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Prescription for Pain: FDA Push for More Disclosures in Broadcast Drug Ads May Amount to De Facto Ban

By Chris O'Malley

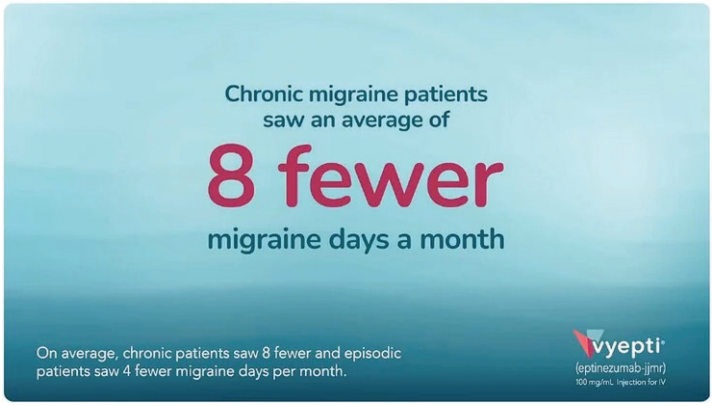
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The future of direct-to-consumer prescription drug advertising hangs in the balance, as the Food and Drug Administration is expected to propose a rule as early as next month that could make broadcast commercials prohibitively long and expensive.

The rule is expected to eliminate the decades-old "adequate provision" standard, which allows companies to recite a vague "major risk" statement in the ad and then steer consumers to external channels, such as websites, for a full summary of side-effects and contraindications.

The FDA's proposed "Transparency in Direct-to-Consumer Advertising" rule would eliminate that loophole—requiring companies to cram into the commercial a summary of that safety information.

That would pose a challenge for many broadcast and online ads considering that even a boiled-down version of prescribing information for some drugs is ponderous enough as it is, even on a website.



Credit: YouTube

Screenshot of TV Commercial AD of VYEPTI from a YouTUbe channel.

"If it is the agency's expectation that you read aloud all of that material that would otherwise be in a print ad then it would become impractical," Latham & Watkins partner William McConagha said of broadcast ads.

"Without it (loophole), every television or radio ad would need to recite the full prescribing information risk disclosures, which for most drugs would run several minutes," Foley Hoag partner Bryant Godfrey said in a client note.

So unwieldy, in fact, that the FDA's proposal could ignite a firestorm of legal challenges by pharmaceutical companies, advertising firms

and trade groups.

"As it relates to the industry on the whole we certainly are hearing noises about potential challenges to a rulemaking should it go forward," McConagha said.

Broader Crackdown

Removing the adequate provision loophole is part of the Trump administration's September 2025 announcement it plans a major reform of pharmaceutical advertising standards. It cited deceptive practices that confuse patients and stoke often inappropriate patient demand for a product.

Since then, the FDA ramped-up issuance of "untitled letters" alleging drug companies have failed to meet the current requirements for disclosing side-effects or patient harm in their ads.

From just four untitled letters alleging advertising violations in 2024, the FDA sent out 47 such letters last year and at least 20 in 2026.

For example, in April the FDA told Bayer HealthCare Pharmaceuticals that ads for its Nubeqa tablets to treat prostate cancer omitted a warning from the drug's patient prescription information that stated: "You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others."

The agency even called out use of "attention-grabbing visuals," such as vibrant colors and motion in the scenes that it said "interfere with comprehension" of the major risk statement.

Pharmaceutical companies and their trade groups have been largely quiet in anticipation of a new rule, likely keeping their powder dry until when or if it publishes the notice of proposed rulemaking.

"We have every reason to believe the administration is still interested in this," said McConagha, "and that we will see a proposed rulemaking at some point, whether it will be in December or slip to 2027."

Big Business

At stake are billions of dollars—not only for drug companies but for broadcast networks and their local affiliates, who might also jump aboard a litigation bandwagon.

Direct-to-consumer prescription drug advertising totaled $1.3 billion in 1997, when the FDA published draft guidance on the adequate provision loophole, according to a study published in the Journal of the American Medical Association.

That ballooned to $14 billion in 2023 among 10 major drug companies, according to Campaign for Sustainable Rx Pricing data.

The ads often sport saccharine depictions of smiling patients strolling through daily activities, as a fast-paced voice rattles off a staccato of drug indications and potential side effects.

The cumulative effect of such ads over the years has been to whet consumer appetite for drugs they may not need, according to the Trump administration. Late last year, Health and Human Services Secretary Robert Kennedy Jr. said the ads "hooked this country on prescription drugs."

He vowed to "shut down that pipeline of deception and require drug companies to disclose all critical safety facts in their advertising. Only radical transparency will break the cycle of over-medicalization that drives America's chronic disease epidemic," Kennedy said.

Rule's Side-Effects

An FDA rule change requiring greater disclosure of drug information in broadcast advertising could disproportionately affect more complex drugs, including those with boxed warnings, said Latham & Watkins partner Jennifer Bragg.

It also could disproportionately affect newer product entrants, in contrast to products that have been on the market for the last several years. "The more stringent requirements may make it harder for newer products to gain traction because they will be entering the market with more stringent advertising restrictions and just won't have had that same opportunity," Bragg added.

Potentially, a middle ground may be found. McConagha wondered aloud whether the FDA might ultimately permit continued use of major risk statements, but require an enhanced voiceover of safety details and other prescribing information that goes beyond the current approach.

While it's difficult to anticipate the final form of a revised advertising rule, outside counsel for drug manufacturers already see a couple of potential legal strategies for fighting regulators.

Drug companies could argue that onerous disclosure requirements violate the First Amendment, per the commercial speech framework under *Central Hudson v. Public Service Commission*, which established a test for government regulation of commercial speech.

Companies could also invoke *Zauderer v. Office of Disciplinary Counsel*, where the court found disclosure requirements cannot be "unjustified or unduly burdensome" in a way that chills protected commercial speech.

In fact, companies could argue that a full recital of risk information within a broadcast ad would overwhelm and confuse consumers—a danger the FDA has previously recognized as a problem.

They might also argue a rule requiring more extensive disclosure of drug information would be so prohibitive that it amounted to a de facto prohibition on broadcast advertising of prescription drugs.

"I think all responsible actors are looking closely at their own approach to advertising and trying to evaluate it against what the FDA has been doing of late and trying to reconcile it against their own views of their legal rights under the First Amendment," McConagha said.

In the mean time, Bragg suggests that companies analyze and document the business impact of more restrictive rule, including their advertising expenditures, and ponder alternative channels. Compiling such information could be useful for preparing comments to submit when a notice of proposed rulemaking is unveiled.

In addition, they should ensure their ads are in harmony with the FDA's current expectations, Bragg said.

"Warning letters that show missteps actually help support the government's position. I'd be pretty focused on making sure my ads were buttoned up, not triggering enforcement from the agency."

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