

ACNU: Industry reacts to new regulatory pathway

Additional Conditions for Nonprescription Use (ACNU), a new regulatory pathway for drugs to be marketed without a prescription if paired with an additional step, such as a questionnaire or other intervention, came into effect in the USA in late May 2025. Early consumer research indicates that the public wants this class of drugs, however, the rule that was eventually approved has received mixed reviews from industry, especially because of a provision allowing simultaneous Rx and OTC marketing of an ACNU drug.

Consumer benefits

A 2022 study conducted by Persuadable Research (with SBL Consulting and the CHPA) in 2022 indicates that people are ready for ACNU drugs. Notably, 2/3 of the study's 1,000 respondents reported having a member of the household treating chronic conditions, including heart disease, high cholesterol, diabetes or depression, with an Rx medicine. A similar proportion of respondents were, or had a household member, suffering acute conditions, including ED, acne, migraine, Covid-19 / flu, UTI, acne and sleep disturbances, that they treat with Rx and OTC drugs, plus other natural remedies, or not at all.

Erika Herrin, Director of Operations for Persuadable Research, told *INA*: “We found that overall interest in the idea is positive, and there is a need, given the current and growing rate



of Americans suffering from chronic & non-chronic conditions.” However, responses varied by health condition. “Respondents were more open to the idea when it came to medications

to treat non-chronic conditions, such as the flu, acne, migraines, or UTIs. There is more hesitation regarding medications to support chronic conditions such as diabetes and depression.”

The study also unlocked other consumer preferences. Older adults tended to believe many medications have a long history of safe use and should be available without a prescription, and they think OTC medications cost less than prescription medications. Women and younger adults (25-64 years) believe that certain medications should be available without a prescription because they often face challenges in getting timely access to their doctors.

People also held differing perspectives on sharing personal health information, such as an underlying health condition or medication use, that may be required to prove that they are a good candidate to safely & effectively use an ACNU drug. Herrin observed, “the implementation of each ACNU will ultimately determine its success, as consumers are divided on their opinion of the necessary steps needed to obtain prescription medications without seeing a doctor.”

According to the study, although providing personal information to gain access to medications will not generally deter use,

potential privacy sensitivities include providing sexual health info and sharing recent diagnostic tests measuring women's health.

Industry weighs in

ACNU drugs' success will be assessed on a case-by-case basis, influenced by consumers' willingness to share information, drug prices and insurance coverage, as well as commercial values such as drug lifecycle management and competition, but many opinion leaders are enthusiastic about ACNU.



Industry veteran **Mary Alice Lawless**, Founder, Biograph Inc, President, Everything Health & Nicholas Hall Network Partner, who has worked on potential

ACNU processes for years, commented: "With the application of interoperable healthcare data, proven quality processes, and networked technology systems, consumers can be empowered to safely select and use ACNU products to treat common conditions and remain compliant with chronic regimens. Imagine the opportunity in reversing medication non-compliance and undertreatment. Everybody wins!"

Paul Wardle, SVP, Innovation Consulting, Klick (pictured at top of opposite column), who previously worked on switches at Pfizer and HRG, observed: "This pathway offers a tailored approach that aligns with individual medical needs and circumstances if an OTC NDA is not possible. An ACNU drug may include validated technology interfaces, instead of healthcare provider prescriptions, to determine if self-

directed consumer access to the drug is appropriate without a prescription. Consumers requiring greater clinical scrutiny will continue to require a prescription. ACNU drugs are nonprescription because eligible consumers do not require a provider interaction but are distinct from OTC medicines where no such interface exists.



Product development pipelines

Traditionally, Rx-to-OTC switch has been a growth driver for the consumer health industry. Investment in consumer education and marketing to support expanded mass market access of previously Rx drugs has yielded powerful brands such as **Claritin** (Bayer) and **Allegra** (Opella), with 2024 retail sales of around \$432mn and \$297mn respectively, according to Nicholas Hall's **DB6** Global CHC database.

However, some complex Rx-to-OTC switch programmes have been on pause for years while ACNU has been developed. **Tim Smith**, Semaine Health, VP, Commercial & BD, who worked on switch programmes in previous positions, commented: "After years of deliberation, I am pleased that we now have clear guidance and a formalised pathway for ACNU. This clarity enables the integration of an OTC switch into Rx brand strategies earlier in the product lifecycle management process. For consumers, this development offers the



potential for expanded access to critical therapies at potentially lower costs, while maintaining safety and ensuring appropriate product selection. I eagerly anticipate the first approval through this pathway, which will validate the envisioned success of this model.”

Challenges ahead

While ACNU offers expanded opportunities, it also challenges the benefits of the traditional Rx-to-OTC investment model. CHPA, which advised and negotiated with the FDA throughout the process, commented before the rule was finalised: “It cannot be emphasised enough how vital expanded access to OTC medicines is to public health, and the Rx-to-OTC switch process has delivered safe, effective, and affordable options for decades. In fact, the Office of Management & Budget estimates that future Rx-to-OTC switches could save consumers nearly \$27 per purchase. While the new rule enabling these switches through modern technology is a promising step forward, CHPA is concerned the rule’s preamble unnecessarily raises issues about simultaneously marketing prescription and nonprescription versions of the same product — an issue that doesn’t belong in this context.”


Later in 2025, expressing disappointment over the simultaneous marketing provision in the final

rule, CHPA vowed to “use all available pathways to advocate for this portion of the rule to be rescinded.”

Taking a more general approach, **Paul Sklar**, Principal, Paul Sklar Consulting, who worked on switches during his 18-year career



with GSK CH (now Haleon) advised: “Personally, if I were involved in a switch, I would seek any way possible to avoid an ACNU due to likely continued competition from Rx generics, the additional costs of filing an ACNU, the reduction in consumer target population due to the ACNU, and reporting requirements whenever consumers access the product without properly following the ACNU.”

Sklar continued: “Still, perhaps there may be circumstances where an ACNU is the only way to accomplish a switch and the opportunity is sufficiently large, despite the negatives I’ve listed above, that it can be profitable ... TBD.” 

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