



New Developments in DTC Television Advertising:

Disclosing Prescription Drug List Prices

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Introduction

In May 2018, amidst mounting public discussion, the Department of Health and Human Services (HHS) released a sweeping document entitled “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Cost.” Among the Blueprint’s many proposals was a call for the Food and Drug Administration (FDA) “to evaluate the inclusion of list prices in direct-to-consumer advertising.”¹ Commenters on the Blueprint raised a variety of objections, including the potential for confusion among

patients (who typically do not pay list price), FDA’s lack of statutory authority to regulate drug prices or to mandate pricing disclosures, and significant First Amendment concerns.² Nevertheless, the proposal evolved, taking shape in the form of a final rulemaking by the Centers for Medicare and Medicaid Services (CMS)—not FDA—requiring prescription drug manufacturers to disclose list prices in their direct-to-consumer (DTC) television advertising. Industry has now also successfully challenged the Final Rule. On July 8, 2019, the U.S. District Court for the District of Columbia held that HHS lacked the statutory



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authority under the Social Security Act to adopt the Final Rule. The issue of DTC list price disclosures remains live, however, as Congress has examined proposals to enshrine disclosure requirements in statute. HHS, meanwhile, left open the door for potential appeal (as of this article's writing).³ All the while, industry has attempted to navigate these shifts through self-regulatory initiatives and modification of advertising practices.

This article briefly describes FDA's historical approach to regulating drug pricing information in advertising, provides an overview of the genesis of the Final Rule, and ends with some key legal issues and questions facing all prescription drug manufacturers who seek to continue to engage with consumers through broadcast advertising.

Background

Over the past two years, significant shifts have occurred in public debate on drug prices and their inclusion in advertising. FDA has historically avoided applying advertising and labeling requirements to prescription drug communications that merely communicate product price or insurance coverage information, particularly in the absence of an affirmative statement of safety or efficacy. Instead, FDA has focused on improper pricing comparisons that suggest one drug is clinically more effective than another without adequate substantiation or in a way that misleads viewers about the relative safety risks. The Blueprint and subsequent related rulemakings generated public discussion over whether FDA should regulate list price disclosures or whether the gap should be filled by another agency or by industry self-regulation.

FDA Regulation of Prescription Drug Advertising Before the Blueprint

While FDA has the authority to regulate prescription drug advertising under the Federal Food, Drug, and Cosmetic Act (FDCA),⁴ prior to the HHS "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Cost," FDA had not attempted to weigh in on the criteria for substantiating pricing statements in prescription drug advertising. Instead, FDA's regulation of prescription drug advertising primarily focused on safety and

efficacy claims, including those in DTC media. FDA monitors DTC promotion to help ensure that adequate contextual and risk information, presented in understandable language, is included both to fulfill the requirement for fair balance and to help the consumer accurately assess promotional presentations.⁵ FDA has been active in its enforcement and surveillance activities concerning DTC advertisements across various broadcast media types—often issuing enforcement letters (i.e., Untitled and Warning Letters) for allegedly non-compliant promotion. Issues commonly cited in enforcement letters include omission and minimization of risk information, overstatement of efficacy, failure to submit on Form FDA 2253 (relating to the submission of advertising and promotional labeling) at the time of initial use or dissemination, use of misleading and/or unsubstantiated claims, among others.⁶

Interestingly, at least since the 1970s, FDA has recognized that pricing information may be provided by manufacturers to consumers as part of a "price reminder advertisement"—a sort of subset of unbranded reminder advertising whose sole purpose is to provide consumers with information concerning the price charged for a prescription drug without making any representations about its safety, effectiveness, or intended uses.⁷ FDA also has generally declined to regulate pricing discussions between payors and manufacturers of drugs and devices, so long as the information that manufacturers provide to payors is unbiased, factual, accurate, and non-misleading, and is presented with certain other information necessary to contextualize discussion of unapproved uses.⁸ To the extent the agency has taken steps to affect drug pricing, the agency has generally taken a more holistic policy approach that influences pricing indirectly by encouraging fair competition, often in response to Congressional/statutory mandates, such as prioritizing review and approval of generic products⁹ and biosimilars¹⁰ and targeting "gaming" of the REMS system.¹¹ Thus, the recent interest shown by FDA in entering the debate about consumer education around prescription drug pricing is largely unprecedented.



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The Shift: HHS Asks FDA to Require Prescription Drug Price Disclosure in Television Advertising

In the spring of 2018, HHS released its Blueprint, addressing mounting public pressure for drug pricing reform. Prior to this point, it was not clear what role, if any, FDA might play in HHS efforts to advance new policy. However, immediately following the Trump Administration's announcement of the Blueprint, HHS Secretary Alex Azar asserted that regulation of DTC advertising related to FDCA "fair balance" requirements for drug advertising:

[W]e are having the FDA look at how we can require in direct-to-consumer TV ads that you have to disclose the list price of your drug. We believe it's an important part of fair balance that if you're telling a patient, activating a patient to have a discussion with their doctor about a drug, telling them all the good things that drug can do for them, it's material and relevant to know if it's a \$50,000-drug or a \$100-drug, because often that patient is going to have to bear a lot of that cost.¹²

Azar referenced the proposal further in statements before the Senate Health, Education, Labor, and Pensions (HELP) Committee¹³ and Finance Committee.¹⁴ Meanwhile, then-Commissioner Scott Gottlieb stated in a press interview that FDA was exploring ways to implement the proposal.¹⁵ Gottlieb also echoed the concerns of HHS Secretary Alex Azar, the Trump Administration, and members of Congress through a series of Twitter dialogues.¹⁶

Industry Responds, Questioning FDA's Authority and Expertise Regarding Pricing Advertising

Many companies were concerned about aspects of the HHS proposal to formalize and standardize pricing communications, including the risk that patients, who typically pay an amount lower than the list price, might be deterred from seeking treatments they could actually afford. Further, legal commenters on the HHS Blueprint objected that FDA lacked statutory or administrative authority to implement the rule described. Against this backdrop, the industry proposed methods to integrate pricing information into their ads in advance of any final rule, beginning with the "Direct to Consumer Advertising Principles" published by the Pharmaceutical Research & Manufacturers of America (PhRMA) in October 2018.¹⁷ Individual manufacturers also made public commitments. For example, in January 2019, one major pharmaceutical company disseminated a television commercial that used PhRMA's self-regulatory recommendations as a guidepost, directing consumers to a website and toll-free phone number with pricing information about the advertised product.¹⁸ In February 2019, another major company announced it would begin providing information about list prices and out-of-pocket costs for its products in its DTC television advertisements.¹⁹

CMS Issues Regulation to Require Drug Pricing Transparency

Ultimately, questions regarding FDA's involvement in a DTC list price disclosure rule remained unanswered. Instead, HHS changed course, and the rule was taken up by FDA's sister agency CMS, which administers the Medicare program and partners with states to implement Medicaid, the Children's Health

Insurance Program (CHIP), and health insurance portability standards. CMS first issued a proposed rule on October 18, 2018²⁰ and then adopted a final rule on May 10, 2019²¹ ("Final Rule") requiring manufacturers to include specific list price disclosure language for products exceeding a predetermined price threshold. Commenters on the proposed rule had questioned whether CMS possessed the requisite authority to issue the rule, given that Congress never explicitly granted CMS authority to regulate DTC advertising or pricing for prescription medicine.²² Nevertheless, CMS asserted broadly in the Final Rule that regulation of television advertising was consistent with its statutory authority under the Social Security Act to issue regulations necessary for the efficient administration of Medicare and Medicaid.²³ CMS also argued in the Final Rule preamble that the rule was consistent with current CMS rules that regulate broadcast advertisements and other media in the context of marketing by Medicare Advantage and Part D plans.²⁴ These arguments did not convince the D.C. District Court, which vacated the Final Rule based on a lack of HHS/CMS regulatory authority under the Social Security Act.

Nevertheless, the Final Rule and D.C. District Court decision raise interesting questions about how the government might attempt to regulate or mandate list price disclosures in the future. An overview of the Final Rule, the included enforcement provisions, and the District Court decision is provided below.

The Final Rule

The Final Rule was to go into effect July 9, 2019 and would require:

Any advertisement for any prescription drug or biological product on television (including

broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast.²⁵

The required format for the statement would be: “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”²⁶ For drugs where the typical course of treatment varies by indication, the Final Rule would require that the pricing disclosed be for the primary indication addressed in the advertisement.²⁷ The rule would apply to broadcast television advertisements for a prescription drug or biological product reimbursable under Medicare or Medicaid, with an exception for any products with a list price of less than \$35 per month for a 30-day supply or typical course of treatment.²⁸ The disclosure would have to be presented at the end of the advertisement in a “legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.”²⁹

The Final Rule Enforcement Provisions

Interestingly, CMS did not attempt to create a mechanism for itself to enforce the law directly, perhaps due to uncertainty surrounding the scope of its own authority. The only HHS enforcement mechanism CMS included in the Final

Rule would have been CMS/HHS’s online publication of a list of manufacturers who have violated the rule’s requirements.³⁰ Instead, CMS asserted that the primary mechanism for enforcement would be by private parties under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).³¹ Section 43(a) creates a private right of action against “any person” who makes a “false or misleading representation of fact” about the “nature, characteristics, qualities or geographic origin” of his or her own “or another person’s goods, services, or commercial activities.”³² While CMS acknowledged that standing to bring suit under the Lanham Act is limited to competitors who can allege injury to commercial interests and not consumers, CMS states it believes competitors “are best positioned to identify and act upon advertisements that violate this regulation.”³³ CMS also dismissed the notion that enforcing such actions through the Lanham Act would be costly or would contribute to drug manufacturers raising list prices to account for litigation costs, arguing that the sophistication of parties would reduce the probability of meritless lawsuits.³⁴ CMS asserted that failure to disclose pricing information from a DTC advertisement would be actionable under section 43(a) since it is “affirmatively misleading, partially incorrect, or untrue as a result of failure to disclose a material fact.”³⁵

In keeping with shifting enforcement to the private sector, CMS included an express preemption provision in the Final Rule preventing state and local governments from implementing any different or additional requirements concerning the disclosure of pricing in TV ads for prescription drugs or biological products.³⁶ CMS wrote, “consistent with our not proposing any HHS-specific

enforcement mechanism, we proposed at § 403.1204(b) that this rule preempt any state-law-based claim that depends in whole or in part on any pricing statement required by this rule.”³⁷ CMS explained, the rule was not intended to “create a regulatory ‘floor’” or to allow states to “impose varying disclosure requirements on television advertisements that may air in each respective state.”³⁸ Although CMS did not discuss current specific initiatives that would be affected, the preemption provision notably would have curtailed states, who have most frequently stepped into the regulatory void on drug price transparency, from implementing proposals. Such proposals have included Oregon H.B. 2961, a 2019 bill that would have required manufacturers to disclose wholesale prices paid by pharmacies in Oregon in any prescription drug advertisement, subject to monetary penalties.³⁹

The Final Rule also provided interesting insight into the agency’s view on these topics in response to comments. CMS defended its choice to focus on television advertising on the grounds that it is a “universal medium watched by beneficiaries,” that “reaches about 87 percent of the adult population,” and that “television advertising makes up over two thirds of the DTC spend for pharmaceuticals.”⁴⁰ Further, CMS attempted to resolve questions about which agency (FDA or CMS) should have authority to promulgate this price transparency rule by noting that the Final Rule “take[s] no position ... on whether FDA has the authority to require the listing of drug prices in DTC advertisements ... [w]hether FDA possesses such authority is not dispositive of the question of CMS’s authority to implement the disclosure requirement necessary for the efficient administration of Medicare and Medicaid,” and ultimately

that “[t]he statutory authority to issue rules . . . rests with and can always be exercised by the Secretary [of the Department of Health and Human Services], even if such authority has been delegated to individual agencies.”⁴¹ For some critics of the Final Rule, these statements will likely continue to fuel the debate about the appropriateness of the new law and CMS’s ability to issue it.

The Court’s Decision to Vacate the Final Rule

Plaintiffs, several pharmaceutical manufacturers, and a major advertising industry trade association filed a complaint and Motion to Stay the Final Rule against defendants, HHS and CMS, in federal court in the District of Columbia.⁴² Plaintiffs advanced two key arguments: (1) the rule exceeded HHS’s statutory authority; and (2) the rule violated the First Amendment in compelling manufacturers’ and advertisers’ speech. The court vacated the rule based on the first theory and did not reach the second.

Using a *Chevron* analysis, the court found HHS lacked authority under the Social Security Act to adopt the Final Rule.⁴³ Specifically, as the court noted, neither the “Act’s text, structure, nor context evince[d] an intent by Congress,” either directly or indirectly, “to empower HHS to issue a rule that compels drug manufacturers to disclose list prices.”⁴⁴ HHS and CMS pointed to Sections 1102 and 1871 of the Social Security Act as the source of their rulemaking authority. Those provisions provide that: (1) The “Secretary of Health and Human Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which” the Secretary is charged by the Social Security Act, which include the Medicare and Medicaid

programs, 42 U.S.C. § 1302(a); and (2) “The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter,” which establishes the Medicare program, id. § 1395hh(a)(1).⁴⁵ However, while HHS/CMS attempted to justify the rule as “necessary” to carry out the functions described in these provisions, the court concluded the key inquiry was whether the rule fell within HHS’s authority to take action to carry out the “administration” of Medicare and Medicaid under the Social Security Act.⁴⁶ The court concluded it did not.⁴⁷ The court found the plain statutory text does not support HHS authority to regulate the marketing of prescription drugs, nor authorize such regulation “in the name of attempting to reduce costs, to regulate the health care market itself or market actors that are not direct participants in the insurance programs.”⁴⁸

Additionally, the court rejected defendants’ contention that its rulemaking authority combined with the absence of a clear statutory restriction demonstrated Congress’ intent that HHS exercise broad regulatory authority over subjects affecting the costs of Medicare and Medicaid programs.⁴⁹ The court concluded HHS’s “grant of rulemaking authority does not sweep so broadly as to authorize HHS to regulate the marketing of prescription drugs” and “were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony.”⁵⁰

The court also analyzed other statutory provisions that “may bear on Congress’s intent” in concluding Congress did not intend to extend authority under the Social Security Act for HHS to mandate list price disclosures in advertising.⁵¹

As the court explained, “Congress has legislated on the subject of direct-to-consumer advertising of pharmaceutical products multiple times under a different statute—the [FDCA].”⁵² The court cited express provisions in the FDCA granting HHS the power to regulate DTC advertisements to ensure they are truthful and non-misleading—authority that HHS has delegated to FDA. The court also cited content requirements for prescription drug advertisements contained in the Drug Amendments of 1962, which amended the FDCA to require that advertisements contain the drug’s established name; ingredients; and “such other information in brief summary related to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary” of HHS.⁵³ Additionally, the court described later amendments requiring the inclusion of contact information for adverse event reports and certain minimum content requirements for drugs that must be administered under the supervision of a licensed practitioner (due to toxicity or other potentiality for harmful effect, method of use, or collateral measures necessary for use).⁵⁴ “As these amendments to the FDCA demonstrate,” the court wrote, “Congress knows how to prescribe the content of drug advertising when it chooses to do so.”⁵⁵

The court also looked to other provisions in the FDCA allowing FDA pre-review of television advertisements, and the fact that Congress limited FDA from ordering companies to make direct changes to their advertisements, except in instances where “the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may

require inclusion of such disclosure in the advertisement.⁵⁶ Finally, the court assessed the content of the Final Rule itself and determined it fell far outside a “common sense” interpretation of how Congress intended to delegate authority to HHS; no wonder, perhaps, that HHS had never before attempted to invoke the Social Security Act in directly regulating the pharmaceutical marketplace.⁵⁷

The court concluded that given CMS’s apparent lack of statutory authority to issue the Final Rule and the indicia of congressional intent that such authority be located *elsewhere* (as where Congress gave FDA limited authority to regulate certain *aspects* of television advertising for drugs), “The [Wholesale Acquisition Cost] Disclosure Rule feels like agency action in search of a statutory home.”⁵⁸

What Does this Mean for Companies?

Regulation of DTC list price disclosures is an evolving area. As described above, there has been debate over who has the authority to issue rules in this domain, and indeed, over what scope of regulation, if any, is even permissible under existing law. Although the CMS Final Rule has been vacated as of this writing—we cannot predict with certainty what lies ahead in this field of regulation. Affected stakeholders should consider the following steps to stay ahead of the curve.

Continue to Monitor Developments in this Area

In tandem with HHS rulemaking, members of Congress have also proposed legislation in this area. This means companies should monitor the swift changes occurring in sources and focal points of regulation.

For example, following the publication of the Final Rule, Senators Dick Durbin (D-IL), Chuck Grassley (R-IA), Angus

King (I-ME), and Lamar Alexander (R-TN) proposed a bill codifying the rule. The bill as introduced cited the new CMS regulations and states that the rule was issued “pursuant to [CMS’s] existing authority” and that the purpose of the bill is “[t]o support the permanence and clarity of this policy, and to facilitate future planning.”⁵⁹ The bill would have directed HHS to “require that each direct-to-consumer advertisement for a prescription drug or biological product for which payment is available under [Medicare] or [Medicaid] includes an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.”⁶⁰ The bill specified that CMS “shall determine the components of the requirement . . . such as the forms of advertising, the manner of disclosure, the price point listing, and the price information for disclosure.”⁶¹ In passing the baton to CMS, the bill walked back the aggressive approach taken in previous Durbin and Grassley proposals from 2017-2018, including bills that would have subjected advertisers to significant monetary penalties for failing to disclose list prices or that would have made failure to include wholesale acquisition cost (WAC) in DTC advertising a crime in violation of the FDCA prohibition against misbranding.⁶² In future legislation, legislators may heed the court’s apparent call for Congress to speak more clearly in order to allow CMS—or perhaps FDA—to step into the fray.⁶³ Accordingly, it would not be surprising to see additional legislative proposals in this vein. Further, in the absence of express preemption by a federal regulation (as would occur if the Final Rule became effective) or by Congress, it appears quite possible that states may still attempt to pass related laws, as indicated by Oregon’s stalled proposal in H.B. 2961.

Familiarize Yourself with the Lanham Act

Although the Final Rule was vacated by the D.C. District Court, CMS’s guidance raised the suggestion that the Lanham Act could be used to challenge advertising in the event drug manufacturers do include list prices in their advertisements. To state a claim under the Lanham Act, a plaintiff must demonstrate the following:

- 1) that the defendant has made false or misleading statements as to his own product [or another’s];
- 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;
- 3) that the deception is material in that it is likely to influence purchasing decisions;
- 4) that the advertised goods traveled in interstate commerce; and
- 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.⁶⁴

While examples of Lanham Act cases addressing pricing disclosures are limited, they are several relevant cases, including *Heartland Payment Sys., Inc. v. Mercury Payment Sys., LLC*⁶⁵ and *Bayer Healthcare Pharm., Inc. v. RJ Health Sys. Int’l, LLC*.⁶⁶ In *Heartland*, the Federal District Court for the Northern District of California considered a challenge by Heartland Payment System’s competitor Mercury of pricing information posted on Heartland’s website, which Heartland advertised as “fair and upfront pricing” to its customers. Mercury argued under the Lanham Act that Heartland did not disclose all fees (e.g., settlement, early termination) upfront, and thus Heartland’s claim of “fair and upfront pricing” to its customers was false and misleading. However, the *Heartland* court found that Mercury could not support its claim that

Heartland’s advertisements were false and misleading since Mercury did not demonstrate these fees were not disclosed elsewhere prior to a merchant signing a contract.⁶⁷ Ironically, the plaintiff’s theory in *Heartland* was based on the fact that hidden fees were not disclosed—perhaps the opposite principle from what is at play in CMS’s guidance, which asserts that a drug’s WAC is the most appropriate benchmark price for consumers, notwithstanding the fact that WAC does not reflect rebates and discounts and is not the amount paid by the typical patient. 84 Fed. Reg. at 20741.

Bayer may provide a more relevant precedent for stakeholders; while the case does not deal with advertising per se, it illustrates the principle that a plaintiff only has to show a “tendency to mislead” to show sufficient injury under the Lanham Act. In *Bayer*, Bayer challenged RJ Health’s incorrect listing, on RJ Health’s website, of pricing for Bayer’s product Mirena®, a hormonal intrauterine device used for birth control; the website provided data that insurance companies used to adjudicate reimbursement claims.⁶⁸ Bayer alleged that it offered a price-match discount on Mirena® in order to avoid the lost business and loss of goodwill it feared would result from purchasers being reimbursed for a lesser amount than the cost of the drug.⁶⁹ Further, in *Bayer*, the court held that a competitor need not be a direct competitor—another ruling that could have relevance in enforcing the Final Rule (“Here, although RJ Health is not in direct competition with Bayer, if it is shown that the website misstates the price for Mirena®, this could affect Bayer’s sales. Such allegations are sufficiently plausible to state a claim under the Lanham Act”). The court also rejected RJ Health’s argument that Bayer failed to allege anyone had

actually been misled—Bayer was merely required to plead that the misstatements had a “tendency to mislead,” which the court concluded had been done.

While the Lanham Act has not been frequently used, if at all, in cases involving disclosures of prices in prescription drug advertising, it is an authority that companies should better understand as they consider different regulatory authorities’ attempts to create new frameworks for regulating in this space.

Consider the Applicability of Other Consumer Protection Regimes

Finally, companies must remember that other frameworks continue to apply to prescription drug advertising. Companies should consider guidance provided by deceptive pricing case law and regulation in the consumer product context. For example, the Federal Trade Commission “Guides Against Deceptive Pricing,” codified at 16. C.F.R. Part 233, provide some guidance for companies on how to effectively provide consumers with price comparisons in a truthful and non-misleading manner. In pertinent part, the Guides outline standards for conveying comparative pricing information to consumers, including comparisons to former prices and promotions touting “wholesale” prices. Similarly, existing state laws regulate instances where advertisers make comparative pricing claims or advertise sales or discounts. For example, state regulators, including those in California⁷⁰ and Ohio,⁷¹ have brought actions against companies for allegedly using deceptive *reference* pricing (which allegedly gives consumers a deceptive sense of the savings achieved through their purchase of a product, and is also referred to as “comparison” pricing in certain states⁷²). Similarly, there has been an uptick in consumer class actions alleging that a

company’s price comparisons violate state law because the merchandise was either (1) not offered for a substantial period of time or the required, specific period of time at the higher reference price; or (2) never offered for sale at the higher, reference price.⁷³

In sum, until this area of regulation has found a settled “home” in statute or regulation, companies should continue to monitor developments and employ the strategies described above. ▲

1. HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692, 22695 (May 16, 2018).
2. See, e.g., PhRMA, Comments of the Pharmaceutical Research and Manufacturers of America (July 16, 2018), *available at* regulations.gov.
3. Rachel Cohrs, “HHS Leaves Door Open For Potential DTC Ad Rule Appeal” Inside Health Policy (July 9, 2019).
4. FDA has the authority to regulate written, printed, graphic, or broadcast matter that accompanies a prescription drug in interstate commerce. 21 U.S.C. § 352; 21 C.F.R. § 201; *Kordel v. United States*, 335 U.S. 345 (1992). Prescription drug advertising cannot be false or misleading in any particular; and, where prescription drug safety or efficacy claims are made (i.e. where the material contains express or implied representations about a referenced prescription drug product’s safety or effectiveness to treat a particular population or condition), the material must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece. Section 502(n) of the FDCA requires advertisements to contain “information in brief summary relating to side effects, contraindications, and effectiveness.” FDCA § 502(n); 21 U.S.C. § 352(n). FDA implementing regulations permit advertisements broadcast through media such as television, radio, or telephone communications systems to disclose the product’s major risks in a summary fashion in either the audio or audio and visual parts of the presentation; this is sometimes called the “major statement.” 21 C.F.R. 202.1(e)(1). On

- September 27, 2007, President George W. Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act (“FDAAA”) (Public Law No. 110-85), which (among other things) amended the FDCA by adding to section 502(n) (21 U.S.C. § 352(n)) the provision that “[i]n the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner” (emphasis added) (Section 901(d)(3)(A) of FDAAA).
5. 60 Fed. Reg. 42581–82 (1995); See also 21 C.F.R. § 202.1(e)(5).
 6. See “enforcement actions” posted on the Office of Prescription Drug Promotion’s webpage, available at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm> (last visited November 8, 2018).
 7. See 21 C.F.R. § 200.200 (Prescription Drugs; Reminder Advertisements and Reminder Labeling to Provide Price Information to Consumers).
 8. See, e.g., Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers: Guidance for Industry and Review Staff, at 19–20 (June 2018).
 9. See, e.g., FDA Office of Generic Drugs, 2017 Annual Report, at 6 (Jan. 2018), <https://www.fda.gov/media/111198/download> (describing updates to policies and procedures to priority review of generic drug applications until there are three generics approved for a brand product; and enhancing development and review of abbreviated new drug applications (ANDAs) for complex generic drug products).
 10. Biosimilars Action Plan: Balancing Innovation and Competition, FDA (Jul 2018), <https://www.fda.gov/media/114574/download>.
 11. See, e.g., FDA, Reference Listed Drug (RLD) Access Inquiries (Feb. 7, 2019), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rla-access-inquiries>.
 12. *Press Briefing by Secretary Sanders and HHS Secretary Alex Azar*, The White House, (May 11, 2018) <https://www.whitehouse.gov/briefings-statements/press-briefing-press-secretary-sarah-sanders-hhs-secretary-alex-azar-051118/>.
 13. Written Testimony by Alex M. Azar II Secretary, U.S. Department of Health and Human Services on President Trump’s Drug Pricing Plan Before United States Senate Committee on Health, Education, Labor, and Pensions, U.S. Senate Committee on Health, Education and Pensions (June 12, 2018), <https://www.help.senate.gov/imo/media/doc/Azar1.pdf>.
 14. Written Testimony by Alex M. Azar II Secretary, U.S. Department of Health and Human Services on President Trump’s Drug Pricing Plan Before United States Senate Committee on Finance, U.S. Senate Committee on Finance (June 26, 2018), <https://www.finance.senate.gov/imo/media/doc/26JUN2018AzarSTMNT.pdf>.
 15. Cory L. Andrews, Washington Legal Foundation, FDA-Mandated Listing Of Drug Pricing In Ads Would Flunk Legal And Constitutional Tests, Forbes, (Aug. 27, 2018, 10:45 AM) <https://www.forbes.com/sites/wlf/2018/08/27/fda-mandated-listing-of-drug-prices-in-ads-would-flunk-legal-and-aonstitutional-tests/#9f53bc86752a>.
 16. Scott Gottlieb, M.D., @SGottliebFDA, Twitter (Dec. 25, 2017), <https://twitter.com/SGottliebFDA/status/945322600133283841> (“#FDA is taking new steps to stem pricing abuses. Branded companies can help too, by contracting carefully when they choose to out-license old generic drugs; building into these contracts provisions that would help prevent abusive pricing by the acquirers.”).
 17. Direct to Consumer Advertising Principles, PhRMA (Oct. 15, 2018), <https://www.phrma.org/codes-and-guidelines/direct-to-consumer-advertising-principles>.
 18. Beth Snyder Bulik, “Eli Lilly’s New Trulicity TV Ad Counters Trump With First-Ever Pricing Information,” FiercePharma (Jan. 9, 2019), <https://www.fiercepharma.com/marketing/lilly-becomes-first-pharma-to-add-pricing-information-tv-ads-following-up-trade-group; see also Lilly, ‘Lilly Pricing Info’> (last visited Feb. 21, 2019), <https://www.lillypricinginfo.com/>.
 19. Johnson & Johnson, “What Cost Information Helps Patients in a TV Ad? We Asked Them” (Feb. 7, 2019), <https://www.jnj.com/our-company/what-cost-information-helps-patients-most-we-asked-them>.
 20. Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 83 Fed. Reg. 52,789 (Oct. 18, 2018).
 21. Final Rule, 84 Fed. Reg. 20732 (May 10, 2019).
 22. See, e.g., PhRMA, Comments Re: Regulation to Require Drug Pricing Transparency; Request for Comments, Docket No. CMS-4187-P, 83 Fed. Reg. 52,789 (Oct. 18, 2018), available at www.regulations.gov.
 23. 84 Fed. Reg. 20738 (citing Social Security Act §§ 1102, 1871).
 24. 84 Fed. Reg. at 20738.
 25. 42 C.F.R. § 403.1202.
 26. 42 C.F.R. § 403.1202.
 27. 42 C.F.R. § 403.1202.
 28. 42 C.F.R. § 403.1200.
 29. 42 C.F.R. § 403.1203.
 30. 42 C.F.R. § 403.1204(a).
 31. 84 Fed. Reg. at 20751.
 32. 15 U.S.C. § 1125(a).
 33. 84 Fed. Reg. at 20752. CMS quoted source material noting that “Most courts recognize that there is a ‘strong public interest’ in using the Lanham Act to prevent misleading advertising and presume that consumers’ as well as competitors’ interests are to be protected under the Act.” *Id.* (quoting Ross D. Petty, *Competitor Suits Against False Advertising: Is Section 43(a) of the Lanham Act a Proconsumer Rule or an Anticompetitive Tool?*, 20 U. Balt. L. Rev. 381, 395 (1991)).
 34. 84 Fed. Reg. at 20752.
 35. *Id.* See 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, sec. 27.65 (5th ed. 2018) (citations omitted) (emphasis added). Failure to disclose the list price in a DTC advertisement, if required to do so by § 403.1202, makes that advertisement false and misleading.
 36. 42 C.F.R. § 403.1204(b).
 37. 84 Fed. Reg. at 20751-52.
 38. 84 Fed. Reg. at 20753.
 39. House Bill 2961, 80th Or. Legislative Assembly (2019 Regular Session) <https://olis.leg.state.or.us/liz/2019R1/Measures/Overview/HB2961>.
 40. CMS, Preamble to Final Rule, Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency 25, available at <https://www.hhs.gov/sites/default/files/cms-4187-f.pdf>.
 41. *Id.* at 24.

42. *See* Complaint, Merck & Co. Inc., et. al v. United States Dept. of Health and Human Servs., No. 1:19-cv-01738, ECF No. 1 (D.D.C. June 14, 2019); Order, Merck & Co. Inc., et. al v. United States Dept. of Health and Human Servs., No. 1:19-cv-01738, ECF No. 32 slip op. at 8 (D.D.C. July 8, 2019).
43. *Id.* at 26–27.
44. *Id.* at 2.
45. *Id.* at 12.
46. *Id.* at 13.
47. *Id.*
48. *Id.* at 14, 15.
49. *Id.* at 15.
50. *Id.* at 17.
51. *Id.* at 20.
52. *Id.* at 21.
53. *Id.* at 21 (citing Pub. L. No. 87-781, § 131(a), 76 Stat. 791–92 (Oct. 10, 1962) (codified at 21 U.S.C. § 352(n)).
54. *Id.* at 21 (citing Pub. L. No. 110-85, § 906(a), 121 Stat. 949–50 and Pub. L. No. 110-85, § 901(d)(3)(A), 121 Stat. 940).
55. *Id.* at 21.
56. *Id.* at 21 (citing 21 U.S.C. § 353c(e)(1)).
57. *Id.* at 24.
58. *Id.* at 25.
59. S.1437, 116th Congress (2019–2020) (as printed in Cong. Rec. S2791 (May 13, 2019)).
60. *Id.*
61. *Id.*
62. *See* S.A. 3611 to H.R. 6147, 115 Cong. (2018); S. 2157, Drug-Price Transparency in Communications Act (introduced Nov. 16, 2017).
63. Rachel Cohrs, “Grassley Says Congress Should Take Up DTC Ad Bill After Loss” Inside Health Policy (July 9, 2019).
64. *Groupe SEB United States, Inc. v. Euro-Pro Operating, LLC*, 774 F.3d 192, 198 (3d Cir. 2014).
65. *Heartland Payment Sys., Inc. v. Mercury Payment Sys., LLC*, No. C 14-0437 CW, 2016 WL 304764, at *1 (N.D. Cal. Jan. 26, 2016).
66. *Bayer Healthcare Pharm. Inc., v. RJ Health Sys. Int’l, LLC*, No. 15-6952 (KM) (MAH), 2016 WL 3574325 (D.N.J. June 30, 2016). The court denied RJ Health’s motion to dismiss because Bayer would have sufficient injury if it instituted its price-match discount on Mirena® in order to avoid the lost business resulting from purchasers being reimbursed for a lesser amount than the cost of the drug due to RJ Health’s website misstatements. *Id.* at 3.
67. *Heartland Payment Sys., Inc. v. Mercury Payment Sys., LLC*, No. C 14-0437 CW, 2016 WL 304764 (N.D. Cal. Jan. 26, 2016). Mercury relied on unattributed oral statements by sales representatives that were insufficient to meet pleading standards under Rule 9(b) (which required Mercury to “allege the names of the persons who made the . . . representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written”). *Id.* at 1.
68. *Bayer Healthcare Pharm., Inc. v. RJ Health Sys. Int’l, LLC*, No. 15-6952 (KM) (MAH), 2016 WL 3574325, at *3 (D.N.J. June 30, 2016).
69. *Id.*
70. *People v. Overstock.com*, 12 Cal. App. 5th 1064 (Cal. Ct. App. 2017).
71. *State ex rel. Celebrezze v. Nationwide Warehouse & Storage, Inc.*, 1990 WL 692680, No. 90-CVH-08-6199 (Ohio Ct. Common Pleas Aug. 15, 1990).
72. *See, e.g., Cal. Bus. & Prof. Code* § 17501 (“No price shall be advertised as a former price of any advertised thing, unless the alleged former price was the prevailing market price as above defined within three months next immediately preceding the publication of the advertisement or unless the date when the alleged former price did prevail is clearly, exactly and conspicuously stated in the advertisement.”); Ohio Admin. Code § 109:4-3-12 (“Price comparisons”) (implementing the general principle of Ohio Rev. Code § 1345.02 that “it is deceptive for any claimed savings, discount, bargain, or sale not to be genuine, for the prices which are the basis of such comparisons not to be bona fide, genuine prices, and for out-of-store advertisements which indicate price comparisons to create false expectations in the minds of consumers”).
73. *E.g., Order Re: Plaintiffs’ Motion for Preliminary Approval of Class Action Settlement and Certification of Settlement Class, Jacobo v. Ross Stores*, 2:15-cv-04701-MWF-AGR, ECF No. 138 (C.D. Cal. Dec. 7, 2018) (preliminarily approving settlement payment of over \$4.85M to settle claims that the defendant violated California’s False Advertising Law and Unfair Competition Law through the use of misleading displays of a “sale price” and “Compare At” price which reasonable consumers would have interpreted to represent the amount charged for an identical price in other stores); Preliminary Approval Order, *Gattinella v. Michael Kors (USA), Inc.*, No. 14-05731, ECF No. 45 (S.D.N.Y. Aug. 10, 2015) (approving settlement class action for approximately \$4.88M); *see also Mulder v. Kohl’s Dept. Stores*, 865 F.3d 17 (1st Cir. 2017); *Gerbec v. ContextLogic, Inc.* (6th Cir. 2017); *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732 (7th Cir. 2014).