

Key Trends For Life Sciences Cos. To Watch In 2026

By **Scott Liebman, Dominick DiSabatino and Arushi Pandya** (January 8, 2026)

Following a year of drastic — and in some ways unprecedented — change at the [U.S. Food and Drug Administration](#), predicting what comes next might seem difficult, but there are at least two distinct themes.

First, through its initiatives in the past year, the FDA has indicated that one of its primary objectives is to lower the cost of drugs, and second, there is an inherent tension between the priorities of the administration more broadly and that of the FDA and [U.S. Department of Health and Human Services](#), particularly as it relates to American health.

In light of this, there are distinct legal and regulatory trends and developments that life sciences companies should track as the year unfolds, including tariffs, the Prescription Drug User Fee Act, direct-to-consumer advertising, telehealth, the voucher program, single randomized clinical trials and the agency's use of artificial intelligence.

Tariffs

In the spring of 2025, the Trump administration announced baseline and country-specific tariffs across various industries. Tariffs on imported pharmaceutical products were announced later in the year, and have still to go into effect, leaving a wake of uncertainty.

However, the administration stated that pharmaceutical manufacturers could avoid tariffs by building manufacturing facilities in the U.S., including by breaking ground or being under construction.

Following the administration's announcement, multiple manufacturers entered into deals with the administration where, in exchange for a grace period from tariffs, the company would invest in U.S. manufacturing and development, participate in the TrumpRx platform, and lower drug prices in the Medicaid program.



Scott Liebman



Dominick
DiSabatino



Arushi Pandya

Although the future impact of tariffs on supply chains and global sales remains to be seen, the tariffs are emblematic of this administration's push for "America First" policies and bring manufacturing and corporate deals onshore.

Given that simply the tariff announcements are already achieving these goals, additional deals between the administration and manufacturers are expected, and pharmaceutical tariffs may even be pushed indefinitely.

PDUFA

The PDUFA permits the agency to charge (1) an application fee that is due when a sponsor submits a new drug application or a biologics license application and (2) an annual program fee for most approved prescription drug products without an approved generic.

Congress must reauthorize the PDUFA every five years and during that time, industry stakeholders are invited to negotiate the new fees. Negotiations are well underway, but the path of PDUFA VIII's passage, currently slated to occur in 2027, is still unfolding.

It's likely that, similar to above and in line with drug pricing, incentivization of onshoring, lower prices and fast-tracking product developments are key focuses as the first batch of negotiation meeting minutes indicates that the FDA has already proposed to create user fee incentives for domestic drug development.

Direct-to-Consumer Advertising

As the world of pharmaceutical advertising has changed with social media, influencers and nonmanufacturers entering the mix, certain members of the administration have expressed a desire to end direct-to-consumer, or DTC, pharmaceutical ads.

In mid-September, a Make America Healthy Again Commission report called for the FDA, [Federal Trade Commission](#) and [U.S. Department of Justice](#) to increase oversight and enforcement for violations of DTC prescription advertising laws and to prioritize violations by social media influencers and DTC telehealth companies.

Shortly after, the president released a memorandum on "misleading" DTC prescription drug advertisements, and the FDA announced a crackdown on DTC drug advertising. Following the announcements, the FDA issued 40 untitled letters, 80 warning letters and approximately 100 cease-and-desist letters.

DTC advertising enforcement has remained a priority for the agency, and as the FDA enforces in this area, the way in which the FDA subjectively evaluates DTC advertising is developing.

If 2026 is the year FDA releases rulemaking restricting DTC advertising, it is expected to face serious First Amendment scrutiny and industry — both pharmaceutical and media — pushback resulting in indefinite litigation and implementation. 2026 is likely to be the year, though, that the FDA ramps up enforcement against advertising by influencers and on social media, which will likely occur heavily.

Telehealth

With the soaring popularity of GLP-1s and a boom in telehealth after the COVID-19 pandemic, pharmaceutical companies have established, or partnered with, telehealth platforms that allow consumers to directly connect with practitioners to purchase prescription drugs.

In 2025, these arrangements were the subject of bipartisan senatorial letters to pharmaceutical manufacturers, noting concerns related to inappropriate prescribing, kickbacks, off-label prescribing and failure to provide a fair balance of risk information.

Despite these concerns, multiple manufacturers recently implemented DTC programs with discounts, and the administration itself announced its own DTC website that is expected to go live this month.

The continued development of DTC telehealth arrangements, coupled with the FDA's focus on DTC advertising, especially in social media and influencer marketing, is sure to create an interesting tension and opportunity for scrutiny.

While these platforms may provide drugs at lower cost and provide patients with a more efficient pathway for access, the arrangements more holistically are ripe for enforcement in 2026.

Voucher Program

In the summer of 2025, the FDA announced the Commissioner's National Priority Voucher pilot program. Through the program, selected sponsors will receive nontransferable

vouchers that can be redeemed for expedited review of their drug or biologic product candidates. The voucher will reduce drug review time from 10-to-12 months to one-to-two months, but the voucher process must be commenced within two years of receipt from the FDA.

Although the FDA initially stated it would issue five vouchers in the first year, a total of 15 vouchers have been announced so far, and it is possible that more will be announced this year.

The program has received serious scrutiny, though, from FDA directors, lawmakers, industry groups and policy experts who have noted concerns related to the FDA's limited operational capacity to review applications, lack of statutory authorization, safety and efficacy risks, and potential conflicts of interest.

The program is likely to face continued pushback in 2026, and concerns about the program's legality could lead to court challenges.

Single Randomized Clinical Trial

The FDA will soon begin requiring one randomized clinical trial instead of two, for drug and other medical products approvals. The goal of the policy change is to accelerate review times, reduce bureaucracy and accelerate the rate at which medical products are brought to market.

The FDA, though, has always had the authority to permit one randomized clinical trial, especially in situations where two trials may be impractical or infeasible, and approves almost two-thirds of novel products with a single randomized clinical trial already.

After the FDA formally announces this policy shift, it is likely that the change will not happen overnight as policies and guidance documents will need to be revised.

Requiring two randomized clinical trials has been significant in bolstering public confidence and reinforcing safety and efficacy, and the shift to a single trial may receive bipartisan pushback due to concerns of safety.

AI

The FDA has aggressively embraced AI, and in this administration, the use of AI by the

agency itself rather than industry has received the most attention. AI is currently being used by the FDA to support internal operations, review workflows and accelerate clinical protocol reviews and scientific evaluations.

Over the summer, the FDA rolled out Elsa, an agencywide AI tool, to assist in reviews. In December, the FDA announced that agentic AI capabilities were available to agency employees to support complex workflows.

The FDA is expected to continue incorporating AI into its activities in its push for efficiency and faster reviews, as well as its enforcement activities. To the extent that the FDA is not already using AI to analyze promotional materials, these tools will likely be utilized in 2026 for industry surveillance, conducting investigations and perhaps even training algorithms

Conclusion

Although the FDA has adopted a broad range of regulatory initiatives, a central theme of its actions and goals has been to reduce the cost of pharmaceuticals for American consumers and, in somewhat of a contradictory fashion, limit pharma's sphere of influence while simultaneously providing easier avenues for getting drugs to market.

As described above, the FDA has already demonstrated that these goals can be achieved in a variety of ways, but also reflect tensions in the agency's competing priorities.

Despite this administration's push for deregulation, enacting these goals requires, by their very nature, increasing agency action through more enforcement, guidance documents, etc.

These goals also push against the Make America Healthy Again movement's goal for greater substantiation of safety and efficacy in pharmaceutical products. In the face of ongoing regulatory uncertainty, these areas are key for life sciences companies to watch in the upcoming year.

[Scott Liebman](#) is a partner and leader of the life sciences team at [Sheppard Mullin Richter & Hampton LLP](#).

[Dominick DiSabatino](#) is a partner at the firm.

Arushi Pandya is an associate at the firm.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of their employer, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.