

# "Pharm-to-Table": The Impact of Direct-to-Consumer Pharmaceutical Sales on Patient Access, Market Dynamics and Investor Strategy

#### **September 29, 2025**

Direct-to-consumer ("DTC") sales of prescription drugs is a growing trend in the United States, both for commercial and policy reasons. DTC pharmaceutical sales platforms enable pharmaceutical companies to advertise and sell their brand-name drugs directly to patients at discounted cash prices, bypassing traditional distribution channels. The Trump administration has embraced DTC sales as one potential method to lower drug prices, a key policy focus for the administration. Following a May 12, 2025, executive order addressing drug pricing, President Trump sent letters to certain major pharmaceutical companies directing them to adopt DTC sales models. Although DTC sales have been increasing for some time, several companies reacted to the President's letters by indicating their willingness to expand DTC offerings.

Pharmaceutical companies with DTC sales models should be aware of criticisms and compliance pitfalls. For example, some caution that DTC platforms may increase demand for expensive, brand-name drugs that may not provide significant clinical benefit over more cost-effective alternatives. DTC platforms must be carefully structured to avoid implicating state and federal anti-kickback statutes, which have been the focus of a recent senatorial investigation and a lawsuit in Texas. The administration is also critical of DTC drug advertising, and FDA recently announced a crackdown on deceptive ads.<sup>3</sup> Overall, DTC platforms offer potentially lucrative investment opportunities, but investors must remain apprised of the regulatory changes that continue to shape the pharmaceutical industry, as well as potential political and legal risks.

## **Commercial Incentives Driving DTC Pharmaceutical Sales Platforms**

By implementing DTC sales platforms, pharmaceutical companies can advertise, or sell, their own branded drugs directly to patients—"pharm-to-table"—bypassing traditional

<sup>&</sup>lt;sup>1</sup> CMS Statement on Lowering the Cost of Prescription Drugs.

<sup>&</sup>lt;sup>2</sup> Executive Order 14297.

<sup>&</sup>lt;sup>3</sup> News Release: FDA Launches Crackdown on Deceptive Drug Advertising.



distribution channels and intermediaries, such as pharmacy benefit managers ("PBMs"). Many drug companies have embraced DTC sales in recent years. Although heralded as a means of curtailing prescription drug prices, the reality of patient access and affordability remains up for debate. What is clear, however, is that DTC pharmaceutical sales are impacting market dynamics and will continue to influence investor strategy as the industry responds to the evolving regulatory landscape.

Through DTC sales platforms, the role of pharmaceutical companies is expanding to include prescription facilitation and fulfillment, which allows companies to collect and retain information that is typically lost through traditional retail pharmacy channels, including firsthand data on patient behavior and medication adherence. Pharmaceutical companies can also potentially use their DTC platforms to better engage with patients, create brand awareness and strengthen brand loyalty.

### **Political and Policy Backdrop**

On May 12, 2025, President Trump issued an executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" (the "MFN EO"), which sets forth the administration's policy objectives to implement "most-favored-nation" ("MFN") pricing for prescription drugs to cap what Americans pay at the level consumers pay abroad. The pharmaceutical industry has long blamed high pharmaceutical prices on the role of PBMs, third-party "middlemen" that operate within the highly complex and opaque prescription drug supply chain. According to pharmaceutical companies, PBMs retain a large portion of rebates from drug manufacturers rather than passing such savings along to consumers and are, therefore, responsible for high out-of-pocket costs.

On July 31, 2025, following issuance of the MFN EO, President Trump sent letters to 17 major pharmaceutical companies directing them to voluntarily take actions to implement MFN pricing by adopting DTC sales models by September 29, 2025, among other steps. According to the MFN EO, implementing DTC sales models can achieve MFN pricing by bypassing PBMs, which inflate costs, thereby lowering prices for consumers. Although the enforcement mechanisms for MFN pricing remain vague, some pharmaceutical companies have embraced DTC sales models, viewing them as platforms capable of improving prescription drug affordability while increasing pricing transparency.

<sup>&</sup>lt;sup>4</sup> Executive Order, *supra* note 2.

See Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs.

## Market Dynamics Driven by GLP-1s and Chronic Therapies

DTC models for obesity and lifestyle drugs, including Eli Lilly's Zepbound and Novo Nordisk's Wegovy, are illustrative. Prior to President Trump's recent actions, Eli Lilly and Novo Nordisk implemented DTC models for their weight-loss drugs, offering discounted cash prices to patients who do not pay through health insurance programs. In doing so, patients can access weight loss drugs that may not be covered by their insurance, and companies can capture profits that would otherwise be diverted to PBMs. During Eli Lilly's most recent earnings call, it was reported that about one-fifth of total prescriptions for Zepbound are attributable to cash-pay patients.

Bristol Myers Squibb and Pfizer recently launched a joint DTC program for their widely used blood thinner, Eliquis. The program allows uninsured, underinsured and self-pay patients with an Eliquis prescription to purchase the drug directly at a discounted rate of more than 40% off the current list price.<sup>6</sup>

The pricing offered to patients through DTC sales platforms requires a careful balancing act for pharmaceutical companies that wish to expand DTC models enough to appease regulators and capture revenue but not so much that insurers drop coverage of a drug entirely. This is because DTC models have the potential to result in increased demand for expensive, brand-name drugs by creating brand recognition and patient demand; in response to patient-driven demand for high-cost drugs, insurers may decide to remove such drugs from their formularies as a means of managing costs and preserving negotiating leverage. Regardless, industry analysts anticipate that DTC programs for additional drugs will continue to emerge, particularly for lifestyle drugs that require discretion (e.g., weight loss, mental health, sexual health, hair loss), as well as chronic conditions that require regular refills (e.g., high blood pressure, diabetes, asthma).

Although DTC models can expand access to drugs for uninsured and self-pay patients, those who rely on insurance coverage or are unable to afford cash prices are unlikely to benefit. Additionally, DTC spending does not count towards insurance deductibles or out-of-pocket maximums, which may leave some patients financially exposed in the long term.

#### **Telehealth and Data Considerations**

Telehealth has transformed how patients interact with providers and receive care, often lowering barriers to access that may exist with traditional distribution channels. DTC

<sup>&</sup>lt;sup>6</sup> Press Release: Bristol Myers Squibb and Pfizer Announce Direct-to-Patient Eliquis® (apixaban) Option.

platforms typically integrate with third-party telehealth providers to provide remote healthcare services through video, phone and secure messaging, which are often coupled with patient support services. By partnering with independent telehealth companies, pharmaceutical companies provide interested patients with convenient access to telehealth providers who then determine whether to prescribe the company's brand-name drug.

Within the current regulatory landscape, DTC platforms must maintain compliance with federal and state laws, including professional board regulations and data privacy and security laws. Given the extensive data collection through DTC programs, pharmaceutical companies have unprecedented visibility into patient behavior, which may fuel targeted marketing, clinical trial recruitment and future product development, raising privacy questions as well as risks regarding fraud and abuse, informed consent and transparency, which are addressed below.

#### **Conflict-of-Interest Concerns**

DTC platforms present conflict-of-interest concerns: patients may "pre-select" drugs prior to consultations with medical professionals about treatment options, creating tension between medical judgment and consumer choice. In response to DTC advertising, patients are more likely to request specific, brand-name drugs, which influences prescribing patterns in favor of expensive branded drugs that may not provide significant clinical benefit over more cost-effective alternatives. The American Medical Association has, for example, called for a ban on DTC advertising, citing increased pressure on physicians to prescribe drugs that may not be the safest or most cost-effective option. For this reason, critics argue that DTC models do not merely bypass PBMs and health insurers but doctors as well, putting patients at risk. Further, as addressed below, the Trump administration has taken actions to radically change DTC pharmaceutical advertising, citing conflict-of-interest concerns, among other considerations.

# Oversight and Regulatory Scrutiny Under the Federal Anti-Kickback Statute

Companies with DTC pharmaceutical sales models, as well as investors, must carefully consider the potential for legal and regulatory risks. A recent investigation into DTC programs by Senators Richard Durbin (D-IL), Bernard Sanders (I-VT), Elizabeth Warren (D-MA) and Peter Welch (D-VT) sought to determine whether such programs violate the Federal Anti-Kickback Statute, which makes it illegal to induce the purchase or recommendation of federally insured items or services. The investigation culminated in



a report that states that DTC programs "appear intended to steer patients toward particular medications. At best, these relationships raise questions about conflicts of interest. At worst, they create the potential for [prescribing patterns] that can unnecessarily increase spending for federal health care programs." According to the report, DTC pharmaceutical models create an opportunity for influence over prescribing actions if, for example, telehealth clinicians are aware that patients were routed to them through a pharmaceutical company's DTC program. It is alleged that DTC advertising for insurer-covered drugs incentivizes patients to request advertised, brand-name drugs, resulting in increased patient-driven demand for such drugs, which physicians may acquiesce to despite the availability of less expensive alternatives.

The report found high rates of prescribing, ranging from 74–85%, sometimes without video exams. The report further notes that, in some cases, patients can choose the drug they are interested in ahead of a consultation with a provider, which purportedly raises concerns about care quality and oversight. The investigation uncovered significant differences between the business practices and safeguards implemented by different DTC telehealth partners, highlighting—according to the report—both the potential for compromised clinical judgement and the opportunity for compliant practices.

On June 12, 2025, Senators Bernard Sanders (I-VT) and Angus King (I-ME) introduced the "End Prescription Drug Ads Now Act." The bill seeks to amend Section 502 of the Federal Food, Drug and Cosmetic Act to ban drug manufacturers from using DTC advertising to promote their products. Senator King has noted that the "widespread use of direct-to-consumer advertising by pharmaceutical companies drives up costs and doesn't necessarily make patients healthier." This is because DTC ads encourage patients to request prescriptions for specific brand-name drugs that are often more expensive than available, comparably effective alternatives. As addressed below, this legislation will face legal challenges by the pharmaceutical industry, most notably under the First Amendment right to free speech.

## **Anti-Kickback Litigation**

DTC sales platforms must be carefully structured to avoid implicating fraud and abuse laws, including state and federal anti-kickback statutes. For example, recent litigation in

<sup>9</sup> Id.

10 Id

<sup>11</sup> End Prescription Drug Ads Now Act.

<sup>12</sup> Press Release: Sanders, King Introduce Bill to Ban Prescription Drug Ads.

<sup>&</sup>lt;sup>7</sup> Big Pharma's New Sales Scheme: Expanding Patient Access or a Virtual Pill Mill? A Direct-to-Consumer Telehealth Platform Investigation.

<sup>8</sup> Id



Texas against Eli Lilly indicates that under certain circumstances company-sponsored patient support programs may be challenged as illegal remuneration.

Launched in 2024, Eli Lilly's "Lilly Direct" was the first DTC platform to offer consultations with third-party telehealth providers, prescribing and home delivery of its drugs. Further, the platform allows patients to access free nursing services as well as reimbursement support services. On August 12, 2025, the Texas Attorney General sued Eli Lilly, alleging such services incentivized providers to prescribe an array of the company's high-profile therapies, which are used to treat chronic conditions (e.g., cancer, diabetes, migraines, obesity), creating long-term, potentially lifelong, prescription revenue streams. The complaint alleges the company has thereby submitted "millions of dollars in claims to Texas Medicaid that were tainted by Eli Lilly's illegal marketing and quid pro quo arrangements" in violation of the Texas Anti-Kickback Statute, which prohibits offering or providing, directly or indirectly, anything of value, in cash or in kind, to induce or influence goods or services reimbursable under Medicaid. 14

First, the complaint alleges that the company's free nurse program—which consists of injection training, patient follow-ups and ongoing patient monitoring—constitutes inappropriate in-kind remuneration.<sup>15</sup> By absorbing the operational costs of services that physicians would otherwise have to provide and pay for, Eli Lilly is alleged to have created a financial incentive for physicians to prescribe the company's products over alternatives. Second, the complaint alleges that providing free reimbursement support services (e.g., insurance verification, prior authorization assistance, appeals management, patient communication, paperwork assistance) is also an in-kind benefit that reduces or eliminates providers' administrative costs.<sup>16</sup>

The allegations are, as yet, unproven. Eli Lilly maintains that providers are independent and exercise autonomous clinical judgment, stating that the company will defend against the allegations. It remains to be seen how the current lawsuit will impact the trajectory of DTC platforms. If the court determines that such programs are capable of implicating the Texas Anti-Kickback Statute, the case would impact many existing programs and potentially become a catalyst for additional litigation.

Press Release: Attorney General Ken Paxton Sues Big Pharma Drug Manufacturer Eli Lilly for Bribing Providers to Prescribe Its Medications.

<sup>&</sup>lt;sup>14</sup> Compliant: The State of Texas ex rel. Health Choice Alliance, LLC v. Eli Lilly & Company, Inc. (2025).

<sup>15</sup> I.d

<sup>&</sup>lt;sup>16</sup> *Id.* 

## Crackdown on DTC Pharmaceutical Advertising

Companies with DTC sales platforms should carefully review accompanying advertising in light of the administration's recent crackdown on DTC drug advertising. On September 9, 2025, President Trump signed a memorandum directing the Department of Health and Human Services ("HHS") Secretary Robert F. Kennedy Jr. and Food and Drug Administration ("FDA") Commissioner Marty Makary to rein in allegedly misleading DTC pharmaceutical advertising by increasing oversight and ensuring heightened transparency and accuracy. <sup>17</sup> On the same day, HHS issued a press release <sup>18</sup> and an accompanying fact sheet<sup>19</sup> on reforming DTC pharmaceutical advertising; separately, FDA issued a press release stating that "FDA is sending thousands of letters warning pharmaceutical companies to remove misleading ads and issuing approximately 100 cease-and-desist letters to companies with deceptive ads."20 Further, FDA stated that it will initiate a rulemaking to roll back the 1997 "adequate provision" policy that has afforded pharmaceutical companies greater latitude in advertising by relaxing requirements around the disclosure of drug side effects in broadcast ads. Given the typically short duration of broadcast ads, this change would be expected to significantly limit or preclude DTC broadcast advertising.

Efforts to reform FDA's longstanding regulatory framework are likely to face constitutional, statutory and administrative challenges, most notably on First Amendment grounds. Even if the Trump administration's current efforts fall short of HHS Secretary Robert F. Kennedy Jr.'s call for an outright ban on DTC pharmaceutical advertising, the pharmaceutical industry is expected to challenge any policy changes in court. Although the future of DTC prescription drug advertising remains somewhat uncertain, any reduction in such advertising would be expected to decrease participation in DTC sales programs.

# **Looking Ahead**

Following early adopters, additional pharmaceutical companies are likely to pilot their own DTC sales models, especially for high-demand, partially uncovered drugs. While the MFN EO hinted at a federal DTC portal, it is unclear whether the government will actively facilitate such a platform or rely instead on private sector pilot programs. While DTC pharmaceutical sales models offer potentially lucrative investment opportunities,

<sup>&</sup>lt;sup>17</sup> <u>Memorandum: Addressing Misleading Direct-To-Consumer Prescription Drug Advertisements.</u>

Press Release: HHS, FDA to Require Full Safety Disclosures in Drug Ads.

Fact Sheet: Ensuring Patient Safety Through Reform of Direct-to-Consumer Pharmaceutical Advertisement Policies.

News Release, supra note 3.



investors must remain cognizant of potential political and legal risks, most notably under anti-kickback statutes, and carefully monitor current lawsuits, investigations and public skepticism about motives.

We will continue to follow these developments. Please do not hesitate to contact us with any questions.



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