Empowering Consumers, Reducing Costs, Improving Health

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Reforming the Prescription to Over-the-Counter Drug Pathway – A Patient-Centric Approach

EXECUTIVE SUMMARY

For decades, the reclassification of certain prescription (Rx) medicines to nonprescription, or over-the-counter (OTC), status has been a powerful strategy in efforts to improve public health by expanding access to safe, effective treatments. Commonly referred to as "Rx-to-OTC switch," the pace of these drug reclassifications has slowed considerably over the past several years, limiting access to critical self-care solutions.

This white paper highlights insights from a recent roundtable discussion convened by the Alliance for Women's Health and Prevention (AWHP) and the Alliance for Aging Research (AAR), which brought together 16 diverse patient groups to discuss these important topics. After hearing presentations from former FDA leaders and non-prescription switch experts outlining status quo challenges, participants identified key barriers to effective Rx-to-OTC switch and outlined strategies to create a new, patient-centric process at the FDA.

KEY THEMES THAT EMERGED INCLUDE:

- **The current issues with the FDA's prescription to non-prescription drug process.**
  - FDA's current risk-benefit calculus overemphasizes potential harms of switching while overlooking the consequences of limited access.
  - Patient perspectives are not sufficiently integrated into regulatory decisions.
  - Overly restrictive criteria limit the number of drugs eligible for nonprescription status.
- **The need for improved education for patients, caregivers, and providers.**
- **The importance of amplifying patient voices in the switch process.**
- **The opportunity for greater collaboration on this issue among stakeholders.**
- **The need for a roadmap that outlines challenges and envisions a more efficient path forward.**

This white paper offers recommendations to policymakers, healthcare leaders, and industry stakeholders on reforming the Rx-to-OTC switch process to better serve patients and strengthen public health. This push is not novel — throughout

> "OTC drugs play a vital role in our healthcare system. They provide an efficient, low-cost way for Americans to manage everyday health needs. The vast majority of drugs are OTC including hundreds that are sold with ingredients or dosage strengths formerly available only in Rx products"
>
> **Dr. Andrea Leonard-Segal, Mr. Bernard Simone, American Journal of Medicine, 2025**

"I think there's a lot of areas where we can ask, does a drug need a prescription when it can be over-the-counter?"

FDA Commissioner, Dr. Marty Makary (Senate HELP Confirmation Hearing 2025)

the document, you'll also see interspersed quotes that showcase the breadth of support and momentum from external thought leaders and decisionmakers in multiple publications and other public forums.

INTRODUCTION

OTC medicines unquestionably give consumers greater control over their health. From allergy medications to pain relievers, OTC products allow individuals to manage their health without the need for a healthcare visit or prescription. Beyond convenience, OTC products promote preventive care, improve access to healthcare, and alleviate pressure on overburdened primary care systems. Making essential treatments more readily available enables patients to take proactive steps in managing their health.

"High prescription drug prices are hurting Americans and must be lowered—without increasing government control and sacrificing innovation... The FDA should also appropriately switch prescription-only medications to available over-the-counter drugs..."

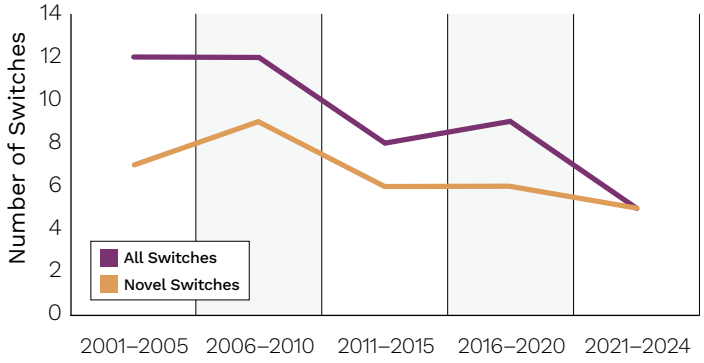
Center for a Healthy America, Research Report, 2021

The Rx-to-OTC switch process has long played a critical role in improving public health by expanding access to safe and effective treatments for common everyday health conditions that can be self-diagnosed and self-treated. This system was implemented by the Durham-Humphrey Amendment to the FDA's Federal Food, Drug and Cosmetic Act, which classifies medications as either Rx or OTC, and lays the groundwork for the OTC drug system as we know it. By empowering patients with self-care options, OTC products reduce the need for clinical visits for conditions that can be self-managed, bolstering both patient convenience and public health outcomes, while potentially saving time and money for individuals as well as the health system overall.

However, over the past two decades, the pace of Rx-to-OTC reclassification at the FDA has slowed considerably. What was once a steady pipeline of five to six new OTC products annually has dwindled to just two to three switches every few years.

This decline may reflect ever-evolving risk-benefit calculations at the FDA, where a more precautionary

Prevalence of OTC Switches Since 2001



approach[1] and competing priorities may have led to a de-prioritization of the switch process.

> "If they can be over-the-counter we can feel confident about public safety with those products on the shelf at a pharmacy."
>
> **FDA Commissioner, Dr. Marty Makary (Senate HELP Confirmation Hearing 2025)**

Despite this slowdown, real-world experiences and studies alike[2] have shown consumers are comfortable with and empowered by self-care. As individuals and healthcare systems are increasingly challenged by rising rates of chronic disease, infectious disease threats, and persistent economic and social barriers to good health, consumers are actively seeking self-care options that bypass traditional barriers to primary care. Patient and consumer advocates have voiced strong support for more accessible treatment pathways that put healthcare in their hands.

In response to this shifting landscape, AWHP and AAR convened a roundtable of 16 diverse patient and consumer advocacy organizations to assess the current state of the Rx-to-OTC switch process and identify opportunities for improvement. This discussion underscored the urgent need to reform the process — one that will address regulatory uncertainty, improve education for patients and providers, seek to identify ways to update antiquated delivery of care and treatment for patients, and strengthen collaboration across stakeholders. By better understanding the process and its surrounding factors, we can better appreciate the contribution of OTC therapies, understand the current hurdles to the switch process, and determine a path forward that will improve both individual and public health.

This paper reflects the broad benefits of OTC products through the perspectives of patient groups representing varying disease states and specific at-risk populations, healthcare providers, and industry leaders. By examining the evolving landscape and identifying actionable solutions, this white paper outlines a roadmap to address barriers to Rx-to-OTC switch and encourage the FDA to reprioritize this important healthcare pathway.

RECOGNIZING THE VALUE OF OTC FOR PATIENTS AND OPTIMIZING FDA'S APPROACH

During the roundtable, stakeholders noted the importance of Rx-to-OTC switch for patients, providers, and the healthcare system as well as the need for reforms to ensure improved consumer access to safe and effective OTC products. Specific observations and recommendations were as follows:

Rx-to-OTC Switch Benefits Patients, Providers, and Healthcare System

- **Reduces Time and Costs, and Expands Access:** OTC switch creates new opportunities for individuals to manage common conditions without the need for costly or time-consuming clinical visits, missed time from work, etc. Improved access is particularly vital in rural and underserved areas where healthcare resources are more difficult to access.
- **Reduces the Burden for Primary Care Providers:** With primary care providers increasingly

> "Other strategies could include the way we look at generic drugs, moving medications to over-the-counter."
>
> **FDA Commissioner, Dr. Marty Makary (Senate HELP Confirmation Hearing 2025)**

> "We conclude our Forbes piece with a recommendation that the… administration and Congress build upon this deregulation, such as by allowing patients greater access to OTC drugs…"
>
> **Paragon Health Institute, Forbes, 2022**

stretched thin and difficult for patients to access, expanding OTC options offers a path to alleviate non-urgent visits. Conditions that lend themselves well to OTC solutions often share key characteristics: they are self-diagnosable, episodic or low-risk, and have clear treatment protocols. For instance, some urinary and/or sexual health conditions could be safely managed at home with improved OTC options — easing the strain on an overburdened healthcare system.

- **Generates Savings for the Healthcare System:** OTC products reduce costs for the healthcare system and improve outcomes. Managing common conditions at home reduces the strain on the healthcare system and allows individuals to be more productive with work and family responsibilities.
- **Empowers Consumers and Addresses Demand for Self-Care:** Consumers are already searching online for remedies that don't require a prescription. OTC medicines give consumers expanded, easier, and faster access to effective FDA-approved options that are readily accessible to treat their condition and empower them to manage their own care.

The Rx-to-OTC Switch Process Needs to be Reformed

A reformed pathway must offer predictability, patient engagement, and a clear process:

- **Engage Patient Voices in Policy Discussions:** Patients — the ones most impacted by these decisions — deserve a stronger voice in regulatory and policy conversations on OTC switch. Ensuring that patient and consumer advocates are actively engaged in proposed policy discussions will help align new solutions with real-world needs.
- **Broaden Pool of Switch Candidates:** In late 2024, the FDA finalized a rule allowing certain nonprescription drugs to include an "Additional Condition for Nonprescription Use" (ACNU).[3] This pathway enables the use of companion tools — such as digital questionnaires or apps — to support consumers in determining whether an OTC drug is appropriate and safe for them. While no products have yet been approved under this framework, the ACNU Rule has the potential to expand the pool of switch candidates by allowing a wider range of prescription drugs to move to OTC with appropriate safeguards in place.

> "The future public health benefits from Rx-to-OTC switches can only be realized with innovations in the regulatory environment driven by broad public and political support for the initiatives."
>
> **Dr. Eric Brass, Professor Emeritus of Medicine, UCLA**

Innovation and Education Are Key to Long-Term Success

While Rx-to-OTC switch can be a powerful tool to improve individual and public health, there is a need for ongoing innovation and education to ensure the best results for patients:

- **Consumer Campaigns to Support Safe Use:** Consumer education must be a core component of future Rx-to-OTC switches. Providing clear, accessible information about proper use, potential drug interactions, and when to seek professional care will reduce safety concerns while improving self-care outcomes.
- **Provider Awareness and Education:** Healthcare providers must be equipped with guidance on when and how OTC products can replace prescriptions. Incorporating OTC options into care management frameworks can improve patient outcomes and reduce reliance on clinical visits for common ailments.
- **Supplementary Diagnostics for Safe Self-Management:** For certain conditions, OTC medications may be most effective when paired with simple diagnostic tools to help patients assess whether the drug is right for them. Encouraging diagnostic innovation will ensure patients are better informed and equipped to manage their wellness without the need for a doctor's visit.

> "The FDA should exert its regulatory authority per the DHA [Durham-Humphrey Amendment] and use good judgment to streamline OTC drug development processes to improve the public health."
>
> **Dr. Andrea Leonard-Segal, Mr. Bernard Simone, American Journal of Medicine, 2025**

CONCLUSION

Reforming the Rx-to-OTC switch process offers a powerful opportunity to expand access and empower consumers, improve patient outcomes, and reduce strain on the healthcare system. By adopting a patient-centric approach and implementing clear reforms, stakeholders can ensure this process better serves consumers' needs while maintaining the highest standards of safety and efficacy.

AWHP and AAR encourage policymakers, healthcare leaders, and industry stakeholders to work together to help build a future where patients are empowered with a growing array of safe, effective, and accessible self-care solutions.

SUMMARY OF RECOMMENDATIONS FOR ADVOCATES, INDUSTRY, AND REGULATORS

As we seek to build a better Rx-to-OTC switch process, there are clear lanes for patient advocates, industry, and regulators to come together to propel Rx-to-OTC switch into the 21st century:

Industry

Invest in Switch Innovation	• Prioritize the development of OTC products for common, self-diagnosable/treatable conditions (e.g., UTIs, pain, respiratory issues)
Support Education Campaigns	• Collaborate with advocacy groups to educate consumers about safe OTC use and proper self-care • Support provider education around when OTC options are appropriate alternatives to prescriptions
Engage Patients in Development	• Include patient perspectives early in the R&D process and when designing switch applications to align with real-world needs
Use Case Studies to Guide Strategy	• Analyze past successful and failed switches to refine internal processes and inform future submissions

Patient Advocates

Create a Place for Collaboration	• Collectively align and share perspectives with the FDA
Promote Storytelling & Advocacy	• Raise awareness among policymakers and influencers about the value of switch to patients and the healthcare system • Engage diverse experts to improve messaging and increase trust
Form Alliances, Find Common Ground	• Seek input across the health care ecosystem on opportunities to support switch and optimize access

FDA

Reconsider Risk-Benefit Calculation	• Recognize the risk of inaction
Reform the FDA's Process	• Establish clearer approval processes for switches
Include Patient Voices	• Create structured pathways for patient group input into FDA reviews and policy reforms
Broaden Pool of Switch Candidates	• Implement ACNU to broaden the types of nonprescription drugs available to consumers

Support for this event was provided by the Consumer Healthcare Products Association.

Roundtable Discussion Participants

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