



Drug Price Disclosures and the First Amendment

Updated July 9, 2019

Update: On July 8, 2019, the U.S. District Court for the District of Columbia [held](#) that the Department of Health and Human Services (HHS) exceeded its statutory authority in promulgating its new rule on drug list price disclosures. As the court explained, “[n]either the [Social Security] Act’s text, structure, nor context evince an intent by Congress to empower HHS to issue a rule that compels drug manufacturers to disclose list prices. The Rule is therefore invalid.” The court ultimately vacated the rule. Because the court concluded that the agency lacked the statutory authority to issue the rule, the court did not evaluate whether the rule violated the First Amendment. HHS has not yet signaled whether it will appeal the decision.

The original post from July 5, 2019 is below.

On May 10, 2019, the Centers for Medicare & Medicaid Services (CMS) [published a final rule](#) that will require direct-to-consumer (DTC) television advertisements for certain prescription drugs and biologics to include the wholesale acquisition cost of covered pharmaceuticals, also known as the list price, in those ads. During the comment period on the rule, a [number of commenters](#) raised concerns about two distinct legal issues: (1) whether the disclosure requirement would unlawfully compel advertisers’ speech in violation of the Free Speech Clause of the Constitution, and (2) even if the new rule is permissible as a constitutional matter, whether CMS possesses the statutory authority to promulgate this rule in the first place. This Sidebar investigates the first question. (Another [Sidebar](#) will focus on the statutory interpretation issue.)

CMS Regulation to Require Drug Pricing Transparency

The [final rule](#), scheduled to become effective on July 9, 2019, provides that DTC television ads for prescription drugs and biological products for which payment is available under Medicare or Medicaid “must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment.” The rule specifies the precise statement to be made:

“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.”

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The rule also requires that the statement be presented “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.” The quoted provisions are identical to the [rule proposal](#) that CMS issued in late 2018. CMS [says](#) that the rule is intended to “improve the efficient administration of the Medicare and Medicaid programs” by providing consumers “with relevant information about the costs of prescription drugs,” ensuring that “they can make informed decisions” to minimize costs.

Commercial Disclosure Requirements and the First Amendment

During the comment period, a [number of groups argued](#) that the proposed rule violated the First Amendment by compelling manufacturers to state a drug’s list price in DTC advertisements. The rule’s disclosure requirement likely *does* regulate speech rather than [non-expressive conduct](#): the Supreme Court [held in 1976](#) that “prescription drug price advertising” is protected by the First Amendment, and more recently, [said](#) that if the government regulates “the communication of prices rather than prices themselves,” the government is regulating speech. Further, as discussed in more detail in [this report](#), the Supreme Court has said that, generally, disclosure requirements compel speech and are accordingly subject to [heightened scrutiny](#) under the First Amendment.

CMS, however, [maintains](#) that the new list-price disclosure requirement is constitutional under the authority of a Supreme Court decision called *Zauderer v. Office of Disciplinary Counsel*—also discussed in [the report](#) mentioned above. In *Zauderer*, the Court considered a First Amendment challenge to a [state rule](#) requiring attorney advertisements that mentioned contingent-fee rates to disclose how the fee would be calculated. The Supreme Court [acknowledged](#) that in other contexts, it had previously ruled that the government could not compel speech. For example, in *West Virginia State Board of Education v. Barnette*, the Court [held](#) that a state could not punish students who refused to salute the flag. In subsequent years, the Supreme Court has affirmed that, as a [general matter](#), a government law compelling [noncommercial](#) speech will be subject to strict scrutiny and presumptively unconstitutional.

But in *Zauderer*, the Court [said](#) that the free speech interest of the attorney challenging the state rule was “not of the same order” as the interests discussed in *Barnette*. The Court has generally treated [commercial speech](#)—[defined as](#) speech that “does no more than propose a commercial transaction”—differently than “other constitutionally guaranteed expression,” and has [said](#) that the Constitution “accords a lesser protection to commercial speech.” Noting that commercial speech is valuable because of its potential to inform consumers, the Court [concluded](#) in *Zauderer* that the attorney’s First Amendment “interest in *not* providing any particular factual information in his advertising is minimal.” Under the circumstances, the Court [held](#) “that an advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the State’s interest in preventing deception of consumers.” The Court concluded that this standard was met in the case before it, [stating](#) that the possibility of deception was “self-evident” because “members of the public are often unaware of the technical meanings of such terms as ‘fees’ and ‘costs’—terms that, in ordinary usage, might well be virtually interchangeable.” Consequently, the Court [said](#) that the state’s “position that it is deceptive to employ advertising that refers to contingent-fee arrangements without mentioning the client’s liability for costs is reasonable enough to support a requirement that information regarding the client’s liability for costs be disclosed.”

Therefore, for certain commercial disclosure requirements, to survive a constitutional challenge, *Zauderer* requires the government to show only that a disclosure requirement is “[reasonably related](#)” to a sufficient government interest. This standard is easier for the government to meet than [strict scrutiny](#), which requires the government to show that the law is “narrowly tailored to serve compelling state interests.” *Zauderer* is also a more lenient test than the [intermediate scrutiny](#) standard that generally applies to commercial speech, which requires that a regulation “directly advance” a “substantial” governmental interest and be no “more extensive than is necessary to service that interest.” However, as the Supreme Court recently

emphasized, “[e]ven under *Zauderer*, a disclosure requirement cannot be unjustified or unduly burdensome.”

Importantly, courts have concluded that *Zauderer*’s “reasonably related” standard only applies to certain types of disclosure requirements: in particular, *Zauderer* governs the constitutional analysis of provisions that compel the disclosure of “factual and uncontroversial” commercial information related to the goods or services the speaker provides. Some judges have argued that to be eligible for review under *Zauderer*’s more lenient standard, the government must also justify the requirement by citing an interest in preventing misleading speech, rather than, for example, an interest in protecting public health and safety. However, most courts that have considered the question have rejected this position, applying *Zauderer* and upholding disclosure requirements even where the government asserts an interest other than preventing consumer deception. (The Supreme Court has not specifically addressed this last question.)

Assessing the New CMS Rule under the First Amendment

A number of parties commenting on CMS’s proposed list-price disclosure rule argued that *Zauderer* does not apply and the rule should be subject to heightened First Amendment scrutiny. Some commenters claimed that a drug’s list price is not “purely factual” or “uncontroversial” because the list price does not reflect the cost paid by most consumers. For example, many patients pay lower prices because insurance covers some of the cost. Commenters also argued that *Zauderer* should not apply because CMS was not claiming that prescription drug advertisements are misleading or that the disclosure would prevent consumer deception. Others claimed that even if *Zauderer* governs the analysis, the rule should nonetheless be considered unconstitutional because it was unjustified, arguing that CMS has not proved that consumers are currently unaware of drugs’ prices or that providing consumers with that information would help lower drug prices. Still others argued that the rule was unduly burdensome, forcing drug manufacturers to devote a relatively significant portion of their limited television advertising space to a government-scripted message that would distract from their own message.

In its explanation of the final rule, CMS addressed these arguments, describing a drug’s list price as “an objective fact” and claiming that because the list price “is a truthful statement of objective fact that is not subject to dispute, it is ‘uncontroversial.’” The agency also said that the final sentence in the disclosure, advising consumers that if they have insurance, their costs may be different, “directly addresses” the concern that consumers might “misunderstand” the list price disclosure. With respect to the argument that *Zauderer* only applies to disclosures intended to prevent consumer deception, CMS cited lower court decisions to the contrary and concluded that the better view of “current law” is “that the *Zauderer* test is not limited to disclosures designed to prevent consumer deception.” The agency further argued that its interest in combating “rising drug prices” was sufficient to justify the disclosure requirement. But CMS also claimed that ads that do not include the list price may be misleading because without access to that information, “consumers appear to dramatically underestimate their [out-of-pocket] costs for expensive drugs.” Finally, CMS said that the disclosure would not be unduly burdensome, because the “brief textual statement . . . neither drowns out the speaker’s message nor rules out broadcast advertisements as a mode of communication.”

CMS also argued in the alternative that even if the rule did not qualify for *Zauderer* review, the disclosure requirement would withstand the intermediate scrutiny that generally applies to government acts affecting commercial speech. The intermediate scrutiny standard requires the government regulation to “directly advance” a “substantial” interest and be no “more extensive than is necessary to service that interest,” CMS first said that it has a “substantial government interest in reducing prescription drug or biological product costs generally, as well as the costs borne by Medicare and Medicaid.” Further, the agency argued that disclosure of the list price “clearly and directly advances this interest” by improving market efficiencies and “helping consumers make informed choices.” Turning to the question of whether the rule burdened more speech than necessary to serve its interest, some commenters had argued that as a less

speech-restrictive alternative, CMS should “encourage companies to institute voluntary price disclosure measures.” (At least one industry group [announced](#) last year that members would soon include a website in their DTC television ads where consumers could find more information about medicine costs.) In response, CMS [concluded](#) that these “voluntary measures will be insufficient to ensure the continued commitment of all of the relevant companies.”

Ultimately, if the rule is challenged in court, it is somewhat difficult to predict whether a court would agree with CMS’s assessment of the disclosure’s constitutionality. While lower courts have [upheld](#) a wide variety of commercial disclosure requirements, the Supreme Court has left open a number of significant questions regarding when and how to apply *Zauderer*. In addition, the Supreme Court may have [signaled](#) last term that lower courts should, in the future, apply more rigorous review to commercial disclosure requirements when applying *Zauderer*. In *National Institute of Family and Life Advocates (NIFLA) v. Becerra*, the Court considered a First Amendment challenge to a California law that [required](#) certain crisis pregnancy centers to disclose in their advertising that the facilities were “not licensed as a medical facility.” A majority of the Court [concluded](#) that even under the more deferential *Zauderer* standard, California had not proved that its disclosure requirement was justified and not unduly burdensome. One attorney for the Washington Legal Foundation—a group that filed a [comment](#) opposing the adoption of the list-price disclosure rule—has [argued](#) that *NIFLA* suggests that the Court may be shifting its approach to commercial speech, subjecting government restrictions on commercial speech to heightened scrutiny. But as CMS [noted](#) in its final rule, the Supreme Court has not expressly overruled its cases affording less protection to commercial speech, and so far, has continued to review restrictions on commercial speech under a more permissive standard.

Implications for Congress

This rulemaking highlights the First Amendment issues that may arise if the government requires the disclosure of prescription drug price information—issues that Congress may confront as it evaluates legislative proposals concerning [medical bills](#) and drug pricing. Congress has in the past [considered bills](#) that would require drug manufacturers to disclose drug prices in commercial advertisements as well as other communications with health care practitioners. At least [one bill](#) introduced this session would require pharmacists to disclose certain drug costs to customers. And a [number of bills currently pending](#) would require drug manufacturers to report various pricing information to the government. To the extent that these efforts could be viewed as [compelling](#) or [otherwise burdening](#) protected speech, they may implicate the First Amendment. Disclosure requirements that apply outside the context of advertising, however, may raise distinct First Amendment concerns.

But not every regulation of speech is unconstitutional, and courts may uphold disclosure requirements even if they do burden a drug manufacturer’s free speech rights, so long as the court determines that the burden is sufficiently justified and tailored to the problem at hand. For example, in *Citizens United v. Federal Election Commission (FEC)*, the Supreme Court [upheld](#) a federal provision requiring persons who spent more than \$10,000 on electioneering communications to file disclosure statements with the FEC—even though the provision did “burden the ability to speak.” The evaluation of any given disclosure requirement’s constitutionality under the First Amendment would likely be highly fact-specific and context-dependent, given the nature of the law in this area.

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