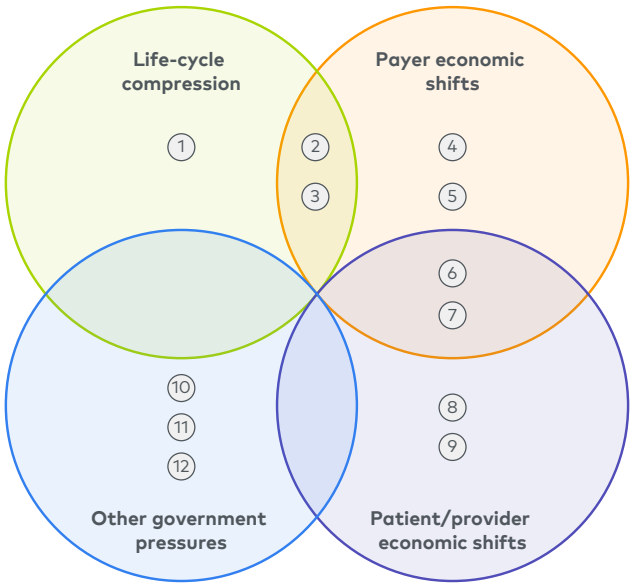
EXECUTIVE INSIGHTS

Not Dead Yet: OTC and DTC Approaches in Creating Value for Late-in-Life-Cycle Pharmaceuticals

All pharmaceutical franchises must come to an end. Between 2025 and 2030, over $300 billion in prescription (Rx) drug revenues are expected to lose exclusivity.[1] Traditional loss-of-exclusivity (LOE) strategies — including product/patent hopping,[2] authorized generics[3] and brand-for-generic contracting[4] — are well known. However, several emerging trends and policies have added pressure to the drug life-cycle and/or the ability to effectively implement such strategies (see Figure 1).

Figure 1

Policies and trends impacting LOE strategy



1. Greater biosimilar interchangeability
2. Medicare price negotiation (IRA)
3. Part D redesign
4. PBM reform
5. Rise of white-labeled, vertically integrated biosimilars
6. Payer, PBM and provider network consolidation
7. Accumulator/maximizer scrutiny
8. Biosimilar buy-and-bill reimbursement changes (temporary change under IRA)
9. 340B scrutiny
10. Most-favored nation
11. FTC pressure on product hopping and drug advertising
12. Tariffs

Note: LOE=loss-of-exclusivity; IRA=Inflation Reduction Act; PBM=pharmacy benefit manager; 340B=U.S. drug pricing program (Section 340B of the Public Health Service Act); FTC=Federal Trade Commission
Source: L.E.K. research and analysis

As pricing policy, payer economics and patient purchasing channels evolve, biopharmaceutical companies need to evaluate whether selected mature assets can preserve value through self-care migration via over-the-counter additional condition for nonprescription use (OTC-ACNU), targeted cash-pay access through manufacturer direct-to-consumer (DTC) platforms or both.

Over the past approximately 12 months, two new significant programs have launched, with the potential to expand value creation from late-in-life-cycle drugs:

- **OTC-ACNU**, a new option for converting Rx drugs to OTC, which went live in 2Q2025, though no OTC products have been approved through it yet
- **DTC platforms**, with TrumpRx launching in February 2026 following manufacturer platforms (2024-present) and Most-Favored-Nation (MFN) dealmaking (September 2025-January 2026)

In this edition of L.E.K. Consulting's *Executive Insights*, we discuss OTC-ACNU and DTC as potential life-cycle management tools for preserving value.

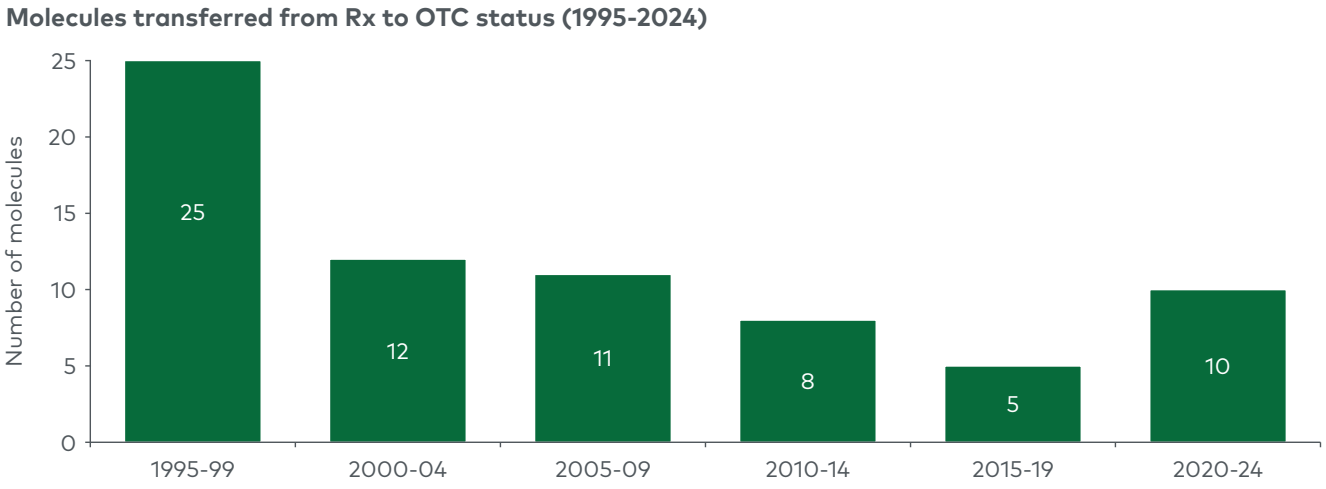
ACNU: A new option for Rx-to-OTC conversion

In the U.S., medications can be acquired through two routes: Rx and OTC. Rx drugs are dispensed by pharmacies, leaving patient oversight and counseling responsibilities to the clinicians who write the scripts. OTC drugs are sold directly to consumers with standardized "Drug Facts" labeling and usage instructions.[5] They are safe and effective for self-directed use when taken as labeled. Typically, these are high-volume drugs for mass consumption, indicated for non-life-threatening diseases and made available at relatively low price points.

Rx drugs can be converted to OTC, which may help expand their market while adding three years of market exclusivity if supported by the proper clinical studies and filings.[6] After declines since the mid-1990s, there has been recent growth in Rx-to-OTC conversions, which may reflect evolving Food and Drug Administration (FDA) openness to OTC conversions (see Figure 2).

Figure 2

ACNU poised to accelerate a recent reversal in Rx-to-OTC decline



Note: ACNU=additional condition for nonprescription use; OTC=over-the-counter
Source: CHPA; FDA

Traditionally, Rx-to-OTC conversions could be executed through a "full switch" or a "partial switch" (designating certain conditions of use to be OTC or Rx), but were limited to drugs that were clearly safe and appropriate for self-selection and self-use.

At the end of 2024, the FDA announced a new option for Rx-to-OTC conversions when paired with ACNU (see Figure 3). This option aims to expand the set of drugs appropriate for OTC use. Previously, OTC designation was focused on drugs that could be safely used based solely on consumer-friendly labeling. ACNU introduces an extra step for self-selection, such as a questionnaire, a required digital video or an automated telephone response system. Unlike traditional pathways, ACNU products can exist as both Rx and OTC, allowing for greater flexibility across patients and providers.

Figure 3

ACNU introduces a new "third way" to OTC use

Pathway	Definition		Early regulatory engagement	Key studies and development	Application	Launch and postlaunch marketing
	OTC	Rx				
Full switch	**Available** for all drug versions	**No longer available**	• Align on OTC concept	• LCS • SSS • AUT (if necessary)	• Efficacy supplement to NDA or 505(b)2	• Standard postlaunch marketing safety reporting
Partial switch	**Available** for some conditions of use (e.g., indications, strengths)*	**Available** for remaining conditions of use available	• Align on OTC concept • Confirm "meaningful difference" between Rx and OTC SKUs	• LCS • SSS • AUT (if necessary)	• New NDA	• Standard postlaunch marketing safety reporting
ACNU	**Available** if consumers complete an extra step**	**Potentially available** but may coexist with OTC-ACNU***	• Describe why label alone is insufficient and purpose/ necessity of ACNU • Align on tool validation and study designs	• Tool development and human-factor testing • LCS and SSS (must show label alone fails and ACNU improves results) • AUT with ACNU	• New NDA (includes detailed ACNU description and implementation plan)^	• Coordinate with retailers and online distributors to operationalize ACNU • Monitor and report ACNU failures^^

*Same active ingredient can be marketed as both Rx and OTC only if there is a "meaningful difference" between Rx and OTC products; if no such difference exists, then simultaneous Rx and OTC marketing is not permitted
**Extra steps may include questionnaire, digital confirmation, in-store kiosks, automated telephone, etc.
***If the brand switches to OTC with ACNU, generics may remain Rx-only
^Proposed definition of ACNU is intentionally broad to give applicants flexibility regarding the types of additional conditions and how they can be implemented
^^Failure in implementing a key ACNU element or in operationalization of ACNU
Note: ACNU=additional condition for nonprescription use; OTC=over-the-counter; Rx=prescription; SKUs=stock-keeping units; LCS=label comprehension study; SSS=self-selection study; AUT=actual use trial; NDA=new drug application; 505(b)2=section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, an NDA pathway that can rely in part on existing data
Source: FDA; Skadden; Meghana et al. (2021)

This differs from the partial switch OTC path, which allows for Rx and OTC sales with meaningful differences (e.g., indications, strengths). The ACNU definition is intentionally broad, allowing manufacturers flexibility in tailoring the extra step. This flexibility may prove important as manufacturers balance clinical risk, user experience and preferences across stakeholders (see Figure 4).

Figure 4

Pathway selection must balance the motivations of stakeholders across the value chain

Pathway	Consumer	Physician	Retailer	Pharmacy	Payer	Manufacturer
Full switch	Appealing to self-directed patients, limiting for HCP-dependent ones	Less oversight (positive vs. negative, depending on patient/ indication)	Shift to front of store/online: simple and promotable	Loss of Rx revenue; any counseling/ work uncompensated	Removes liability, enabling tighter formulary control for close substitutes	Standard pathway; streamlined channel
Partial switch	Broad appeal	Some oversight	Mixed management, adding complexity	Some Rx revenue retained	Potential limitations on payer ability to tighten formulary controls (dependent on Rx/OTC split)	Standard pathway, retaining some Rx sales
ACNU	Broad appeal, but potential friction from extra step	Some oversight; reduces concern for inappropriate use	Potential workflow and shelf management complexities	Increased workload and operational burden without reimbursement	Depends on labeling differences — potential to limit use of Rx versions	Potential OTC approval for products not suitable via traditional pathways, limited precedence; increased development investment and launch complexity

Relative attractiveness by stakeholder: Higher | Mixed | Lower

Note: HCP=healthcare provider; Rx=prescription; OTC=over-the-counter; ACNU=additional condition for nonprescription use
Source: L.E.K. research and analysis

While still an emerging pathway with limited precedent and operational uncertainties, ACNU may make OTC conversion more feasible for patient-directed care across a broader set of drugs (e.g., statins, asthma inhalers, migraine medications).[7] With less prescriptive ACNU guidance, there remains significant operational questions open for the initial pathway approvals to tackle. Manufacturers willing to invest in the required studies and market-shaping activities may benefit from extended exclusivity and a new purchasing channel.

For assets with strong safety profiles and straightforward patient use, ACNU may expand the drug life-cycle beyond the Rx years.

TrumpRx: A central platform for DTC sales

The expansion of telehealth, accelerated by the COVID-19 pandemic, together with the strong demand for anti-obesity medications prompted several manufacturers to launch their own DTC platforms. Lilly announced LillyDirect in early 2024, offering a digital pharmacy coupled

with access to telehealth and in-person providers and educational information; it's focused on patients with obesity, migraine and diabetes.[8] Notably, it offers patients the option to self-pay at a discount to list price, outside the traditional insurance benefit. Other manufacturers followed suit, launching their own platforms, including PfizerForAll[9] and NovoCare Pharmacy,[10] through early 2025.

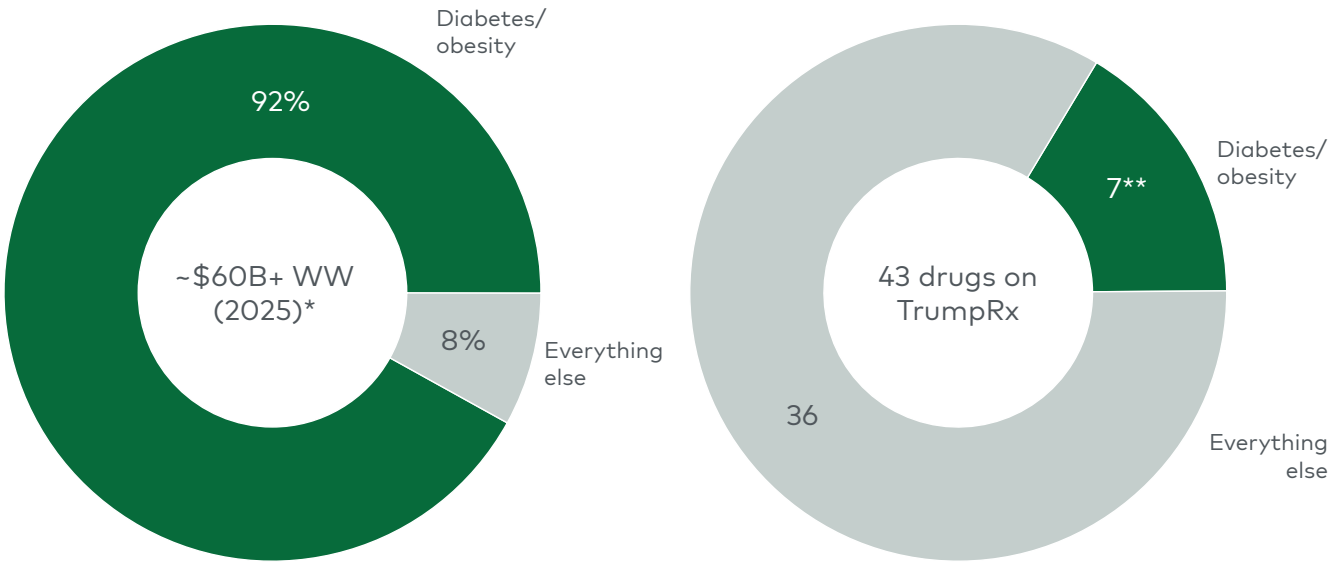
An executive order issued in May 2025[11] increased focus on DTC, making it one of the four pillars of the Trump administration's MFN pricing policy. After receiving letters from the administration,[12] 17 pharmas struck deals addressing each of the MFN pillars.

TrumpRx[13] launched on Feb. 5, 2026, with 43 drugs from five manufacturers.[14] The site advertises MFN pricing through GoodRx-powered pharmacy coupons[15] or pass-throughs to manufacturer sites. Diabetes and obesity are the clear centerpiece of the initial portfolio, with the roughly seven indicated drugs representing over 90% of the estimated 2025 worldwide revenues associated with the portfolio (see Figure 5).

Figure 5

The initial Trump Rx "portfolio" sales are primarily in diabetes/obesity

Breakdown of products listed on TrumpRx



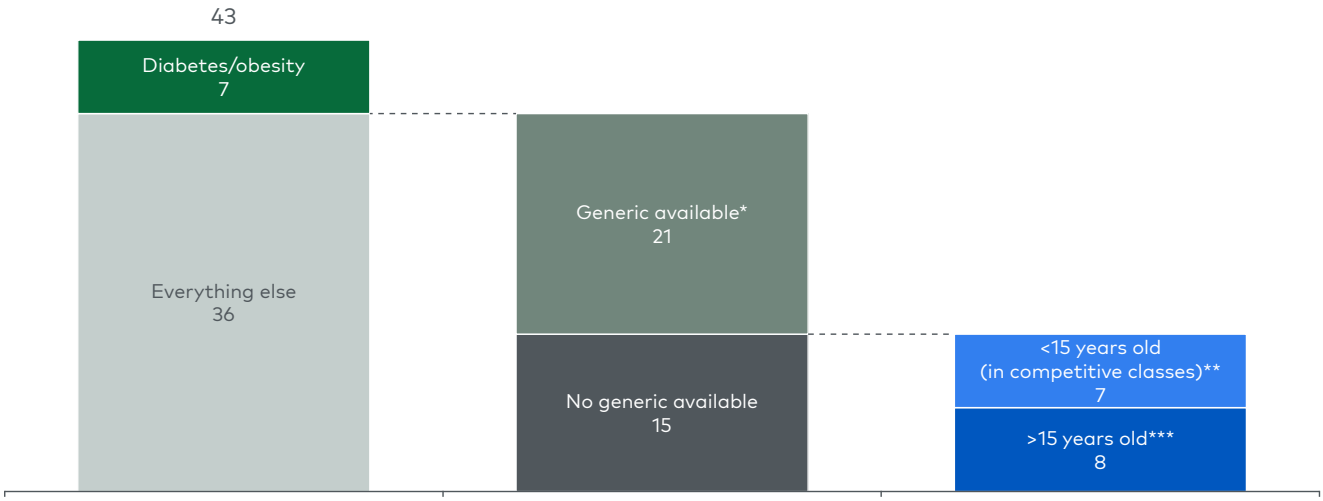
*$59 billion in available 2025 sales and sales estimates; 11 products not available, with EvaluatePharma Premarin estimate assumed to be indicative of the family (similar to 2024)
**Sales estimates stem from five of the seven drugs (insulin lispro, Farxiga, Ozempic, Wegovy and Zepbound); no sales available for Xigduo XR and Wegovy pill, launched in 2026; TrumpRx lists unbranded insulin lispro from Lilly — sales assumed to be Humalog's
Note: WW=worldwide; XR=extended release
Source: EvaluatePharma; company 10-Ks/annual reports; Biomedtracker

Many of the remaining products appear older, with about 80% of these drugs genericized or more than 15 years old and others in competitive classes (see Figure 6). Likewise, brands added to TrumpRx later and brands mentioned for DTC in MFN deals and not yet on TrumpRx largely share similar characteristics: They're at or nearing the end of their life-cycle or in a competitive class.

Figure 6

Trump Rx is primarily enhancing DTC opportunities for late-in-life-cycle products

Breakdown of products listed on TrumpRx



*Farxiga and Xigduo XR have authorized generics; Lilly offers unbranded insulin lispro
**Includes a Humira biosimilar
***Includes Ngenla (human growth hormone analog), Zavzpret (CGRP nasal spray), Eucrisa (atopic dermatitis topical) and Xeljanz (JAK inhibitor with generics/IRA negotiation expected in the near term)
Note: DTC=direct-to-consumer; IRA=Inflation Reduction Act
Source: TrumpRx

For most patients, DTC and TrumpRx are unlikely to be transformative — patients can access their medications or generic equivalents through insurance with a lower out-of-pocket cost. However, this provides a consolidated channel for patients who are uninsured or underinsured or who might prefer branded options. It allows manufacturers to cut out some of the traditional drug channel intermediaries, enabling the discount pricing.

For assets with cash-pay demand, brand loyalty or access friction, DTC may create a targeted late-life-cycle channel even if it does not reshape access for the broader market.

Next steps for biopharmas

Both ACNU and TrumpRx are live, and precedents are still being set, for biopharmas with assets approaching LOE in the next two to five years. Strategic decisions being made over the next 12 to 24 months will determine which companies capture value from these channels

and which cede it to generics and intermediaries by default. In planning for LOE, biopharmas should consider the full suite of strategic levers. OTC-ACNU and DTC platforms, such as TrumpRx, serve as two newer methods with different requirements for execution.

	ACNU	DTC
Relevant drug characteristics	• Strong safety • Straightforward use • High volume for mass consumption	• Cash-pay demand • Strong brand loyalty • Access friction
Benefits	Three-year market exclusivity	Direct access to uninsured and underinsured patients
Design and data requirements	• "Extra step" tool development and human-factor testing • Label comprehension study • Self-selection study • Actual use trial	Platform development
Capability requirements	OTC channel	E-commerce

If you are evaluating strategies for capturing value for mature and late-in-life-cycle products, including OTC, DTC or other LOE defense strategies, please **contact us**. For more information on DTC strategies, please see our recent article on the topic[16]. We have also published on consumer health OTC considerations, please see our recent article.[17]

Endnotes

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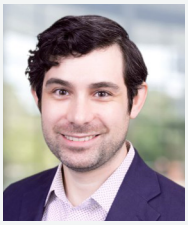

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