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December 17, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4187-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4187-P; 83 Fed. Reg. 52789 (October 18, 2018)
Regulation to Require Drug Pricing Transparency

Dear Ms. Verma,

The Washington Legal Foundation (WLF) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule that would require pharmaceutical manufacturers to convey the list price of any prescription drug or biological product they advertise in direct-to-consumer (DTC) television ads.

Founded in 1977, WLF is a public-interest law firm and policy center with supporters nationwide. WLF often appears before federal courts and administrative agencies to promote free enterprise, individual liberty, limited government, and the rule of law. To that end, WLF routinely defends commercial speech rights by appearing as an *amicus curiae* in state and federal courts in important First Amendment cases.[1]

WLF has actively litigated in favor of First Amendment limits on the Food and Drug Administration's (FDA) authority to restrict manufacturer speech.[2] As a result of that litigation, FDA is subject to a permanent injunction limiting the FDA's authority to bar manufacturers from sharing peer-reviewed medical texts and journal articles about off-label uses of their FDA-approved products. WLF also

[1] *See, e.g., Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); *United States v. Phillip Morris USA Inc.*, 801 F.3d 250 (D.C. Cir. 2015).

[2] *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

played a pivotal role in a successful First Amendment challenge to FDA's compelled-speech regime for cigarettes.[3]

CMS proposes to add "a new subpart L to part 403 to title 42 that would require that for prescription drug and biological products that can be reimbursed directly or indirectly through or under Medicare or Medicaid, DTC ads on television (including broadcast, cable, streaming, and satellite communication) for such products must include the product's current list price, defined as the Wholesale Acquisition Cost."[4] CMS estimates that complying with the rule will cost drug makers $5.2 million in its first year and $2.4 million each later year.[5]

Pharmaceutical companies spend vast sums of money each year promoting their life-saving drugs. "A dollar spent at the pharmacy does more to combat disease and disability than a dollar spent anywhere else, and newly developed drugs are credited with most of the recent gains in longevity."[6] Many manufacturers invest in DTC television ads, which provide useful information to help patients make informed medical decisions with their doctors.

Yet as we explain in detail below, CMS lacks any statutory authority to compel drug makers to disclose the wholesale-acquisition cost, or "list price," for a 30-day supply of any drug promoted in DTC television ads. WLF also doubts the constitutionality of CMS's proposed mandated disclosure, which would unduly burden drug makers' First Amendment right to speak truthfully about their products. For these reasons, CMS should withdraw the proposed rule.

I. THE PROPOSED RULE WOULD EXCEED CMS'S STATUTORY AUTHORITY.

"[A]n administrative agency's power to regulate … must always be grounded in a valid grant of authority from Congress."[7] As a division of the U.S. Department of Health and Human Services (HHS), CMS's regulatory authority over drug makers' television ads must arise from some statute Congress enacted to delegate that authority. Yet *no* statute authorizes CMS to require disclosure of list prices in DTC television ads.

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[3] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

[4] 83 Fed. Reg. 52791.

[5] 83 Fed. Reg. 52798.

[6] John Tierney, *What the Prescription Drug Debate Gets Wrong*, City Journal, at 2 (Autumn 2018).

[7] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

CMS candidly admits that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public."[8] Although Congress granted the HHS Secretary narrow authority to ensure the health and safety information in DTC television ads,[9] CMS does not invoke that statute. Instead, CMS contends that since Congress "directed HHS to operate Medicare and Medicaid programs efficiently" under the Social Security Act, it implicitly authorized CMS to compel drug makers to convey the list price of prescription drugs in DTC television ads.[10]

In particular, CMS claims that the "proposed rule is issued pursuant to sections 1102 and 1871 of the Social Security Act."[11] But those two statutory provisions, first enacted in 1935, cannot possibly bear the significance that CMS attributes to them.[12] While the Secretary enjoys generic rule-making authority for both Medicare and Medicaid under §§ 1102(a) and 1871(a), that authority is not boundless. Like all federal agencies, CMS is bound "not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."[13] A careful review of those statutory provisions reveals nothing that would remotely support mandating the disclosure of list prices in television ads.

Neither statutory provision says anything about prescription drugs, their prices, or ads about them. That Congress "recognized the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures"[14] is simply not enough. And while CMS insists that requiring drug makers to disclose list prices is part of "efficiently" operating Medicare and Medicaid, the relevant statute does not define "efficient." Whatever "efficient" fairly may encompass, it does not authorize CMS to compel private companies both to broadcast and to subsidize the government's message.

Unsurprisingly given the proposed rule's extra-statutory reach, CMS proposes no enforcement mechanism for its list-price-disclosure mandate. Of course,

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[8] 83 Fed. Reg. 52791.

[9] *See* 21 U.S.C. § 353c.

[10] *Id.*

[11] 83 Fed. Reg. 52790.

[12] *See* 42 U.S.C. §§ 1302(a), 1395hh.

[13] *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994).

[14] 83 Fed. Reg. 52791.

if Congress had intended CMS to mandate the disclosure of prices in DTC television ads, it would have enacted a statutory enforcement mechanism and allocated resources for that purpose. That CMS recognizes it cannot rely on Congress for enforcement allocations is further evidence that Congress never authorized CMS to mandate price disclosures in DTC television ads to begin with.

Instead, if a drug manufacturer fails to disclose its list price, CMS will add that manufacturer's name to a "shame" list of violators on the CMS website.[15] CMS assumes that some private enforcement will come from false- or misleading-advertising claims under the Lanham Act.[16] Though CMS describes the threat of meritless, *in terrorem* enforcement suits as "acceptably low,"[17] that hardly seems intuitive. Any claim under the Lanham Act would be baseless because it is implausible that a drug maker's DTC television ad is misleading merely for failure to include a list price.[18] If that were true, we already should have seen an avalanche of Lanham Act recoveries for pharmaceutical DTC television ads by now.

At all events, Congress never vested CMS with the authority to compel drug makers to disclose list prices in DTC television ads. That is why Senator Dick Durbin has introduced a bill "[t]o require drug manufacturers to disclose the prices of prescription drugs in any direct-to-consumer advertising and marketing to practitioners of a drug."[19] The bill would amend the FDCA to authorize FDA to impose civil monetary penalties on sponsors that fail to disclose a drug's list price in any DTC ad.[20] Senator Durbin also introduced (unsuccessfully) three amendments to the FDA appropriations bill, H.R. 6147, that would have authorized FDA to require list-price disclosures in DTC ads and appropriated funds for it to do so.[21] Because it would make no sense for Congress to grant HHS statutory authority that

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[15] 83 Fed. Reg. 52794.

[16] *Id.*

[17] *Id.*

[18] To establish the "false or misleading statement" element of a Lanham Act claim, a plaintiff must prove that "the statements at issue were either '(1) commercial claims that are literally false as a factual matter,' or '(2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1261 (11th Cir. 2004) (quoting *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998)).

[19] S. 2157, 115th Cong. (2017).

[20] *Id.*

[21] *See* S. Amdt. 3612, 115th Cong. (2018); S. Amdt. 3611, 115th Cong. (2018); S. Amdt. 3510, 115th Cong. (2018).

it already enjoys, this proposed legislation is strong evidence that CMS lacks the statutory power to mandate list-price disclosures in DTC ads. If CMS were to adopt the proposed rule, it would exceed the lawful limits of its statutory power.

II. THE PROPOSED RULE WOULD VIOLATE THE FIRST AMENDMENT.

While CMS anticipated First Amendment objections to its proposed rule, the agency's perfunctory First Amendment analysis gives short shrift to drug makers' free-speech rights. CMS claims that "[w]hen the government requires accurate disclosures in the marketing of regulated products under appropriate circumstances, it does not infringe on protected First Amendment interests."[22] But the First Amendment protects a speaker's choices about "both what to say and what *not* to say."[23] And by compelling drug makers "to speak a particular message" in their ads, the proposed rule "alters the content of [their] speech."[24]

A. *Zauderer* Cannot Save CMS's Proposed Rule.

Seeking to minimize the First Amendment's protections against compelled speech, CMS invokes *Zauderer v. Office of Disciplinary Counsel* as justification for the proposed rule.[25] But *Zauderer* was a mostly successful First Amendment challenge to Ohio's efforts to restrict truthful attorney advertising. Applying *Central Hudson's* four-pronged test,[26] the Court struck down (1) prohibitions on soliciting clients through ads containing advice on specific legal problems and (2) restrictions on using illustrations in attorney advertising.[27]

True, *Zauderer* upheld Ohio's decision to discipline an attorney because he advertised his services on a "no cost" contingency-fee basis without disclosing that clients could be liable for litigation costs.[28] But this was merely a special application of the *Central Hudson* test.[29] The Court determined that by imposing

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[22] 83 Fed. Reg. 52793.

[23] *Riley v. Nat'l Fed. of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796-97 (1988).

[24] *Id*. at 795.

[25] 471 U.S. 626 (1985).

[26] *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 562-63 (1980).

[27] *Id.* at 639-49.

[28] *Id.* at 650–52.

discipline on the attorney, Ohio was directly advancing its substantial interest in preventing consumer confusion, and that requiring a company to include an advertising disclaimer designed to prevent consumer deception is preferable to prohibiting ads altogether.[30] Properly understood, then, *Zauderer* directs governments to prefer disclaimer requirements as a more narrowly tailored alternative to outright speech bans when seeking to guard against consumer deception.

But *Zauderer* does not hold that government *compulsion* of commercial speech deserves less First Amendment scrutiny than *restrictions* on commercial speech. Ohio was compelling speech only to the extent that it required attorney ads to include additional language "to dissipate the possibility of consumer confusion or deception."[31] And *Zauderer* is strictly limited to cases where the compelled government speech is both factual and uncontroversial.[32] As shown below, compelling drug makers to confront potential consumers with list prices they most likely will never be charged is highly controversial. *Zauderer* thus provides no support for the view that CMS may require drug makers to add virtually any "factual" speech to their ads—especially when it will increase rather than dissipate the likelihood of consumer confusion.

The Supreme Court recently reiterated the narrow scope of permissible government-compelled speech in *National Inst. of Family & Life Advocates (NIFLA) v. Becerra.*[33] There the Court held that (1) compelled speech must aim "to remedy a harm that is potentially real, not purely hypothetical"; (2) it must "extend no more than reasonably is necessary"; and (3) the government bears "the burden to prove that the [compelled speech] is neither unjustified nor unduly burdensome."[34]

NIFLA struck down California laws compelling crisis-pregnancy centers to notify women of California's free or low-cost health services, including abortion. In holding that California's laws violated the centers' First Amendment rights, the Court imposed meaningful limits on *Zauderer*. It affirmed that *Zauderer*'s "lower

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[29] *See Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (describing *Zauderer* as "an application of *Central Hudson*, where several of *Central Hudson*'s elements have already been established").

[30] *Id.*

[31] *Id.* at 651.

[32] *Id.*

[33] 138 S. Ct. 2361 (2018).

[34] *Id.* at 2377.

level of scrutiny" for compelled speech is limited to the mandatory "disclosure of purely factual and uncontroversial information about the terms under which … services will be available."[35] Because the message compelled by California was not so limited, it violated the First Amendment.

Above all, *Zauderer* provides no support for CMS's effort to compel drug makers to disclose list prices in their DTC television ads. The proposed rule's stated purpose is to inform consumers of the drug's cost, not to prevent consumer deception. Unlike in *Zauderer*, the ads here contain no deception. Viewers of pharmaceutical DTC ads are not misled about the safety, efficacy, or price of the advertised drug. And the mandated disclosure hardly qualifies as "uncontroversial," given that so few consumers pay the list price and most likely will be confused by the disclosure. The mere fact that strong views predominate on both sides of the policy argument shows that the mandatory labeling of list prices is controversial. Besides, CMS has offered no evidence that the proposed rule will achieve the stated purpose of lowering CMS-related drug costs.

Because *Zauderer* does not govern the constitutional analysis here, CMS's proposed rule must pass muster under a First Amendment standard at least as stringent as that supplied by *Central Hudson*.

B. CMS's Proposed Rule Cannot Survive *Central Hudson.*

Central Hudson's first prong requires a court to consider whether the commercial speech at issue concerns unlawful activity or is inherently misleading. Because FDA has approved drug makers' DTC television ads for years with no disclosure of list prices, CMS cannot seriously contend that such truthful commercial speech is inherently misleading. As to *Central Hudson*'s second prong, a challenger is unlikely to contest that CMS has a substantial interest in reducing Medicare and Medicaid costs.

Even so, the proposed rule violates the First Amendment unless CMS can show that the rule (1) "directly advances" CMS's substantial interest in reducing costs and (2) is no "more extensive than is necessary to serve that interest."[36] As shown below, the proposed rule flunks both requirements.

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[35] *Id.* at 2372 (citing *Zauderer*, 471 U.S. at 651).

[36] *Central Hudson*, 447 U.S. at 566.

i. The Proposed Rule Neither Directly Advances CMS's Purported Interest Nor Materially Alleviates the Relevant Harms.

Central Hudson's third prong requires CMS to prove that the proposed rule's restrictions on commercial speech "directly advance the governmental interest asserted,"[37] and that they do so "to a material degree."[38] This prong is "critical" because, without it, the government "could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression."[39]

According to CMS, the proposed rule's purpose is to reduce the price to consumers of prescription drugs by providing "relevant information" to Medicare and Medicaid beneficiaries.[40] This, in turn, is somehow supposed to help consumers minimize their own out-of-pocket costs as well as the costs to Medicare and Medicaid.[41]

But it remains unclear why a drug's *list price* is "relevant information." As CMS readily concedes, a drug's list price bears no semblance to the consumer's out-of-pocket cost for that drug. For example, a Medicare beneficiary's out-of-pocket costs will vary dramatically depending on the stage of the Part D benefit she is in and on whether she is eligible for "extra help" from the Low-Income Subsidy (LIS). Beyond those factors, actual cost turns on the consumer's supplemental insurance plan, if any, including any co-pay and deductible amounts. And in many cases, the consumer's co-pay is a fixed dollar amount that bears no relation to the list price. A drug's final cost also depends on the consumer's eligibility to participate in third-party co-pay and assistance programs.

A cost is only relevant to a television viewer who must incur that cost. But, as shown, disclosing the list price in a DTC ad will *not* inform a potential consumer of his or her actual cost for the advertised drug. That is why FDA has cautioned drug makers that comparing competitors' list prices in ads is inherently misleading. FDA has objected, for example, to drug makers' cost-effectiveness claims because list-

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[37] 447 U.S. at 566.

[38] *Edenfield*, 507 U.S. at 771.

[39] *Id.*

[40] 83 Fed. Reg. 52791.

[41] *Id.*

price cost comparisons "do not necessarily reflect a cost advantage" and "prices derived from list prices" do not "necessarily reflect actual prices paid by consumers or dispensers."[42] CMS should talk to FDA about the utility and wisdom of list-price comparisons.

Nor has CMS offered any empirical evidence that predicts how consumers are likely to behave once aware of a drug's list price. A consumer who views a television ad and compares the list prices of two competing drugs may explore only the one with the lowest list price—even though the co-pay for that drug may be the same or even higher. Still other consumers may behave counterintuitively. For example, "[i]f a consumer has a choice of five drugs and one is more expensive, the consumer may think the more expensive drug is the better drug. That's often how people make decisions."[43] Even worse, a person might be deterred by the list price from even consulting a doctor to obtain a prescription for the drug, get much sicker as a result, and end up costing CMS *more* than if he'd never considered the list price. Gaming out such scenarios is inherently unreliable. Confusion abounds.

CMS answers that over 40% of beneficiaries in the commercial market are in high-deductible plans and may pay thousands of dollars in drug costs.[44] But that is constitutionally irrelevant. Besides, under Medicare and Medicaid—CMS's only claimed statutory basis for promulgating the rule—drug deductibles are extremely low or nonexistent. For example, no Medicare drug plan has a deductible of more than $405 in 2018.[45] Even during the deductible period, Medicare Part D enrollees pay a "negotiated price" roughly equal to the amount that Plan D reimburses the pharmacy for the drug.

"To the individual consumer, the list price is often a fantasy number."[46] Even a drug with an annual $50,000 wholesale-acquisition cost may cost the average customer only a few hundred dollars per year in co-pays.[47] In any event, depending

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[42] FDA Warning Letter to Eli Lilly & Co., July 19, 1994.

[43] Wendy W. Blackburn, quoted in Robert Pear, *Requiring Prices in Drug Ads: Would It Do Any Good? Is It Even Legal?*, N.Y. Times, May 19, 2018, at A16.

[44] 83 Fed. Reg. 52790.

[45] Centers for Medicare & Medicaid Services, *Your Guide to Prescription Drug Coverage*, June 2018, at 14, available at https://www.medicare.gov/Pubs/pdf/11109-Your-Guide-to-Medicare-Prescrip-Drug-Cov.pdf.

[46] Dr. Blase N. Polite, quoted in Pear, *supra* n.43.

[47] Arlene Weintraub, *You May Start Seeing Drug Prices In Ads, But Will you Understand The Point?*, Forbes, Aug. 28, 2018.

on the severity of the patient's prognosis, price may well be irrelevant. "When a doctor tells a cancer patient that this therapy potentially has a cure rate of 10 or 15 percent, people don't care that the drug costs $120,000 because the costs are usually covered by third parties."[48]

As FDA has long acknowledged, a major aim of DTC ads is to encourage patients to ask their doctors about particular drugs. Any such discussion often will include price—especially for expensive drugs. But that is no less likely to happen with a compelled list-price disclosure than without one. And CMS offers no evidence to the contrary. Without price information in television ads, an interested patient will first check with a physician to determine the best treatment, then with the insurer to calculate the out-of-pocket cost, if any, and then make an informed decision.

Another reason CMS's proposed rule lacks any reasonable fit with its stated goal of lowering prescription-drug costs is that it assumes, without evidence, that higher drug costs result from a lack of transparency about drug prices. But that is a conclusion without empirical support. As FDA Commissioner Gottlieb has recently acknowledged, many drug prices are dictated by supply and demand. According to FDA, more than 100 drugs have faced a shortage this year.[49] These shortages "are being driven in part by diminishing supplies of many older, widely used medications that reap little if any profit for manufacturers."[50] According to Commissioner Gottlieb, these critical drugs "may sometimes be priced too low relative to the full cost of reliably producing a predictable and high-quality pharmaceutical product."[51] If more than 100 drugs are priced too low to satisfy market demand, it's far from clear that inflated drug prices are the driving force behind rising health-care costs.

CMS's evidentiary burden under the First Amendment is not light. Nor is it "satisfied by mere speculation or conjecture."[52] In *none* of its commercial speech cases has the Supreme Court ever been willing, when deciding whether a regulation

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[48] *Id.*

[49] FDA, *FDA Drug Shortages*, available at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

[50] Cynthia Koons, & Riley Griffin, Bloomberg, *A Common Childbirth Drug Doubles in Price as Shortages Drag On*, available at https://www.bloomberg.com/news/articles/2018-12-06/pitocin-and-ketamine-prices-are-surging-as-shortages-drag-on.

[51] FDA, *FDA Is Advancing New Efforts to Address Drug Shortages*, available at https:/www.fda.goc/NewsEvents/Newsroom/FDAVoices/ucm626108.htm.

[52] *Edenfield v. Fane*, 507 U.S. 761, 770 (1993).

advances a government interest, to defer to the government's own say-so on the challenged regulation's efficacy in advancing that interest. Any such deference would ignore the government's heavy burden to prove that its speech restrictions alleviate real harms "to a material degree."[53]

Yet without evidence, CMS insists that requiring disclosure of information of limited interest to some patients—but of no relevance to most patients—somehow advances the government's stated interest to a material degree. CMS merely asserts an untested, theoretical link between a mandated list-price disclosure and a reduction in overall health-care costs. That is not enough under *Central Hudson*.

ii. The Proposed Rule Is Not Narrowly Tailored and Affects More Speech than Is Necessary.

Even if CMS could prove that the proposed rule directly advances its claimed interest, *Central Hudson* still requires a showing that the rule is no "more extensive than is necessary to serve that interest."[54] Under this prong, the existence of "numerous and obvious less-burdensome alternatives to the restriction on commercial speech" shows that the "fit" between means and ends is unreasonable.[55]

The leading case is *Thompson v. Western States Medical Center*, which involved a federal attempt to prohibit pharmacies from advertising compounded drugs.[56] The federal law at issue exempted compounded drugs from the FDA's rigorous drug-approval process, so long as pharmacies selling those drugs complied with several restrictions, "including that they refrain from advertising or promoting particular compounded drugs."[57] The advertising ban was necessary, the government insisted, to prevent "large-scale [drug] manufacturing" from occurring "under the guise of pharmacy compounding."[58]

But the Court held that the government may not restrict pharmacists' speech instead of their conduct: "If the First Amendment means anything, it means that

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[53] *Id.* at 771.

[54] 447 U.S. at 566.

[55] *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993).

[56] 535 U.S. 357 (2002).

[57] 535 U.S. at 360.

[58] *Id.* at 371.

regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try."[59] In other words, "if the Government could achieve its interests in a manner that does not restrict speech … [it] must do so."[60]

Contending that the proposed rule is narrowly tailored under the First Amendment, CMS insists that the drug "manufacturer has the ability to convey other information of its choosing in the remainder of the advertisement."[61] But CMS's discussion betrays little familiarity with FDA's own regulation of prescription-drug advertising. As CMS should know, FDA requires all DTC advertising to include a "fair balance" of risk and benefit information.[62] That includes a requirement that every DTC television ad include a "major statement" of detailed risk information. It is not uncommon for a drug's major statement to take up to 30 seconds of air time. Even if the CMS-mandated list-price disclosure took only another five to ten seconds (long enough to be read on screen), that would leave precious little time for the drug maker to "convey other information of its choosing." Besides, an opportunity to provide counter-speech does not cure a First Amendment violation.

One alternative that would not abridge manufacturers' free-speech rights is simply to defer to manufacturers' own cost-transparency initiatives. PhRMA, the Pharmaceutical Research and Manufacturers of America, has announced its members' voluntary commitment to—by April 15, 2019—provide relevant cost information available in their DTC television ads by, for example, directing viewers to a company website. Those websites would provide consumers with a variety of pricing information including (1) the list price of the drug, (2) the average, estimated, or typical out-of-pocket costs, and (3) some helpful context.[63] If CMS desires to give consumers more, not less, information, then PhRMA's plan would appear to do just that.

CMS need not commandeer the speech of prescription drug makers to communicate drug prices to consumers. CMS is perfectly free to share

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[59] *Id.* at 373.

[60] *Id.* at 371.

[61] 83 Fed. Reg. 52793.

[62] 21 CFR §§ 202.1(e)(1), 202.1(e)(5)(ii).

[63] PhRMA, *PhRMA Guiding Principles: Direct to Consumer Advertisements about Prescription Medicines*, available at phrm-docs.phrma.org/files/dmfile/PhRMA_Guiding_Principles_2018.pdf.

pharmaceutical list prices on its own, without altering the speech of drug makers. After all, a prescription drug's list price is not a trade secret. CMS could, for example, publish every list price for every drug covered under Medicare and Medicaid and provide that list directly to covered beneficiaries with their statement of benefits. But, as in *Western States*, "there is no hint that the Government even considered these or any other alternatives."[64] Instead, as the proposed rule confirms, compelling manufacturer speech was CMS's first, not last, resort. The proposed rule is not narrowly tailored.

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WLF appreciates the opportunity to submit this comment on CMS's proposed rule. For the reasons explained above, CMS's adoption of the proposed rule would not only be inconsistent with CMS's statutory authority under the Social Security Act, but it also would be inconsistent with settled First Amendment limitations on compelled speech. Given these statutory and constitutional defects, CMS should withdraw the proposed rule.

Sincerely,

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[64] 535 U.S. at 373.