THE PRICE OF PHARMA PROMOTION

Direct-to-consumer pharmaceutical advertising has a real impact on employer drug costs. What can be done to rein in its effects?

BY ZACH WEST

A middle-aged man sweats over a woodworking table, crafting a new guitar, only to be interrupted by the urge to itch an ugly rash at the back of his neck. A woman swings into the saddle of a horse, only to be distracted by the need to scratch at her arm.

"The itch and rash of moderate to severe eczema disrupts my skin—night and day," a voice intones over this television advertisement. "Despite treatment, it's still not under control." But with a flash and a crescendo in the music, the voice names a drug that has finally helped. The voice boasts of itch relief in as little as two days and "dramatic skin clearance" in as little as two weeks.

Here's what viewers might miss: small gray text at the bottom of the screen explaining that in clinical trials, "many had itch relief and rash improvement at 16 weeks." And, later, the acknowledgement that patients in those clinical trials experienced 75% skin clearance at 16 weeks.

Similarly, the list of side effects, including a higher risk for serious infections, lymphoma, and skin cancer, comes and goes quickly over idyllic clips of the horse rider brushing her steed, the luthier showing off his handmade creation to a customer.

This is a real televised version of product claim direct-to-consumer pharmaceutical advertising, which sometimes seems inescapable across the United States. Whether it's the Super Bowl, a nightly news show, or reality television, commercial breaks will often include an advertisement about a great new drug you should ask your doctor about.

Product claim advertising is one of three kinds of pharmaceutical advertising defined by the Food and Drug Administration (FDA); as the name suggests it makes specific claims about the benefits of taking the drug. The other forms are reminder advertising, which can name a specific drug but can't mention or even imply the drug's benefits or side effects; and help-seeking advertising, which doesn't recommend a specific drug but describes the symptoms of a condition or illness and recommends speaking to your doctor if you have them, which may lead to a drug prescription.

The U.S. pharmaceutical industry spent $7.6 billion on product claim direct-to-consumer advertising (DTCA) in 2022, up from $6.8 billion in 2021, with $1.68 billion of that for just 10 drugs.

The United States and New Zealand are the only two countries to allow DTCA of prescription drugs. The European Union as well as other countries ban the practice entirely.

A growing chorus of medical associations, brokers, insurers, and pharmacy benefit managers (PBMs) accuse DTCA of contributing to higher drug costs by inducing demand among patients for more expensive brand-name prescription drugs. Pushing demand could also lead to overprescription or inappropriate prescription of those drugs, they say.

"When you sit in front of the TV in the evening, between seven and ten o'clock at night, and you watch those commercials and you listen to those side effects, some of the side effects are scarier than the actual thing they're solving," says Andria Herr, executive vice president of employee benefits at broker Hylant. "[Side effects aren't] just allergic reactions anymore, but heart attacks or strokes, because we're creating more and more complicated formulas, and so I do think that it will have an impact."

These concerns have led to calls to entirely prohibit product claim direct-to-consumer advertising, though the federal government has shown no sign it is considering such a move.

FAST FOCUS

- **Pharmaceutical company spending on direct-to-consumer advertising reached a record $7.6 billion in 2022.**
- **Prescription drug spending for employer plans rose by 8.4% in 2023, and studies show an association between advertising and higher drug spending.**
- **Major U.S. medical organizations call for a ban on the practice, but government action so far has been limited.**

DOES DTCA DRIVE UP DRUG SPENDING?

Evidence for a direct link between direct-to-consumer pharmaceutical advertising and higher drug spending for employers appears ambiguous. But several experts from the healthcare and employee benefits spheres interviewed by *Leader's Edge* all drew a clear connection between the two.

"I'll connect the dots very directly. We can always see as the marketing ramps up, a ramp-up in market share for the pharma firms, which always translates into higher claims for the employers that are paying for the cost of this," Herr says. "There is a direct correlation to direct-to-consumer advertising."

Advertising is likely to push consumers toward the most expensive option, even if cheaper drugs or alternative forms of treatment are available, says Ali Goodwin, director of corporate relations at PBM TrueScripts. "When a drug commercial directly encourages patients to seek out specific treatments and discuss them with their providers, of course it leads to an increase in appointment requests," she says. "And I will say that many drug ads are focused on medications that aren't likely to be prescribed by primary care providers—Skyrizi, Rinvoq. These are all specialty medications."

The link between marketing and increased specialty drug sales becomes evident when comparing the 10 products for which the pharmaceutical industry spent the most on advertising in 2023 and the sales of those drugs for the same year. For example, drug manufacturer AbbVie in 2023 invested almost $580 million in promoting Skyrizi (the highest among the top 10), most of which was put into television ads, according to industry publication Fierce Pharma, which drew from advertising intelligence platform Vivvix. That was up from $229 million in 2022 for the drug prescribed for psoriatic arthritis, Crohn's disease, and other diseases. Sales of the drug reached

Illustration by Brian Stauffer

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$7.8 billion in 2023—$6.7 billion in the United States alone—a 50% increase from 2022, according to AbbVie's annual sales report. AbbVie did not respond to a request for comment.

Pick any drug from Fierce Pharma's top 10 list and that link holds. Take rheumatoid arthritis treatment Rinvoq, also produced by AbbVie. Ad spending, again mostly on television and web video on sites like YouTube, increased by 16% from $425 million in 2022 to $495 million in 2023; sales for the drug in the United States increased by 57%. Amid an ad spending push by manufacturer Novo Nordisk, U.S. sales for Type 2 diabetes drugs Rybelsus and Ozempic increased by around 38% and 62%, respectively, from 2022 to 2023, according to the company's 2023 sales report. A company spokesperson said Novo Nordisk does not discuss its ad spend and that advertising efforts "have always been rooted in educating about chronic diseases, known risk factors for the conditions, management tips, potential treatment options, and the importance of talking to a healthcare professional."

Meanwhile, results for Mercer's National Survey of Employer-Sponsored Health Plans showed prescription drug costs for employer plans rose by 8.4% from 2022 to 2023, and overall premiums for employer-sponsored health insurance rose by a 22% in the same year, according to a May 2024 report from the Kaiser Family Foundation. More than 60% of people under age 65 in the United States have employer-sponsored health insurance, the Foundation report says. Given those numbers, it's likely that insurers and employers are bearing a portion of the cost of those increased drug sales.

Studies exploring the direct connection between DTCA and increased spending on drugs by health plans have been few in number.

However, in October 2024, the Congressional Budget Office (CBO) released a report on different approaches the federal government could take to rein in prescription drug prices. According to the analysis, prohibiting DTCA for three years after the FDA approves a drug for sale would lead to a reduction of up to 1% in the price of that drug. The effect would likely be even larger if DTCA was prohibited altogether, though the CBO did not cite a specific figure. The report notes that this cut in drug prices would account for just one-fifth of the reduction of drug spending that could come from some form of DTCA prohibition—a drop in drug sales would account for the bulk of the remainder of reduction in this scenario.

The CBO also analyzed three separate studies to assess the link between DTCA and drug spending: "Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D" in *The Journal of Public Economics* in 2023; "Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand" in *The Southern Economic Journal* in 2012; and "Demand Effects of Recent Changes in Prescription Drug Promotion," in *Frontiers in Health Policy Research* in 2003. The CBO found that for every 10% increase in overall DTCA expenditures, there is likewise an increase in health plan drug spending of 1% to 2.3%.

Taking that finding, we can look at the reported 12% increase in pharmaceutical spending on DTCA from 2021 to 2022 and calculate that it would correspond to an estimated increase in drug spending of 1.2% to 2.8%. The Mercer survey found that prescription drug costs for employer plans rose by 6.4% between 2021 and 2022—suggesting DTCA could be responsible for between a fifth to more than a third of that increase.

Edward Devaney, president of the employer division at pharmacy benefit manager CVS Caremark, says DTCA for a particular product might be used to camouflage an opportunity for employers to save money on a generic version.

"A lot of these advertisements that come out of pharma happen very close to patent expiration, and as they're trying to move people from an expensive brand drug A to expensive brand drug B," Devaney explains. "As a pharmacy benefit manager, when a drug loses patent and becomes available generically, we work very hard at converting them to low-cost generic medications. To me, the biggest risk of direct-to-consumer pharmaceutical advertising is members moving into other high-cost brand medications versus staying on a generic which is substantially cheaper."

Goodwin echoes this sentiment. "I would say there's a pretty direct intersection between the direct-to-consumer advertising by drug companies and the work that we're doing as a PBM to help lower drug costs," Goodwin says.

The financial impact of higher spending on DTCA could extend to pharmacy benefit managers themselves, according to Herr. PBMs must invest money and personnel in managing rising drug demand. Goodwin, from PBM TrueScripts, concurred with Herr's assessment, adding: "When the insurer or PBM comes along, who [the patient] inherently do[es] not trust, and tries to make a change, they just assume our efforts are not made with good intentions," resulting in additional education and communication efforts with the patient and sometimes their prescribing provider.

The nature of the business means that the more PBMs must invest in managing drug demand, the more insurers and employers must pay in fees—and the more, ultimately, the consumer has to pay, whether in premiums or out of pocket.

THE MIXED CASE FOR DTCA BENEFITS

There are a few main arguments in favor of DTCA in its current form, primarily centered on its ability to inform consumers about treatments they may not have known about. According to a 2011 literature review by consultant medical writer C. Lee Ventola in the journal *Pharmacy and Therapeutics*, studies show that DTCA can encourage patients to talk to their physician, strengthening the patient-physician relationship, and even promote user compliance with drug regimens.

Ventola's review cited an FDA survey that showed "53% of physicians said DTCA led to better discussion with patients and 73% believed that consumer drug advertising helped patients ask more thoughtful questions."

But the claim that DTCA empowers patients through education requires closer examination. A 2023 study in the *Journal of the American Medical Association* demonstrated that in 2020 DTCA spending

was approximately 14.3% higher for drugs "rated as having lower added clinical benefit than for those having higher added clinical benefit." What's more, 68% of the surveyed 150 top-selling drugs in that study were rated as having low added clinical benefit.

In line with that, "two heavily promoted diabetes treatments, rosiglitazone and pioglitazone, were found to be no more effective—or safe[r]—than older drugs, even though they were much more expensive," according to the Ventola review. "In another study, older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as $600 per month less than olanzapine, quetiapine, or risperidone."

Likewise, an analysis of prime-time direct-to-consumer product claim ads conducted in 2018 for the *Annals of Family Medicine* showed that education was not the focus for many of the advertisements. The analysis results found an overall "substantial decrease" in the percentage of ads discussing risk factors for and prevalence of the condition the drug was meant to treat, an increased emphasis on portraying positive experiences with the product, and almost no mention of alternatives to treat the condition, even though lifestyle changes can be almost as effective as pharmaceutical treatments in some cases.

"In terms of patient education, if you walked into a physician's office and asked them for a drug based on an advertisement, you may get a prescription for that drug. And could it work? Yes, it could work," Hylant's Herr says. "I doubt the physician would give you a prescription for something that he thought would create a bad outcome, but I bet you there are other drugs on the list of possibilities for treatment that may actually be just as helpful at a much lower cost."

The Ventola review for *Pharmacy and Therapeutics* highlighted a specific example of a drug being promoted before its possible side effects were entirely clear. Merck spent more than $100 million annually from 1999 to 2004 promoting Vioxx, a drug for arthritis and other health issues, driving U.S. sales above $1 billion.

"Patients requesting Vioxx thought that they were advocating for themselves by asking for a drug that they thought was better than its competitors, not knowing that it could lead to stroke or myocardial infarction [heart attack]," Ventola wrote. "On September 30, 2004, Merck voluntarily withdrew Vioxx from the market." That was three years after studies were first published definitively showing the drug led to increased risk of heart attacks, NPR reported in 2007. The piece cites research from *The Lancet* estimating 38,000 people died from heart attacks as a result of taking the drug.

Merck did not respond to a request for comment.

Other examples of drugs heavily advertised before being withdrawn due to often lethal side effects were treatments for arthritis, diabetes, gastric reflux, high cholesterol, and irritable bowel syndrome, Ventola noted.

Even if there are benefits, Caremark's Devaney argues this kind of education should not be promoted in the healthcare space at all. "I'm a little more 'old school,' but I believe that pharma shouldn't create a demand for a product," he says. "Rather, if there are health issues, working directly with a doctor and prescriber to understand the right next steps is always the preferred approach, as opposed to members walking into a doctor's office believing that they need access to a certain medication."

Besides driving higher drug spending and advertising drugs before their side effects are fully known, Devaney says DTCA can also sabotage the important relationship between patient and doctor. The Ventola review also cited evidence that denying prescriptions decreases patient satisfaction, increases physician switching, and results in patients trying to find the drug elsewhere. One study of oncology nurse practitioners the review drew on even found 74% of their patients asked for an inappropriate drug after seeing DTCA, and 43% of the practitioners felt pressured to prescribe it anyway.

FEDERAL ACTION SO FAR

The U.S. government has recently taken action to address the perceived harms of DTCA. On Nov. 21, 2023, the FDA finalized a rule establishing a statutory requirement that "in human prescription drug advertisements presented directly to consumers in television or radio format (DTC TV/radio ads), and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner."

The FDA has a longstanding requirement that DTCA include a "true statement" of the side effects and contraindications of an advertised drug. However, this new rule, slated to come into effect a year after its finalizing, flowed from language in the 2007 Food and Drug Administration Amendments Act instructing the FDA to determine the standards for clear, conspicuous, and neutral. (See Sidebar: Clear, Conspicuous, and Neutral)

The agency justified federal action by pointing to the vast increase in spending on DTCA, research showing a significant lack of consumer comprehension of drug side effects and contraindications, and the potential impact this advertising can have on drug demand.

The FDA was especially concerned that 0% of television advertising it evaluated over the preceding 10 years would meet the "dual modality" standard established by the final rule—presenting the side effects and contraindications of a drug both in audio and visually in text at the same time. DTCA often features a mismatch between audio and visuals (consider the example at the beginning of this article), and the Ventola review for *Pharmacy and Therapeutics* pointed to research that showed this mismatch typically results in viewers not processing the risk information presented through audio.

Disregarding the dual modality standard, FDA research also showed that up to one-third of advertising from the previous decade would violate one or more of the other standards laid out in the final rule.

Both Herr and Goodwin aren't particularly hopeful regarding the impact of the new rule, estimating it will have little effect on advertising practices. "I would tell you that where the rule probably will have the most impact is in the prescribing physician's office with a healthy discussion about those [side effects]. But I think for the most part, physicians believe that the side effects happen to such a small

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minority of individuals that they're not openly discussed to the degree that they need to be discussed," Herr says.

Herr's optimism is a cautious kind, however. "I don't hold out much hope for a large impact, because there's still the picture of the person skipping through the meadow after the drug has solved all issues. And you know, [drug manufacturers] have a formula for this. It's absolutely formulaic in terms of how it's advertised."

Similarly, Goodwin does not believe the rule is charting any new course for the healthcare industry at large. In her view, the rule only exists to address the issue that consumers did not know the risks of medications they were asking for, in line with FDA findings—and so the most it will do is require those major side effects to be conveyed more clearly.

"So, you can picture a drug commercial, any given ad on the TV, and it hyper focuses on all the benefits, and then at the end, it just rattles off really quickly all the side effects—even including death—and then moves on. This new rule is not much of an advancement, in my opinion, but maybe we'll be surprised."

Goodwin says she hopes the FDA rule prompts consumers to be more informed and cautious about medication use. That could also steer them away from pharmaceuticals with higher risks, she says, before adding: "But then we know the pharmaceutical companies would just adapt their marketing and development strategy accordingly."

PROHIBITION?

There appears to be a consensus across much of the healthcare industry—excluding pharmaceutical manufacturers—that DTCA should be banned outright. In 2023, the American Medical Association (AMA) reaffirmed a resolution that

Clear, Conspicious, and Neutral

According to guidance released by the U.S. Food and Drug Administration, the statement of a drug's side effects and contraindications must meet five standards to be considered "clear, conspicuous, and neutral."

- **Standard 1:** The statement is presented in consumer-friendly language and terminology that is readily understandable.
- **Standard 2:** The statement's audio information, in terms of volume, articulation, and pacing, is at least as understandable as the audio information presented in the rest of the advertisement.
- **Standard 3:** In advertisements in television format, the statement is presented concurrently using both audio and text (dual modality). To achieve dual modality:
  - Either the text displays the verbatim key terms or phrases from the corresponding audio, or the text displays the verbatim complete transcript of the corresponding audio; and
  - The text is displayed for a sufficient duration to allow it to be read easily. For purposes of the standard, the duration is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio.
- **Standard 4:** In advertisements in television format, for the text portion of the statement, the size and style of font, the contrast with the background, and the placement on the screen allow the information to be read easily.
- **Standard 5:** During presentation of the statement, the advertisement does not include audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.

calls for a "ban on direct-to-consumer advertising for prescription drugs and implantable medical devices." When the resolution was first passed in 2015, then AMA Board Chair-elect Patrice Harris, MD, MA, cited the "role that marketing costs play in fueling escalating drug prices" and the "inflate[d] demand for new and more expensive drugs, even when these drugs may not be appropriate."

Along the same lines, the American Pharmacists Association Academy of Student Pharmacists opposes DTCA "to reduce unnecessary treatments and strain on the patient-provider relationship." Additionally, the American Society of Health-System Pharmacists also advocates for lobbying Congress to ban DTCA, pointing to the negative impacts including drug overuse, less effective treatments, inappropriate prescription of drugs, medicalization of symptoms not previously considered an illness, and the increased healthcare costs that flow from those factors.

Major medical organizations in the only other country that allows unrestricted DTCA, New Zealand, are also calling for a ban on this kind of advertising. The Royal New Zealand College of General Practitioners, for example, "advocates that legislation should be amended to prioritize the protection of public health over the interests of private industry: DTCA of prescription medications should be prohibited."

The college highlighted the same issues as cited by the U.S. organizations: "considerable public harm through misinformation and the stimulation of demand for unsuitable or unnecessary, costly treatment, leading to inappropriate prescribing."

The Council of Medical Colleges in New Zealand, the New Zealand Medical Association, and the Royal Australian & New Zealand College of Psychiatrists, among other organizations, all support a prohibition of DTCA.

Herr and Goodwin would also like to see DTCA banned in the United States, but both acknowledge it isn't likely. At time of writing, there has been no movement in Congress or in the states to restrict DTCA; the closest Congress, rather than an agency, came to addressing the issue was the Banning Misleading Drug Ads Act of 2022, which would have finalized the new FDA rule had the agency not done so last year.

Goodwin, though, thinks regulations could go farther, even if prohibition isn't an option. She proposes mandating post-market surveillance, requiring a drug company to publicly report data on the side effects of and likelihood of those side effects for each drug it advertises. She believes this would help inform consumers, since advertising doesn't often address the likelihood of side effects it lists.

The AMA also has a laundry list of proposals for new regulations and other government action that don't go as far as blanket prohibition. Besides calling for additional agency-conducted or -funded research into the effects of DTCA on the physician-patient relationship, health outcomes, and drug costs, the AMA also supports the applicable federal agencies requiring a statement of the advertised drug's suggested retail price within the advertisement itself.

The additional research the AMA promotes would also support another federal undertaking: that the government, through the Agency for Healthcare Research and Quality or another agency, regularly review existing evidence about the "impact of DTCA on health outcomes and the public health." And if the evidence suggests that impact is negative, then Congress ought to consider legislation to further regulate or prohibit DTCA.

Finally, if a total ban isn't an option, the AMA suggests a moratorium on advertising for a particular drug until enough time has passed to allow full determination of possible side effects, including rarer ones or those that only begin after extended usage—as with the heart attacks from taking Vioxx. edge

Zach West is a content specialist for Leader's Edge.