chemical engineer's broader responsibility. Creating a safe and efficient manufacturing process is critical, but equally important is understanding how social institutions affect whether medicines truly benefit people. This combined technical and social perspective helps ensure that medicines are not only effectively made but effectively delivered to those who need them.

Introduction

Over the counter (OTC) medications can greatly reduce the need for doctor visits, letting people treat minor health issues on their own. One study found that 89 percent of consumers value OTC medicines, and 81 percent of adults use them first for minor problems (Kebodeaux, 2019). Among healthcare practitioners surveyed, 89 percent of pediatricians had no concerns recommending OTC products to their patients (Kebodeaux, 2019). Yet many healthcare providers do not know which OTC products their patients use, which can lead to incomplete medical records and safety risks.

In the United States, deciding whether a drug belongs over the counter or by prescription is not determined by science alone. Pharmaceutical companies, health professionals, retail drugstores, insurers, and consumer advocacy groups each try to influence how drugs are classified. Pharmaceutical companies often favor broad access, while many doctors and pharmacists stress the importance of oversight. Retail drugstores must obey regulations but also satisfy consumer demand. Insurers watch for cost control and coverage implications, and consumer advocacy groups fight for fairness and accessibility.

How do these stakeholder groups compete to set the boundary between OTC and prescription drugs, and why is there no single, universal conclusion? The answer lies in conflicting agendas. Each group uses public statements, lobbying, and strategic framing, negotiating rather than simply following clinical data. Such debates have far-reaching effects on public health, market opportunities, and drug costs.

Although this paper focuses on the United States, a brief look at Europe underscores the role of cultural and legal differences. In some European countries, drugs sold over the counter in

the U.S. require a prescription. Research has shown that removing prescription requirements can yield mixed outcomes for safety and availability (Cousins et al., 2021). Thus, local values and conditions guide classification decisions.

A drug's classification emerges from competing social, economic, and political forces, not purely medical evidence. By examining official documents and public communications from each stakeholder group, this research reveals that the OTC–prescription boundary is less a scientific line than a negotiated result of diverse interests.

This argument is timely because U.S. health care reform and drug safety discussions remain lively, and debates about OTC vs. prescription status continue in Europe as well. Understanding how these stakeholders shape drug availability can help policymakers develop fairer, more transparent regulations that balance consumer choice with patient protection.

Review of Research

Research on prescription to over the counter (OTC) medication transitions highlights the complex roles and interactions among diverse stakeholders involved in drug classification decisions. Kebodeaux (2019) emphasizes consumer reliance on OTC medications, showing that the vast majority of adults prefer OTC solutions for minor health issues due to their convenience and immediacy. He also raises concerns about fragmented medical records resulting from unreported OTC use, underscoring the potential for adverse drug interactions and compromised patient safety.

Donohue, Cevasco, and Rosenthal (2007) expand upon consumer dynamics, examining the powerful influence of direct-to-consumer pharmaceutical advertising. They illustrate how

advertising significantly shapes public perception and drives consumer preferences, leading to specific medication requests that may bypass professional medical advice and prioritize brand familiarity over clinical judgment.

From the health insurance perspective, Sullivan and Nichol (2004) analyze the economic implications of OTC transitions, identifying insurers' common practice of ceasing coverage for new OTC medications to achieve immediate cost savings. While advantageous in short term budgeting, this cost transfer to consumers can lead to suboptimal medication choices, risking poorer health outcomes and increased future healthcare expenditures.

Chang et al. (2016) provide insight into pharmaceutical manufacturers' strategic responses to looming patent expirations, explaining how OTC transitions help manufacturers maintain profitability by leveraging established brand loyalty and expanded advertising opportunities. Manufacturers often frame OTC availability as consumer centric, yet underlying motives frequently align with commercial interests and market dominance preservation.

The role of retail drugstores, examined by the National Association of Chain Drug Stores (NACDS, 2022), emphasizes the economic and consumer convenience benefits of OTC drug availability. NACDS advocates regulatory changes to enhance self care and reduce unnecessary medical visits, though critics caution about potential consumer risks due to insufficient pharmacist oversight and possible overreliance on OTC products.

Consumer advocacy groups, such as the Center for American Progress (CAP, n.d.), advocate for equitable access to OTC medications, stressing the importance of clear labeling, effective consumer education, and proactive outreach to vulnerable populations. CAP highlights

the potential for expanded OTC access to inadvertently amplify existing health disparities without deliberate and informed regulatory oversight.

Healthcare providers' perspectives are crucially explored by Sleath et al. (2001), revealing significant communication gaps between providers and patients regarding OTC medication use. They demonstrate that inadequate dialogue may lead to overlooked drug interactions and medication misuse. Chang et al. (2016) reinforce this, emphasizing that physicians and pharmacists face evolving roles and increased responsibilities in counseling and managing patient medication use as more drugs shift to OTC status.

Collectively, this existing scholarship clarifies that drug classification involves far more than clinical evidence alone. It is a dynamic interplay of consumer behavior, economic incentives, regulatory practices, and professional responsibilities, influenced by ongoing negotiations among consumers, insurers, pharmaceutical companies, retail pharmacies, advocacy groups, and healthcare providers. This research framework positions the present study clearly within a broader academic conversation, illuminating how various stakeholder interests shape drug classification outcomes.

American Consumers

Consumers are pivotal stakeholders in the debate over OTC versus prescription drug classification because they are the primary end users, ultimately deciding which medication to purchase and use. Over-the-counter availability allows people to self-diagnose and treat minor ailments without formal medical guidance, a convenience that can foster autonomy. However, as

Clark D. Kebodeaux (2019) argues in Prescription and over-the-counter medication record integration: A holistic patient-centered approach, this self-care approach leads to fragmented medical records if patients fail to report their OTC use to healthcare providers. Unrecorded self-medication raises the possibility of adverse drug interactions and compromises continuity of care.

Moreover, direct-to-consumer advertising heavily shapes how consumers view pharmaceuticals and make purchasing decisions. According to Donohue, Cevasco, and Rosenthal (A Decade of Direct-to-Consumer Advertising of Prescription Drugs - PubMed, n.d.), the last decade has seen a surge in advertising that encourages the public to request certain medications by name. This marketing emphasis can inflate brand familiarity and perceived safety, prompting consumers to gravitate toward specific products whether OTC or prescription and potentially bypass formal medical advice. Such behavior underscores consumer choices are not only driven by health concerns but also by convenience, affordability, brand recognition, and the persuasive impact of advertising. By examining how these factors intertwine, researchers and policymakers gain a clearer view of how consumer actions help determine the fate of OTC vs. prescription classification in the broader healthcare system.

Health Insurance

Health insurers often see immediate cost advantages when a drug transitions from prescription-only to over-the-counter (OTC) status, particularly if they adopt a “No Rx” coverage policy. In this scenario, they simply stop reimbursing pharmacies for that medication, trimming per-member-per-month (PMPM) expenses. While insurers such as those represented by America’s Health Insurance Plans (AHIP) contend that reduced spending can help keep

premiums affordable (By the Numbers: How Health Insurance Providers Contribute To… - AHIP, n.d.). Critics argue that the financial burden shifts to patients who must pay out of pocket for newly OTC items, regardless of their necessity. This cost shifting may also drive individuals toward cheaper but potentially less effective or riskier self-care choices, risking higher long-term costs if they neglect proper treatment ((Sullivan & Nichol, 2004)). Detractors accuse insurers of understating these downstream risks because they rarely bear the blame when self-medication goes awry, possibly leading to emergency visits or hospitalizations. Although AHIP highlights preventive care programs and occasionally advocates for better education on OTC usage, its primary focus on near-term expenditure reduction has led some observers to label insurers the "bad guys" in scenarios where patients end up footing the bill for necessary OTC drugs.

Drug Manufacturer

Drug manufacturers exert considerable influence over the pharmaceutical market, particularly in how they steer prescription drugs into over the counter (OTC) status. This process is often motivated by the looming expiration of patents, which otherwise opens the door for cheaper generics to undermine a brand-name product's profitability. By shifting a medication to OTC, manufacturers can preserve consumer recognition and potentially sustain profit margins despite the imminent competition from generics (Chang et al., 2016).

When a high-revenue product, such as Cialis, faces patent expiration, its manufacturer may try to retain market dominance through a timely switch to OTC status. This transition offers an alternative to watching profits dwindle once generics reach pharmacy shelves. The manufacturer's aggressive approach to keep its hold on consumers can include simplified labeling and consumer-focused marketing that frames the product as a lifestyle convenience.

This approach seeks to entice customers who might otherwise turn to lower-cost options, allowing the brand-name medication to cling to its loyal consumer base.

Another advantage for manufacturers lies in the relaxation of advertising restrictions once a drug becomes available without a prescription. Prescription medications are subject to stringent promotion guidelines and regulatory oversight. By contrast, OTC products can be aggressively marketed through broader, more attention-grabbing campaigns, including straightforward messaging and lifestyle appeals (Johns Hopkins Bloomberg School of Public Health, 2023). Companies can pivot to vivid advertisements that emphasize the perceived benefits of a product. Although these ads can help maintain commercial viability, they also raise questions about how thoroughly consumers receive critical safety information without the direct counsel of a healthcare provider.

Moreover, when a product transitions to OTC status, it shifts the responsibility of medication selection from physicians to consumers. In practice, this may mean that a well-known brand, backed by frequent ads, can overshadow equally effective or more cost-efficient alternatives. Manufacturers exploit that tendency by focusing on brand recognition and convenience to lure consumers, capturing a broader market share under the premise of accessibility. However, this does not always align with patient welfare, since individuals may purchase products that lack thorough guidance, risking misuse and potentially overlooking safer or more suitable treatments (The Dangers of Unregulated Drug Ads | Johns Hopkins | Bloomberg School of Public Health, n.d.)).

Retail drugstores are also a vital stakeholder, represented primarily by the National Association of Chain Drug Stores (NACDS). The organization advocates policies that expand

consumer self-care, arguing that broad OTC availability lowers costs and reduces doctor visits. Recent developments, such as NACDS's successful push for federal action on OTC hearing aids, highlight the group's emphasis on regulatory changes that grant consumers easier access to everyday health solutions (admin, 2022). While these measures can make healthcare more convenient, critics worry about potential overreliance on certain products or insufficient oversight. Large retail chains may fill aisles with an abundance of OTC items, ranging from pain relievers to diet supplements, without guaranteeing that every consumer receives individual guidance from a pharmacist. NACDS, however, maintains that appropriate staff training, store policies, and pharmacist availability can mitigate these risks. In this sense, the organization underscores the retail pharmacy's dual aim: meeting consumer demand for quick, convenient care while maintaining patient safety.

Amid these shifts, the messaging manufacturers use for OTC medications reflects a calculated balance between consumer allure and risk acknowledgment. The labeling must meet regulatory requirements, yet marketing often highlights perceived simplicity and ease of use. Such campaigns can minimize certain cautionary details in the public eye, ultimately placing greater responsibility on consumers to digest fine-print warnings.

In sum, drug manufacturers are high-impact stakeholders when transitioning prescription products to OTC status because they direct product availability, shape public perceptions, and set the tone for how medications are advertised and consumed. Their moves to retain market position during patent expiration drive this process, resulting in prominent ads and consumer-driven sales models. While this tactic helps companies guard their profits, it also points to an environment where corporate interests and broader public health considerations remain in careful tension.

Consumer Advocacy Group

Consumer Advocacy Groups (Center for American Progress) Consumer advocacy groups play a crucial watchdog function in these debates, often stressing affordability and equitable access. The Center for American Progress (CAP) has advocated for policies that protect consumers from high drug prices, while simultaneously championing greater availability of lifesaving or quality-of-life-improving medications (Center for American Progress, n.d.). CAP frames Rx-to-OTC switches as beneficial for many people, particularly those with limited time or resources who might otherwise forgo medical treatment entirely. However, the group also raises concerns that large-scale OTC expansions, absent robust public education, can exacerbate health disparities. Those with lower health literacy or limited English proficiency may be especially vulnerable to marketing-driven purchases and might misunderstand labeling. CAP thus recommends a balance: open access should be paired with easy-to-understand labeling, language assistance, and guidelines for when to seek professional help. From their perspective, an equitable healthcare system requires that consumers not only have more options on store shelves, but also the knowledge to choose and use those options safely.

Health Care Providers

Healthcare providers, especially physicians and pharmacists, are among the most influential stakeholders when prescription medications transition to over the counter (OTC) status, since these moves have substantial implications for their clinical workflows, responsibilities, and interactions with patients (Chang et al., 2016); (Abuse of Over-the-Counter Medicines: A Pharmacist's Perspective | IPRP, n.d.). Physicians, for instance, often benefit from reduced appointment loads for minor or routine concerns after an Rx-to-OTC switch, because

patients who might previously have scheduled a visit simply to obtain a prescription can now self-manage these conditions. By freeing up time in their schedules, physicians can pay closer attention to individuals with more severe or complicated health issues, thereby improving the efficiency of care for those who most need it. This shift, however, does not diminish the physician's role in patient education or overall health management, since they remain key informants for questions about the appropriateness of OTC products, potential side effects, and drug interactions that might arise in a patient's broader treatment plan.

Pharmacists, on the other hand, shoulder an increased share of patient interaction once a medication moves into the OTC category. While fewer prescriptions for easily self-managed conditions may come across the pharmacy counter, pharmacists are still tasked with guiding patient decisions in the OTC aisle, ensuring that individuals understand product labeling, dosage recommendations, and potential adverse effects. This counseling role represents a critical dimension of OTC usage: patients often rely on pharmacists for swift, on-the-spot guidance about symptoms, drug compatibility with existing therapies, and possible adverse reactions. In that sense, pharmacists function as a vital checkpoint for those looking to self-medicate for headaches, allergies, or other minor ailments. Their expertise and availability can help mitigate risks that might otherwise go unnoticed if a patient simply picks a product off the shelf without seeking counsel. Consequently, many professional pharmacy bodies emphasize the need for robust educational strategies, so that pharmacists stay current on evolving OTC formulations and regulations.

Nonetheless, several studies highlight how communication gaps can persist in everyday practice (Sleath et al., 2001). Patients do not always volunteer information about which OTC products they are using, even though many do believe it is important for healthcare providers to

know about their self-medication habits. This lack of transparency presents challenges for both physicians and pharmacists, who must balance a respect for patient autonomy with the necessity of maintaining clear, accurate medical records. Without complete information, healthcare providers risk missing critical details such as drug duplications, interactions, or the potential for misuse. Sleath and colleagues (2001) discovered that physicians asked patients about OTC use in fewer than 40% of the encounters studied, yet over half of those patients reported having used an OTC medication during the previous month. Such discrepancies underscore how vital it is for physicians and pharmacists to proactively inquire about nonprescription drug usage in all patient consultations.

Conclusion

Ultimately, the role of healthcare providers as stakeholders in OTC transitions hinges on their capacity to educate and monitor patient activity in a more decentralized environment. Physicians guide appropriate usage by setting contextual treatment goals, while pharmacists serve as first-line advisors within community settings and retail spaces. Together, they help ensure that Rx-to-OTC switches deliver genuine benefits enhanced access, convenience, and cost savings while minimizing potential risks related to misuse or oversight.

Stakeholder competition over OTC drug classification emerges from the interplay of convenience, profit, clinical oversight, and consumer autonomy. Consumers demand easy access to minor ailment treatments, but incomplete reporting of OTC usage can endanger patient safety by complicating medical records. Insurers capitalize on short-term cost savings when prescription drugs switch to OTC status, yet downstream risks may raise overall healthcare expenses. Pharmaceutical manufacturers navigate looming patent expirations by shifting

products to OTC shelves, prolonging brand dominance and optimizing marketing tactics, albeit sometimes at the cost of rigorous safety measures. Healthcare providers particularly pharmacists and physicians carry the dual burden of counseling patients appropriately while ensuring they receive sufficient guidance for safe OTC use. Consequently, a purely scientific rationale does not govern these classifications. Instead, commercial strategies, regulatory constraints, and public perception steer negotiations. Recognizing these competing forces is key to shaping balanced, transparent policies that support patient autonomy while minimizing misuse and safeguarding public health (By the Numbers: How Health Insurance Providers Contribute To… - AHIP, n.d.).

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