CMS Issues Final Rule Requiring Disclosure of Drug "List Prices" in Television Advertisements: Lanham Act and First Amendment Implications

May 16, 2019

On May 8, 2019, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule (the "Final Rule") that requires direct-to-consumer ("DTC") television advertisements for a prescription drug or biologic covered by the Medicare or Medicaid programs to disclose the product's "list price" (provided it is $35 or more for a one-month supply or the usual course of therapy).[1]

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The Final Rule was published on May 10, 2019, and will become effective on July 9, 2019.[2] It was finalized largely as proposed with primarily minor modifications and revisions. Debevoise previously issued a client alert after the proposed rule was published on October 15, 2018, where we addressed, among other things, the unique enforcement mechanism whereby CMS would rely on private lawsuits filed pursuant to Section 43(a) of the Lanham Act.[3]

In a conference call with reporters, Department of Health and Human Services ("HHS") Secretary Alex M. Azar II analogized the new requirement to mandatory price disclosures required for the automobile industry—despite the fact that cars are not reimbursed by the government, subject to co-pays, prescribed by third parties who function as gatekeepers, or subject to complex arrangements with prescription benefit managers (PBMs) and other healthcare providers. The strained analogy to automobile price disclosures reflects the legal complexities implicated by this unprecedented requirement and the absence of relevant precedent.

Below is an overview of key provisions of the Final Rule:

- The Final Rule provides that the requirement to disclose the "list price" applies to "advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII [Medicare] or XIX [Medicaid] of the Social Security Act," except for "any

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1 https://www.hhs.gov/sites/default/files/cms-4187-f.pdf.

2 https://www.federalregister.gov/documents/2019/05/10/2019-09655/medicare-and-medicaid-programs-regulation-to-require-drug-pricing-transparency.

3 https://www.debevoise.com/insights/publications/2018/10/cms-proposed-rule-regarding-disclosure.

prescription drug or biological product that has a list price…less than $35 per month for a 30-day supply or typical course of treatment…"

- The Final Rule defines "list price" as a drug's Wholesale Acquisition Cost ("WAC"). The WAC is the "manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in prices, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data." CMS strongly disagreed with comments that WAC is not standardized or well defined, arguing that Congress defined WAC in section 1847A of the Social Security Act and that WAC is the most common benchmark for purchasing and reimbursement.

- Any television advertisement for a prescription drug or biologic 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…" The specific textual disclosure required by the Final Rule is: "**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.**" The drug company will be responsible for drafting the bracketed language and incorporating the "list price." The textual statement must appear "at the end of an 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." CMS rejected proposals that called for omitting the "list price" from television advertisements and instead directing viewers to other resources (such as websites) where the "list price" and other relevant information could be found, an approach recommended by the Pharmaceutical Researchers and Manufacturers of America ("PhRMA") in its 2018 document: *PhRMA Guiding Principles—Direct to Consumers Advertisements About Prescription Drugs*.[4]

- The Final Rule permits manufacturers to provide an up-to-date competitor product's price, as long as they provide it in a truthful and non-misleading manner. Responding to comments that manufacturers will always list the highest competitor price available, which may confuse patients if other cheaper alternatives are available, CMS maintained that providing information about the prices of therapeutic alternatives provides valuable context for patients. Nonetheless, CMS reiterated that manufacturers must comply with all applicable FDA requirements when engaging in

[4] http://phrma-docs.phrma.org/files/dmfile/PhRMA_Guiding_Principles_2018.pdf.

this sort of comparative advertising and that nothing in the Final Rule is intended to supersede any FDA requirement (including FDA requirements applicable to comparative prescription drug advertising).

- According to the press release announcing the publication of the Final Rule, if a manufacturer includes price information in DTC television advertising, that information will not require review by the FDA's Office of Prescription Drug Promotion ("OPDP"). "OPDP does not review price information in prescription drug advertisements and does not intend to do so in the future, unless the price information explicitly or implicitly incorporates safety or efficacy information about the drug, or makes express or implied claims about the safety or efficacy about the drug."[5]

- Responding to comments highlighting a potential ambiguity in the proposed preemption provision, CMS revised the state law preemption language to clarify that the Final Rule does not create a regulatory "floor" that would allow states to impose varying alternative requirements applicable to television advertisements. Specifically, the Final Rule does not allow states and their political subdivisions to "establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by" the Final Rule. This change was the only substantive change to the proposed rule.

- The Final Rule confirms that private lawsuits under the Lanham Act will be the primary enforcement mechanism. In an effort to generate enforcement, the Secretary of HHS "will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation" of the Final Rule. Though several commenters were concerned that private actions under the Lanham Act would not be an adequate enforcement mechanism, CMS maintained that competing drug manufacturers "are best positioned to identify and act upon advertisements that violate this regulation." Addressing comments that it would be difficult to demonstrate falsity under the Lanham Act, CMS asserted that failure to disclosure the "list price" in a DTC advertisement would render the advertisement false and misleading. Under this logic, CMS presumes that consumers would be aware of the details surrounding the Final Rule and would therefore assume the drug's "list price" is less than $35 in the absence of a disclosure. Similarly, in addressing comments that it would be difficult to demonstrate harm under the Lanham Act, CMS argued that a plaintiff could establish harm under the theory that if a consumer believes a drug has a "list price" below $35, this assumption may

[5] https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html.

impact the consumer's decision to use that drug (ignoring, among other things, the gatekeeper role played by licensed healthcare providers).

LANHAM ACT AND FIRST AMENDMENT IMPLICATIONS OF THE FINAL RULE

Lanham Act Implications

Despite CMS' contentions to the contrary, private enforcement of the Final Rule through competitors' Lanham Act lawsuits may prove challenging in situations where a company fails to provide a "list price" in television advertising (in contrast to a situation where a company includes a materially inaccurate "list price").

- Courts evaluating Lanham Act false advertising claims may not accept the presumptions expressed by CMS in the Final Rule. For instance, the mere identification of a defendant as a violator of the Final Rule may hold little weight in the eyes of a court evaluating a Lanham Act claim, as a violation of the Final Rule alone does not establish falsity for Lanham Act purposes as a matter of law. Relatedly, it may be challenging to attribute any direct injury to the alleged falsity associated with failure to disclose a "list price" when patients and healthcare providers may prefer one drug over another for a variety of reasons entirely unrelated to price.

- Omissions (*e.g.*, failure to disclose the "list price") can be actionable under the Lanham Act only to the extent that they render affirmative statements false or misleading.[6] It would appear challenging for a plaintiff to establish that failure to disclose a "list price" renders affirmative statements in a television advertisement false or misleading.

- Another potential hurdle for Lanham Act challenges is the need to prove materiality. To be actionable under the Lanham Act, a plaintiff must demonstrate that a competitor's failure to disclose its "list price" was material: it must be likely to influence a consumer's purchasing decision.[7] As most consumers will not pay the "list price" for their prescription drugs or biologics but rather the co-pay required by their insurance coverage, it may prove challenging for a plaintiff to establish that a competitor's failure to disclose its "list price" is material.

- Lanham Act lawsuits can typically only be brought by manufacturers of competing products. Depending on the particular drug class and the number of competing products, this may make Lanham Act enforcement infeasible. Manufacturers with

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[6] *See e.g.*, *Casper Sleep, Inc. v. Mitcham*, 204 F. Supp. 3d 632, 638 (S.D.N.Y. 2016).

[7] *See e.g.*, *Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016).

competing products may lack standing in many instances if they cannot show they were harmed by a particular advertisement's failure to disclose the "list price." Relatedly, competitors may lack the economic incentive to bring these challenges. The costs of litigation and risk of counterclaim liability may substantially outweigh the likelihood of obtaining an injunction and collecting lost sales from a competitor's failure to disclose its "list price." Accordingly, Lanham Act lawsuits may be reserved for situations where the competitive landscape, and size of the market, would support a time-consuming and complex legal challenge.

- The Final Rule's preemption provision should preempt any state laws or regulations that require drug pricing disclosure requirements that are different from or in addition to what is required under the Final Rule (*e.g.*, a requirement that the "list price" be larger than the remainder of the text in the television advertisement). Consumer class action plaintiffs may nonetheless attempt to bring actions under state Unfair, Deceptive or Abusive Acts or Practices ("UDAP") acts and may seek to avoid preemption by arguing that failure to follow the Final Rule is necessarily an improper business practice. Pharmaceutical company defendants, however, may be able to argue that the claim is nonetheless preempted because the Final Rule contemplates enforcement exclusively through the Lanham Act, and thus any type of state law claim is precluded by the preemption provision.

- Successful challenges before the National Advertising Division of the Better Business Bureau ("NAD") may also prove elusive. Defendant advertisers may refuse to participate in the NAD process, as there may be no adverse consequences associated with nonparticipation. Specifically, because there are no federal agencies (*e.g.*, FDA or FTC) authorized to enforce against noncompliance with the Final Rule, the NAD would not be in position to make a successful law enforcement referral.

First Amendment Implications

Does the disclosure requirement enunciated in the Final Rule unlawfully compel an advertiser's speech in violation of the First Amendment? The answer to this threshold question may depend upon the level of scrutiny applied by the courts to the compelled disclosure.

As a general rule, the Supreme Court has held that disclosure requirements that compel speech—including commercial speech—are subject to "heightened scrutiny" (also known as "strict scrutiny") under the First Amendment. Other options, however, include "intermediate scrutiny" as established in the *Central Hudson Gas & Elec. Corp. v.*

Pub. Serv. Comm'n[8] decision, or the more lenient test for the government as established in the *Zauderer v. Office of Disciplinary Counsel*[9] decision.

CMS argued that the more lenient standard enunciated in *Zauderer* should apply. CMS further contended that *Zauderer* permits "the disclosure of factual information in marketing commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech." Although CMS maintained that *Zauderer* provides the appropriate framework for review, the agency also contended that the Final Rule would satisfy the intermediate scrutiny test articulated in *Central Hudson*, which provides that agencies can regulate speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest.

Under all of these tests, but in particular "heightened scrutiny" and the "intermediate scrutiny" test applied under *Central Hudson*, the government's First Amendment defense of the Final Rule appears tenuous based upon the absence of any direct link between a "list price" and the price ultimately paid by consumers. In other words, even if the government can establish a legitimate interest in disclosing prices to consumers, it is unclear if requiring the disclosure of "list prices" would satisfy the government's obligations under any First Amendment standard. Additionally, just last term, the Supreme Court appears to have indicated that lower courts should apply more rigorous review to commercial disclosure requirements when applying *Zauderer*. In *National Institute of Family and Life Advocates (NIFLA) v. Becerra*,[10] the Supreme Court heard a First Amendment challenge to a California law requiring certain crisis pregnancy centers to disclose in their advertising that the facilities were "not licensed as a medical facility." A majority of the Supreme Court held that even under the more deferential *Zauderer* standard, the state had failed to demonstrate that its disclosure requirement was justified and not unduly burdensome, emphasizing, "[e]ven under *Zauderer*, a disclosure requirement cannot be unjustified or unduly burdensome."[11] The courts will ultimately have to determine the correct standard for review and whether the Final Rule violates the First Amendment in accordance with recent precedent.

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Please do not hesitate to let us know if you have any questions.

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8 447 U.S. 557 (1980).

9 471 U.S. 626 (1985).

10 138 S. Ct. 2361 (2018).

11 *Id.* at 2377 (internal quotation omitted).

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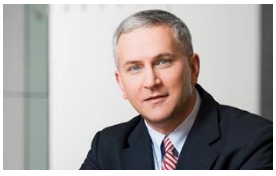

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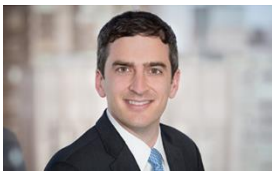

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